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DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 1

[Docket No. USDA–2021–0009]

RIN 0503–AA74

Production or Disclosure of Official Information in Legal Proceedings

AGENCY: Office of the Secretary, USDA.

ACTION: Direct final rule.

SUMMARY: We are revising our regulations regarding the production or disclosure of official information in legal proceedings (referred to as *Touhy* regulations). These regulations are being updated to promote consistent processing of *Touhy* requests among U.S. Department of Agriculture (USDA or Department) agencies; clarify the responsibilities of all parties in the *Touhy* process; and provide additional information about criteria that USDA agencies should consider in the *Touhy* process.

DATES: This rule will be effective on April 29, 2022, unless we receive written adverse comments or written notice of intent to submit adverse comments on or before March 30, 2022. If we receive written adverse comments or written notice of intent to submit adverse comments, we will publish a document in the **Federal Register** withdrawing this rule before the effective date.

ADDRESSES: You may submit comments or written notice of intent to submit adverse comments using the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and search for docket number USDA–2021–0009.

FOR FURTHER INFORMATION CONTACT: Karen Carrington Fletcher, Senior Counsel, Office of the General Counsel, USDA, 1400 Independence Ave. SW, Room 103–W, Washington, DC 20250; *karen.fletcher@usda.gov;* (202) 720–0944.

SUPPLEMENTARY INFORMATION:

Background

Under 5 U.S.C. 301, the ''Housekeeping Statute,'' and in response to a demand for official information that arises out of a legal proceeding, many agencies have regulations governing the production of official information and employee testimony relating to official information. Known as *Touhy* regulations, these regulations usually prohibit unauthorized disclosures of official information by employees. These regulations also establish procedures for agencies responding to subpoenas for official information or employee testimony relating to official information. (*See United States ex rel.* v. *Touhy v. Ragen,* 340 U.S. 462 (1951)).

Currently, the Department's *Touhy* regulations are located at 7 CFR part 1, subpart K (§§ 1.210 to 1.219). Those regulations were established in 1990 and have not been amended since 1993. This direct final rule revises subpart K in its entirety, with the new regulations spanning §§ 1.210 through 1.224. The revised regulations are presented in a question-and-answer format to enhance clarity and readability.

The Department is amending its *Touhy* regulations to: (1) Promote consistent processing of *Touhy* requests among USDA agencies; (2) clarify the responsibilities of all parties in the *Touhy* process; and (3) provide additional information about criteria that USDA agencies should consider in the *Touhy* process. A discussion of certain specific changes follows.

The revised regulations set forth the procedures to be followed with respect to a demand seeking official information or employee testimony relating to official information for use in a legal proceeding. The revised regulations also set forth certain definitions that were not used in the existing regulations. The revised regulations define:

- The term ''demand'' to mean any effort or attempt to obtain, for use in a legal proceeding, official information or testimony relating to official information, including any request, order, subpoena, or other command, as well as any informal or other attempt (by any method) to obtain official information, or testimony relating to official information, by an attorney, investigator, or others.
- The term ''legal proceeding'' to mean all pretrial, trial, and post-trial stages of all existing or reasonably anticipated judicial or administrative actions, hearings, investigations, or similar proceedings before courts, commissions, boards, grand juries, or other tribunals. This phrase includes all phases of discovery as well as formal or informal requests by attorneys or others involved in legal proceedings.
- The term ''official information'' to mean all information of any kind, however stored, that is in the custody and control of the Department or relates to information in the custody and control of the Department, or information or knowledge acquired by a Department employee as part of the employee's official duties or because of the employee's official status with the Department.
- The term ''Department'' to mean the United States Department of Agriculture, its constituent agencies, and Department officials authorized to decide whether to allow disclosures of official information or testimony relating to official information in response to a demand.
- The term ''employee'' to mean all employees or officers of the Department, including individuals who are or have been appointed by the Department, or who are or have been subject to the Department's supervision, jurisdiction, or control, including individuals hired through contractual agreements by or on behalf of the Department, or performing services under such agreements for the Department, such as consultants, contractors, subcontractors, and their employees or other personnel. Also included in the definition are former Department employees where the demand seeks testimony relating to official information acquired while the person was an employee of the Department.
- The term ''testimony'' to mean any written or oral statement by an employee, including personal appearances in court or at depositions, interviews, or informal inquiries in person or by telephone, responses to written interrogatories or other written statements such as reports, declarations, or affidavits, or any response involving more than the delivery of documents.
- The term ''appropriate Department official'' to mean the head of a Department agency.

• The term ''Office of the General Counsel'' to mean the Office of the General Counsel of the Department.

• The term ''United States'' to means the Federal Government, its departments, and its agencies.

The revised regulations explicitly state that the following matters are not covered by the regulations:

• Congressional requests and subpoenas seeking official information or employee testimony relating to official information;

• Federal court civil proceedings in which the United States is a party;

• Federal administrative proceedings in which the Department is a party;

• The disclosure of official information or employee testimony relating to official information provided to other Federal agencies in connection with a legal proceeding conducted on behalf of or in defense of the United States or a legal proceeding in which the United States has an interest; and

• Employees who testify on their own time or in approved leave status as private citizens about facts or events that are unrelated to official business.

The revised regulations outline the responsibilities for those involved in the *Touhy* process, *i.e.,* the parties submitting a demand to Department agencies, Department employees who receive a demand, and Department agencies deciding whether to grant or deny a demand.

Parties who submit a demand are to provide the following to the Department:

• Information about the underlying legal proceeding, including copies of the complaint and any relevant pleadings;

• The identity of the Department employee whose testimony is sought and a detailed summary about the relevance of the employee's testimony to the underlying legal proceeding;

• If the demand seeks documents or other materials, a description of the requested official information sought and a detailed summary about its relevance to the underlying legal proceeding;

• An explanation of the unavailability of the requested official information or employee testimony through other sources; and

• An explanation of how each of the factors set forth in 7 CFR 1.220(a) apply to their demand.

The revised regulations require that this information must be submitted at least 14 calendar days before the official information or employee testimony is needed and further require the submission of the above information even if parties serve a subpoena on the Department or a Department employee. A demand may not be granted if a party fails to follow the instructions set forth in the regulations.

Department employees who receive a demand are to:

• Inform their supervisors about the demand so the supervisors may inform an appropriate Department official and the Office of the General Counsel; and

• If appropriate Department officials deny the demand in accordance with the requirements of this regulation, refrain from providing official information and/or testimony in response to the demand.

Employees may be subject to disciplinary action, including termination, if they provide official information or testimony relating to official information pursuant to a demand without approval from appropriate Department officials.

The revised regulations provide that the Department will consider the following criteria when evaluating a demand:

• Whether complying with the demand would be unduly burdensome, disproportionate to the needs of the case, or otherwise inappropriate under the applicable rules of discovery or rules of procedure governing the legal proceeding underlying the demand;

• Whether complying with the demand is appropriate under the relevant substantive law concerning privilege or disclosure of information;

• The public interest;

• The need to conserve the time and expense of Department employees for conducting official business;

• The need to avoid spending the resources of the United States for non-Federal government purposes;

• The need to maintain impartiality between private litigants in cases in which a substantial Department interest is not involved;

• Whether complying with the demand would adversely affect the Department's mission and duties;

• The need to avoid involving the Department in issues unrelated to its mission; and

• Any other factor relevant to the interests of the Department.

In comparison with the existing regulations, the above-referenced factors provide additional detail regarding the considerations that the Department will weigh in deciding whether to grant or deny a demand. The existing regulations list only three factors for Department officials to consider in determining whether to authorize an employee's appearance in a legal proceeding where the Government is not a party. These above-referenced factors apply to all demands for official information or testimony relating to official information.

The revised regulations provide that a demand will be denied if a Department official determines that producing employee testimony or official information would result in:

• Violating a statute, rule of procedure, regulation, or executive order;

• Revealing classified information;

• Revealing confidential commercial or financial information or trade secrets without the owner's consent;

• Revealing the internal deliberative processes of the Executive Branch or other privileged information; or

• Potentially impeding or prejudicing an on-going law enforcement investigation.

The revised regulations clarify the role of USDA's Office of the General Counsel (OGC) and Counsel to the Inspector General in the *Touhy* process and describe how OGC may interact with a party that submits a demand. The proposed regulations also ensure that OGC reviews and concurs with any *Touhy* decision.

Finally, the revised regulations set forth conditions that the Department may place on producing official information or authorizing employee testimony in response to a demand. Specifically, the Department may:

• Require the parties in the legal proceeding underlying the demand obtain a protective order or execute a confidentiality agreement to limit access to the official information or testimony provided;

• Limit the scope of the subject matter areas of the permitted testimony;

• Prescribe the manner, time, location, and duration of any testimony provided by deposition; and

• Impose any other condition deemed to be in the best interests of the United States.

Dates

We are publishing this rule without a prior proposal because we view this action as noncontroversial and anticipate no adverse public comment. This rule will be effective, as published in this document, on April 29, 2022, unless we receive written adverse comments or written notice of intent to submit adverse comments on or before March 30, 2022.

Adverse comments are comments that suggest the rule should not be adopted or that suggest the rule should be changed.

If we receive written adverse comments or written notice of intent to submit adverse comments, we will publish a document in the **Federal**

Register withdrawing this rule before the effective date. We will then publish a proposed rule for public comment.

If we receive no written adverse comments or written notice of intent to submit adverse comments within 30 days of publication of this direct final rule, this direct final rule will become effective 60 days following its publication.

Executive Order 12866 and Regulatory Flexibility Act

The Office of Management and Budget has determined that this regulatory action does not require a significance designation under Executive Order 12866, Regulatory Planning and Review.

The regulations revised by this rule relate to the internal management of USDA insofar as they address the receipt and handling of requests for the production or disclosure of official information in legal proceedings. As such, it is for the use of Department personnel only and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its agencies or other entities, its officers or employees, or any other person. Therefore, we expect the economic impact of this rule, if any, to be minimal and, accordingly, this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule contains no new reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 1

Administrative practice and procedure, Antitrust, Claims, Cooperatives, Courts, Equal access to justice, Fraud, Freedom of information, Government employees, Indemnity payments, Lawyers, Motion pictures, Penalties, Privacy.

Accordingly, we are amending 7 CFR part 1 as follows:

PART 1—ADMINISTRATIVE REGULATIONS

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

Authority: 5 U.S.C. 301, unless otherwise noted.

■ 2. Revise subpart K to read as follows:

Subpart K—Production or Disclosure of Official Information in Legal Proceedings

Sec.

General Information

§ 1.210 What does this subpart cover?

(a) This subpart sets forth the procedures to be followed with respect to demands seeking official information or employee testimony relating to official information for use in a legal proceeding.

(b) This subpart does not apply to:

(1) Congressional requests or subpoenas for official information or testimony relating to official information;

(2) Federal court civil proceedings in which the United States is a party;

(3) Federal administrative proceedings in which the Department is a party;

(4) The disclosure of official information or testimony relating to official information provided to other Federal agencies, including United States Department of Justice attorneys, in connection with a legal proceeding conducted on behalf of or in defense of the United States or a legal proceeding in which the United States has an interest; and

(5) Employees who testify, while on their own time or in approved leave status, as private citizens as to facts or events that are not related to the official business of the Department.

(c) Nothing in this subpart affects the rights, procedures, or Department regulations governing requests for, and release of, records under the Freedom of Information Act (FOIA, 5 U.S.C. 552), the Privacy Act (5 U.S.C. 552a), or the Government in the Sunshine Act (5 U.S.C. 552b).

(d) Nothing in this subpart affects procedures governing requests for authentication or certified copies of records under § 1.10.

(e) Nothing in this subpart permits the Department or employees to disclose official in-formation or give testimony relating to official information if the disclosure or testimony is protected or prohibited by statute or other applicable law.

(f) This subpart only provides guidance for the internal operations of the Department, and neither creates nor is intended to waive the sovereign immunity of the United States or create any enforceable right or benefit against the United States.

§ 1.211 Definitions that apply to this subpart.

For the purpose of this subpart:

(a) The term ''demand'' means any effort or attempt to obtain, for use in a legal proceeding, official information or testimony relating to official information, including any request, order, subpoena, or other command, as well as any informal or other attempt (by any method) to obtain official information, or testimony relating to official information, by an attorney, investigator, or others.

(b) The term ''Department'' means the United States Department of Agriculture, its constituent agencies, and Department officials authorized to decide whether to allow disclosures of official information or testimony relating to official information in response to demands.

(c) The term ''appropriate Department official'' means the head of a Department agency or office.

(d) The term ''employee'' means all employees or officers of the Department, including individuals who are or have been appointed by the Department, or who are or have been subject to the Department's supervision, jurisdiction, or control, including individuals hired through contractual agreements by or on behalf of the Department, or performing services under such agreements for the

Department, such as consultants, contractors, subcontractors, and their employees or other personnel. Also included in the definition are former Department employees where the demand seeks testimony relating to official information acquired while the person was an employee of the Department.

(e) The term ''legal proceeding'' means all pretrial, trial, and post-trial stages of all existing or reasonably anticipated judicial or administrative actions, hearings, investigations, or similar proceedings before courts, commissions, boards, grand juries, or other tribunals. This phrase includes all phases of discovery as well as formal or informal requests by attorneys or others involved in legal proceedings.

(f) The term ''Office of the General Counsel'' means the Office of the General Counsel of the Department.

(g) The term ''official information'' means all information of any kind, however stored, that is in the custody and control of the Department or relates to information in the custody and control of the Department, or information or knowledge acquired by a Department employee as part of the employee's official duties or because of the employee's official status with the Department.

(h) The term ''testimony'' means any written or oral statement by an employee, including personal appearances in court or at depositions, interviews, or informal inquiries in person or by telephone, responses to written interrogatories or other written statements such as reports, declarations, or affidavits, or any response involving more than the de-livery of documents.

(i) The term ''United States'' means the Federal Government, its departments, and its agencies.

§ 1.212 What is the Department's policy on providing official information or testimony relating to official information in response to a demand?

(a) It is the Department's general policy not to allow its employees to provide official information or testimony relating to official information in response to a demand. However, the Department will consider a demand submitted in accordance with this subpart and issue a decision to grant or deny the demand.

(b) No employee may provide official information or testimony relating to official information in response to a demand unless authorized by the Department in accordance with this subpart. *See United States ex rel. Touhy* v. *Ragen,* 340 U.S. 462 (1951). An employee who fails to comply with this regulation may be subject to disciplinary action up to and including removal.

Responsibilities if Making a Demand

§ 1.213 How can I obtain official information or testimony relating to official information in response to my demand?

You must submit a demand in accordance with this subpart (*see United States ex rel. Touhy* v. *Ragen,* 340 U.S. 462 (1951)). The appropriate Department official, in consultation with the Office of the General Counsel, will consider your demand in accordance with this subpart. The Counsel to the Inspector General will consider and make any final determinations regarding all demands seeking official information or employee testimony from the Office of Inspector General.

§ 1.214 What information must I include with my demand?

Your demand must include the following information, if applicable:

(a) The caption of the legal proceeding underlying your demand, including the docket number and the name of the court or other authority involved;

(b) The parties to the legal proceeding underlying your demand and any known relationships they have to the Department's mission or programs;

(c) A copy of the complaint or equivalent document setting forth the assertions in the legal proceeding underlying your demand;

(d) The identity of the employee whose testimony is sought and an affidavit or declaration under 28 U.S.C. 1746 or, if such an affidavit or declaration is not feasible, a written statement by you or your attorney, setting forth a reasonably detailed summary of the testimony sought and its relevance to the legal proceeding underlying your demand. Any authorization the Department decides to grant for testimony by an employee shall be limited to testimony within the scope of the summary provided;

(e) If the demand seeks documents or other materials to be obtained or inspected, a de-scription of the official information and the relevance to the legal proceeding underlying your demand;

(f) A written description of all prior decisions, orders, or pending motions in the legal proceeding underlying your demand that bear on the relevance of the official information or testimony you seek;

(g) A showing that the desired official information or testimony is not reasonably available from any other source, including a showing that no document could be provided and used in lieu of testimony; and

(h) An explanation of how each of the Department's considerations set forth in § 1.220(a) apply to your demand.

§ 1.215 How soon before I need the official information or testimony relating to official information should I submit my demand?

You must submit your demand, including all information identified in § 1.214, at least 14 calendar days before the date when you need the official information or testimony relating to official information.

§ 1.216 If I serve a subpoena, must I also submit information in accordance with § 1.214?

Yes. A subpoena shall be served in accordance with the Federal Rules of Civil Procedure, Federal Rules of Criminal Procedure, or applicable state procedure, as appropriate. If you serve a subpoena, including a subpoena *duces tecum,* together with the subpoena you must also submit information in accordance with § 1.214. If you serve a subpoena on the Department or a Department employee before submitting information in accordance with § 1.214 of this subpart, the Department may oppose the subpoena on the grounds that you failed to follow the requirements of this subpart.

§ 1.217 Where must I send my demand?

(a) Except for subpoenas served in accordance with the Federal Rules of Civil Procedure, Federal Rules of Criminal Procedure, or applicable state procedure as appropriate, you must send your demand, including all information required by § 1.214 of this subpart, to:

(1) The Office of the General Counsel at 1400 Independence Avenue SW, Washington, DC 20250, Attention: ''Touhy Demands,'' or by electronic mail to *OGC_Touhy_Demands@usda.gov;* and

(2) The United States Department of Agriculture agency office from which the official information or testimony is sought.

(b) Notwithstanding paragraph (a) of this section, a demand for Office of Inspector General information or testimony must be sent to the Counsel to the Inspector General, United States Department of Agriculture, Attention: ''Touhy Demands,'' at 1400 Independence Avenue SW, Mail Stop 2308, Washington, DC 20250–2308; by facsimile to (202) 690–1528; or by electronic mail to *OIG.TOUHY-DEMANDS@oig.usda.gov.*

§ 1.218 How much will I be charged?

(a) In the event that a demand is granted, the Department may charge reasonable fees. The appropriate Department official will determine all fees, if any, associated with this subpart and shall timely notify you of the fees, particularly those that are to be paid in advance.

(b) When a demand is granted under this subchapter to permit an employee to testify, you must pay the witness the fee and expenses, including any travel related costs, prescribed for attendance by the applicable rule of court. If no such fees are prescribed, the local Federal district court rule relating to witness fees for the Federal district court closest to where the witness appears will apply.

(c) When a demand is granted under this subchapter to produce documents, blueprints, electronic tapes, or other official information, the fees to be charged and paid prior to production shall be calculated as provided in Department regulations implementing the fee provisions of the FOIA.

Responsibilities of the Department

§ 1.219 How will the Department process my demand?

(a) The appropriate Department official, in consultation with the Office of the General Counsel, will consider your demand, and decide whether to grant or deny it. An Office of the General Counsel attorney or Department official may negotiate with you or your representative to refine or limit your demand. All demands for Office of Inspector General information or testimony will be processed by the Counsel to the Inspector General.

(b) Any decision in response to your demand will be limited to the scope of information requested in accordance with the requirements of this subpart.

(c) If you fail to follow the requirements of this subpart, the Department may decide not to grant your demand. If the Department determines that your demand is not complete, the Department may require that you provide additional information before your demand will be considered.

(d) If your demand is complete, the Department will consider it by applying the criteria under § 1.220.

§ 1.220 The Department's considerations in deciding whether to grant or deny a demand.

(a) In deciding whether to grant or deny a demand, the appropriate Department official should consider the following factors:

(1) Whether compliance with the demand would be unduly burdensome, disproportionate to the needs of the case, or otherwise inappropriate under the applicable rules of discovery or rules of procedure governing the legal proceeding underlying the demand;

(2) Whether compliance with the demand is appropriate under the relevant substantive law concerning privilege or disclosure of information;

(3) The public interest;

(4) The need to conserve the time and expense of Department employees for the conduct of official business;

(5) The need to avoid spending the time and money of the United States for non-Federal government purposes;

(6) The need to maintain impartiality between private litigants in cases in which a substantial Department interest is not implicated;

(7) Whether compliance with the demand would have an adverse effect on the Department's mission and duties;

(8) The need to avoid involving the Department in issues not related to its mission; and

(9) Any other factor the Department determines to be relevant to the interests of the Department.

(b) A demand will not be granted if the disclosure of official information or employee testimony relating to official information:

(1) Would violate a statute or a rule of procedure;

(2) Would violate a regulation or executive order;

(3) Would reveal information properly classified in the interest of national security;

(4) Would reveal confidential commercial or financial information or trade secrets in the absence of the owner's consent;

(5) Would reveal the internal deliberative processes of the Executive Branch or other privileged information; or

(6) Would potentially impede or prejudice an on-going law enforcement investigation.

§ 1.221 In responding to my demand, what conditions or restrictions may the Department impose on the production of official information or testimony relating to official information?

In responding to a demand, the Department may, at its discretion, impose conditions or restrictions on the production of official information or testimony relating to official information. Such conditions or restrictions may include the following:

(a) A requirement that the parties to the legal proceeding underlying your demand obtain a protective order or execute a confidentiality agreement to limit access to, and limit any further disclosure of, official information or testimony provided;

(b) A limitation on the subject matter areas of the permitted testimony;

(c) A requirement that the manner, time, location, and duration of any testimony be prescribed by the Department;

(d) A requirement that the parties to the legal proceeding underlying your demand agree that a transcript of the permitted testimony be kept under seal or will only be used or only made available in the particular legal proceeding underlying the demand;

(e) A requirement that you purchase an extra copy of the transcript of the employee's testimony from the court reporter and provide the Department with a copy at your expense; or

(f) Any other condition or restriction deemed to be in the best interests of the United States.

§ 1.222 Delegation authority for deciding whether to grant or deny a demand.

(a) Except as provided in paragraphs (b), (c), or (d) of this section, the appropriate department official may delegate his or her responsibilities under this subpart to employees of his or her agency as follows:

(1) In the national office of the agency, to a level no lower than two levels below the agency head;

(2) In a field component of an agency, to a level no lower than the official who heads a state office.

(b) Notwithstanding paragraph (a) of this section, the Chief of the Forest Service may delegate his or her responsibilities under this subpart as follows:

(1) In the national office of the Forest Service, to a level no lower than a Deputy Chief of the Forest Service;

(2) In a field component of the Forest Service, to a level no lower than a Regional Forester or Station Director.

(c) Notwithstanding paragraph (a) of this section, the General Counsel may delegate his or her responsibilities under this subpart as follows:

(1) In the national office of the Office of the General Counsel, to a level no lower than an Assistant General Counsel;

(2) In the field component of the Office of the General Counsel, to Regional Attorneys who may redelegate their responsibilities to Associate Regional Attorneys and Assistant Regional Attorneys who report to them.

(d) Notwithstanding paragraph (a) of this section, the Counsel to the Inspector General may delegate his or her responsibility under this subpart to the Deputy Counsel or an Assistant Counsel.

Responsibilities of Department Employees

§ 1.223 What must I, as an employee, do upon receiving a demand?

(a)(1) If you receive a demand, you must immediately notify your supervisor, who must in turn notify the appropriate Department official. Either your supervisor or the appropriate Department official must notify the Office of the General Counsel contact for your region or division for assistance with issuing the proper response.

(2) Demands for Office of Inspector General official information or testimony should be forwarded immediately to the Counsel to the Inspector General.

(b)(1) The appropriate Department official will decide whether to grant or deny the demand. Before a decision granting or denying a demand is made, the Office of the General Counsel contact for your region or division must be consulted for advice. All decisions granting or denying a demand must be in writing and must receive Office of the General Counsel concurrence prior to issuance. Absent Office of the General Counsel concurrence, a demand decision cannot be issued.

(2) The Counsel to the Inspector General will decide whether to grant or deny a demand for Office of Inspector General information and testimony.

(c) In the event that the appropriate Department official decides to deny the demand, the decision shall state that you are not authorized to provide official information or testimony and, if applicable, that you will not personally appear in response to the demand.

§ 1.224 What must I, as an employee, do upon becoming aware that a court or other authority has ordered compliance with a demand?

(a) If you become aware that a court or other authority has ordered compliance with a demand, you must promptly notify your supervisor, who must in turn notify the Office of the General Counsel for your region or division.

(b) In the case of compliance orders involving a demand for Office of Inspector General information and testimony, promptly forward them to your supervisor and the Counsel to the Inspector General.

Dated: September 2, 2021.

David Grahn,

Principal Deputy General Counsel, United States Department of Agriculture.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS–NOP–19–0106; NOP–19–03]

RIN 0581–AD98

National Organic Program; Amendments to the National List of Allowed and Prohibited Substances (2022 Sunset)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the United States Department of Agriculture's (USDA) organic regulations to implement recommendations from the National Organic Standards Board (NOSB). The rule prohibits fourteen nonorganic ingredients, which are currently allowed in the manufacture of organic processed products. The rule also prohibits two substances (vitamin B_1 and procaine), which are currently allowed in organic crop and livestock production. Finally, the rule renews an allowance for two substances (oxytocin and sucrose octanoate esters) in organic production.

DATES:

Effective Date: This rule is effective on March 30, 2022.

Compliance Dates: The compliance date for the amendments that remove vitamin B_1 and procaine from the National List is March 15, 2023. The compliance date for all other amendments that remove substances from the National List is March 15, 2024. Products in the stream of commerce after the compliance date that are labeled as ''organic'' or ''made with organic (specified ingredients or food group(s))'' may contain substances removed in this final rule if manufactured prior to the compliance date. The final rule renews an allowance for two substances (oxytocin and sucrose octanoate esters) in organic production. This rule maintains the current regulatory structure with regard to these two substances upon publication for up to five years.

FOR FURTHER INFORMATION CONTACT: Jared Clark, Standards Division, National Organic Program. Telephone: (202) 720–3252 or Email: *Jared.Clark@usda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary of Agriculture (''Secretary'') established the Agricultural Marketing Service's (AMS) National Organic Program (NOP) and the USDA organic regulations (65 FR 80547). Within the USDA organic regulations (7 CFR part 205) is the National List of Allowed and Prohibited Substances (or ''National List''). The National List identifies the synthetic substances that may be used in organic crop and livestock production as well as the nonsynthetic (natural) substances that may not be used. It also identifies the nonorganic substances that may be used in or on processed organic products.

AMS is finalizing 16 amendments to the National List in accordance with the procedures detailed in the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501–6524). OFPA establishes what may be included on the National List and the procedures that the USDA must follow to amend the National List (7 U.S.C. 6517). OFPA also describes the NOSB's responsibilities in proposing amendments to the National List, including the criteria for evaluating amendments to the National List (7 U.S.C. 6518).

To remain on the National List, substances must be: (1) Reviewed every five years by the NOSB, a 15-member federal advisory committee; and (2) renewed by the Secretary (7 U.S.C. 6517(e)). This action of NOSB review and USDA renewal is commonly referred to as the ''sunset review'' or ''sunset process.'' AMS published information about this process in the **Federal Register** on September 16, 2013 (78 FR 56811). The sunset date (*i.e.,* the date by which the Secretary must renew a substance for the listing to remain valid on the National List) for each substance is included in the NOP Program Handbook (document NOP 5611).

The removal of substances from the National List addresses National Organic Standards Board (NOSB) recommendations submitted to the Secretary after the conclusion of the NOSB's public meetings on October 29, 2015; November 2, 2017; October 26, 2018; and October 30, 2020.

During a 60-day comment period that closed on October 25, 2021, AMS received 60 comments on the proposed rule. See below for a discussion of the comments received and AMS's responses to comments. Comments on the proposed rule can also be viewed through *Regulations.gov.* Use the search area on the homepage at *https://www.regulations.gov* to enter a keyword,

title, or docket ID (the docket number for this rule is AMS–NOP–19–0106).

II. Overview of Amendments

This rule removes fourteen ingredients and two substances from the National List and retains (or ''renews'') two substances on the National List. Additional background on the NOSB's review of the substances may be found in the proposed rule (86 FR 47242; August 24, 2021).

This final rule removes the following synthetic substances, which are currently allowed in organic crop and livestock production (7 CFR 205.601 and 205.603):

- Vitamin B_1 (crop production); and
- Procaine (livestock production).

As noted in the **DATES** section, AMS is providing a one-year implementation period for these changes to provide time for certifying agents to communicate the changes to organic operations and for organic producers to cease use.

Additionally, AMS is removing the following nonorganic ingredients, which are currently allowed in organic handling (§§ 205.605 and 205.606):

- Alginic acid;
- Colors (black currant juice color, blueberry juice color, carrot juice color, cherry juice color, grape juice color, paprika color, pumpkin juice color, turmeric extract color);
- Kelp;
- Konjac flour;
- Sweet potato starch;
- Turkish bay leaves; and
- Whey protein concentrate.

Finally, this rule renews sucrose octanoate esters for organic crop and livestock production and oxytocin for organic livestock production. The new sunset date for the two substances (three listings on the National List) is March 15, 2027.

Below, AMS describes each substance in alphabetical order, sorted by use (*i.e.,* crop production, livestock production, handling). Sucrose octanoate esters is discussed first because it is used in both crop and livestock production. For each substance, AMS outlines the NOSB's sunset review, discusses comments received, and describes the final action by this rule.

Implementation Period. As noted in the **DATES** section, AMS is providing a one-year implementation period for producers to cease use of vitamin B_1 and procaine. For all other substances removed by this final rule, AMS is providing a two-year implementation period. A shorter implementation period for vitamin B_1 and procaine is appropriate because there is no evidence these substances are currently used in organic production. A 2-year implementation period is provided for organic handling operations to cease use of the nonorganic ingredients (including alginic acid) above. AMS believes that a two-year implementation period provides certifying agents with the necessary time to communicate the changes to organic operations and for operations to source organic forms of the ingredients (if necessary), revise labels, and/or adjust recipes. Public comment indicated a two-year implementation period would be adequate. AMS notes that while the final rule provides a two-year implementation period, organic handlers may not use nonorganic forms of ingredients when organic forms of the ingredients are commercially available (see 7 CFR 205.301(f)(6)).

Sucrose Octanoate Esters (§ 205.601 and § 205.603)

This final rule renews the allowances for sucrose octanoate esters at 7 CFR 205.601(e)(10) and 205.603(b)(11).[1] Sucrose octanoate esters is a pesticide that targets mites (*e.g., Varroa* mites, a pest that attacks honeybees) and certain soft-bodied insects (*e.g.,* aphids).

NOSB Review and Recommendation

Following the sunset review of sucrose octanoate esters, the NOSB recommended removing sucrose octanoate esters from the National List. As described in the Background section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

Prior to the NOSB's 2018 Fall meeting, the NOSB received information indicating there were no current U.S. Environmental Protection Agency (EPA) registrations for sucrose octanoate esters at the time and therefore no approved pesticide applications. Based on this information, the NOSB reasoned that no argument could be made that this substance remains an essential tool for organic production if there was no current legal use consistent with the National List restrictions. The Board then voted to remove both the crop use listing (at § 205.601(e)) and the livestock use listing (at § 205.603(b)).[2] [3] In both organic crop and livestock production, sucrose octanoate esters are allowed as an insecticide and parasiticide, with the latter including treatment of *Varroa* mites in honeybees. Honeybees are regulated as livestock under the USDA organic regulations (see definition of ''livestock'' at § 205.2), allowing substances on the National List for livestock production to be used in organic apiculture (beekeeping).

Comments Received

Most comments on the proposed rule related to the proposed removal of sucrose octanoate esters from the National List.

Lack of approved alternatives. Most comments supported keeping sucrose octanoate esters on the National List. Commenters stated that removing this substance would have a negative impact on organic farmers and beekeepers, as it is a primary ingredient in OrganiShield—a common product used in Integrated Pest Management (IPM) systems. Commenters stressed that there is no comparable product on the market that is safe, effective, and approved for use in organic crop and livestock production.

Environmentally friendly pesticide. Commenters noted that the use of sucrose octanoate esters benefits crop-friendly insects such as pollinators, biodegrades rapidly after use, and does not negatively impact the environment. Multiple commenters highlighted that sucrose octanoate esters play a key role as an organic pesticide, specifically in controlling *Varroa* mites.

Change in market situation. Commenters highlighted that the NOSB voted to remove both the crop use listing at § 205.601(e) and the livestock use at § 205.603(b) during the Fall 2018 meeting. The NOSB's rationale was that sucrose octanoate esters could not be considered an essential tool for organic production if there were no legally approved uses (*i.e.,* there were no active EPA pesticide registrations at the time). Commenters noted that the market situation has changed since the NOSB's 2018 decision, as there have since been new EPA registrations for sucrose octanoate esters.

AMS Response

AMS had tentatively suggested removal of sucrose octanoate esters in the proposed rule based on the lack of EPA-approved uses for this substance back when the NOSB recommended its removal in 2018 (86 FR 47242, August 24, 2021). Following the 2018 NOSB

[1] Sucrose octanoate esters is cited in NOSB recommendation(s) at 7 CFR 205.603(b)(10). The current citation for sucrose octanoate esters is 7 CFR 205.603(b)(11).

[2] National Organic Standards Board, *Sunset Review of Substances Listed at §§ 205.601 and 205.602, https://www.ams.usda.gov/sites/default/files/media/CS2020SunsetFinalRecOct2018.pdf.*

[3] National Organic Standards Board, *Sunset Review of Substances Listed at § 205.603, https://www.ams.usda.gov/sites/default/files/media/LS2020SunsetFinalRecOct2018.pdf.*

meeting, the EPA received product registrations for sucrose octanoate esters in December 2020. Subsequent comments demonstrated that the market situation had changed since the 2018 NOSB recommendation, with recent product registrations and increased use of sucrose octanoate esters. Additionally, comments noted this substance is not harmful to the environment and cited the lack of alternatives approved for organic use. In response to comments identifying the recent registration, increased use, and a lack of alternatives, AMS is not removing sucrose octanoate esters from the National List at §§ 205.601(e)(10) and 205.603(b)(11). The substance will undergo another sunset review prior to the new March 15, 2027 sunset date. At that time, the Board will have another opportunity to evaluate the substance against OFPA criteria considering this recent registration and increase in use.

Vitamin B_1 (§ 205.601)

This final rule amends the National List to prohibit use of synthetic vitamin B_1 in organic crop production by removing vitamin B_1 from 7 CFR 205.601(j)(9).

NOSB Review and Recommendation

Following the sunset review of vitamin B_1, the NOSB recommended removing vitamin B_1 from the National List. As described in the Background section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

In support of their sunset review,[4] the NOSB requested a third-party technical report on the use of vitamins B_1, C, and E in crop production.[5] The technical report stated these vitamins are generally used for stimulation of crop growth and plant protection but found that previous claims about root growth and reduction of transplant shock associated with vitamin B_1 were largely unsubstantiated outside of a laboratory environment. Due to this, and the lack of support voiced during the public comment process regarding efficacy or necessity, the NOSB recommended removal.

Comments Received

AMS received no comments in support of keeping synthetic vitamin B_1 on the National List for organic crop production. One commenter requested the NOP allow for a 12-month implementation timeline.

AMS Response

As commenters noted, the NOSB voted to remove vitamin B_1 from the National List at the Fall 2017 meeting on the basis that it is not essential for organic crop production and because its primary use for root growth and reduction of transplant shock was not substantiated by technical information. Given this information regarding use and efficacy, AMS is removing vitamin B_1 from the National List for organic crop production. Further, the 2015 technical report on vitamins for crop production identified several natural (nonsynthetic) alternatives to vitamin B_1, including yeast, various meals (*e.g.,* soybean meal, cottonseed meal), and other crop waste or residues. After considering public comments, technical reports, and the NOSB review, AMS is finalizing the removal of vitamin B_1 from the National List at § 205.601(j)(9). As specified in the **DATES** section, organic crop producers will have until March 15, 2023, to comply with this change.

Oxytocin (§ 205.603)

This final rule renews the allowance for oxytocin (an animal drug) for use in post-parturition (birth) therapeutic applications at 7 CFR 205.603(a)(22). Oxytocin will not be prohibited, as proposed, in organic livestock production. A discussion of the compliant uses under the annotation, ''postparturition therapeutic applications,'' is included below in AMS's response.

NOSB Review and Recommendation

Following its sunset review of oxytocin, the NOSB recommended removing oxytocin from the National List.[6] As described in the Background section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

The NOSB requested public comment on whether the substance was essential for organic production and whether there were natural alternative materials and methods that render it unnecessary. In response, the NOSB received public comments indicating the substance was no longer necessary and generally supporting its removal. The NOSB concluded there are numerous alternative methods and materials to oxytocin and that the use of oxytocin no longer meets the criteria at 7 U.S.C. 6518(m)(6). Additionally, the NOSB noted that oxytocin is a synthetic hormone and that hormones are not otherwise permitted in organic production (§§ 205.237(b)(1) and 205.238(c)(3)).

Comments Received

AMS received several comments in response to the proposed sunset removal of oxytocin from the National List.

General opposition. A certifying agent (''certifier'') noted that 35 of the organic dairies they certify include the substance in their Organic System Plans for use in post-parturition therapeutic applications. The commenter stated that those operations use oxytocin for various uses, including uterine care, milk letdown for first-time heifers or as a mastitis treatment, retained placenta, and strained labor treatment. The commenter noted they do not allow routine or repeated use of oxytocin nor permit operations to use oxytocin to promote milk production. The commenter requested that any prohibition of the substance occur following the 2022 spring birthing season.

A dairy manufacturer requested retention for oxytocin on the National List due to a lack of alternatives. The commenter also stated oxytocin is a veterinary control drug that should only be administered or prescribed under veterinary instruction. The commenter recognized alternatives can assist with topical inflammation; however, for uses to assist with inflammation caused by animals withholding milk or to assist with uterine cleaning, the commenter stated there were no compliant alternatives. Another commenter also requested oxytocin to remain an allowed substance on account of its effectiveness as a post-parturition therapeutic to transition a dry cow to a lactating cow.

General agreement. A comment stated that natural alternatives are available to address certain post-parturition complications that can arise in organic dairy cattle and that use of oxytocin would prevent organic producers from claiming their products are ''hormone-free.'' The commenter requested an implementation period of 12 months to

[4] National Organic Standards Board, *Crops 2019 Sunset Substances, https://www.ams.usda.gov/sites/default/files/media/CS2019SunsetsFinalRec.pdf.*

[5] Pesticide Research Institute, *Technical Evaluation Report: Vitamins B_1, C and E, https://www.ams.usda.gov/sites/default/files/media/Vitamins%20B1-C-E%20TR%202015.pdf.*

[6] National Organic Standards Board, *Livestock 2019 Sunset Substances, https://www.ams.usda.gov/sites/default/files/media/LS2019SunsetsFinalRec.pdf.*

allow for industry time to comply with the final rule.

AMS Response

After reviewing public comments, AMS is renewing the listing for oxytocin in this final rule. The substance will remain on the National List, with a new sunset date of March 15, 2027. AMS agrees with commenters that synthetic oxytocin remains essential to organic livestock production in the absence of alternative nonsynthetic (natural) medical treatments for post-parturition emergency treatments (*i.e.,* treatment for severe complications resulting from labor). AMS notes that under current FDA regulations, ''Federal law restricts [oxytocin] to use by or on the order of a licensed veterinarian.'' (21 CFR 522.1680(c)(3)). Although some annotations on the National List for animal drugs specify that they may be used only by or on the order of a veterinarian, the absence of this phrasing in the annotation for oxytocin would not alter a producer's obligations to comply with other federal laws.

By retaining oxytocin on the National List, organic livestock producers will continue to be permitted to use the drug to treat specific conditions within a limited timeframe following parturition without forfeiting the animal's organic status. Additional discussion of the permitted uses of the substance in organic production follows.

Annotation Discussion

AMS is aware there is some confusion around what uses comply with the annotation for oxytocin that reads, ''use in postparturition therapeutic treatments'' (§ 205.603(a)(22)). This discussion is meant to inform certifying agents and organic operations of AMS's current thinking on uses that comply with the annotation.

The current annotation allows producers to use oxytocin to treat conditions related to labor and to an animal's postpartum survival. Its use is not permitted on a routine basis (*i.e.,* as protocol). Instead, it is available for emergency situations and severe complications in the immediate postpartum (following birth of young) period. It may not be administered to increase an animal's milk production (volume) or for milk letdown. As previously noted in this document, Federal law restricts this drug to use by or on the order of a licensed veterinarian (21 CFR 522.1680(c)(3)).

AMS's interpretation of the annotation for oxytocin at § 205.603, ''for postparturition therapeutic applications,'' is informed and supported by its prior discussion of oxytocin in its March 13, 2000 proposed rule (65 FR 13511). AMS believes that discussion is relevant to the meaning of the current annotation in the USDA organic regulations. In the discussion in the proposed rule, AMS noted that oxytocin, ''has some uses that do not involve lactation but are instead related to an animal's postpartum survival'' and that oxytocin was permitted by some certifiers for ''animals that experience severe complications resulting from labor,'' and described those as ''emergency situations'' (65 FR 13511, 13588).

AMS's expectation is that certifiers will always review an organic operation's use of oxytocin to ensure it is used only in postparturition therapeutic applications.

Procaine (§ 205.603)

This final rule amends the National List to remove procaine at 7 CFR 205.603(b)(9) and prohibit its use in organic livestock production.

NOSB Review and Recommendation

Following the sunset review of procaine, the NOSB recommended removing procaine from the National List. As described in the Background section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

In support of their sunset review, the NOSB solicited public comment over two meetings on use of procaine and whether procaine can be sourced without prohibited antibiotics. The comments stated procaine is rarely used, is only available in drug formulations that are combined with prohibited antibiotics, and is not as effective as lidocaine (allowed for organic livestock use at § 205.603(b)(5)). After their review, the NOSB recommended removal of procaine from the National List.

Comments Received

AMS received no comments opposed to removing procaine from the National List. A certifying agent noted the importance of pain relievers but stated that procaine was not an active ingredient in any product currently used by organic operations that it certifies. Another comment highlighted that procaine products are already prohibited for use because they are always formulated with antibiotics that are prohibited in organic livestock production. One commenter requested an implementation timeline of 12 months to allow industry time to comply with the final rule.

AMS Response

As the NOSB referenced in their recommendation, procaine is not available on its own (*i.e.,* not compounded with an antibiotic). A search of the FDA's animal drug database (*https://animaldrugs atfda.fda.gov/*) indicates that all 16 of the FDA approved drugs that contain procaine also contain an antibiotic (*e.g.,* Penicillin G Procaine). Furthermore, another National List material, lidocaine, could be used to perform the same function (as a local anesthetic). This information supports that procaine is not currently used in organic production and no longer meets the exemption requirement (7 U.S.C. 6517(c)(1)(A)(ii)). AMS agrees with commenters and the NOSB that procaine is not essential to organic livestock production. AMS is finalizing the removal of synthetic procaine from the National List at § 205.603(b)(9) to prohibit its use in organic livestock production. As specified in the **DATES** section, organic livestock producers will have until March 15, 2023, to comply with this change.

Alginic Acid (§ 205.605)

This final rule amends the National List to remove alginic acid at 7 CFR 205.605(b) and prohibit its use in organic processed products.

NOSB Review and Recommendation

Following the sunset review of alginic acid, the NOSB recommended removing alginic acid from the National List. As described in the Background section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

In support of their sunset review of alginic acid, the NOSB received a third-party technical report in 2015 and solicited public comment at their Spring 2019 meeting.[7] The NOSB received no comments in support of continuing the allowance of, or stating use of, alginic acid. In addition, no certifying agents (''certifiers'') reported this material in use by their certified operations. Further, the 2015 technical report cited other National List materials (including agar-agar, carrageenan, gellan gum, and xanthan gum) as possible alternatives to alginic acid. Based on this, the NOSB

[7] OMRI, *Technical Evaluation Report: Alginic Acid, https://www.ams.usda.gov/sites/default/files/media/Alginic%20Acid%20TR.pdf.*

determined that there are readily available alternatives and recommended removal.

Comments Received

AMS received no comments in favor of retaining alginic acid on the National List. One comment agreed with the NOSB's rationale for removing alginic acid from the National List and requested a 24-month implementation period to comply with the final rule.

AMS Response

Given that there were no reports of operations using alginic acid and the availability of possible alternatives on the National List (as referenced in the technical report), this substance no longer appears to meet the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). AMS is finalizing the removal of alginic acid from the National List at § 205.605(b) to prohibit its use in organic processed products. As identified in the **DATES** section, organic processors will have until March 15, 2024, to comply with this change.

Colors (§ 205.606)

This final rule amends the National List to remove eight nonorganic colors from the National List at § 205.606(d):

- Black currant juice color—derived from *Ribes nigrum* L.;
- Blueberry juice color—derived from blueberries (*Vaccinium spp.*);
- Carrot juice color—derived from *Daucus carota* L.;
- Cherry juice color—derived from *Prunus avium* (L.) L. or *Prunus cerasus* L.;
- Grape juice color—derived from *Vitis vinifera* L.;
- Paprika color—derived from dried powder or vegetable oil extract of *Capsicum annuum* L.;
- Pumpkin juice color—derived from *Cucurbita pepo* L. or *Cucurbita maxima* Duchesne;
- Turmeric extract color—derived from *Curcuma longa* L.

NOSB Review and Recommendation

The NOSB recommended the removal of these colors at their Fall 2020 meeting.[8] The effect of these removals means that only organic forms of these colors will be allowed in organic handling. The NOSB solicited public comments in support of their sunset review of these colors at the Spring and Fall 2020 meetings. The NOSB noted these public comments were mixed regarding the availability and necessity of these colors. Additionally, in the case of carrot juice color and grape juice color, the NOSB noted that the availability of these crops in organic forms should provide an adequate supply of organic carrot juice and organic grape juice for color production and cited that as a reason for their recommended removal.

Comments Received

AMS received few comments in response to the proposed removal of eight nonorganic colors from the National List.

General opposition. A comment requested retaining turmeric extract color on the National List because there is no readily available organic alternative in the marketplace. Another comment requested retaining paprika color on the National List as there are no commercially-available, organic alternatives for the color; however, the commenter stated there are readily-available, organic raw materials that may allow an organic version of the color to be developed. The commenter estimated a two-year implementation period would provide enough time for color development, shelf-life trials, and commercialization.

General agreement. A certifier noted limited use of the nonorganic colors in this final rule among the organic handlers they certify. The comment noted there is limited use of nonorganic paprika color, grape juice color, and cherry juice powder. A certifying agent was particularly concerned about an insufficient supply of blueberry juice color, carrot juice color, paprika color, and turmeric extract color. The commenter cited an internal survey (of organic operations) that indicated the supply of organic colors is fragile and that removal from the National List may be premature, especially without a substantial implementation period. The commenter requested an implementation timeline of 24 months to allow industry time to comply with the final rule.

AMS Response

In the rule proposing removal of these colors, AMS requested comments regarding whether any of these colors are necessary and whether there are enough organic versions available to meet demand. Comments received suggested there may not be sufficient supplies of certain organic colors but that supply would likely develop over the course of the 24-month implementation period. None of these comments suggested an inability to produce or develop organic versions of these colors, given sufficient time. As such, AMS is finalizing the removal of these non-organic colors from the National List at § 205.606(d). To support the development of an adequate supply of organic colors, as requested by commentors, organic processors will have until March 15, 2024 (a 24-month implementation period) to comply with these changes.

Kelp (§ 205.606)

This final rule amends the National List to remove kelp at 7 CFR 205.606(k) and prohibit its use. Wakame seaweed and Pacific kombu remain allowed in § 205.606 in organic processed products.

NOSB Review and Recommendation

Following the sunset review of kelp at their Fall 2020 meeting, the NOSB recommended removing kelp from the National List. Only organic forms of kelp (other than wakame seaweed and Pacific kombu, which remain allowed in § 205.606), would be allowed in organic handling. As described in the Background section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

During its sunset review, the NOSB received comments in support of removing, as well as relisting, kelp. The NOSB determined that there were alternatives to kelp on the National List (namely Pacific kombu and wakame) and therefore recommended removing kelp from the National List in § 205.606.

Comments Received

AMS received no comments in favor of retaining nonorganic kelp on the National List for organic handling. A comment requested an implementation period of 24 months to allow industry time to comply with the final rule.

AMS Response

According to the Organic Integrity Database, there are currently 104 certified crop, wild crop, and handling operations that list ''kelp'' as a certified organic product.[9] Organic kelp appears to be commercially available; therefore, this substance is no longer necessary and no longer meets the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). AMS did not receive any comments challenging this conclusion and is finalizing the removal of non-organic kelp from the National List at § 205.606(k). As identified in the

[8] National Organic Standards Board, *2022 Sunset Reviews—Handling (§§ 205.605, 205.606), https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf.*

[9] Organic Integrity Database, accessed January 5, 2022: *https://organic.ams.usda.gov/integrity/Search.aspx.*

DATES section, organic processors will have until March 15, 2024, to comply with this change.

Konjac Flour (§ 205.606)

This final rule amends the National List to remove konjac flour at 7 CFR 205.606(l) and prohibit its use in organic processed products.

NOSB Review and Recommendation

Following the sunset review of konjac flour at their Fall 2017 meeting, the NOSB recommended removing konjac flour from the National List. As described in the Background section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

In support of their recommendation, the NOSB solicited public comment regarding the use and necessity of konjac flour in organic handling as well as the availability of organic konjac flour. The NOSB received little feedback from industry in response. One trade organization reported one organic producer using konjac flour but was unsure if it was for products sold as ''organic.'' Several certifiers stated they had not received any feedback from their clients regarding the need for, or use of, nonorganic konjac flour in their products. Ultimately, the NOSB voted to recommend removal of konjac flour from the National List at § 205.606(l) due to available alternatives.

Comments Received

AMS received no comments in favor of retaining nonorganic konjac flour on the National List for organic handling. A comment requested an implementation period of 24 months to allow industry time to comply with the final rule.

AMS Response

A search in the Organic Integrity Database for ''konjac'' shows 30 operations with some form of certified organic konjac products (*e.g.,* powder, starch, konjac tubers).[10] Given the lack of reported use of, or need for, nonorganic konjac flour, and the availability of organic konjac flour and konjac tubers, nonorganic konjac flour no longer meets the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). AMS did not receive any comments challenging this conclusion and, as such, is finalizing the removal of non-organic konjac flour from the National List at § 205.606(l). As identified in the **DATES** section, organic processors will have until March 15, 2024, to comply with this change.

Sweet Potato Starch (§ 205.606)

This final rule amends the National List to remove sweet potato starch at 7 CFR 205.606(s)(2) and prohibit the use of non-organic sweet potato starch in organic products.

NOSB Review and Recommendation

Following the sunset review of sweet potato starch at their Fall 2020 meeting, the NOSB recommended removing sweet potato starch from the National List. As described in the Background section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

During its sunset review, the NOSB solicited public comment on the use and necessity of sweet potato starch but received little feedback. The comments suggested there is scant use of nonorganic sweet potato starch, that alternatives are readily available, and that organic sweet potato starch is available. Further, comments noted that the continued listing of nonorganic sweet potato starch is inhibiting production of organic forms of sweet potato starch. Based on this information, the NOSB recommended the removal of this substance due to available alternatives.

Comments Received

AMS received no comments in favor of retaining nonorganic sweet potato starch on the National List for organic handling. A comment requested an implementation period of 24 months to allow industry time to comply with the final rule.

AMS Response

A search in the Organic Integrity Database for ''potato starch'' shows 60 operations with some form of certified organic potato starch and another 27 operations with some form of certified organic pea starch, a cited alternative to sweet potato starch.[11] Given the low reported use of nonorganic sweet potato starch and the availability of organic sweet potato starch and organic pea starch, nonorganic sweet potato starch no longer meets the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). AMS did not receive any comments challenging this conclusion and, as such, is finalizing the removal of non-organic sweet potato starch from the National List at § 205.606(s)(2). As identified in the **DATES** section, organic processors will have until March 15, 2024, to comply with this change.

Turkish Bay Leaves (§ 205.606)

This final rule amends the National List to remove Turkish bay leaves at 7 CFR 205.606(v) to prohibit its use in organic products.

NOSB Review and Recommendation

Following the sunset review of Turkish bay leaves at their Fall 2020 meeting, the NOSB recommended removing Turkish bay leaves from the National List. As described in the Background section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

During its sunset review, the NOSB received many comments supporting the removal of Turkish bay leaves due to the availability of organic versions. The NOSB called attention to one comment received at its Fall 2020 meeting from an organic producer who uses Turkish bay leaves in a wide range of organic canned soups. This food manufacturer noted that organic forms of Turkish bay leaves are readily available. Further comments from certifiers indicated that few, if any, of their operations use nonorganic Turkish bay leaves. Based on this information, the NOSB recommended the removal of this substance due to available alternatives.[12]

Comments Received

AMS received no comments in favor of retaining nonorganic Turkish bay leaves on the National List for organic handling. A commenter noted that the NOSB received multiple comments supporting the removal of Turkish bay leaves from the National List during the 2020 sunset review. The commenter stated that Turkish bay leaves only remained on the National List after the NOSB's Fall 2015 meeting due to the lack of available, organic alternatives.

AMS Response

Previously, AMS proposed removing Turkish bay leaves from § 205.606 following a Fall 2015 NOSB

[10] Organic Integrity Database, accessed January 5, 2022: *https://organic.ams.usda.gov/integrity/Search.aspx.*

[11] Organic Integrity Database, accessed January 5, 2022: *https://organic.ams.usda.gov/integrity/Search.aspx.*

[12] National Organic Standards Board, *2022 Sunset Reviews—Handling (§§ 205.605, 205.606), https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf.*

recommendation.[13] At the time, AMS received comments stating organic whole Turkish bay leaves were not available in the quantity or quality to meet organic handling needs. As a result, AMS did not finalize removing Turkish bay leaves (82 FR 31241, July 6, 2017), and its sunset date was extended five years.

A search in the Organic Integrity Database for ''bay leaves'' shows 143 crop and handling operations with some form of certified organic bay leaves. A search using the term ''Turkish bay leaves'' shows six operations, as it appears that only one certifying agent identifies bay leaves with that level of specificity in the Organic Integrity Database.[14] Given that comments to the NOSB indicated organic Turkish bay leaves are readily available in all forms and the high number of operations reported in the Organic Integrity Database with organic bay leaves (of which a subset are Turkish bay leaves), nonorganic Turkish bay leaves no longer meet the requirements for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). During this current rulemaking, AMS received no comments challenging this conclusion and is removing non-organic Turkish bay leaves from the National List at § 205.606(v). As identified in the **DATES** section, organic processors will have until March 15, 2024, to comply with this change.

Whey Protein Concentrate (§ 205.606)

This final rule amends the National List to remove whey protein concentrate at 7 CFR 205.606(x) and prohibit its use in organic processed products.

NOSB Review and Recommendation

Following the sunset review of whey protein concentrate at their Fall 2020 meeting, the NOSB recommended removing whey protein concentrate from the National List. As described in the Background section, the sunset process is a system of regular evaluation of National List substances against criteria in the OFPA. If a substance is found to no longer satisfy these criteria, the NOSB may recommend removal of the substance.

During this sunset review, the NOSB received many comments supporting the removal of whey protein concentrate due to the availability of organic versions. The NOSB highlighted several commenters, who demonstrated that they produce a robust supply of organic whey protein concentrate in several forms and sell excess to the conventional market. A comment noted that the international supply chain of organic whey-based products is also robust. Further comments from at least one certifier indicated that none of their operations are using nonorganic whey protein concentrate. Based on this information, the NOSB recommended the removal of this substance based on available alternatives.[15]

Comments Received

AMS received no comments in favor of retaining nonorganic whey protein concentrate on the National List for organic handling. A certifier noted that an organic operation they certify previously used non-organic whey protein concentrate but no longer does. Another commenter noted that the NOSB received many comments supporting the removal of whey protein from the National List during the 2020 sunset review, including from several manufacturers who demonstrated they produce a robust supply of organic whey protein concentrate. The commenter noted that removing the allowance of a nonorganic form will help support organic cheese manufacturers. A comment requested an implementation period of 24 months to allow industry time to comply with the final rule.

AMS Response

Previously, AMS proposed removing whey protein concentrate from § 205.606, following a Fall 2015 NOSB recommendation.[16] At that time, AMS received comments stating organic whey protein concentrate was essential for organic processed products and that there were no commercially available, organic products. As a result, AMS did not finalize the removal of whey protein concentrate from the National List (82 FR 31241, July 6, 2017).

A search in the Organic Integrity Database for ''whey protein concentrate'' shows 23 operations with some form of certified organic whey protein concentrate. The NOSB also received comments suggesting a substantial supply of all forms of organic whey protein concentrate and cited the diversion of some quantity to the conventional market as evidence that there is enough supply to meet the demand for organic whey protein concentrate. Given the comments submitted to the NOSB outlining the lack of use and stated abundance of supply, nonorganic whey protein concentrate no longer meets the requirement for inclusion on the National List at 7 U.S.C. 6517(c)(1)(A)(ii). During this current rulemaking, AMS received no comments challenging this conclusion and is removing non-organic whey protein concentrate from the National List at § 205.606(x). As identified in the **DATES** section, organic processors will have until March 15, 2024, to comply with this change.

III. Related Documents

AMS published notices in the **Federal Register** to announce the NOSB meetings where the Board discussed these substances. The notices invited public comments on the NOSB recommendations addressed in this final rule. Transcripts of the meetings, along with the NOSB recommendations, can be found on the AMS website at: *https://www.ams.usda.gov/rules-regulations/organic/nosb/meetings.* The AMS proposed rule that preceded this final rule was published on August 24, 2021 (86 FR 47242).

IV. Statutory and Regulatory Authority

The OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. The OFPA authorizes the NOSB to develop recommendations for submission to the Secretary to amend the National List and establish a process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List (7 U.S.C. 6518(k) and (n)). Section 205.607 of the USDA organic regulations permits any person to petition to add or remove a substance from the National List and directs petitioners to obtain the petition procedures from USDA (7 CFR 205.607). The current petition procedures published in the **Federal Register** (81 FR 12680, March 10, 2016) for amending the National List can be accessed through the NOP Handbook on the NOP website as document NOP 3011 at *https://www.ams.usda.gov/rules-regulations/organic/handbook*.

[13] National Organic Standards Board, *Sunset 2017 NOSB Final Review Handling Substances, https://www.ams.usda.gov/sites/default/files/media/HS%202017%20Sunset%20Final%20Rvw%20605%28a%29_%28b%29_606_final%20rec.pdf.*

[14] Organic Integrity Database, accessed January 5, 2022: *https://organic.ams.usda.gov/integrity/Search.aspx.*

[15] National Organic Standards Board, *2022 Sunset Reviews—Handling (§§ 205.605, 205.606),https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf.*

[16] National Organic Standards Board, *Sunset 2017 NOSB Final Review Handling Substances, https://www.ams.usda.gov/sites/default/files/media/HS%202017%20Sunset%20Final%20Rvw%20605%28a%29_%28b%29_606_final%20rec.pdf.*

A. Executive Order 12866 and Regulatory Flexibility Act

This final rule does not meet the criteria of a significant regulatory action under Executive Order 12866 as supplemented by Executive Order 13563. Therefore, the Office of Management and Budget (OMB) has not reviewed this rule under those Orders.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS) to delineate which operations qualify as small businesses.[17] The SBA classifies small agricultural producers that engage in crop and animal production as those with average annual receipts of less than $1,000,000 (13 CFR 121.201). Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific type of manufacturing. Certifying agents fall under the NAICS subsector ''all other professional, scientific, and technical services.'' For this category, the small business threshold is average annual receipts of less than $16.5 million.

Producers. AMS has considered the economic impact of this final rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics Service (NASS) and the NOP indicate most of the certified organic production operations in the United States would be considered small entities. According to the 2017 Census of Agriculture, 16,585 organic farms in the United States reported sales of organic products and total farmgate sales more than $9.9 billion.[18] Based on that data, organic sales average just under $600,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the $1,000,000 sales threshold to qualify as a small business.

Handlers. According to the NOP's Organic Integrity Database (OID), there are 10,971 U.S.-based organic handlers that are certified under the USDA organic regulations.[19] The Organic Trade Association's 2020 Organic Industry Survey has information about employment trends among organic manufacturers. The reported data are stratified into three groups by the number of employees per company: Fewer than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector and the lower bound (50) of the range for the larger manufacturers is significantly smaller than the SBA's small business thresholds (500 to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

Certifying agents. The SBA defines ''all other professional, scientific, and technical services,'' which include certifying agents, as those having annual receipts of less than $16,500,000 (13 CFR 121.201). There are currently 76 USDA-accredited certifying agents, based on a query of the OID database, who provide organic certification services to producers and handlers. While many certifying agents are small entities that would be affected by this final rule, we do not expect that these certifying agents would incur significant costs as a result of this action as certifying agents already must comply with the current regulations (*e.g.,* maintaining certification records for organic operations).

AMS does not expect this rule to have a significant economic impact on entities affected by this rule. Alternatives exist to the substances that this rule prohibits, as determined by the NOSB and AMS. Additionally, AMS is providing a 12- to 24-month implementation period, depending on the substance or ingredient, to allow affected entities time to modify practices.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect. Accordingly, to prevent duplicative regulation, states and local jurisdictions are preempted under OFPA from creating programs of accreditation for private persons or state officials who want to become certifying agents of organic farms or handling operations. A governing state official would have to apply to the USDA to be accredited as a certifying agent, as described in the OFPA (7 U.S.C. 6514(b)). States are also preempted from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA (7 U.S.C. 6503–6507).

Pursuant to the OFPA (7 U.S.C. 6507(b)(2)), a state organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state. Such additional requirements must: (a) Further the purposes of OFPA, (b) not be inconsistent with OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to 7 U.S.C. 6519(c)(6), this final rule does not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056) concerning meat, poultry, and egg products, respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

C. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, Office of Management and Budget (OMB) clearance is not required

[17] ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes,'' U.S. Small Business Administration, August 19, 2019, *https://www.naics.com/wp-content/uploads/2017/10/SBA_Size_Standards_Table.pdf.*

[18] ''2019 Organic Survey,'' 2017 Census of Agriculture, U.S. Department of Agriculture National Agricultural Statistics Service, table 1, *https://www.nass.usda.gov/Publications/AgCensus/2017/Online_Resources/Organics/ORGANICS.pdf.*

[19] Organic Integrity Database, U.S. Department of Agriculture, accessed October 27, 2021, *https://organic.ams.usda.gov/Integrity.*

by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501, Chapter 35.

D. Executive Order 13175

This final rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on: (1) Policies that have tribal implication, including regulation, legislative comments, or proposed legislation; and (2) other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.

AMS has assessed the impact of this final rule on Indian tribes and determined that this rule would not have tribal implications that require consultation under Executive Order 13175. AMS hosts a quarterly teleconference with tribal leaders where matters of mutual interest regarding the marketing of agricultural products are discussed. Information about the proposed changes to the regulations are shared during quarterly calls with Tribal leaders, who have the opportunity to submit comments. AMS works with the USDA Office of Tribal Relations to ensure meaningful consultation is provided as needed with regards to the NOP regulations.

E. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

F. General Notice of Public Rulemaking

This final rule reflects recommendations submitted by the NOSB to the Secretary to remove fourteen nonorganic ingredients and two substances from the National List. This final rule retains (or ''renews'') two substances on the National List.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agricultural commodities, Agriculture, Animals, Archives and records, Fees, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205 is amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

■ 1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6524.

■ 2. Amend § 205.601 by revising paragraph (j)(9) to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(j) * * *

(9) Vitamins, C and E.

* * * * *

§ 205.603 [Amended]

■ 3. Amend § 205.603 by removing paragraph (b)(9) and redesignating paragraphs (b)(10) through 12 as paragraphs (b)(9) through (11).

§ 205.605 [Amended]

■ 4. Amend § 205.605(b) by removing the words ''Alginic acid (CAS #9005–32–7)''.

■ 5. Amend § 205.606 by revising paragraphs (d) through (t) and removing paragraphs (u) through (w).

The revisions read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ''organic.''

* * * * *

(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(1) Beet juice extract color—derived from *Beta vulgaris* L., except must not be produced from sugarbeets.

(2) Beta-carotene extract color—derived from carrots (*Daucus carota* L.) or algae (*Dunaliella salina*).

(3) Black/purple carrot juice color—derived from *Daucus carota* L.

(4) Chokeberry, aronia juice color—derived from *Aronia arbutifolia* (L.) Pers. or *Aronia melanocarpa* (Michx.) Elliott.

(5) Elderberry juice color—derived from *Sambucus nigra* L.

(6) Grape skin extract color—derived from *Vitis vinifera* L.

(7) Purple sweet potato juice color—derived from *Ipomoea batatas* L. or *Solanum tuberosum* L.

(8) Red cabbage extract color—derived from *Brassica oleracea* L.

(9) Red radish extract color—derived from *Raphanus sativus* L.

(10) Saffron extract color—derived from *Crocus sativus* L.

(e) Cornstarch (native).

(f) Fish oil (Fatty acid CAS #'s: 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with ingredients on the National List, §§ 205.605 and 205.606.

(g) Fructooligosaccharides (CAS # 308066–66–2).

(h) Gelatin (CAS # 9000–70–8).

(i) Glycerin (CAS # 56–81–5)—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under § 205.270(a).

(j) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).

(k) Inulin—oligofructose enriched (CAS # 9005–80–5).

(l) Lecithin—de-oiled.

(m) Orange pulp, dried.

(n) Orange shellac—unbleached (CAS # 9000–59–3).

(o) Pectin (non-amidated forms only).

(p) Potassium acid tartrate.

(q) Seaweed, Pacific kombu.

(r) Tamarind seed gum.

(s) Tragacanth gum (CAS # 9000–65–1).

(t) Wakame seaweed (*Undaria pinnatifida*).

* * * * *

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–03851 Filed 2–25–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

7 CFR Part 4280

[Docket No. RBS–20–BUSINESS–0027]

RIN 0570–AA98

Rural Energy for America Program

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Final rule; confirmation and response to comments.

SUMMARY: The Rural Business-Cooperative Service (RBCS or the Agency), a Rural Development agency of the United States Department of Agriculture (USDA), is confirming the final rule published in the **Federal Register** on April 27, 2021, to remove the provisions relating to guaranteed loans and to make other revisions to enhance program delivery and customer service for the Rural Energy for America Program (REAP). This notice presents the opportunity for the Agency to provide its responses to the public comments received on the final rule and to confirm the final rule as published.

DATES: As of February 28, 2022, the effective date of the final rule published

April 27, 2021, at 86 FR 22304, is confirmed as July 26, 2021.

FOR FURTHER INFORMATION CONTACT: Sami Zarour, Program Management Division, U.S. Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250–3201; telephone (202) 720–9549; email: *sami.zarour@usda.gov.*

SUPPLEMENTARY INFORMATION: Rural Development administers a multitude of programs, ranging from housing and community facilities to infrastructure and business development. Its mission is to increase economic opportunity and improve the quality of life in rural communities by providing leadership, infrastructure, capital, and technical support that can support rural communities, helping them to prosper.

To achieve its mission, Rural Development provides financial support (including direct loans, grants, loan guarantees, and direct payments) and technical assistance to help enhance the quality of life and provide support for economic development in rural areas.

On July 14, 2020, at 85 FR 42494, the Agency promulgated 7 CFR part 5001, the OneRD guaranteed loan regulation, which combined four Agency guaranteed loan program regulations, including REAP, into one comprehensive guaranteed loan processing and servicing regulation. The final rule being confirmed amends 7 CFR part 4280, subpart B accordingly to remove references to the guaranteed loan provisions of REAP as these references have become superfluous in light of the promulgation of 7 CFR part 5001. Furthermore, program modifications required by the Agriculture Improvement Act of 2018 (2018 Farm Bill), as well as provisions that have been previously published via funding opportunities in **Federal Register** publications, have been incorporated into this final rule to eliminate the need for annual notification and to enhance program delivery.

Summary of Comments and Responses

RBCS invited comments on the final rule published on April 27, 2021, in the **Federal Register** (86 FR 22304). RBCS received twenty-eight (28) comments from five commenters. The commenters were: The American Biogas Council (ABC), Agriculture Energy Coalition (AgEC), Ebenezer MGMT, LLC, Environmental Law & Policy Center (ELPC) and CROPP Cooperative (CROPP). The Agency's responses to the 28 comments, of which six (6) were duplicative, are as follows:

Comment 1: Both the ABC and the AgEC believe the March 31 grant application deadline creates a barrier to a timely transition between the grant process and project initiation for companies who want to partner with farms to produce biogas. As grant application reviews typically last a few months, and applications are not guaranteed to be successful, small businesses are often forced to delay capital outlays for construction until a grant is awarded. By the time the grant is awarded, it is usually summer, and the awardee has missed out on a significant portion of construction season and faces unnecessary challenges securing labor and equipment that is already obligated to projects that began in the spring. Thus, these projects are often delayed until the following year. For companies who want to partner with farms to convert manure or other organic materials into biogas, this nine-month delay is too frequently an impediment initiating a reciprocal business relationship between small farms and small biogas companies. Additionally, the ABC and the AgEC feel the current practice requires that projects seeking a REAP grant as well as participation in the loan guarantee program complete a combination application. Coupling these separate paths together creates a significant obstacle to small and mid-size applicants because lenders often do not count potential REAP grant funding among a borrower's assets. Specifically, in the loan application process, some companies rely on REAP grant funding to demonstrate the viability of the projects for which they are seeking loans. Lenders are typically less likely to approve loans when the applicant is relying on uncertain federal grant funding to demonstrate the viability of the project. The result is an increased rate of loan denials for small businesses. If, however, loan guarantee applicants were allowed to begin that process with grant funding already in-hand, their proposed projects would present as more stable to lenders.

Agency response: Applications for REAP assistance can be filed any time during the year and once a complete application is filed it can be processed and readied for competition. The receipt of program funds to make awards are contingent upon the federal budget process. Historically, the Agency has received REAP funds in January. REAP grants are typically very competitive given the limited amount of grant funds available. The Agency must meet the statutory provision of obligating no less than 20 percent of REAP funds for grants applications requesting $20,000 and less by June 30. Therefore, the Agency utilizes an October 31 deadline for these grants so that the statutory provision can be met each year. The Agency has also adopted a single deadline (March 31) for grant applications requesting more than $20,000 to ensure that there is a fair and transparent process for competition across the nation.

Furthermore, the Agency desires to fund applications that are shovel ready and can be completed when REAP funding is awarded. As such, part of the application requirements is to demonstrate how the project will be financed and that those funds, both grant, loan and other are available. The Agency acknowledges that grant funds are much more competitive than guaranteed loan funds and it can take longer to process the volume of grant applications received compared to guaranteed loan applications.

Comment 2: Ebenezer MGMT, LLC stated that the final rule ''was published April 27th with an effective date of July 26th. USDA released a NOSA published 11/25/2020 that substantially changed how applications are reviewed and scored, with no comment period. The final program due date each year is currently March 31st. All proposed changes to procedure or scoring should occur or become effective on the day following the final due date for applications.

Applicants submit applications throughout the year, after reading current rules and with guidance from USDA staff. All applicants have an expectation of consistency. To make changes mid-year puts some applicants at a disadvantage to others. It requires enormous amounts additional staff time to rescore or gather additional information when changes are made mid-year. By announcing ahead of time that the changes would occur each April 1st. Applicants would be better served; and state staff could manage their workload more efficiently.''

Agency response: REAP applications can be filed at any time during the year which makes it difficult to find an ideal time to initiate program changes. The Agency ensures that all applicants are afforded the same opportunity to supplement application materials as necessary when program changes are initiated after complete applications have been filed.

Comment 3: ABC and AgEC both raised the same concerns that the scoring criteria do not properly support project diversity and commercial yet underserved renewable technologies. ABC and AgEC are both very supportive of REAP and its broad reach. However, they are concerned that several elements

of the scoring criteria outlined in § 4280.121 ''Scoring RES and EEI grant applications'' risk continued limits on the diversity of applicants and technologies supported by the program.

ABC and AgEC are concerned that ''the following scoring criteria risk further inhibiting underserved renewable technologies for REAP grants, such as biogas systems and distributed wind:

(1) ''The quantity of energy generated or replaced per grant dollar requested'' is a key scoring criterion outlined in the final rule. While efficient use of program funds is a worthwhile objective, this criterion favors the most established renewable energy technologies over underserved technologies.

(2) The emphasis on ''energy replaced'' also favors technologies with the best economics based on energy alone, pushing toward technology that has penetrated the market more successfully to date, rather than underserved technologies that may support additional environmental and economic benefits and also might accommodate the specific needs of the applicant. For example, a significant component of the economic value of biodigesters comes from reduced manure disposal costs. This underserved technology would be at a disadvantage relative to an energy-only project.

(3) The criteria for ''energy saved'' also favors technologies with the highest economic efficiency in today's market, limiting diversity.

(4) Awarding points for firm letters of credit for cost share favors those with access to capital, rather than marginalized communities or borrowers. Because one of the objectives of REAP is to support economic development and to strengthen rural communities, ensuring access to all eligible members of the rural community should be reflected in the final rule.

(5) Awarding points for firms already in the market poses a potential barrier against new entrants and marginalized communities. Strengthening rural communities should include efforts to support fledgling businesses rather than place them at a disadvantage to their peers.

(6) REAP is solely concentrated on energy production and does consider any of the environmental aspects of digesters. The qualities include preventing the emissions of methane, recycling of nutrients, cleaning and recycling of water or protecting water quality, requesting carbon by reusing nutrients. All of these elements are part of the reasons that farmers want to use digesters but none of them are taken into consideration by the current REAP scoring system. Given the USDA's renewed focus on fighting climate change, we, again, urge USDA to update its scoring criteria to include not only aspects of energy generation but also aspects of GHG emission reduction and environmental savings.''

Agency response: The Agency acknowledges that technology diversity is important. In fact, the Administrator has added discretionary points for underserved technology for the past several years in an effort to diversify the REAP portfolio. In response to the six individual issues raised, the Agency submits the following:

ISSUE 1: This criterion is evaluating the energy savings/generation impact of the dollars being invested in the project. The installation cost is one variable, but the amount of the request is a second variable. Some technologies may have lower installation costs, but the amount of the request is defined by the applicant.

ISSUES 2 and 3: RBCS acknowledges the concerns raised. REAP has always looked at only direct project benefits such as kWh/BTU's saved/generated or by-products. The Agency is open to further discussion on additional project benefits; however, the Agency is concerned about how alternatives could be quantified and valued in a fair manner to ensure consistent program delivery.

ISSUE 4: The Agency removed financial need from the program in 2014. The Agency's goal is to participate in projects that are shovel ready to ensure timely and prudent investment of REAP program dollars. Commitment of funds demonstrates project support, backing, and a higher probability of project completion.

ISSUE 5: The Agency is assuming this concern is related to the five (5) points for existing businesses. The points for an existing business were added to strengthen opportunity for main street businesses as opposed to creating a barrier for new entities. REAP has a primary focus on energy generation and savings.

ISSUE 6: The current scoring criteria does award up to five (5) points for environmental benefits. The concern is being raised that more emphasis should be placed on GHG emission reduction and environmental savings, including water, etc. The Agency acknowledges the importance of environmental benefits and will consider how the priority system could place more value on such benefits.

Comment 4: ABC expressed concerns the provisions outlined in § 4280.121(h) ''State Director and Administrator priority points'' providing discretionary points to underrepresented technologies, geographic diversity, and underserved populations are a great step in the right direction, and ABC strongly supports this, but they are concerned that the points are insufficient to offset the criteria favoring lowest cost technologies and certain applications outlined above.

Agency response: While the Agency appreciates the comment, the Agency will continue to apply State Director and/or Administrator points in order to meet the objectives of the program. The Agency is open to further discussion on additional project benefits, however, the Agency is concerned about how alternatives could be quantified and valued in a fair manner to ensure consistent program delivery.

Comment 5: Ebenezer MGMT, LLC states that ''Administrator points should not be available in the pooling rounds of competition. The State Directors have an intimate knowledge of their states and the needs of residents. The Administrator does not have this knowledge and should not have the ability to add 10 points to an application score. All funding determinations at the National Office should be by initial score alone. If Administrator points are used, the Administrator should state what conditions will receive additional points at the beginning of each fiscal year. Historically it appears the National Office has skewed results to penalize states proficient in utilizing the program; eliminating the Administrator points would alleviate this problem.''

Agency response: The concern regarding awarding Administrator points for national office competition is acknowledged. However, the competition is a national competition and the Administrator has discretion to apply additional points to support administration goals and objectives from a national perspective. Recent application of Administrator points has focused on underserved technology to diversify the national portfolio and assisting projects located in distressed communities.

Comment 6: CROPP requested an adjustment to the scoring criteria to accommodate local utility net-metering restrictions, specifically in scoring criteria #2 (quantity of energy replaced), sub-criteria 2a (energy replacement) and #6 (simple payback). CROPP believes this decreases the competitiveness of their producer applications and put producers at a disadvantage. Producers are disadvantaged by these criteria due to the net-metering limitations imposed

by utilities. Those net-metering limits restrict the size of a RES an agriculture producer can install and thereby preclude producers from gaining the maximum scorable points.

''Net metering restrictions that limit the size of a RES that a farmer can install are pervasive from coast-to-coast across nearly all electric utility providers. Farmers should not be at a REAP disadvantage simply because their utility restricts the size of a RES; it is largely out of their hands and represents a scoring-criteria that should be rectified.''

Agency response: The Agency acknowledges the concern that net-metering can lead potential REAP applicants to design smaller systems; however, the Agency has no control over state or utility net-metering limitations.

Comment 7: ''AgEC and ABC as a member of AgEC has received considerable support from the agriculture community and representatives in Congress for bolstering underserved and nascent renewable technologies to help ensure continued development and penetration into the marketplace, especially through a reserve of funds for these technologies. To that end AgEC would propose an addition to ''§ 4280.121 Scoring RES and EEI grant applications.''

Specifically, AgEC and ABC would propose adding section (i) at the end: ''(i) Notwithstanding the scoring rules above, no less than 15% of funding for a competition shall be awarded to nascent and/or underserved renewable [commercial] technologies separately from the remainder of the competition(s), on an annualized basis.''

A complimentary definition in ''§ 4280.103 Definitions'' would include ''Nascent and underserved (or underused) renewable technologies. Nascent and underserved/underused technologies are those renewable energy technologies that have received less than 10 percent of program funding support in the last three years.''

AgEC and ABC also continue to advocate for a grants reserve fund for underserved renewable technologies, to support these technologies in achieving cost and scale.''

Agency response: The Agency continues to support the requirement for technology to be commercially available to be eligible for REAP assistance. The Agency has and continues to apply State Director and Administrator points to underserved technology in efforts to diversify the REAP portfolio. The commenters propose reserving a set amount of funds to facilitate the selection of underrepresented technologies. The REAP statute does not provide the flexibility to establish reserve funding. If such a provision came to fruition, careful planning must occur to ensure that REAP projects continue to realize benefit. The current program contains state allocated and national competitions for funding and also includes a set-aside of funds (reserve of funds) for $20,000 or less applications for renewable energy systems and energy efficiency. If funds are subdivided further to represent each under-represented technology for state allocations, grant requests would need to be smaller. It is likely that a state would not be able to fully utilize its allocation as any remaining funds after the subdivision would be below the minimum required grant amount. Additionally, any administrative burden costs to implement another reserve must be included in the planning.

Comment 8: ''AgEC and ABC believe a robust loan guarantee component of REAP remains important as well.

AgEC and ABC greatly appreciates USDA's efforts under the OneRD program to remove regulatory barriers to make it easier for private lenders to use USDA programs and invest in rural America.

Yet it is vital that energy efficiency and renewable energy systems find full support under the consolidated program.

We urge USDA to ensure that the availability of OneRD funding is clearly communicated under all REAP funding opportunities, and urge REAP program officers to support grant applicants in obtaining complimentary loan funding where appropriate.

In addition, we would urge a new category of loan guarantee of 90% for distributed generation projects of less than $1,000,000. This would serve to support smaller-scale, and smaller businesses and/or individual applicants in the market.

Distributed generation is an important public policy area that the Administration wants to help for all of the myriad benefits it provides, including local economic development, localized energy production and ownership, grid and community resilience, and energy security (ex., much harder to succeed in cyber-attacks against millions of small solar and distributed wind installations)''.

Agency response: The Agency appreciates the comment and will continue to amplify the availability of REAP guarantee funding in our external communication strategies. We understand the importance of distributed generation projects and will continue to finance them under the REAP guaranteed loan and grant programs. The 2018 Farm Bill specifically outlines how REAP funds should be used (*i.e.,* technical assistance, small grants, energy efficient equipment and systems, etc.). Changes to the 2018 Farm Bill would be needed to create a new category of loan guarantees for distributed generation projects.

Comment 9: AgEC and ABC believe it is ''incumbent upon USDA to properly staff the Rural Development mission area for better implementation of REAP and related energy or bioeconomy programs such as 9003. We would urge USDA to look at this further, hire and train as needed, and continue to communicate to Congress the importance of a robust staffing budget to efficiently support the administration of important programs.''

Agency response: Thank you for the comment, the Agency recognizes the importance of proper staffing and training.

Comment 10: AgEC and ABC ''urge USDA again to further streamline, and simplify the REAP applications process across the board, but with a particular emphasis on lower cost grant applications for individual farmers and others. This is an issue we've raised for years.

We recognize the vital importance of due diligence, and agency fiduciary responsibilities, but the arduous applications process is inhibiting equity and opportunity in ag based energy. For example, some prospective applicants have to hire consultants, paying over $1,000 for an under $20,000 grant application for the hope of an award. The time that it takes, the cost, can have a ''chilling effect'' on program participation.

As Congress increasingly looks at REAP as a climate change and rural economic development program worthy of greater funding, the stakes grow as to program application simplification. More REAP funding in conjunction with a more streamlined approach will equal greater success, in terms of lowered costs to constituents, greater energy production, deployment of renewables and energy efficiency investments.''

Agency response: The Agency continues to look for additional efficiencies while remaining compliant with federal grant requirements. The updated rule adopts certifications related to applicant eligibility, modifies the feasibility study requirement, lessens the technical report requirements, and streamlines the annual reporting process.

Comment 11: The ELPC believes ''REAP's complex application burden

has been often discussed and is a drag on program success. It's important to note that the application burden has the effect of skewing the program towards those with the financial wherewithal to hire application writers and consultants and away from those with the most need.

Over the years, the USDA has taken steps to simplify the REAP application process. Most recently, the USDA expended great effort to simplify the application process for guaranteed loans and adopted innovative solutions for the OneRD Guarantee Loan Initiative. ELPC supports REAP simplification efforts and encourages USDA to expend a similar level of effort to simplify the application process for grants as the agency applied to OneRD. The USDA has demonstrated an ability to substantially revise and simplify the loan guarantee portion of REAP and should now apply as much effort to simplifying the majority of the program.

With new attention focused on REAP as a key USDA climate program it is more important and pressing than ever that the agency take strong action to simplify the REAP grant application process.''

Agency response: The updated rule adopts certifications related to applicant eligibility, modifies the feasibility study requirement, lessens the technical report requirements, and streamlines the annual reporting process. The Agency continues to look for additional efficiencies while remaining compliant with federal grant requirements and the REAP statute which mandates three tiers of applications.

Comment 12: Ebenezer MGMT, LLC commented that in ''4280.103 Definitions, Small business means (A) Number of employees If Number of Employees is the SBA criteria to determine eligibility. Tax returns or annual receipt information should not be required as part of the submission. Tax returns are not needed for any other portion of applications that are under $200,000 in size. Tax returns should not be required if not needed for eligibility or scoring.''

''4280.103 Definitions, Small business means (B) Calculation of annual receipts Requiring 5 years of annual receipts information is excessive. Current rule utilizes three years. The extra paperwork and time spent accumulating and reviewing will not add substantially to any changes in eligibility. Rule does not state what types of records are required to document; it is hoped tax returns would not be the only source of documentation that could be used.''

Agency response: The Agency agrees that employee numbers can be verified using means other than tax returns and this is consistent with existing Agency policy. The Agency is bound to use the SBA definitions which have moved to a 5-year average. The alternative size standard may also be used. Please note that the new rule allows for certification of eligibility without providing all documentation to streamline the application process. If the Agency determines that the application needs additional documentation to support the applicant's eligibility, the Agency will accept tax return information, financial statements or other means that support the income or employee numbers.

Comment 13: Ebenezer MGMT, LLC commented that ''the current DUNS (UEI) and System for Awards Management process continues to be slow and onerous on applicants. Applicants need to register in *SAM.gov* which most recently revised the website making the site less user friendly than the past, if there are problems the applicant must contact the Federal Service Desk or the Defense Logistics Agency depending on what stage the registration is in, making the process for the applicant difficult and cumbersome. These agencies have little knowledge of agriculture and the types of businesses and structures they use. Obtaining the SAM registration is the biggest roadblock to applicant participation in the program. Simply put, the process is not set up for grant purposes. Since USDA Rural Development NRCS does not require DUNS/SAM registration for their grant programs; REAP should also be exempt for any requirement.''

Agency response: The Agency acknowledges the concerns with the SAM registration process but must require SAM registration in accordance with 2 CFR part 25. The 2 CFR part 25.110(c)(2)(iii) allows recipients a 30-day window after award to complete their registration in exigent circumstances.

Comment 14: Since the guarantee program components have been removed from the regulation; Ebenezer MGMT, LLC questions ''why such excessive financial information is required. This is a grant program; other than to prove eligibility and ability to operate; additional information should not be required. For a simple solar installation or energy efficiency installation when a feasibility study is not required; the financial information adds nothing to the grant review process. The financial information would be important for a guarantee review; however, for a grant program it is unnecessary and a waste of staff time to review. Nothing is gained by having the additional information.''

Agency response: The statute requires more documentation for applications with larger project costs. Financial statements are used by staff to review the financial stability of the applicant entity and to ensure the viability of the proposed project. A risk evaluation is required for grants as noted in 2 CFR 200.206(b).

Comment 15: ELPC commented that ''REAP benefits should be available to all in agriculture, including historically underserved and disadvantaged farmers. We welcome Secretary Vilsack's commitment to addressing historical discrimination against Black Farmers by USDA. This commitment should include REAP.

ELPC supports awarding State Director and Administrator priority points for applications from unserved or under-served socially-disadvantaged groups. These points should be required across the country, so the USDA ensures equity in the program, with increased attention, outreach and education. USDA should engage in specific outreach to these communities to help them learn of program availability and benefits and to assist in the application process.''

Agency response: The Agency agrees with the commentor and continues to look for ways to diversify program participation. REAP is a pilot program for the Justice40 Initiative where at least 40 percent of overall benefits from Federal investments in climate and clean energy go to disadvantaged communities.

Comment 16: ELPC states that ''to substantially simplify the REAP program, the USDA should adopt a rebate program to broadly deliver energy savings and clean energy savings. A REAP rebate would cover pre-approved technologies that cut energy costs and carbon pollution. This could be applied to grants under $20,000 to ease access to the program and facilitate more rapid deployment of energy efficiency and renewable energy systems in rural communities.

Such approaches are used in some state energy programs and they provide funding on a first-come, first-served basis. Adopting a rebate program would help the USDA address several program priorities, including simplification, improving equity and providing broader geographic coverage.''

Agency response: The REAP statute does not provide flexibility to administer a rebate or other payment program. As such, the Agency can only administer grant and guaranteed loan program funding.

Comment 17: ''ELPC encourages the USDA to enable dual or combined

applications and awards under the Energy Audits and Renewable Energy Development Assistance (EA/REDA) subprogram as much as possible in program application and administration. This change would allow grant recipients to apply for and receive grants for providing both energy audits and renewable energy development assistance. Importantly, the enabling legislation does not call for separation.

This change will improve EA/REDA continuity from learning with energy audits to acting with investments for energy savings and renewable energy production. Energy audits, in themselves, do not result in energy changes but with follow through in development advice more action is likely. Facilitating dual EA and REDA awards will help move projects forward in the development pipeline from problem identification to understanding options and implementing solutions.

As regards a specific program change mentioned in the draft rule, we encourage the USDA to allow for ''funding to train individuals to become qualified to perform EA or REDA assistance'' in those cases where the applicant has already demonstrated they have ''experienced resource providers at time of application.'' Especially in this economy, organizations need to address inevitable turnover in staff over time. This change also helps states to build REAP capacity by growing the ranks of energy experts.

ELPC supports the ''minimum score of 40 points to compete for EA/REDA funding'' for the purpose of maintaining program quality.''

Agency response: The Agency allows an applicant to apply for one EA and one REDA in a fiscal year so that both tasks may be undertaken by the same entity; however, separation allows for an easier way to track project impacts. For example, the Agency could verify if EEI applications for a particular state increased in future years as a result of having EA audit services. Furthermore, the EA component requires that 25 percent of the cost of the energy audit be paid by the ag producer or rural small business where the REDA component does not have a similar requirement. Separation allows the Agency to easily track that this requirement is met for EA projects. The Agency has limited funding for EA/REDA and wants to ensure that funds are used for services that directly support rural small businesses and ag producers rather than professional development for the recipient organization to train auditors.

Comment 18: ''ELPC supports State Director and Administrator priority points for applications including under-represented technologies. But the USDA needs to take steps beyond point scoring to diversify technology support.

The USDA has taken steps in the past to increase technology diversity in determining REAP awards. The USDA employed a ''normalization'' process developed by the National Renewable Energy Laboratory (NREL). The normalization process took place after proposals were all scored and sought to preserve some degree of balance among the technologies supported in the program. The normalization process, however, was abandoned after it became burdensome.

The USDA should implement a simpler approach with a grants reserve fund as described by the Ag Energy Coalition to maintain technology diversity among major energy types such as solar, wind, biomass, energy efficiency, hydropower, etc. In implementing the grants reserve fund and to the extent adequate applications are available, the agency should apply a minimum score of 40 points or more, as used elsewhere in program administration.''

Agency response: The Agency acknowledges that there are other ways beyond scoring to maintain technology diversity. However, with limited staffing resources, it would be difficult for the Agency to complete the normalization process and still meet statutory obligation deadlines. Limited staff resources and the program's continued growth challenges the Agency's ability to add another layer of complexity in processing applications.

Comment 19: ELPC states that ''in the 2016 the USDA released a report, USDA Building Blocks for Climate Smart Agriculture and Forestry. The Building Blocks report identified REAP as a key USDA program for addressing climate change. In Congress, REAP is often regarded as a key program for reducing carbon pollution from the agricultural sector and is included in legislation to scale up the program.

The USDA needs to act now to increase the emphasis on environmental benefits of the REAP program, beginning with increasing the share of program points attributed to environmental benefits. For example, scoring should increase for projects that provide non-energy environmental benefits such as water conservation and protection.

With the growing climate crisis, the agency also needs to act now to develop practice and standards for carbon pollution reduction by technology that reflect modern science on life cycle impacts of each technology. This is urgent and requires USDA action as soon as possible.''

Agency response: The Agency acknowledges this concern and is exploring environmental project benefits via the Justice40 Initiative.

Comment 20: CROPP commented that ''the revised RES residential language will significantly limit program access and increase the application burden experienced by small and mid-size family farms; farms owned and operated by a single-family unit that resides on the farm. The majority of CROPP Cooperative's nearly 1,800 farmer-members live and work on the same property that comprises the family farm. The final rule's revised RES residential language does not specify what ''greater degree of documentation'' will be required for a RES project where a residence is closely associated with an agriculture operation to ensure that 50 percent or greater of energy generated by the RES will benefit the farm.

Providing no explanation of the ''greater degree of documentation'' required could prove costly and time consuming, especially for small to mid-size farms, and may require professional services above and beyond that which is typically provided by a RES installer/vendor.

CROPP Cooperative uses a residential audit to verify if 50 percent or greater of energy generated by the RES, will benefit the farm. It is not clear if a residential audit satisfies the intent of the rule change.

More generally, this continually elevated residential-use prohibition seems a distraction and does not seem to recognize the dynamic of many family-run businesses which may have home offices or connected facilities.''

Agency response: The updated rule removes the ''certification only'' option for projects. All other processes remain the same with the goal of ensuring sufficient documentation that 50 percent or more of the proposed energy to be generated will benefit the agricultural producer or rural small business. The Agency has been requiring clarifying documentation on this provision for some time. The Agency did not intend to add burden by removing the ''certification only'' option. Instead, it was intended to facilitate consistency in processing applications while ensuring there is adequate file documentation that 50 percent or more of the projected renewable energy will benefit the agricultural producer or rural small business. The residential audit should be acceptable to meet the requirement provided it clearly establishes the amount of historical energy consumed

by the residence to allow for the calculation of historical business energy use from total energy consumption.

Comment 21: CROPP would like an adjustment to $20,000 or Less Funding Pool.

''With nearly 15 years' experience with REAP applications, we believe that increasing the maximum award request in the smaller project funding pool is long overdue and will significantly increase program access and accelerate renewable energy projects in rural areas.

Currently, the average small to mid-size Organic Valley dairy requires a 40kW–50kW RES to offset 100% of the farm's non-renewable energy consumption. Our estimation is a solar array to service this energy need is in the range of $130,000–$150,000, which would exceed the threshold of maximum allowed cost-share in the $20,000 funding pool. We recommend increasing the maximum award request to $40,000 in the smaller project funding pool. A simple adjustment for inflation since the program's start would validate an increase and be more reflective of the overall needs of farmers and rural businesses in this category of need. It is our experience that RES in the 40kW–50kW range do not receive support in the larger, unrestricted funding pool. This pool is typically obligated to a very small number of large RES projects.''

Agency response: The Agency has concern that fewer projects would be funded by the suggested change. The $20,000 or less maximum award request limitation would require a statutory change.

Comment 22: CROPP says it has been their experience that ''significant delays (12+ months) in the obligation of funds at the state level is impacting project success and farmer interest in the program. Historically, the obligation of funds has been within a timeframe of three to six months. Within the previous two years, we have seen the obligation timeframe extend to 12+ months.

Administrative delays need to be addressed to ensure that project bids and farmer costs remain timely and relevant to avoid significant unexpected cost and installation burdens. It is unacceptable to expect an applicant to maintain contractual obligations that extend out as far as a year, as material and labor costs, as well as service availability, fluctuate sometimes monthly.''

Agency response: Obligation of funds is tied to annual application and statutory obligation deadlines. October 31 is the application deadline for grant requests of $20,000 or less that wish to compete for the first half of the state allocation of set-aside funds. March 31 is the application deadline for grants requests of $20,000 or less that wish to compete for the second half of the state allocation of set-aside funds. March 31 is also the deadline for all other REAP applications regardless of the size of the grant request. Complete and eligible projects with completed environmental reviews are able to compete for funding. Applicants should contact Agency staff early in the process to discuss application requirements including the environmental review process.

The Agency appreciates the interest of the American Biogas Council, Agriculture Energy Coalition, Ebenezer MGMT, LLC, Environmental Law & Policy Center and CROPP Cooperative with regard to the Rural Energy for America Program final rule and thanks them for their submissions. The Agency confirms the rule without change.

Karama Neal,

Administrator, Rural Business and Cooperative Service.

[FR Doc. 2022–03884 Filed 2–25–22; 8:45 am]

BILLING CODE 3410–XY–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 702

[NCUA–2022–0005]

RIN 3133–AF19

Prompt Corrective Action: Earnings Retention Waivers and Net Worth Restoration Plans

AGENCY: National Credit Union Administration (NCUA).

ACTION: Interim final rule.

SUMMARY: The NCUA Board (Board) is extending two temporary changes to its prompt corrective action (PCA) regulations to help ensure that federally insured credit unions (FICUs) remain operational and liquid during the COVID–19 crisis. The first amends these regulations to temporarily extend the Board's ability to issue an order applicable to all FICUs to waive the earnings retention requirement for any FICU that is classified as adequately capitalized. The second extends a provision that modifies the specific documentation required for net worth restoration plans (NWRPs) for FICUs that become undercapitalized. These temporary modifications will remain in place until March 31, 2023. This rule is substantially similar to an interim final rule that the Board published on April 19, 2021 (''2021 PCA interim final'').

DATES: This rule is effective on February 28, 2022. Comments must be received on or before April 29, 2022.

ADDRESSES: You may submit written comments, identified by RIN 3133–AF19, by any of the following methods. Please send comments by one method only.

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments for Docket # NCUA–2022–0055.
- *Fax:* (703) 518–6319. Include ''[Your Name]—Comments on ''Prompt Corrective Action: Earnings Retention Waivers and Net Worth Restoration Plans'' in the transmittal.
- *Mail:* Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

Public Inspection: You may view all public comments on the Federal eRulemaking Portal at *https://www.regulations.gov* as submitted, except for those we cannot post for technical reasons. The NCUA will not edit or remove any identifying or contact information from the public comments submitted. Due to social distancing measures in effect, the usual opportunity to inspect paper copies of comments in the NCUA's law library is currently unavailable. After social distancing measures are relaxed, visitors may make an appointment to review paper copies by calling (703) 518–6540 or emailing *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: *Policy and Analysis:* Kathryn Metzker, Risk Officer, or Victoria Nahrwold, Associate Director, Office of Examination and Insurance, at (703) 518–6360; *Legal:* Marvin Shaw, Senior Staff Attorney and Thomas Zells, Senior Staff Attorney, Office of General Counsel, at (703) 518–6540; or by mail at: National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314.

SUPPLEMENTARY INFORMATION:

I. Legal Authority

The Board is issuing this interim final rule pursuant to its authority under the Federal Credit Union Act.[1] The Act grants the Board a broad mandate to issue regulations that govern both federal credit unions and, more generally, all FICUs. For example, Section 120 of the Act is a general grant of regulatory authority and authorizes the Board to prescribe rules and

[1] 12 U.S.C. 1751 *et seq.*

regulations for the administration of the Act.[2] Section 209 of the Act is a plenary grant of regulatory authority to issue rules and regulations necessary or appropriate for the Board to carry out its role as share insurer for all FICUs.[3] Other provisions of the Act confer specific rulemaking authority to address prescribed issues or circumstances.[4] Such specific rulemaking authority is set forth in Section 216(b) about PCA.[5]

II. Prompt Corrective Action Background

A. Statutory Provisions

In 1998, Congress enacted the Credit Union Membership Access Act (''CUMAA'').[6] CUMAA amended the Federal Credit Union Act (''the Act'') to require the NCUA to adopt, by regulation, a system of PCA consisting of minimum capital standards and corresponding remedies to improve the net worth of federally-insured ''natural person'' credit unions.[7] The purpose of PCA is to ''resolve the problems of insured credit unions at the least possible long-term loss to the [National Credit Union Share Insurance Fund ('NCUSIF')].'' [8] The PCA section of the Act does not apply to corporate credit unions.[9]

The statute designated three principal components of PCA: (1) A framework combining mandatory actions prescribed by statute with discretionary actions developed by the NCUA; (2) an alternative system of PCA to be developed by the NCUA for FICUs which CUMAA defines as ''new;'' and (3) a risk-based net worth requirement to apply to FICUs which the NCUA defines as ''complex.'' Besides those FICUs that meet the statutory definition of a ''new'' FICU, CUMAA mandated a framework of mandatory and discretionary supervisory actions indexed to five statutory net worth categories. These categories are: ''well capitalized,'' ''adequately capitalized,'' ''undercapitalized,'' ''significantly undercapitalized,'' and ''critically undercapitalized.'' The mandatory actions and conditions triggering conservatorship and liquidation are expressly prescribed by statute.[10] To supplement the mandatory actions, the statute directed the NCUA to develop discretionary actions which are ''comparable'' to the ''discretionary safeguards'' available under Section 38 of the Federal Deposit Insurance Act, which is the statute that applies PCA to other federally-insured depository institutions.[11]

The Act addresses the earnings retention requirement applicable to FICUs that are not well capitalized.[12] Such FICUs are required to annually set aside as net worth an amount equal to not less than 0.4 percent of their total assets.[13] The Board has the authority to decrease the earnings retention requirement.[14] To do this, the Board may issue an order if it determines that the decrease is necessary to avoid a significant redemption of shares and further the purpose of that PCA provision of the Act. The Act also requires the Board to periodically review any order issued under that section.[15]

Separately, the Act sets forth requirements related to NWRPs, which FICUs must submit to the NCUA when it becomes undercapitalized.[16] The regulatory provisions addressing the procedures and documentation requirements for NWRPs are codified at 12 CFR 702.111 and are detailed below.

B. Regulatory Provisions

In February 2000, the Board adopted part 702 and subpart L of part 747 establishing a comprehensive system of PCA that combines mandatory supervisory actions prescribed by the statute with discretionary supervisory actions developed by the NCUA (2000 final rule).[17] Each of these supervisory actions is indexed to the five statutory net worth categories noted above. The 2000 final rule also permits the NCUA to impose ''other action to better carry out the purpose of PCA'' than any discretionary supervisory action available in that category.[18] In the proposal that provided the basis for the 2000 final rule, the Board noted that ''[p]art 702 also amplifies the terms of the statutory exception to the 0.4 percent minimum set aside. Specifically, the Board stated that it interprets the phrase *by order* to indicate that exceptions to the 0.4 percent statutory minimum are to be granted on a case-by-case basis.'' [19] But the Board revisited this interpretation in the May 2020 interim final rule on this subject, finding that the Act does not require FICUs to send a specific application or the NCUA to issue individual orders for each FICU.[20] The Board also notes that the current, specific requirements on earnings retention waivers are based on a regulatory provision rather than a specific statutory directive.[21] Thus, issuing a broadly applicable order is consistent with the overall statutory structure of PCA, which combines both mandatory and discretionary provisions. During the COVID–19 pandemic, many FICUs have broadly faced similar economic circumstances that affect net worth and earnings. Given these experiences, and the potential for similar volatility and uncertainty in the future, the Board has determined it is appropriate to implement the changes in this rule to extend the provisions that authorize a broadly applicable order to decrease the earnings-retention requirements for multiple FICUs and to allow a streamlined NWRP in certain circumstances.

III. Recent Interim Final Rules

A. May 2020 Interim Final Rule

On May 21, 2020, the Board approved an interim final rule that temporarily amended two provisions in the PCA regulations in part 702.[22] The first amendment addressed the earnings retention requirement in § 702.201 for FICUs classified as adequately capitalized.[23] The second amendment addressed the NWRPs for FICUs in § 702.206(c) that have become undercapitalized.[24]

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[2] 12 U.S.C. 1766(a).

[3] 12 U.S.C. 1789.

[4] An example of a provision of the Act that provides the Board with specific rulemaking authority is Section 207 (12 U.S.C. 1787), which is a specific grant of authority over share insurance coverage, conservatorships, and liquidations.

[5] 12 U.S.C. 1790d(b).

[6] Pub. L. 105–219, 112 Stat. 913 (1998).

[7] 12 U.S.C. 1790d *et seq.*

[8] 12 U.S.C. 1790d(a)(1).

[9] 12 U.S.C. 1790d(m). Part 704, which this rulemaking does not affect, applies capital and PCA requirements to corporate credit unions.

[10] 12 U.S.C. 1790d(e), (f), (g), and (i); 12 U.S.C. 1786(h)(1)(F); 12 U.S.C. 1786(a)(3)(A)(1).

[11] 12 U.S.C. 1790d(b)(1)(A); S. Rep. No. 193, 105th Cong., 2d Sess. 12 (1998) (S.Rep.); H.R. Rep. No. 472, 105th Cong; *see also* 12 U.S.C. 1831o (Section 38 of the Federal Deposit Insurance Act setting forth the PCA requirements for banks).

[12] 12 U.S.C. 1790d(e).

[13] 12 U.S.C. 1790d(e)(1).

[14] 12 U.S.C. 1790d(e)(2).

[15] 12 U.S.C. 1790d(e)(2)(B).

[16] 12 U.S.C. 1790d(f).

[17] 65 FR 8560 (Feb. 18, 2000).

[18] 12 CFR 702.107(b)(9), which applies to undercapitalized FICUs.

[19] 64 FR 27090 (May 18, 1999).

[20] 85 FR 31952, 31954 (May 28, 2020).

[21] The Board notes that 12 U.S.C. 1790d(e)(1) requires earnings retention. However, additional provisions in 12 CFR part 702, including those related to timing and the content of the application, supplement this statutory provision.

[22] 85 FR 31952 (May 28, 2020) (''2020 PCA interim final rule'').

[23] As detailed subsequently in this preamble, the NCUA's 2015 final rule (80 FR 66626 (Oct. 29, 2015)) on risk-based capital went into effect on January 1, 2022, and amended certain provisions in part 702. As a result, the earnings retention requirement in § 702.201 was moved to § 702.106. Accordingly, this interim final rule implements the amendment made by the 2020 and 2021 PCA interim final rules to § 702.201 in § 702.106.

[24] As detailed subsequently in this preamble, the NCUA's 2015 final rule on risk-based capital went

Continued

The May 2020 interim final rule was issued in response to the COVID–19 pandemic and sought to ensure that FICUs continue to operate efficiently, to ensure that FICUs maintain sufficient liquidity, and to account for the potential temporary increase in shares that FICUs may experience during the COVID–19 pandemic. Specifically, the Board believed the temporary amendments in the interim final rule would allow FICUs to better utilize resources by reducing the administrative burden associated with a temporary increase in shares. The Board concluded that the amendments would provide FICUs with necessary additional flexibility in a manner consistent with the NCUA's responsibility to maintain the safety and soundness of the credit union system. The Board made the temporary amendments effective upon publication and specified that they would remain in place through the end of calendar year 2020. The Board sought comment on the interim final rule.

On June 5, 2020, pursuant to the changes made by the May 2020 interim final rule, the Board issued a temporary order decreasing the earnings retention requirement.[25] Specifically, the Board determined that, due to economic circumstances caused by the COVID–19 pandemic, decreasing the earnings retention requirements set forth in the NCUA's regulations was necessary to avoid a significant redemption of shares. This action would further the purposes of the PCA regulations. Accordingly, the Board ordered that any consumer FICU whose net worth classification, as defined in part 702 of the NCUA's regulations, was adequately capitalized between March 31, 2020, and December 31, 2020, could decrease its earnings retention requirement to zero as set forth in part 702. The order was effective through and including December 31, 2020.[26]

As noted, the Board solicited comment on the May 2020 interim final rule. The Board received comments from a credit union trade association, two state credit union leagues, and an organization of state credit union supervisors. All commenters supported the interim final rule, and no commenter opposed it. All commenters stated that the changes were appropriate, noting that they provided regulatory relief and flexibility to credit unions to manage their liquidity and address financial hardships caused by COVID–19.

The interim final rule's two provisions expired on December 31, 2020. All commenters requested that the temporary amendments be extended or made permanent. One commenter stated that if the economic dislocation caused by the pandemic lingers, the regulatory relief may be necessary beyond the end of 2020. Among the recommendations to extend the effective date were: (1) Making the rule permanent; (2) extending the applicability until the COVID–19 pandemic was declared over by the Center for Disease Control or other Federal agency; or (3) making the end date December 31, 2021.

B. April 2021 Interim Final Rule

Based on information available in December 2020, the Board did not extend these provisions but continued to consider this issue. In light of new facts and circumstances, the Board subsequently determined in April 2021 that it was appropriate to reinstate these amendments to the PCA regulations in part 702 on a temporary basis.[27] Specifically, based on the enactment of the American Rescue Plan Act of 2021 [28] to provide direct financial relief to individual taxpayers, the Board expected that credit unions would receive a significant increase in deposits due to stimulus checks. Accordingly, the Board determined that it was appropriate to reinstitute the changes to the PCA provisions that had been adopted in May 2020. The Board also sought comments in the April 2021 interim final rule.

The NCUA received seven substantive comments in response to the interim final rule, all of which offered support. Commenters stated that the interim final rule provides assistance to FICUs that have experienced pandemic-related hardships; reduces regulatory burden; does not unduly increase risk to the NCUSIF; allows otherwise healthy FICUs to focus on serving members without discouraging deposits; provides FICUs and the NCUA flexibility during a time of unprecedented deposit growth; and helps ensure the relief is available throughout the pandemic and resulting economic turbulence. Commenters also addressed the duration of the extension, requesting that the termination date either be extended beyond March 31, 2022, or be made permanent.

C. This Interim Final Rule

As noted above, the two temporary PCA-related provisions are set to expire on March 31, 2022. Based on the agency's experience and lessons learned during the last two years as well as the ongoing economic fallout related to the COVID–19 pandemic, the Board has determined that it is appropriate to issue another interim final rule to extend these provisions until March 31, 2023. Share growth remains unusually high compared to pre-pandemic levels. Specifically, share growth from September 30, 2020, to September 30, 2021, exceeded 14 percent.[29] The COVID–19 pandemic and Congressional responses to it were the initial impetus for the two previous interim final rules that temporarily amended the two PCA provisions. While the environment that precipitated these temporary amendments has evolved, substantial uncertainties about the continued impact of the pandemic and the evolving economic environment remain. Macroeconomic uncertainty has been particularly significant over the last few months. Inflation, geopolitical tensions, and a new COVID–19 variant have introduced new economic challenges. Ultimately, the combined effects of these factors on share growth and net worth ratios could be quite significant, leading to potentially greater volatility in those measures in the year ahead.

Also, the flexibilities provided by these temporary amendments have proven to benefit both the NCUA and FICUs. The Board believes the agency can use these flexibilities judiciously to address challenges posed by the current environment and potential issues that may arise while the rule remains in effect without imposing any additional safety and soundness risk. Accordingly, the Board believes it is appropriate to extend these provisions until March 31, 2023. The Board requests comments on all aspects of this interim final rule.

The Board notes that this interim final rule incorporates new amendatory language given that the agency's 2015 final rule on risk-based capital amended certain provisions in part 702.[30] Specifically, that final rule amended part 702 by removing §§ 702.201 and 702.206 and moving them, mostly unchanged, to new §§ 702.106 and

into effect on January 1, 2022, and amended certain provisions in part 702. As a result, the requirements for NWRPs in § 702.206(c) were moved to § 702.111(c). Accordingly, this interim final rule implements the amendment made by the 2020 and 2021 PCA interim final rules to § 702.206(c) in current § 702.111(c).

[25] *https://www.ncua.gov/regulation-supervision/letters-credit-unions-other-guidance/temporary-order-decreasing-earnings-retention-requirement.*

[26] 12 CFR 702.301. The term consumer FICU is being used instead of the term natural person FICU. This terminology is being used for clarity, however, the term natural person FICU will continue to be used for the accompanying regulatory text changes for consistency with other sections of the NCUA's regulations.

[27] 86 FR 20258 (Apr. 19, 2021).

[28] Pub. L. 117–2 (Mar. 11, 2021).

[29] Average annual share growth in the 10 years preceding the pandemic was only 5.8 percent.

[30] 80 FR 66626 (Oct. 29, 2015).

702.111. As a result, the current regulatory text does not reflect the April 2021 interim final rule. Because the Board is extending this authority, it is revising the affected provisions to include these authorities to run from the effective date of this interim final rule until March 31, 2023, to ensure there is no interruption in the flexibility.

IV. Section-by-Section Analysis

A. Section 702.106—Earnings Retention Requirement for ''Adequately Capitalized'' FICUs

A FICU that is classified as ''adequately capitalized'' or lower must increase the dollar amount of its net worth quarterly by an amount equivalent to at least 1/10th of a percent of its total assets and must retain at least that amount (for a total of 0.4 percent annually) every quarter until it is ''well capitalized.'' [31] The purpose of this provision is to restore a FICU that is less than well capitalized to a well-capitalized position in an incremental manner. The Board notes that newly chartered FICUs are excluded from this relief given that the relief is intended for FCUs experiencing growth as a result of the COVID–19 pandemic.

As discussed previously, current § 702.106 provides that the Board may waive this requirement on a case-by-case basis upon application by an affected FICU. The Act provides broader authority for the Board to issue an order to waive this requirement and does not require an application or individual orders.[32] In response to recent economic conditions, there were previous infusions of stimulus funds and an increased propensity for consumers to save due to the variety of pandemic-related circumstances. Thus, the Board has determined that it is appropriate to extend its decision to amend § 702.106 temporarily to provide express regulatory authority for the Board to issue a single order waiving the earnings retention requirement for all FICUs that are classified as adequately capitalized during this time. As with the previous orders issued under the May 2020 and April 2021 interim final rules, the Board would provide in the order that the applicable Regional Director has authority to subsequently require an application if a particular FICU poses undue risk to the NCUSIF or exhibits material safety and soundness concerns. Extending this regulatory provision will allow the Board to respond to circumstances broadly affecting many FICUs with a single issuance rather than numerous individual waiver approvals. This provision will expire on March 31, 2023.

In a separate action that will be published on the NCUA website after this interim final rule becomes effective, the Board intends to issue the order described above, which will be applicable to adequately capitalized FICUs and will grant relief from the earnings retention requirement without requiring those FICUs to submit applications and receive individual waiver approvals, subject to the qualification noted above.

The Board is exercising this authority under 12 U.S.C. 1790d(e)(2) to enhance flexibility in the application of the earnings retention requirement. The Board believes that this relief remains necessary to avoid a reduction of shares and thus retain system liquidity and capital adequacy, thereby furthering the purpose of PCA. Economic uncertainty caused by the COVID–19 pandemic and its effect on the economy have resulted in significant asset growth within the credit union industry. This growth may impact the PCA classification of many credit unions, resulting in an increased number of credit unions being subject to the earnings retention requirement. Based on the September 30, 2021, Call Report, 223 credit unions are classified as less than well capitalized and are thus subject to the earnings retention requirement. Of those, 42 percent report negative earnings as of September 30, 2021. With continued uncertainty caused by the COVID–19 pandemic, the credit union system continues to experience the effects of pandemic-related share growth and additional credit unions may be subjected to the earnings retention requirement. A comparison of Call Report data from March 31, 2020, to September 30, 2021, reveals 101 credit unions experienced a decline in their PCA classification from ''well capitalized'' to ''adequately capitalized'' from March 31, 2020, despite having reported a positive return on average assets in September 2021. This illustrates the continued impact of the flight to safety experienced by the industry.

Specifically, during the time period that the two interim final rules have been effective, the Board issued orders providing that any consumer FICU that had a net worth classification, as defined in part 702 of the NCUA's regulations, of adequately capitalized could decrease its earnings-retention requirement to zero as set forth in part 702. These orders enabled FICUs to better utilize resources by eliminating the need to request a waiver of the earnings-retention requirement from their Regional Director. While the interim final rules and earnings-retention orders have been in effect, the number of FICUs that benefitted from this relief has varied from an estimated 77 FICUs as of June 2020 to as many as 179 as of June 30, 2021, based on Call Report data. The FICUs benefitting from the earnings-retention requirement reduction have assets representing less than one percent of industry assets as of September 30, 2021. Accordingly, the Board believes that this amendment and the implementing orders have not posed an undue risk to the NCUSIF.

The Board further notes that FICU operations continue to be significantly disrupted due to social distancing practices, remote work, supply chain disruption, and related complications. Also, the unprecedented amount of fiscal stimulus and decreased spending opportunities have led to a significant increase in the personal saving rate over the last two years. This, in turn, has resulted in extraordinary share growth, leaving net worth ratios artificially depressed.

Given current macroeconomic conditions, downward pressure on net worth ratios will likely persist in the coming year. Although consumer spending has rebounded somewhat, the amount of excess savings—the accumulation of savings over and above pre-pandemic levels—remains significant and is not likely to abate any time soon. Consumer spending on services—the most significant share of expenditures—continues to lag, as the pandemic is resulting in consumers spending less on travel and other activities that are highly social and could potentially expose them to COVID–19. Also, strong gains in employment are supporting incomes and certain loan forbearance programs—which decrease debt service payments—still remain in effect.

By avoiding the need for numerous waiver applications and responses, the simplified procedure that this interim final rule extends will reduce the administrative burden on FICUs and the NCUA. The Board notes qualifications in the planned order regarding FICUs that pose undue risk or material safety and soundness concerns will help ensure that the purposes of PCA are maintained during this time.

B. Section 702.111—NWRPs; Contents of NWRP

As for NWRPs, the Act provides a broad directive that a FICU that is less than adequately capitalized must submit

[31] This relief is provided for FICUs that are required to retain earnings under §§ 702.106, 702.107, 702.108, and 702.109.

[32] *See* 1 U.S.C. 1 (providing that unless context indicates otherwise, words importing the singular also apply to several persons or parties).

an applicable NWRP to the NCUA. The NCUA, by regulation, has provided additional details to supplement this statutory provision. Section 702.111(a) of the NCUA's regulations specifies the schedule for filing the plan, and § 702.111(c) of the NCUA's regulations outlines the contents of a NWRP.

The Board has decided that it is appropriate to continue waiving the NWRP content requirements for FICUs that become classified as undercapitalized predominantly as a result of share growth for Call Reports filed for the periods effective March 31, 2022, June 30, 2022, September 30, 2022, and December 31, 2022. In these cases, the FICU may submit a significantly simpler NWRP to the applicable Regional Director noting that the FICU's PCA classification fell to undercapitalized because of share growth. Specifically, a FICU would be required to attest that its reduction in capital was caused by share growth and that such share growth is a temporary condition due to the COVID–19 pandemic. Federally insured, state-chartered credit unions must comply with applicable state requirements when submitting NWRPs for state supervisory authority approval.

When reviewing NWRPs submitted under this authority, the Regional Director will determine if the decrease in the net worth ratio was predominantly a result of share growth. To assess the reason for the decrease, the Regional Director will analyze the numerator and denominator of the net worth ratio. If there is no change, or if there is an increase in the numerator and an increase in the denominator, this would indicate that the decrease in the net worth ratio was due to share growth. If there is an increase in the denominator and a decrease in the numerator, the Regional Director will analyze whether the decrease in the numerator would have caused the FICU to fall to a lower net worth classification if there were no change in the denominator. If so, the FICU's net worth decline would not be predominantly due to share growth, and thus the FICU would not be eligible to submit a streamlined NWRP.

The Board has determined it is appropriate to extend this regulatory flexibility for NWRPs given the continued economic disruption and the corresponding uncertainty caused by the COVID–19 pandemic.

Since the Board published the interim final rule on May 28, 2020, permitting FICUs that become classified as undercapitalized as a result of share growth to submit a streamlined NWRP, fourteen credit unions have submitted such streamlined NWRPs. Of the fourteen streamlined NWRPs submitted, nine NWRPs were approved, and five streamlined NWRPs were denied. The denials of the streamlined NWRPs were based on those FICUs' decline in PCA classification being the result of other economic factors, and not predominantly the result of share growth. Further, the Board notes that the FICUs submitting streamlined NWRPs were generally smaller, or non-complex credit unions, thus presenting limited risk to the NCUSIF.

Based on September 30, 2021, Call Report data, 59 FICUs would require a NWRP to be in place or be submitted for approval based on their PCA classification. This is an increase of over 22 percent from the 48 credit unions required to have a NWRP to be in place or be submitted for approval based on December 31, 2020, Call Report data, illustrating an upward trend.

The streamlined NWRP will provide sufficient information, based on current economic conditions, to determine if the credit union is prepared to manage the volatility associated with the COVID–19 pandemic and the impact on the FICU's financial and operational position.

As it concluded in the April 2021 interim final rule, the Board continues to believe it can fulfill its statutory duty to evaluate the NWRPs even if the plans are more concise and streamlined than plans submitted before the COVID–19 pandemic. Such a streamlined approach is acceptable because the more extensive information required under the current requirements may not be practicable or useful under the current situation. The Board believes it can determine if a plan is acceptable even if it lacks some of the detailed submissions that the permanent regulatory provision requires.

A FICU's eligibility to submit a streamlined NWRP to the NCUA will be determined based on the effective date of the credit union's PCA classification, as defined in part 702 of the NCUA's regulations.[33] The streamlined NWRP will apply on a case-by-case basis to FICUs that become classified as undercapitalized (those that have a net worth ratio of 4 percent to 5.99 percent) predominantly as a result of share growth. To further clarify, a FICU that has a declined PCA classification will be permitted to submit a streamlined NWRP as reflected in the following table.

Call Report effective sate	PCA classification sate	Streamlined NWRP permissible
March 31, 2022	April 30, 2022	Yes.
June 30, 2022	July 30, 2022	Yes.
September 30, 2022	October 31, 2022	Yes.
December 31, 2022	January 30, 2023	Yes.
March 31, 2023	April 30, 2023	No.

V. Regulatory Procedures

A. Administrative Procedure Act

The Board is issuing the interim final rule without prior notice and the opportunity for public comment and the delayed effective date ordinarily prescribed by the Administrative Procedure Act (APA).[34] Pursuant to the APA, general notice and the opportunity for public comment are not required about a rulemaking when an ''agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' [35]

The Board believes the public interest is best served by implementing the interim final rule immediately upon publication in the **Federal Register**. The Board notes that the economic disruption caused by the COVID–19 pandemic is unprecedented. Even after nearly two years, the situation continues to evolve, thereby making it difficult to anticipate how pandemic-induced disruptions will manifest themselves within the financial system and how individual FICUs may be impacted. The continued relief measures, including the most recent infrastructure legislation, combined with the flight to safety and

[33] 12 CFR part 702.

[34] 5 U.S.C. 553

[35] 5 U.S.C. 553(b)(3).

reduced spending, places a strain on FICU net worth. To disrupt or end the regulatory relief in place would conflict with preserving the safety and soundness of the industry. Because the unprecedented expansionary monetary and fiscal policies, combined with precautionary savings, is placing a strain on FICU net worth, the Board believes it has good cause to determine that ordinary notice and public procedure are impracticable and that moving expeditiously in the form of an interim final rule is in the public's best interests and the FICUs that serve that public. The temporary regulatory changes are necessary steps designed to alleviate potential liquidity and resource strains including stress on capital adequacy and are undertaken with expedience to ensure the maximum intended effects are in place at the earliest opportunity.

The Board values public input in its rulemakings and, to that end, believes that regulations are enhanced when the public has the opportunity to comment. Accordingly, the Board is soliciting comments on this interim final rule. The amendments made by the interim final rule will automatically expire on March 31, 2023 and are limited in number and scope. For these reasons, the Board finds there is good cause consistent with the public interest to issue the rule without advance notice and comment.

The APA also requires a 30-day delayed effective date, except for (1) substantive rules which grant or recognize an exemption or relieve a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause.[36] Because the rule relieves currently codified limitations and restrictions, the interim final rule is exempt from the APA's delayed effective date requirement. As an alternative to making the rule effective without the 30-day delayed effective date, the Board finds there is good cause to do so for the same reasons set forth above regarding advance notice and opportunity for comment.

B. Congressional Review Act.

For purposes of the Congressional Review Act (CRA),[37] the Office of Management and Budget (OMB) decides whether a final rule constitutes a ''major'' rule. If the OMB deems a rule to be ''major,'' the CRA generally provides that the rule may not take effect until at least 60 days following its publication.

The CRA defines a ''major rule'' as any rule that the Administrator of the OMB's Office of Information and Regulatory Affairs finds has resulted in, or is likely to result in, (A) an annual effect on the economy of $100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or 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.[38]

For the same reasons noted above, the Board is adopting the interim final rule without the delayed effective date generally prescribed under the CRA. The delayed effective date required by the CRA does not apply to any rule for which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.[39] In light of current market uncertainty, the Board believes that delaying the effective date of the rule would be contrary to the public interest for the same reasons discussed above.

As required by the CRA, the Board will submit the final rule and other appropriate reports to Congress and the Government Accountability Office for review.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) requires OMB to approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a valid OMB control number. The information collection requirements prescribed by the May 2020 interim final rule under PCA remains in effect and are cleared under OMB control number 3133–0154.

D. Executive Order 13132

Executive Order 13132[40] encourages independent regulatory agencies to consider the impact of their actions on state and local interests. The NCUA, an independent regulatory agency, as defined in 44 U.S.C. 3502(5), voluntarily complies with the Executive order to adhere to fundamental federalism principles. The interim final rule 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. The Board has thus determined that this rule does not constitute a policy that has federalism implications for purposes of the Executive order. But the Board notes that it has consulted with state regulators, as described in the PCA section of the Act, and will continue to do so during the comment period and implementation of this interim final rule.[41]

E. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this interim final rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, 1999.[42]

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that when an agency issues a proposed rule or a final rule pursuant to the APA[43] or another law, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the **Federal Register**.[44] Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. For purposes of the RFA, the Board considers FICUs with assets less than $100 million to be small entities.[45]

As discussed previously, consistent with the APA,[46] the Board has determined for good cause that general notice and opportunity for public comment is unnecessary, and thus, the Board is not issuing a notice of proposed rulemaking. Rules that are exempt from notice and comment procedures are also exempt from the RFA requirements, including conducting a regulatory flexibility analysis, when among other things the agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest. Accordingly, the Board has concluded that the RFA's requirements

[36] 5 U.S.C. 553(d).

[37] 5 U.S.C. 801–808.

[38] 5 U.S.C. 804(2).

[39] 5 U.S.C. 808.

[40] Executive Order 13132 on Federalism was signed by former President Clinton on August 4, 1999, and subsequently published in the **Federal Register** on August 10, 1999 (64 FR 43255).

[41] 12 U.S.C. 1790d(*l*).

[42] Public Law 105–277, 112 Stat. 2681 (1998).

[43] 5 U.S.C. 553(b).

[44] 5 U.S.C. 603, 604.

[45] NCUA Interpretive Ruling and Policy Statement (IRPS) 15–1. 80 FR 57512 (Sept. 24, 2015).

[46] 5 U.S.C. 553(b)(3)(B).

relating to initial and final regulatory flexibility analysis do not apply.

Nevertheless, the Board seeks comment on whether, and to what extent, the interim final rule would affect a significant number of small entities.

List of Subjects in 12 CFR Part 702

Credit unions, Reporting and recordkeeping requirements.

By the NCUA Board, this 17th day of February 2022.

Melane Conyers-Ausbrooks,

Secretary of the Board.

For the reasons set forth in the preamble, the Board is amending 12 CFR part 702 as follows:

PART 702—CAPITAL ADEQUACY

■ 1. The authority citation for part 702 continues to read as follows:

Authority: 12 U.S.C. 1766(a), 1790d.

■ 2. Amend § 702.106 by redesignating paragraphs (b)(1) and (2) as paragraphs (b)(1)(i) and (ii), respectively, and adding a new paragraph (b)(2) to read as follows:

§ 702.106 Prompt corrective action for adequately capitalized credit unions.

* * * * *

(b) * * *

(2) Notwithstanding paragraph (a) of this section, from February 28, 2022, until March 31, 2023, for a credit union that is adequately capitalized:

(i) The NCUA Board may issue an administrative order specifying temporary revisions to the earnings retention requirement, to the extent the NCUA Board determines that such lesser amount—

(A) Is necessary to avoid a significant redemption of shares; and

(B) Would further the purpose of this part.

(ii) Despite the issuance of an administrative order under paragraph (b)(2) of the section, the Regional Director may require a credit union to submit an earnings retention waiver under paragraph (b)(1) if the credit union poses an undue risk the National Credit Union Share Insurance Fund or exhibits material safety and soundness concerns.

* * * * *

■ 3. Amend § 702.111 by adding paragraph (c)(4) to read as follows:

§ 702.111 Net worth restoration plans (NWRP).

* * * * *

(c) * * *

(4) Notwithstanding paragraphs (c)(1), (2), and (3) of this section, the Board may permit a credit union that is undercapitalized to submit to the Regional Director a streamlined NWRP attesting that its reduction in capital was caused by share growth and that such share growth is a temporary condition due to the COVID–19 pandemic. A streamlined NWRP plan may be accepted from February 28, 2022, until March 31, 2023.

* * * * *

[FR Doc. 2022–03845 Filed 2–25–22; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0729; Project Identifier MCAI–2021–00364–R; Amendment 39–21948; AD 2022–04–06]

RIN 2120–AA64

Airworthiness Directives; Bell Textron Canada Limited Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021–06–06, which applied to certain Bell Textron Canada Limited Model 505 helicopters. AD 2021–06–06 required repetitive fluorescent penetrant inspections (FPIs) of the pilot collective stick and grip assembly and revising the existing Rotorcraft Flight Manual (RFM) for your helicopter. Since the FAA issued AD 2021–06–06, the pilot collective stick and grip assembly has been redesigned. This AD retains certain requirements of AD 2021–06–06, requires modifying your helicopter to include the improved pilot collective stick tube and adds a terminating action for the repetitive FPIs. This AD also prohibits installing any pilot collective stick and grip assembly unless certain requirements of this AD are met. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 4, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 4, 2022.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of March 31, 2021 (86 FR 14366, March 16, 2021).

ADDRESSES: For service information identified in this final rule, contact Bell Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone 1–450–437–2862 or 1–800–363–8023; fax 1–450–433–0272; email *productsupport@bellflight.com;* or at *https://www.bellflight.com/support/contact-support.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. Service information that is incorporated by reference is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA 2021–0729.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0729; 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 Transport Canada AD, 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: Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267–9167; email *hal.jensen@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2021–06–06, Amendment 39–21473 (86 FR 14366, March 16, 2021) (AD 2021–06–06), for Bell Textron Canada Limited Model 505 helicopters, serial number (S/N) 65011 and subsequent. The NPRM published in the **Federal Register** on September 14, 2021 (86 FR 51035). In the NPRM, the FAA proposed to retain some of the requirements of AD 2021–06–06, including, before further flight, revising Section 1, the Limitations section of the existing RFM for your helicopter to prohibit single pilot operations from the right crew seat, require the pilot in command (PIC) to occupy the left crew seat for dual pilot operations, and depending on configuration, prohibit the use of SPLIT–COM mode. The NPRM also proposed to require, before further flight, and thereafter at intervals

not to exceed 25 hours time-in-service (TIS), removing the pilot collective stick and grip assembly and performing an FPI for a crack and depending on the inspection results, removing a certain part from service. The NPRM proposed to require, within 12 months, removing a certain part-numbered pilot collective stick tube from service and installing an improved pilot collective stick tube in accordance with the manufacturers service information and thereafter, removing a certain part-numbered pilot collective stick tube from service before it accumulates 300 total hours TIS.

Additionally, the NPRM would consider certain proposed actions to be a terminating action for other actions proposed in the NPRM. The NPRM also proposed to prohibit installing any pilot collective stick and grip assembly unless certain proposed actions were accomplished. Finally, the NPRM proposed to require revising the Limitations section of the existing RFM for your helicopter; the owner/operator (pilot) may incorporate the RFM revisions and the owner/operator must enter compliance with the applicable paragraphs of the AD into the aircraft records in accordance with 14 CFR 43.9(a)(1) through (4) and 14 CFR 91.417(a)(2)(v). This is an exception to the FAA's standard maintenance regulations.

The NPRM was prompted by Transport Canada AD CF–2021–05R3, dated March 19, 2021 (Transport Canada AD CF–2021–05R3), issued by Transport Canada, which is the aviation authority for Canada, to correct an unsafe condition for Bell Textron Canada Limited Model 505 helicopters, S/Ns 65011 through 65347. Transport Canada advises that the pilot collective stick and grip assembly has been redesigned to address the root cause of the cracking. Accordingly, Transport Canada AD CF–2021–05R3 retains the requirements of Transport Canada Emergency AD CF–2021–05R2, dated March 4, 2021 (Transport Canada Emergency AD CF–2021–05R2), which prompted AD 2021–06–06, and requires installing the newly designed pilot collective stick and grip assembly, which is a terminating action for the requirements of Transport Canada Emergency AD CF–2021–05R2. Transport Canada AD CF–2021–05R3 also revises the applicability to include only helicopters that have not incorporated the redesigned pilot collective stick and grip assembly during production.

Therefore, the FAA determined that it is necessary to supersede AD 2021–06–06 and the required actions as proposed in the NPRM include a terminating action for the repetitive FPI inspections.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from one commenter; Bell. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request for Changes to the Required Actions

Bell requested that the FAA revise the life limit of pilot collective stick tube part number (P/N) M207–20M301–043. Bell stated that 300 total hours TIS was only an interim life limit and after the completion of fatigue testing, the life limit of 6,250 total hours TIS has been approved by Transport Canada. Specifically, Bell requested that the FAA change the required action to, ''Replace the pilot collective stick tube P/N M207–20M301–043 at or before reaching its Life Limit as defined in Table 1 of the Maintenance Planning Information (MPI) Chapter 4 Airworthiness Limitations Schedule (ALS), BHT–505–MPI Chapter 4 Issue 09, dated 12 March 2021, or later revisions of the ALS approved by Transport Canada.''

The FAA partially agrees. The FAA disagrees with changing the action from removing the pilot collective stick tube from service to ''replace the pilot collective stick tube'' because this is a life limit and, once the life limit is reached, the part must be removed from service and never installed on any aircraft again. Additionally, due to eligibility requirements in 1 CFR part 51, the FAA cannot mandate use of ''later revisions'' of service information directly in an AD. However, the FAA agrees with the life limit threshold increasing from 300 total hours TIS to 6,250 total hours TIS and, accordingly has changed that life limit in this final rule.

Bell requested that the FAA revise paragraph (g)(6) of the Required Actions that states relief under any Master Minimum Equipment List or Minimum Equipment List for the Audio Panel is prohibited when the aircraft is operated with a single pilot. Bell stated that this restriction is only applicable when operated from the left hand seat, and the aircraft must be flown from the right hand seat when SPLIT–COM mode is enabled. Bell further stated this is consistent with the limitations of the flight manual.

The FAA agrees and has revised the required actions in this final rule accordingly.

Request for Changes to the Credit for Previous Actions

Bell requested that the FAA allow credit for the required actions through an approved AMOC and service information. Bell stated that the FAA approved an AMOC to AD 2021–06–06 on March 26, 2021, which allowed operators to implement a terminating action based on the instructions contained in Bell Alert Service Bulletin 505–21–20, Revision C, dated March 11, 2021 (ASB 505–21–20 Rev C). Bell requested that the approved AMOC and ASB 505–21–20 Rev C be included in the Credit for Previous Actions paragraph.

The FAA agrees with the request to allow credit; however, the FAA disagrees with putting this information in the Credit for Previous Actions paragraph. The FAA agrees that the previously approved AMOC to AD 2021–06–06 continues to be valid to address the unsafe condition. Accordingly, the FAA has revised the AMOC paragraph in this final rule by adding paragraph (j)(3), which states ''AMOCs approved previously for AD 2021–06–06 are approved as AMOCs for the corresponding requirements in paragraph (g) of this AD.'' Additionally, the purpose of the Credit for Previous Actions paragraph is to allow credit for required actions accomplished previously in accordance with previous revision(s) of service information. Since ASB 505–21–20 Rev C is required to accomplish certain actions in paragraph (g) of this AD, previous accomplishment of those actions in ASB 505–21–20 Rev C could be considered accomplished by paragraph (f) of this AD.

Other Changes Between the NPRM and This Final Rule

In this final rule, the FAA has changed the effective date of paragraph (g)(1) from ''after the effective date of this AD'' to ''from March 31, 2021 (the effective date of AD 2021–06–06),'' because this paragraph carries-over identical required actions from paragraph (g)(1) of AD 2021–06–06.

Conclusion

These helicopter have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with Canada, Transport Canada, its technical representative, has notified the FAA of the unsafe condition described in its AD. The FAA reviewed the relevant data, considered the 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 these helicopters. Except for minor editorial changes, and any other 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 ASB 505–21–20 Rev C, which provides instructions for an initial and repetitive FPIs for cracks in the pilot collective stick and grip assembly P/N M207–20M478–041/–043/–047 on Bell Textron Canada Limited Model 505 helicopters, serial numbers 65011 through 65347. ASB 505–21–20 Rev C also specifies inserting a temporary revision (TR) into the RFM that prohibits single pilot operations from the right crew seat until further notice, and specifies that if the right crew seat pilot collective stick and grip assembly was previously confirmed serviceable following an FPI, then the 25 flight hour repetitive FPI of the right crew seat pilot collective stick and grip assembly is no longer required provided that the helicopter is only operated single PIC from the left crew seat. ASB 505–21–20 Rev C also introduces procedures to install an improved pilot collective stick tube assembly, along with its initial life limit, and which is also terminating action for the repetitive FPIs and temporary RFM revision.

The FAA also reviewed Bell 505 RFM TR for Pilot Collective (ASB 505–21–20), BHT–505–FM–1, Temporary Revision (TR–6) (BHT–505–FM–1, TR–6) and Bell 505 RFM TR for Pilot Collective (ASB 505–21–20), BHT–505–FM–2, Temporary Revision (TR–1), each dated March 3, 2021. These temporary revisions specify changes to Section 1 of the RFM Limitations Section that the minimum flight crew consists of one pilot that shall operate from the left crew seat and that dual operation is approved provided that the PIC occupies the left crew seat. BHT–505–FM–1, TR–6 also prohibits use of SPLIT–COM mode.

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 Bell ASB 505–21–20, dated February 20, 2021 (ASB 505–21–20), Bell ASB 505–21–20, Revision A, dated February 26, 2021 (ASB 505–21–20 Rev A), and Bell ASB 505–21–20, Revision B, dated March 3, 2021 (ASB 505–21–20 Rev B). ASB 505–21–20 specifies a one-time inspection for cracks of the pilot collective stick and grip assembly. ASB 505–21–20 Rev A removes the visual inspection and adds a repetitive FPI. ASB 505–21–20 Rev B adds the RFM temporary revision and clarifies the compliance time of the repetitive FPI.

Differences Between This AD and Transport Canada AD CF–2021–05R3

This AD prohibits relief under any Master Minimum Equipment List or Minimum Equipment List for the Audio Panel when the aircraft is operated with a single pilot from the left seat, whereas Transport Canada AD CF–2021–05R3 does not. Transport Canada AD CF–2021–05R3 requires the repetitive FPIs if the aircraft is not flown solely from the left crew seat whereas this AD requires repetitive FPIs regardless.

Transport Canada AD CF–2021–05R3 requires operators to ''advise all flight crews'' of changes to the RFM, and thereafter to ''operate the helicopter accordingly.'' However, this AD does not specifically require those actions. 14 CFR 91.9 requires that no person may operate a civil aircraft without complying with the operating limitations specified in the RFM. Therefore, including a requirement in this AD to operate the helicopter according to the revised RFM would be redundant and unnecessary. Further, compliance with such a requirement in an AD would be impracticable to demonstrate or track on an ongoing basis; therefore, a requirement to operate the helicopter in such a manner would be unenforceable.

This AD prohibits installing any pilot collective stick and grip assembly on any helicopter unless the actions required by paragraphs (g)(2) and (3) of this AD have been accomplished, whereas Transport Canada AD CF–2021–05R3 does not.

Costs of Compliance

The FAA estimates that this AD affects 98 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Revising the existing RFM for your helicopter takes about 0.5 work-hour for an estimated cost of $43 per helicopter and up to $4,214 for the U.S. fleet.

Removing, cleaning, and performing an FPI of the pilot collective stick and grip assembly takes about 3 work-hours for an estimated cost of $255 per helicopter and up to $24,990 for the U.S. fleet per inspection cycle.

Installing an improved pilot collective stick tube takes about 5 work-hours and parts cost about $1,256 for an estimated cost of $1,681 per helicopter and up to $164,738 for the U.S. fleet per replacement cycle.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

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:
■ a. Removing Airworthiness Directive 2021–06–06, Amendment 39–21473 (86 FR 14366, March 16, 2021); and
■ b. Adding the following new airworthiness directive:

2022–04–06 Bell Textron Canada Limited: Amendment 39–21948; Docket No. FAA–2021–0729; Project Identifier MCAI–2021–00364–R.

(a) Effective Date

This airworthiness directive (AD) is effective April 4, 2022.

(b) Affected ADs

This AD replaces AD 2021–06–06, Amendment 39–21473 (86 FR 14366, March 16, 2021) (AD 2021–06–06).

(c) Applicability

This AD applies to Bell Textron Canada Limited Model 505 helicopters, serial number (S/N) 65011 through 65347 inclusive, certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6710, Main Rotor Control.

(e) Unsafe Condition

This AD was prompted by a report of a cracked pilot collective stick and grip assembly. The FAA is issuing this AD to detect a cracked pilot collective stick and grip assembly. The unsafe condition, if not addressed, could result in failure of the pilot collective stick and grip assembly and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) From March 31, 2021 (the effective date of AD 2021–06–06), before further flight, revise the Limitations section of the existing Rotorcraft Flight Manual (RFM) for your helicopter by inserting Bell 505 RFM Temporary Revision (TR) for Pilot Collective (ASB 505–21–20), BHT–505–FM–1, Temporary Revision (TR–6) or Bell 505 RFM TR for Pilot Collective (ASB 505–21–20), BHT–505–FM–2, Temporary Revision (TR–1), each dated March 3, 2021, as applicable to your helicopter. Using a different document with information identical to the information for the ''Flight Crew'' and ''Configuration,'' as applicable to your helicopter, in the RFM TR specified in this paragraph for your helicopter is acceptable for compliance with the requirements of this paragraph. This action may be performed by the owner/operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9(a)(1) through (4) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417 or 135.439.

(2) Before further flight after the effective date of this AD, and thereafter at intervals not to exceed 25 hours time-in-service (TIS):

(i) Remove the pilot collective stick and grip assembly from the jackshaft assembly and clean the areas specified in Figure 2 of Bell Alert Service Bulletin 505–21–20, Revision C, dated March 11, 2021 (ASB 505–21–20 Rev C) with a clean cloth C–516C or equivalent moistened with dry cleaning solvent C–304 or equivalent.

(ii) Perform a fluorescent penetrant inspection (FPI) for a crack by following the Accomplishment Instructions, Part I, paragraph 5. (but not paragraphs 5.a. and b.) of ASB 505–21–20 Rev C. Perform this FPI in the areas specified in Figure 2 of ASB 505–21–20 Rev C. If there is a crack, before further flight, remove the pilot collective stick and grip assembly from service.

(3) Within 12 months after the effective date of this AD, remove the pilot collective stick tube from service and install pilot collective stick tube part number (P/N) M207–20M301–043 by following the Accomplishment Instructions, Part II, paragraphs 3. and 4. of ASB 505–21–20 Rev C except where this service information specifies discarding parts, you are required to remove those parts from service instead. Thereafter, remove from service pilot collective stick tube P/N M207–20M301–043 before it accumulates 6,250 total hours TIS.

(4) Completing the actions required in paragraph (g)(3) of this AD constitutes a terminating action for the requirements in paragraphs (g)(1) and (2) of this AD.

(5) As of the effective date of this AD, do not install any pilot collective stick and grip assembly on any helicopter unless the actions required by paragraphs (g)(2) and (3) of this AD have been accomplished.

(6) As of the effective date of this AD, relief under any Master Minimum Equipment List or Minimum Equipment List for the Audio Panel is prohibited when the aircraft is operated with a single pilot from the left seat.

(h) Credit for Previous Actions

If you performed an FPI of the pilot collective stick and grip assembly before the effective date of this AD using Bell Alert Service Bulletin 505–21–20, dated February 20, 2021, Bell Alert Service Bulletin 505–21–20, Revision A, dated February 26, 2021, or Bell Alert Service Bulletin 505–21–20, Revision B, dated March 3, 2021, you met the before further flight FPI requirement of paragraph (g)(2) of this AD.

(i) Special Flight Permits

A special flight permit to a maintenance facility may be granted provided that:

(1) There are no passengers on-board,

(2) The helicopter is flown from the copilot (left) seat only, and

(3) The GMA (intercom) is operative.

(j) 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 International Validation Branch, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed 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.

(3) AMOCs approved previously for AD 2021–06–06 are approved as AMOCs for the corresponding requirements in paragraph (g) of this AD.

(k) Related Information

(1) For more information about this AD, contact Hal Jensen, Aerospace Engineer, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 950 L'Enfant Plaza N SW, Washington, DC 20024; telephone (202) 267–9167; email *hal.jensen@faa.gov.*

(2) Bell Alert Service Bulletin 505–21–20, dated February 20, 2021, Bell Alert Service Bulletin 505–21–20, Revision A, dated February 26, 2021, and Bell Alert Service Bulletin 505–21–20, Revision B, dated March 3, 2021, which are not incorporated by reference, contain additional information about the subject of this AD. This service information is available at the contact information specified in paragraphs (l)(5) and (6) of this AD.

(3) The subject of this AD is addressed in Transport Canada AD CF–2021–05R3, dated March 19, 2021. You may view the Transport Canada AD at *https://www.regulations.gov* in Docket No. FAA–2021–0729.

(l) 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.

(3) The following service information was approved for IBR on April 4, 2022.

(i) Bell Alert Service Bulletin 505–21–20, Revision C, dated March 11, 2021.

(ii) [Reserved]

(4) The following service information was approved for IBR on March 31, 2021 (86 FR 14366, March 16, 2021).

(i) Bell 505 Rotorcraft Flight Manual Temporary Revision for Pilot Collective (ASB 505–21–20), BHT–505–FM–1, Temporary Revision (TR–6), dated March 3, 2021.

(ii) Bell 505 Rotorcraft Flight Manual Temporary Revision for Pilot Collective (ASB 505–21–20), BHT–505–FM–2, Temporary Revision (TR–1), dated March 3, 2021.

(5) For Bell service information identified in this AD, contact Bell Textron Canada

Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone 1–450–437–2862 or 1–800–363–8023; fax 1–450–433–0272; email *productsupport@bellflight.com;* or at *https://www.bellflight.com/support/contact-support.*

(6) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(7) 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: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on February 10, 2022.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–04159 Filed 2–25–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1067; Project Identifier MCAI–2021–00857–T; Amendment 39–21954; AD 2022–05–03]

RIN 2120–AA64

Airworthiness Directives; Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. This AD was prompted by a report that some tie-rod assemblies may have been overtightened during the installation of interior monuments (such as galleys, lavatories, and forward stowage or wardrobes). This AD requires adjusting the tie-rod assemblies, as specified in a Transport Canada Civil Aviation (TCCA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 4, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 4, 2022.

ADDRESSES: For TCCA material incorporated by reference (IBR) in this AD, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://tc.canada.ca/en/aviation.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1067.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1067; 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 mandatory continuing airworthiness information (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: Antariksh Shetty, Aerospace Engineer, Airframe and Propulsion 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

The TCCA, which is the aviation authority for Canada, has issued TCCA AD CF–2021–25, dated July 22, 2021 (TCCA AD CF–2021–25) (also referred to as the MCAI), to correct an unsafe condition for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. The NPRM published in the **Federal Register** on December 17, 2021 (86 FR 71589). The NPRM was prompted by a report that some tie-rod assemblies may have been overtightened during the installation of interior monuments (such as galleys, lavatories, and forward stowage or wardrobes). The NPRM proposed to require adjusting the tie-rod assemblies, as specified in TCCA AD CF–2021–25.

The FAA is issuing this AD to address overtightened (pre-loaded) tie-rods that induce unwanted stress in a monument and may cause the monument to become unconstrained in an emergency landing, potentially blocking exits or injuring occupants. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data 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

TCCA AD CF–2021–25 specifies procedures for, among other actions, adjustment of the affected tie-rod assemblies to remove any pre-load. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 21 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
5 work-hours × $85 per hour = $425	None	$425	$8,925

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:

2022–05–03 Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Amendment 39–21954; Docket No. FAA–2021–1067; Project Identifier MCAI–2021–00857–T.

(a) Effective Date

This airworthiness directive (AD) is effective April 4, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Canada Limited Partnership (type certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Model BD–500–1A10 and BD–500–1A11 airplanes, certificated in any category, as identified in Transport Canada Civil Aviation (TCCA) AD CF–2021–25, dated July 22, 2021 (TCCA AD CF–2021–25).

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by a report that some tie-rod assemblies may have been overtightened during the installation of interior monuments (such as those for the galleys, lavatories, and forward stowage or wardrobes). The FAA is issuing this AD to address over-tightened (pre-loaded) tie-rods that induce unwanted stress in the monument and may cause the monument to become unconstrained in an emergency landing, potentially blocking exits or injuring occupants.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, TCCA AD CF–2021–25.

(h) Exceptions to TCCA AD CF–2021–25

(1) Where TCCA AD CF–2021–25 refers to hours air time, this AD requires using flight hours.

(2) Where TCCA AD CF–2021–25 refers to its effective date, this AD requires using the effective date of this AD.

(3) The inspection specified in the Corrective Actions paragraph of TCCA AD CF–2021–25 does not apply to this AD.

(i) Additional 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 responsible Flight Standards 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; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or TCCA; or Airbus Canada Limited Partnership's TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

For more information about this AD, contact Antariksh Shetty, Aerospace Engineer, Airframe and Propulsion 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*.

(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 this AD specifies otherwise.

(i) Transport Canada Civil Aviation (TCCA) AD CF–2021–25, dated July 22, 2021.

(ii) [Reserved]

(3) For TCCA AD CF–2021–25, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean,

Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *https://tc.canada.ca/en/aviation.*

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

(5) You may view this material 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: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on February 16, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–04145 Filed 2–25–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–1062; Project Identifier MCAI–2021–00886–T; Amendment 39–21957; AD 2022–05–06]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus SAS Model A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes. This AD was prompted by a determination that new or more restrictive airworthiness limitations related to pylon maintenance are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations for pylon maintenance, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 4, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 4, 2022.

ADDRESSES: For EASA material incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1062.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–1062; 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 mandatory continuing airworthiness information (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: Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0181, dated July 30, 2021 (EASA AD 2021–0181) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus SAS Model A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes. The NPRM published in the **Federal Register** on December 17, 2021 (86 FR 71592). The NPRM was prompted by a determination that new or more restrictive airworthiness limitations related to pylon maintenance are necessary. The NPRM proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations for pylon maintenance, as specified in EASA AD 2021–0181.

The FAA is issuing this AD to address fatigue cracking, damage, and corrosion in principal structural elements; such fatigue cracking, damage, and corrosion could result in reduced structural integrity of the airplane. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data 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

EASA AD 2021–0181 specifies new or more restrictive airworthiness limitations for pylon maintenance. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

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

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the agency estimates the average total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

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:

2022–05–06 Airbus SAS: Amendment 39–21957; Docket No. FAA–2021–1062; Project Identifier MCAI–2021–00886–T.

(a) Effective Date

This airworthiness directive (AD) is effective April 4, 2022.

(b) Affected ADs

This AD affects AD 2018–19–17, Amendment 39–19417 (83 FR 48207, September 24, 2018) (AD 2018–19–17).

(c) Applicability

This AD applies to all Airbus SAS Model A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations for pylon maintenance are necessary. The FAA is issuing this AD to address fatigue cracking, damage, and corrosion in principal structural elements; such fatigue cracking, damage, and corrosion could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2021–0181, dated July 30, 2021 (EASA AD 2021–0181).

(h) Exceptions to EASA AD 2021–0181

(1) Where EASA AD 2021–0181 refers to its effective date, this AD requires using the effective date of this AD.

(2) The requirements specified in paragraphs (1) and (2) of EASA AD 2021–0181 do not apply to this AD.

(3) Paragraph (3) of EASA AD 2021–0181 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2021–0181 is at the applicable ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2021–0181, or within 90 days after the effective date of this AD, whichever occurs later.

(5) The provisions specified in paragraph (4) of EASA AD 2021–0181 do not apply to this AD.

(6) The ''Remarks'' section of EASA AD 2021–0181 does not apply to this AD.

(i) Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2021–0181.

(j) Terminating Action for AD 2018–19–17

Accomplishing the actions required by this AD terminates the corresponding requirements of AD 2018–19–17, for the tasks identified in the service information referred to in EASA AD 2021–0181 only.

(k) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(3) *Required for Compliance (RC):* Except as required by paragraph (k)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(l) Related Information

For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3225; email *dan.rodina@faa.gov.*

(m) 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) European Union Aviation Safety Agency (EASA) AD 2021–0181, dated July 30, 2021.

(ii) [Reserved]

(3) For EASA AD 2021–0181, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

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

(5) You may view this material 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: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on February 17, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–04147 Filed 2–25–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0345; Product Identifier 2019–NM–154–AD; Amendment 39–21951; AD 2022–04–09]

RIN 2120–AA64

Airworthiness Directives; AVOX System Inc. (Formerly Scott Aviation) Oxygen Cylinder and Valve Assemblies and Oxygen Valve Assemblies

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain AVOX System Inc. (formerly Scott Aviation) oxygen cylinder and valve assemblies, and oxygen valve assemblies, installed on but not limited to various transport airplanes. This AD was prompted by reports of cylinder and valve assemblies having oxygen leakage from the valve assembly vent hole, caused by the absence of a guide that maintains appropriate spacing between certain parts. This AD requires an inspection of the oxygen valve assemblies, and oxygen cylinder and valve assemblies, to determine the serial number of the valve, cylinder, and entire assembly. For assemblies and parts with certain serial numbers, this AD requires a detailed inspection for correct spacing of the gap between the bottom of the packing retainer and top of the valve body on the assemblies, and replacement of assemblies having unacceptable gaps. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 4, 2022.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of April 4, 2022.

ADDRESSES: For service information identified in this final rule, contact AVOX Systems Inc., 225 Erie Street, Lancaster, NY 14086; telephone 716–683–5100; internet *https://www.safranaerosystems.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 at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0345.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0345; 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: Elizabeth Dowling, Aerospace Engineer, Mechanical Systems and Administrative Services 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

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain AVOX System Inc. (formerly Scott Aviation) oxygen cylinder and valve assemblies, and oxygen valve assemblies, installed on but not limited to various transport airplanes. The NPRM published in the **Federal Register** on May 1, 2020 (85 FR 25353). The NPRM was prompted by reports of cylinder and valve assemblies having oxygen leakage from the valve assembly vent hole, caused by the absence of a guide that maintains appropriate spacing between certain parts. In the NPRM, the FAA proposed to require an inspection of the oxygen valve assemblies, and oxygen cylinder and valve assemblies, to determine the serial number of the valve, cylinder, and entire assembly. For assemblies and parts with certain serial numbers, the NPRM proposed to require a detailed inspection for correct spacing of the gap between the bottom of the packing retainer and top of the valve body on the assemblies, and replacement of assemblies having unacceptable gaps (removing affected assemblies and installing serviceable assemblies). The NPRM also proposed to require reporting and returning of affected parts to the manufacturer. The FAA is issuing this AD to address oxygen leakage from the cylinder, which could result in decreased or insufficient oxygen supply during a depressurization event; and heating or flow friction, which could cause an ignition event in the valve assembly.

Discussion of Final Airworthiness Directive

Comments

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

The FAA received additional comments from five commenters, including American Airlines (AAL), Delta Air Lines (DAL), FedEx Express (FedEx), United Airlines (UAL), and an individual. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Revise Applicability

AAL and UAL suggested revising the applicability statement to include more aircraft manufacturers and models. AAL suggested adding all airplane models that affected assemblies could be installed on, in particular, Boeing Model 737–NG (Next Generation models are 737–600, –700, –700C, –800, –900, and –900ER series), 737–MAX, 777–200, and 777–300 series airplanes. UAL also suggested adding Model 737–NG airplanes. AAL stated that the applicability statement as proposed in the NPRM could mislead operators into believing that the AD would apply only to the airplanes identified in paragraphs (c)(1) through (12) of the AD. UAL believed the suggested change will be beneficial and assist operators in determining if their fleets are affected.

The FAA disagrees with the commenters' request. The FAA does not have a comprehensive list of all possible affected aircraft. To address the incomplete list, paragraph (c) of this AD identifies specific airplane models in paragraph (c) of this AD, but also notes that the assemblies are ''not limited to.'' The FAA has not changed the AD in this regard.

Request To Revise Compliance Time for Parts

AAL stated that the 60-day compliance time should apply only to valve assemblies that are installed on the aircraft and not ones in stock. AAL believes the unsafe condition only exists when an assembly is installed on an airplane, and for those assemblies that are not installed on an airplane, the proposed requirements in paragraph (k) of the proposed AD would ensure that the unsafe condition is addressed before that assembly is installed on an aircraft.

The FAA disagrees with the request to revise the compliance time. The FAA agrees that an affected spare part that is uninstalled and stored off an aircraft would not cause an unsafe condition on an aircraft. The 60-day compliance time applies to parts already installed on an aircraft, and paragraph (k) requires that action to be done on affected spare parts before installation, which could result in a spare part being inspected before the 60-day compliance time. In developing the compliance time for this AD, the FAA considered the urgency associated with the subject unsafe condition and the availability of required parts. The FAA determined that the 60-day compliance time for parts already installed on an aircraft is appropriate for accomplishing the actions required by this AD while maintaining an adequate level of safety. The FAA has not changed this AD in this regard.

Request To Remove Inspection for Serial Numbers or Include Only Valve P/Ns

AAL requested that the inspection to verify the serial number of the oxygen cylinder and entire assembly not be required. DAL requested that paragraphs (c), (h), (i), and (k) of the proposed AD be revised to remove reference to cylinder part numbers (P/Ns) and apply only to valve assembly P/Ns. AAL stated that it reviewed the service information and it seems that the defective part is only the valve assembly or ''hand valve.'' DAL also reasoned that the unsafe condition applies only to the valve assembly and not the cylinder. AAL then reasoned that the inspection to verify the serial number should apply only to the valve assembly or ''hand valve.'' AAL also stated that paragraph (i) of the proposed AD also seems to require the actions of paragraph (h)(1) through (3) of the proposed AD if a serial number of a cylinder was affected and a valve assembly not affected, even though it seems that it should not require those actions.

The FAA disagrees with the request. The parts of the oxygen cylinder and valve assemblies are interrelated, and valves from matched sets could have fit-up issues between parts or be mixed up or swapped during maintenance operations. The serial number inspection as proposed would address this interchangeability. The valve and cylinder that are part of those assemblies must also be inspected to address the unsafe condition, not just the assemblies themselves. Therefore, the FAA specifies to inspect the oxygen valve assemblies, and oxygen cylinder and valve assemblies, to determine the serial number of the valve, cylinder, and entire assembly. The FAA has not changed this AD in this regard.

Request To Clarify Which Components Need To Be Identified

UAL requested a change to the wording of which components need the serial number inspection. UAL stated that the statement in paragraph (h) of the proposed AD can be misconstrued as requiring that each of the three components (valve, cylinder, and entire assembly) be inspected individually for suspect serial numbers. UAL inferred that the intention is to inspect for the serial number of the entire cylinder and valve assembly, and not the individual components. UAL also stated that, for new oxygen cylinder assemblies from AVOX, there are individual placards that itemize the P/N and serial number for each component, and that for some cylinder assemblies, the serialization of the entire cylinder and valve assembly is nearly identical in format to the serialization of sub-component valve assemblies, which could lead to inaccurate reporting of results. The FAA infers that UAL suggested that the relevant numbers on the placards could be confused with other numbers.

The FAA disagrees. Each part and assembly stated in paragraph (h) of this AD are interrelated and must be inspected. The valve and cylinder components that are part of those assemblies must also be inspected for serial numbers, not just the assemblies themselves. If the serial number markings are unclear or missing, the service information contains information on identifying the parts and part assemblies. The FAA has not changed this AD in this regard.

Request To Revise Conditions for Gap Inspection and Related Actions

AAL and DAL requested changes to address concerns about what actions are required if a part is missing a blue dot. DAL stated that it seems best to prohibit all affected serial numbers to avoid a case where an inspected and marked part is installed, but the blue dot fades. AAL pointed to paragraph (i) of the proposed AD that would clarify that only the affected serial numbers of the valve assembly would need additional work, and, for valve assemblies marked with a blue dot, a detailed inspection for correct spacing of the gap between the bottom of the packing retainer and top of the valve body would not be required. AAL stated that, as written, the proposed AD seems to suggest that an inspection of the gap would be required regardless of the presence of a blue dot.

The FAA disagrees with the request. The service information specifies that if there is a doubt on the condition of a part, such as missing serial numbers or a blue dot not definitively identified, then the follow-on inspections are required to ensure that no discrepant or affected part is missed. Paragraph (k) of this AD prohibits installation of assemblies with affected serial numbers unless the actions of paragraph (i) of this AD are accomplished. The FAA has not changed this AD in this regard.

Request To Remove Inspection Report Requirement

DAL requested that the compliance times for the inspection report be removed from paragraph (j)(1) of the proposed NPRM, and if not, the inspection report itself be removed. AAL requested removing the proposed requirement to submit an inspection report after accomplishing the requirements (*i.e.,* gap inspection) of paragraph (i) of the proposed AD. FedEx stated reporting should not be required for units that pass the inspection, and that sending units that failed the inspection to the vendor should be sufficient for reporting those failures. FedEx noted that any reporting requirements should consider the difficulties in reporting findings in a short period of time and noted that the inspector might not have access to the internet, email, and a device capable of printing and scanning. FedEx opined that its proposal would maintain accurate reporting and accommodate the realities of a global workplace. AAL and DAL stated that the reporting seems unnecessary and does not contribute to any additional level of safety. AAL

added that the NPRM would give operators the responsibility of ensuring that any affected part is returned to the manufacturer, and asserted that an equivalent level of safety would be maintained even if the reporting is not accomplished. DAL reasoned that if a cylinder valve assembly is unacceptable, it would be in the operator's best interest to report that finding to AVOX anyways so that it can receive a replacement assembly.

The FAA disagrees. In this case, the inspection results need to be reported to assist in tracking affected parts that are in circulation. In addition, reporting all findings gives assurance that an inspection was performed on an assembly with a given serial number. The FAA has not changed this AD in this regard.

Request To Remove Compliance Time for Returning Parts

AAL, DAL, and UAL requested revising paragraph (j)(2) of the proposed AD to remove a compliance time for returning discrepant parts to the manufacturer. AAL stated that a compliance time would not contribute to the level of safety. AAL also stated that all discrepant assemblies would be returned in a timely manner that is sufficient to the operator. DAL stated that it would be an unnecessary burden on operators to wait for AVOX's response before sending an unacceptable or discrepant part back within the compliance time in exchange for a free-of-charge replacement. DAL also stated that it would also be in the operator's best interest to send in the assembly so that it can qualify for a free-of-charge replacement if AVOX determines the part is unacceptable or discrepant. UAL stated it also believes the instruction to contact AVOX for shipping instructions could impede compliance with the 30-day limit to ship discrepant parts back to AVOX. UAL also stated that it wants to know how, for accurate AD-compliance reporting, it would be determined that a part is being shipped back as a result of this finding from AD-required inspections, or as a result of other, normal repair order processes.

The FAA agrees to clarify. Paragraph (j)(2) of this AD requires returning the assembly to the manufacturer in accordance with paragraph 3.D.(2) or 3.D.(3), as applicable, of the applicable service information. However, the service information does not include instructions to wait for a response from AVOX before returning the part. In addition, the FAA has revised paragraph (j)(2) of this AD to clarify that contacting AVOX for shipping instructions in not required. AVOX is tracking parts that are returned to it during accomplishment of the AD for data collection or analysis of manufacturing issues, and AVOX is also re-conditioning parts where possible. The FAA determined that having a 30-day compliance time for returning the part after an inspection finding is appropriate for this AD. However, under the provisions of paragraph (m) of this AD, an operator may request an approval of an alternative method of compliance (AMOC). The FAA has not changed this AD in this regard.

Request To Allow Later Revisions of Service Information

AAL requested that all the references to the AVOX service information be revised to allow use of subsequent revisions. AAL reasoned that this revision would reduce the number of AMOC requests each time a referenced service bulletin is revised.

The FAA disagrees. In an AD, the FAA may not refer to any document that does not yet exist. In general terms, the FAA is required by the Office of the Federal Register (OFR) regulations for approval of materials incorporated by reference, as specified in 1 CFR 51.1(f), to either publish the service document contents as part of the actual AD language; or submit the service document to the OFR for approval as referenced material, in which case the FAA may only refer to such material in the text of an AD. The AD may refer to the service document only if the OFR approved it for incorporation by reference. See 1 CFR part 51. The FAA disagrees with revising the AD to include specific airplane models based on the corresponding service information because the agency does not have a comprehensive list of the applicable aircraft to which specific AVOX service information could apply. The FAA has not changed this AD in this regard.

Request To Clarify AD Applicability With Reference to Service Information

A commenter requested clarifying paragraph (c) of the proposed AD by including reference to the service information that was identified in paragraph (h) of the proposed AD. The commenter suggested revising the paragraph so that the applicability would include information on the service information definition of the affected units. AAL also requested adding the airplane configuration information in the text of the AD to add further clarification to operators and release the technical data in a more organized fashion.

The FAA disagrees. The definition of the affected units does not need to be moved to paragraph (c) of the AD. The effectivity of the service information is limited to specific airplane models, but the applicability of this AD applies to all aircraft. Because the affected parts could be installed on additional aircraft models, the FAA has determined that the affected parts could later be installed on aircraft that were initially delivered with acceptable parts, thereby subjecting those aircraft to the unsafe condition. The FAA has not changed this AD in this regard.

Request To Revise Compliance Time for Parts Identification

DAL and UAL requested revising the compliance time proposed in paragraph (h) of the proposed NPRM. DAL and UAL stated that since many operators have parked their aircraft or severely reduced usage of aircraft, an extension of the compliance time (either with additional calendar days or adding an option for flight hours and flight cycles), would allow operators additional time for compliance. UAL also stated that the supply chain could be affected due to potential increased shipping time and workforce reductions.

The FAA disagrees with the request to extend the compliance time. The FAA acknowledges the effects that the pandemic response might have on operators' fleet use, supply chain, and maintenance personnel. In developing an appropriate compliance time for this action, the FAA considered the degree of urgency associated with addressing the subject unsafe condition, the manufacturer's recommendation for an appropriate compliance time, and the practical aspect of accomplishing the required inspection within a period of time that corresponds to the normal scheduled maintenance for most affected operators. In addition, the FAA notes that some aircraft may have been in service during the pandemic and must comply within the required compliance time. Operators do have the option to inspect the airplane before the first flight following storage if the airplane is in storage for more than 27 months. However, under the provisions of paragraph (m) of this AD, the FAA will consider requests for an extension of the compliance time if sufficient data are submitted to substantiate that the new compliance time would provide an acceptable level of safety. The FAA has not changed this AD in this regard.

Request To Allow Use of Alternatives for Parts Marking

FedEx requested that the specification to use oil-based blue ink markers be

modified to allow alternative methods and colors such as black indelible ink. FedEx stated that oil-based blue paint markers are not readily available or kept in stock regularly. FedEx suggested that a list of part numbers for approved, aircraft grade, oil-based paint be provided.

The FAA disagrees. While the FAA realizes this is a limitation, there must be one standard to help avoid confusion. The procedures required by this AD specify actions based on the presence or absence of a blue dot in a specific location. The FAA has not seen any difficulties in obtaining the paint markers. However, under the provisions of paragraph (m) of this AD, any person may request an approval of an AMOC. The FAA has not revised this AD in this regard.

Request To Allow Alternative Means of Measuring Gaps

FedEx requested that the proposed AD be revised to allow use of feeler gauges, calipers, and other means of measuring the gap in imperial units of measure. FedEx stated that the service information specifies use of pin gauges that are made for metric units of measure, and that acquiring those metric pin gauges is an extra expense and logistical complication. FedEx recommended adding a tolerance to the gap measurement and specifying a fractional imperial measure (3⁄32-inch) that is close to the metric unit specified. FedEx suggested that if a tolerance or other measurement is not added, then a manufacturer part number (MPN) for a specific tool or supplier should be provided.

The FAA disagrees. Using other means of measuring could introduce or increase variables that could affect the accuracy of the measurement. The FAA understands that not everyone has the same resources, tools, or supplies; however, the FAA also understands that this means of measurement is easily accessible. Under the provisions of paragraph (m) of this AD, operators may request approval of an AMOC if sufficient data are submitted to substantiate that the tolerance would provide an acceptable level of safety. The FAA has not changed this AD in this regard.

Request To Revise Procedure for Shipping an Assembly

FedEx requested that the proposed AD be revised to allow operators to use their own procedures for shipping dangerous goods such as unopened cylinder valve assemblies (CVAs) instead of the procedure specified in the service information. FedEx explained that it has established and accepted procedures for shipping dangerous goods, and that the disposition of an unopened CVA would be done by a department separate from the one doing the inspection. FedEx stated that following the procedures in the service information would require additional coordination time, and that the wording of the procedures would not function properly with its AD compliance mechanisms.

The FAA agrees to clarify. The design approval holder (DAH) of the affected valve assemblies has specified a method for shipping, or returning, an unopened CVA that has been found to be unacceptable or discrepant, specifically a shipping method that is compliant with DOT standard HM–224B. If FedEx has procedures that are compliant with DOT standard HM–224B, then those procedures are acceptable for compliance with this AD. For procedures that are not compliant with DOT standard HM–224B, under the provisions of paragraph (m) of this AD, the FAA will consider requests for an AMOC. The FAA has not changed this AD in this regard.

Request for Clarification on Applicability of AD

FedEx requested clarification on whether the proposed AD is written ''against'' the MPN or the serial numbers within that MPN. FedEx explained the effects on the operator's workload and also on the operational impact of a unit's overhaul cycle in conjunction with a 60-day compliance time and the scope of the applicability. FedEx added that a 180-day compliance time would be more reasonable.

The FAA agrees to clarify. The applicability of this AD is written against the MPN and specific serial numbers, in addition to manufacture dates of the assemblies. The FAA disagrees to revise the compliance time because the FAA has determined that requirement based on a risk calculation. The FAA has not changed this AD in that regard.

Request To Clarify Requirement if Component Number(s) Cannot Be Determined

UAL requested clarification on what actions are required in the event the P/N or serial number information cannot be determined. UAL stated that as a result of in-service activity, that information might be illegible, unintentionally obliterated, or missing from the placard. UAL added that under its normal practices, whenever a part or serial number cannot be determined, the part is considered suspect, made unserviceable, and removed from service. UAL stated that, when the P/N of the entire cylinder and valve assembly can be determined but not the serial number, and the date of manufacture is between January and November 2018, it wants to still be able to establish conformity by inspecting for the presence of the blue dot and accomplish the applicable service information instruction if the blue dot is missing. UAL also stated that depending on the FAA's response to this request, it may apply for an AMOC.

The FAA agrees to clarify. The service information states to inspect for the manufacturing date, serial number, and the presence of a blue dot. The service information then states that if there is doubt or a determination cannot be made (such as the numbers or dot is not clearly identified), to proceed with the follow-on inspection for proper gap spacing (this follow-on inspection is required by paragraph (i) of this AD). The FAA has not changed this AD in this regard.

Request for Clarification on Compliance Time and Method for Inspection Report

UAL requested clarification on how a 30-day requirement for the inspection report was determined, and if a ''comprehensive'' report is acceptable. UAL stated that it understands the need for the information gathered from the reports; however, it does not understand why or how a 30-day compliance time was established. UAL also stated that it assumed that reporting of the results should be done as a single, comprehensive report and not piece-wise (individually for each assembly or aircraft), and that the report does not need to be an exact copy of the report form in the service information.

The FAA agrees to clarify. The FAA determined that the 30-day compliance time is appropriate for this AD. Also, the manufacturer is collecting information for analysis of manufacturing issues. The format of the report may be done as UAL assumed, as long as all documents are labeled correctly. However, under the provisions of paragraph (m) of this AD, an operator may request an approval of an AMOC. The FAA has not changed this AD in this regard.

Request To Provide Clarification on Reporting Form

UAL requested clarification on the definition of ''manufacture date'' in a recording column of a report form in the service information. UAL stated that it is implied that ''manufacture date'' in that column is the manufacture date of

the entire cylinder and valve assembly and not of the valve assembly.

The FAA agrees to clarify. The ''manufacturer date'' is not limited to the date of the entire cylinder and valve assembly, but is the manufacture date of each part or assembly that might be recorded in the inspection report, such as the assemblies listed in Appendix 1 of the service information. The FAA has not changed this AD in this regard.

Conclusion

The FAA reviewed the relevant data, considered any comments 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.

Related Service Information Under 1 CFR Part 51

The FAA reviewed AVOX Systems Inc. Alert Service Bulletins 10015804–35–01, Revision 02, dated October 16, 2019; 10015804–35–02, Revision 2, dated October 31, 2019; and 10015804–35–03, Revision 02, dated October 15, 2019. This service information describes procedures for an inspection to determine the serial numbers of the oxygen cylinder and valve assemblies, and the oxygen valve assemblies, a detailed inspection for correct spacing of the gap between the bottom of the packing retainer and top of the valve body on the assemblies, parts marking, inspection report, and return of parts to the manufacturer. These documents are distinct since they apply to different assembly part numbers. 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 **ADDRESSES**.

Costs of Compliance

The FAA estimates that this AD affects up to 3,034 oxygen cylinder and valve assemblies, and oxygen valve assemblies, installed on various transport category 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 product	Cost on U.S. operators
Serial number inspection	1 work-hour × $85 per hour = $85	None	$85	$257,890
Reporting	1 work-hour × $85 per hour = $85	0	85	257,890

The FAA estimates the following costs to do any necessary follow-on actions that would be required based on the results of the inspection. The FAA has no way of determining the number of aircraft that might need these actions:

ON-CONDITION COSTS *

Action	Labor cost	Parts cost	Cost per product
Detailed inspection	1 work-hour × $85 per hour = $85	None	$85

* The FAA has received no definitive data on the cost of on-condition replacements.

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

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to take approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

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:

2022–04–09 AVOX Systems Inc. (formerly Scott Aviation): Amendment 39–21951; Docket No. FAA–2020–0345; Product Identifier 2019–NM–154–AD.

(a) Effective Date

This airworthiness directive (AD) is effective April 4, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to AVOX Systems Inc. (formerly Scott Aviation) oxygen cylinder and valve assemblies having part number (P/N) 89794077, 89794015, 891511–14, 806835–01, 807982–01, or 808433–01; and oxygen valve assemblies (body and gage assemblies) having P/N 807206–01. These assemblies might be installed on, but not limited to, the aircraft identified in paragraphs (c)(1) through (12) of this AD, certificated in any category.

(1) Airbus SAS Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.

(2) Airbus SAS Model A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, F4–605R, F4–622R, and C4–605R Variant F airplanes.

(3) Airbus SAS Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes.

(4) Airbus SAS Model A318–111, –112, –121, and –122 airplanes.

(5) Airbus SAS Model A319–111, –112, –113, –114, –115, –131, –132, –133, and –151N airplanes.

(6) Airbus SAS Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes.

(7) Airbus SAS Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –252N, –253N, –271N, –272N, –251NX, –252NX, –253NX, –271NX, and –272NX airplanes.

(8) Airbus SAS Model A330–201, –202, –203, –223, –243, –301, –302, –303, –321, –322, –323, –341, –342, –343, and –941 airplanes.

(9) Airbus Model A340–211, –212, –213, –311, –312, –313, –541, and –642 airplanes.

(10) ATR—GIE Avions de Transport Régional Model ATR42–200, –300, –320, and –500 airplanes.

(11) ATR—GIE Avions de Transport Régional Model ATR72–101, –102, –201, –202, –211, –212, and –212A airplanes.

(12) The Boeing Company Model 747–8 series airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen System.

(e) Unsafe Condition

This AD was prompted by reports of cylinder and valve assemblies having oxygen leakage from the valve assembly vent hole, caused by the absence of a guide that maintains appropriate spacing between certain parts. The FAA is issuing this AD to address oxygen leakage from the cylinder, which could result in decreased or insufficient oxygen supply during a depressurization event; and heating or flow friction, which could cause an ignition event in the valve assembly.

(f) Compliance

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

(g) Definition of Detailed Inspection

For the purposes of this AD, a detailed inspection is an intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.

(h) Identification of Affected Cylinder and Valve Assemblies

Within 60 days after the effective date of this AD, inspect the oxygen valve assemblies, and oxygen cylinder and valve assemblies, to determine if the serial numbers of the valve, cylinder, and entire assembly, are listed in Appendix 1, ''Affected Shipments,'' of the applicable service information identified in paragraphs (h)(1) through (3) of this AD. A review of airplane maintenance records is acceptable in lieu of this inspection if the serial numbers can be conclusively determined from that review.

(1) AVOX Systems Inc. Alert Service Bulletin 10015804–35–01, Revision 02, dated October 16, 2019.

(2) AVOX Systems Inc. Alert Service Bulletin 10015804–35–02, Revision 2, dated October 31, 2019.

(3) AVOX Systems Inc. Alert Service Bulletin 10015804–35–03, Revision 02, dated October 15, 2019.

(i) Inspection of the Gap, Parts Marking Actions, and Replacement

If, during any inspection or records review required by paragraph (h) of this AD, any oxygen valve assembly, valve or cylinder of an oxygen cylinder and valve assembly, or oxygen cylinder and valve assembly having an affected serial number is found: Before further flight, do a detailed inspection for correct spacing of the gap between the bottom of the packing retainer and top of the valve body, in accordance with paragraph 3.C. of the Accomplishment Instructions of the applicable service information identified in paragraphs (h)(1) through (3) of this AD.

(1) If the gap is found to be acceptable, as defined in the applicable service information identified in paragraphs (h)(1) through (3) of this AD, before further flight, do the parts marking actions in accordance with paragraph 3.D.(1) of the Accomplishment Instructions of the applicable service information identified in paragraphs (h)(1) through (3) of this AD.

(2) If the gap is found to be unacceptable, as defined in the applicable service information identified in paragraphs (h)(1) through (3) of this AD, before further flight, remove the affected assembly, in accordance with paragraphs 3.D.(2) or 3.D.(3), as applicable, of the Accomplishment Instructions of the applicable service information identified in paragraphs (h)(1) through (3) of this AD; and replace with a serviceable assembly.

(j) Reporting and Return of Parts

(1) Report the results of the inspection required by paragraph (i) of this AD within the applicable time specified in paragraph (j)(1)(i) or (ii) of this AD. Report the results in accordance with paragraph 3.D.(1)(a) of the Accomplishment Instructions of the applicable service information identified in paragraphs (h)(1) through (3) of this AD.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(2) If, during the inspection required by paragraph (i) of this AD, any gap is found to be unacceptable, within the applicable time specified in paragraph (j)(2)(i) or (ii) of this AD, return the assembly to the manufacturer in accordance with paragraph 3.D.(2) or 3.D.(3), as applicable, of the Accomplishment Instructions of the applicable service information identified in paragraphs (h)(1) through (3) of this AD, except you are not required to contact AVOX for shipping instructions.

(i) If the inspection was done on or after the effective date of this AD: Return the assembly within 30 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Return the assembly within 30 days after the effective date of this AD.

(k) Parts Installation Limitation

As of the effective date of this AD, no AVOX Systems Inc. oxygen valve assembly, or valve or cylinder that is part of an oxygen cylinder and valve assembly, or oxygen cylinder and valve assembly having an affected serial number identified in Appendix 1, ''Affected Shipments,'' of any AVOX Systems Inc. service information

identified in paragraphs (h)(1) through (3) of this AD may be installed on any airplane unless the requirements of paragraph (i) of this AD have been accomplished on that affected assembly.

(l) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraphs (h) or (i) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraphs (l)(1) through (5) of this AD.

(1) AVOX Systems Inc. Service Bulletin 10015804–35–01, dated March 6, 2019.

(2) AVOX Systems Inc. Alert Service Bulletin 10015804–35–01, Revision 01, dated July 9, 2019.

(3) AVOX Systems Inc. Alert Service Bulletin 10015804–35–02, Revision 1, dated September 4, 2019.

(4) AVOX Systems Inc. Service Bulletin 10015804–35–03, dated April 11, 2019.

(5) AVOX Systems Inc. Alert Service Bulletin 10015804–35–03, Revision 01, dated May 21, 2019.

(m) Alternative Methods of Compliance (AMOCs)

(1) 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; fax 516–794–5531.

(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.

(n) Related Information

(1) For more information about this AD, contact Elizabeth Dowling, Aerospace Engineer, Mechanical Systems and Administrative Services 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*.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (o)(3) and (4) of this AD.

(o) Material Incorporated by Reference

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

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

(i) AVOX Systems Inc. Alert Service Bulletin 10015804–35–01, Revision 02, dated October 16, 2019.

(ii) AVOX Systems Inc. Alert Service Bulletin 10015804–35–02, Revision 2, dated October 31, 2019.

(iii) AVOX Systems Inc. Alert Service Bulletin 10015804–35–03, Revision 02, dated October 15, 2019.

(3) For service information identified in this AD, contact AVOX Systems Inc., 225 Erie Street, Lancaster, NY 14086; telephone 716–683–5100; internet *https://www.safranaerosystems.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, *fr.inspection@nara.gov*, or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued on February 11, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–04146 Filed 2–25–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 500, 510, 516, 520, 522, 524, 529, 556, and 558

[Docket No. FDA–2021–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of a New Animal Drug Application; Change of Sponsor

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), abbreviated new animal drug applications (ANADAs), and a conditionally approved new animal drug application (cNADA) during July, August, and September 2021. 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 February 28, 2022. The incorporation by reference of certain material listed in this rule is approved by the Director of the Federal Register as February 28, 2022. The incorporation by reference of other material listed in this rule was approved by the Director of the Federal Register as of November 25, 2011.

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 July, August, and September 2021, 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 JULY, AUGUST, AND SEPTEMBER 2021

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
July 7, 2021	200–703	Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211.	Carprofen Tablets	Dogs	Original approval as a generic copy of NADA 141–053.	FOI Summary.
July 15, 2021	141–545	VetDC, Inc., 320 E Vine Dr., Suite 218, Fort Collins, CO 80524.	TANOVEA (rabacfosadine for injection) Powder for Injection.	Dogs	Full approval of conditionally approved cNADA 141–475 for the treatment of lymphoma.	FOI Summary.
August 2, 2021	200–708	Felix Pharmaceuticals PVT Ltd., 25–288 North Wall Quay, Dublin, 1, Ireland.	Enrofloxacin Antibacterial Injectable Solution 2.27%.	Dogs	Original approval as a generic copy of NADA 140–913.	FOI Summary.
August 16, 2021	200–618	Virbac AH, Inc., PO Box 162059, Fort Worth, TX 76161.	ZOLETIL (tiletamine and zolazepam for Injection).	Dogs and cats	Original approval as a generic copy of NADA 106–111.	FOI Summary.
August 18, 2021	200–709	Cronus Pharma Specialties India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India.	Amoxicillin and Clavulanate Potassium for Oral Suspension.	Dogs and cats	Original approval as a generic copy of NADA 055–101.	FOI Summary.
August 19, 2021	141–063	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	NUFLOR–S (florfenicol) Injectable Solution.	Swine	Supplemental approval for the treatment of swine respiratory disease.	FOI Summary.

II. Withdrawal of Approval

Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 093–329 for use of a sustained-release bolus containing sulfamethazine in cattle because the product is no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect this action. Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADA 093–329, and all supplements and amendments thereto, is withdrawn.

III. Change of Sponsor

VetDC, Inc., 320 E Vine Dr., Suite 218, Fort Collins, CO 80524, has informed FDA that it has transferred ownership of, and all rights and interest in, newly approved NADA 141–545 for TANOVEA (rabacfosadine) for Injection to Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140. The codification of this application in new 21 CFR 522.2065 will reflect this change of sponsorship.

IV. Technical Amendments

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

- 21 CFR 500.1410 is amended to add uncooked edible tissues of swine to the standard for residues of *n*-methyl-2-pyrrolidone.
- 21 CFR 510.600 is amended to have sponsor addresses conform to the current style.
- 21 CFR 520.905c is amended to reflect the current label indications for use of fenbendazole paste in horses.
- 21 CFR 520.1044c is amended to reflect a current swine pathogen name for gentamicin soluble powder.
- 21 CFR 520.1660d is amended to revise conditions of use of oxytetracycline in drinking water of swine to reflect approved applications.
- 21 CFR 520.1780 is amended to revise the indications for use of pimobendan tablets in dogs.
- 21 CFR 520.2130 is amended to remove the 90-milligram strength for spinosad chewable tablets.
- 21 CFR 520.2220a is amended to add human food safety warnings for use of sulfadimethoxine concentrate solution and soluble powder.
- 21 CFR 520.2260b is amended to reflect the voluntary withdrawal of approval of an application for sustained-release boluses containing sulfamethazine and to correct the spelling of a disease condition.
- 21 CFR 520.2604 is amended to revise indications for use of tablets in dogs containing trimeprazine with prednisolone.
- 21 CFR 522.558 is amended to reflect the drug labeler code for the current sponsor of a dexmedetomidine injectable solution.
- 21 CFR 522.840 is amended to reflect the current classes of cattle approved for use of estradiol ear implants.
- 21 CFR 522.842 for testosterone propionate and estradiol benzoate implants is renamed to list the drug with the higher concentration first and redesignated to be listed in alphabetical order.
- 21 CFR 522.955 is amended to reflect the current scientific name of a bovine pathogen and the withdrawal

periods for different formulations of florfenicol injectable solution.

- 21 CFR 522.1156 is amended to add subcutaneous administration to the approved conditions of use of imidocarb dipropionate solution in dogs.
- 21 CFR 522.2477 is amended to reorganize an approved use of trenbolone acetate and estradiol implants in steers.
- 21 CFR 524.770 is amended to reflect current label dosage information and human food safety warnings.
- 21 CFR 529.1030 is redesignated as § 529.1004 in conformity with an announced FDA numbering system (40 FR 13802, March 27, 1975).
- 21 CFR 529.1940 is amended to add limitations to the use of progesterone intravaginal inserts in cows.
- 21 CFR 558.59 is amended to reference apramycin's status as a veterinary feed directive (VFD) drug and to add current limitations on VFD refills for apramycin medicated feeds.
- 21 CFR 558.205 is amended to reflect a current egg food safety warning for broiler chickens and growing turkeys fed Type C medicated feeds containing diclazuril.
- 21 CFR 558.254 is amended to remove an erroneous table title.
- 21 CFR 558.261 is amended to correct the upper inclusion rate for florfenicol in Type C medicated feed for freshwater-reared salmonids.
- 21 CFR 558.311 is being amended to codify free-choice Type C medicated cattle feeds containing lasalocid.
- 21 CFR 558.450 is amended to add conditions of use in honey bees for a Type C extender patty containing oxytetracycline.
- 21 CFR 558.633 is amended to add manufacturing limitations for use of Type C medicated swine feeds containing tylvalosin.
- 21 CFR 558.635 is amended to reflect a current egg food safety warning for broiler chickens fed Type C medicated feeds containing virginiamycin and diclazuril.

V. Incorporation by Reference

FDA is incorporating by reference an analytical method approved by the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To obtain a copy of the analytical method, go to: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room.* You may inspect a copy at the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, between 9 a.m. and 4 p.m., Monday through Friday.

This standard adds a method of detection for total for residues of the carcinogenic excipient *n*-methyl-2-pyrrolidone in uncooked edible swine tissues to a section established for a method for residues of *n*-methyl-2-pyrrolidone in uncooked edible cattle tissues.

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 500

Animal drugs, Animal feeds, Cancer, Incorporation by reference, Labeling, Packaging and containers, Polychlorinated biphenyls (PCBs).

21 CFR Part 510

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

21 CFR Part 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 556

Animal drugs, Food.

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 500, 510, 516, 520, 522, 524, 529, 556, and 558 are amended as follows:

PART 500—GENERAL

■ 1. The authority citation for part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

■ 2. Revise § 500.1410 to read as follows:

§ 500.1410 N-methyl-2-pyrrolidone.

(a) *Standard for residues.* No residues of *n*-methyl-2-pyrrolidone may be found in the uncooked edible tissues of cattle and swine as determined by methods in paragraph (b) of this section.

(b) *Incorporation by reference.* The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration's Dockets Management Staff (HFA–305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, between 9 a.m. and 4 p.m., Monday through Friday. It may be obtained from the sources indicated elsewhere in paragraph (b) of this section and at: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room.* It is also available for inspection 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.*

(1) Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855, 240–402–7002.

(i) ''Method of Analysis: *N*-methyl-2-pyrrolidone,'' September 26, 2011; the method of analysis for uncooked edible tissues of cattle.

(ii) [Reserved]

(2) Merck Animal Health, 29160 Intervet Lane, Millsboro, DE 19966, 1–800–211–3573.

(i) ''Determinative and Confirmatory Procedures for the Analysis of N-Methyl-2-pyrrolidone (NMP) in Swine Liver Tissue using LC–MS/MS,'' July 20, 2017; the method of analysis for uncooked edible tissues of swine.

(ii) [Reserved]

(c) *Related conditions of use.* See §§ 522.814 and 522.955 of this chapter.

PART 510—NEW ANIMAL DRUGS

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

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

§ 510.600 [Amended]

■ 4. In § 510.600:

■ a. In the table in paragraph (c)(1), revise the entries for ''Anzac Animal Health, LLC'', ''AquaBounty Technologies, Inc.'', ''Dechra Veterinary Products LLC'', ''Halocarbon Products Corp.'', ''Kindred Biosciences, Inc.'', ''Mizner Bioscience LLC'', ''QBiotics Group Ltd.'', ''Revivicor, Inc.'', and ''Ridley USA, Inc.'', remove ''Suite'' and in its place add ''suite''; and

■ b. In the table in paragraph (c)(2), revise the entries for ''012164'', ''017033'', ''067949'', ''086039'', ''086053'', ''086073'', ''086078'', ''086132'', and ''086134''.

The revisions read as follows:

(c) * * *

(1) ALPHABETICAL LISTING OF SPONSORS

Firm name and address	Drug labeler code
* * * * * * *	
Anivive Lifesciences, Inc., 3250 Airflite Way, Suite 400, Long Beach, CA 90807	086121
Anzac Animal Health, LLC, 218 Millwell Dr., suite B, Maryland Heights, MO 63043	086073
AquaBounty Technologies, Inc., 2 Mill and Main Pl., Suite 395, Maynard, MA 01754	086053
* * * * * * *	
Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211	017033
* * * * * * *	
Halocarbon Products Corp., 6525 The Corners Pkwy., Suite 200, Peachtree Corners, GA 30092	012164
* * * * * * *	
Kindred Biosciences, Inc., 1555 Bayshore Hwy., Suite 200, Burlingame, CA 94010	086078
* * * * * * *	
Mizner Bioscience LLC, 225 NE Mizner Blvd., Suite 760, Boca Raton, FL 33432	086039
* * * * * * *	
QBiotics Group Ltd., Suite 3A, Level 1, 165 Moggill Rd., Taringa, Queensland 4068, Australia	086132
* * * * * * *	
Revivicor, Inc., a wholly owned subsidiary of United Therapeutics Corp., 1700 Kraft Dr., Suite 2400, Blacksburg, VA 24060	086134
Ridley USA, Inc., 111 W Cherry St., Suite 500, Mankato, MN 56001	067949
* * * * * * *	

(2) NUMERICAL LISTING OF SPONSORS

Drug labeler code	Firm name and address
* * * * * * *	
012164	Halocarbon Products Corp., 6525 The Corners Pkwy., Suite 200, Peachtree Corners, GA 30092.
* * * * * * *	
017033	Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211.
* * * * * * *	
067949	Ridley USA, Inc., 111 W Cherry St., Suite 500, Mankato, MN 56001.
* * * * * * *	
086039	Mizner Bioscience LLC, 225 NE Mizner Blvd., Suite 760, Boca Raton, FL 33432.
* * * * * * *	
086053	AquaBounty Technologies, Inc., 2 Mill and Main Pl., Suite 395, Maynard, MA 01754.
* * * * * * *	
086073	Anzac Animal Health, LLC, 218 Millwell Dr., Suite B, Maryland Heights, MO 63043.
086078	Kindred Biosciences, Inc., 1555 Bayshore Hwy., Suite 200, Burlingame, CA 94010.
* * * * * * *	
086121	Anivive Lifesciences, Inc., 3250 Airflite Way, Suite 400, Long Beach, CA 90807.
086132	QBiotics Group Ltd., Suite 3A, Level 1, 165 Moggill Rd., Taringa, Queensland 4068, Australia.
086134	Revivicor, Inc., a wholly owned subsidiary of United Therapeutics Corp., 1700 Kraft Dr., Suite 2400, Blacksburg, VA 24060
* * * * * * *	

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, 360ccc–2, 371.

§ 516.2065 [Removed]

■ 6. Remove § 516.2065.

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. Revise § 520.88h to read as follows:

§ 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.

(a) *Specifications.* When constituted, each milliliter (mL) of suspension contains amoxicillin trihydrate equivalent to 50 milligrams (mg) amoxicillin and clavulanate potassium equivalent to 12.5 mg clavulanic acid.

(b) *Sponsors.* See Nos. 054771 and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.25 mg/lb (1 mL/10 lb of body weight) twice a day. Skin and soft tissue infections such as abscesses, cellulitis, wounds, superficial/juvenile pyoderma, and periodontal infections should be treated for 5 to 7 days or for 48 hours after all signs have subsided. If no response is seen after 5 days of treatment, therapy should be discontinued and the case reevaluated. Deep pyoderma may require treatment for 21 days; the maximum duration of treatment should not exceed 30 days.

(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 *Escherichia coli.* Treatment of periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria.

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

(2) *Cats*—(i) *Amount.* 62.5 mg (1 mL) twice daily. Skin and soft tissue infections such as abscesses and cellulitis/dermatitis should be treated for 5 to 7 days or 48 hours after all symptoms have subsided, not to exceed 30 days. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days.

(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., *Escherichia coli, Pasteurella multocida,* and *Pasteurella* spp. Urinary tract infections (cystitis) due to susceptible strains of *E. coli.*

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

■ 9. In § 520.905c, revise paragraphs (e)(1)(i) to read as follows:

§ 520.905c Fenbendazole paste.

* * * * *

(e) * * *

(1) * * *

(i) *Indications for use and amounts.* (A) For the treatment and control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris*), small strongyles, and pinworms (*Oxyuris equi*). For large strongyles, small strongyles, and pinworms, the recommended dose is 5 mg/kg (2.3 mg/lb).

(B) For treatment and control of ascarids (*Parascaris equorum*). For ascarids, the recommended dose is 10 mg/kg (4.6 mg/lb).

(C) For treatment and control of hypobiotic (encysted early third-stage), late third-stage, and fourth-stage cyathostome larvae, as well as fourth-stage *Strongylus vulgaris* larvae, the recommended dose is 10 mg/kg (4.6 mg/lb) daily for 5 consecutive days.

(D) For the control of arteritis caused by fourth-stage larvae of *Strongylus vulgaris* in horses.

(E) Fenbendazole paste 10 percent may be used concomitantly with approved forms of trichlorfon for the indications provided in paragraph (e)(1)(i)(A) of this section and for treating infections of stomach bots as provided in § 520.2520.

* * * * *

■ 10. In § 520.1044c, revise paragraph (d)(2) to read as follows:

§ 520.1044c Gentamicin sulfate powder.

* * * * *

(d) * * *

(2) *Indications for use.* For control and treatment of colibacillosis in weanling swine caused by strains of *Escherichia coli* sensitive to gentamicin, and for control and treatment of swine dysentery associated with *Brachyspira hyodysenteriae.*

* * * * *

■ 11. In § 520.1660d, revise paragraphs (d)(1)(iii)(A) and (C) to read as follows:

§ 520.1660d Oxytetracycline powder.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(A) *Amount.* Administer 10 milligrams per pound of body weight daily in drinking water. Administer up to 14 days; do not use for more than 14 consecutive days those products sponsored by Nos. 054771, 061133, and 069254. Administer up to 5 days; do not use for more than 5 consecutive days those products sponsored by Nos. 016592 and 061133.

* * * * *

(C) *Limitations.* Withdraw zero days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

■ 12. In § 520.1780, revise paragraph (c)(2) to read as follows:

§ 520.1780 Pimobendan.

* * * * *

(c) * * *

(2) *Indications for use.* For the management of the signs of mild, moderate, or severe congestive heart failure in dogs due to clinical myxomatous mitral valve disease (MMVD) or dilated cardiomyopathy (DCM); for use with concurrent therapy for congestive heart failure (*e.g.,* furosemide, etc.) as appropriate on a case-by-case basis.

* * * * *

■ 13. In § 520.2130, revise paragraph (a) to read as follows:

§ 520.2130 Spinosad.

(a) *Specifications.* Each chewable tablet contains 140, 270, 560, 810, or 1620 milligrams (mg) spinosad.

* * * * *

■ 14. In § 520.2220a, revise paragraphs (d)(1)(iii) and (d)(2)(iii) to read as follows:

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Withdraw 5 days before slaughter. Do not administer to chickens over 16 weeks (112 days) of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(iii) *Limitations.* Withdraw 5 days before slaughter. Do not administer to turkeys over 24 weeks (168 days) of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

§ 520.2260b [Amended]

■ 15. In § 520.2260b, remove and reserve paragraphs (b) and (e); and in paragraph (f)(2)(ii) remove ''diptheria'' and in its place add ''diphtheria''.

■ 16. In § 520.2604, revise paragraph (c)(2) to read as follows:

§ 520.2604 Trimeprazine with prednisolone tablets.

* * * * *

(c) * * *

(2) *Indications for use.* For the relief of itching regardless of cause; and for reduction of inflammation commonly associated with most skin disorders of dogs such as eczema, caused by internal disorders, otitis, and dermatitis, allergic, parasitic, pustular, and nonspecific origins. As adjunctive therapy in various cough conditions including treatment of ''kennel cough'' or tracheobronchitis, bronchitis including allergic bronchitis, infections, and coughs of nonspecific origin.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.558 [Amended]

■ 18. In § 522.558, in paragraph (b)(1), remove ''026637'' and in its place add ''017033''.

■ 19. In § 522.812, revise paragraph (b)(1) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(1) Nos. 016729, 017033, 055529, 058198, and 086101 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section; and

* * * * *

§ 522.840 [Amended]

■ 20. In § 522.840, in paragraph (d)(2), in the first sentence, remove ''confined steers and heifers'' and in its place add ''steers and heifers fed in confinement for slaughter''.

§ 522.842 [Redesignated as § 522.2343]

■ 21. Redesignate § 522.842 as § 522.2343.

■ 22. In § 522.955:

■ a. Revise paragraph (b)(2);

■ b. Redesignate paragraph (b)(3) as paragraph (b)(4) and add new paragraph (b)(3);

■ c. In paragraphs (d)(1)(ii)(A)(*2*) and (d)(1)(ii)(B)(*2*), remove ''*Haemophilus somnus*'' and in its place add ''*Histophilus somni*'';

■ d. Revise paragraph (d)(1)(ii)(C); and

■ e. Add paragraph (d)(2).

The revisions and additions read as follows:

§ 522.955 Florfenicol.

* * * * *

(b) * * *

(2) No. 000061 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(1)(ii) and (d)(2) of this section.

(3) No. 086050 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii) of this section.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(C) *Limitations.* Animals intended for human consumption must not be slaughtered within 28 days of the last intramuscular treatment. No. 000061: Animals intended for human consumption must not be slaughtered within 38 days of subcutaneous treatment. No. 055529: Animals intended for human consumption must not be slaughtered within 33 days of subcutaneous treatment. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Swine—(i) 300 mg/mL florfenicol in the inactive vehicles n-methyl-2-pyrrolidone, propylene glycol, and polyethylene glycol:

(A) *Amount.* 15 mg/kg of body weight as an intramuscular injection. A second dose should be administered 48 hours later.

(B) *Indications for use.* For the treatment of swine respiratory disease associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Salmonella* Choleraesuis, *Streptococcus suis, Bordetella bronchiseptica,* and *Glaesserella (Haemophilus) parasuis* in swine except for nursing piglets and swine of reproductive age intended for breeding.

(C) *Limitations.* Swine intended for human consumption must not be slaughtered within 11 days of the last intramuscular treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) [Reserved]

■ 23. In § 522.1156, revise paragraph (c)(1) to read as follows:

§ 522.1156 Imidocarb solution.

* * * * *

(c) * * *

(1) *Amount.* Administer 6.6 mg per kilogram (3 mg per pound) of body weight by intramuscular or subcutaneous injection. Repeat the dose after 2 weeks for a total of two treatments.

* * * * *

■ 24. Add § 522.2065 to read as follows:

§ 522.2065 Rabacfosadine.

(a) *Specifications.* Each vial of powder contains 16.4 milligrams (mg) rabacfosadine. Each milliliter of constituted solution contains 8.2 mg rabacfosadine.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer rabacfosadine at 1 mg/kilogram body weight as a 30-minute intravenous infusion, once every 3 weeks, for up to 5 doses.

(2) *Indications for use.* For the treatment of lymphoma in dogs.

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

■ 25. Revise the section heading of newly designated § 522.2343 to read as follows:

§ 522.2343 Testosterone propionate and estradiol benzoate.

■ 26. In § 522.2470, revise paragraph (b) introductory text to read as follows:

§ 522.2470 Tiletamine and zolazepam for injection.

* * * * *

(b) *Sponsors.* See Nos. 026637, 051311, and 054771 in § 510.600(c) of this chapter.

* * * * *

■ 27. In § 522.2477, revise paragraph (b)(2), remove paragraph (d)(1)(i)(G), and add paragraph (d)(6) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(b) * * *

(2) No. 000061 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(i)(C), (d)(2)(i)(D), (d)(2)(ii), (d)(2)(iii), (d)(3)(i)(A), (d)(3)(ii), (d)(3)(iii), (d)(4), (d)(5), and (d)(6) of this section.

* * * * *

(d) * * *

(6) *Steers fed in confinement for slaughter*—(i) *Amount.* Each extended-release implant contains 200 mg trenbolone acetate and 40 mg estradiol (one implant consisting of 6 coated and 4 uncoated pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol).

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency for up to 200 days after implantation.

(iii) *Limitations.* Administer implant subcutaneously in the ear only. Do not use in lactating dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Effectiveness and animal safety in veal calves have not been established. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant during the production phase(s) identified on labeling (steers fed in confinement for slaughter) unless otherwise indicated on labeling because safety and effectiveness have not been evaluated.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 29. In § 524.770, revise paragraphs (e)(1) and (e)(3) to read as follows:

§ 524.770 Doramectin.

* * * * *

(e) * * *

(1) *Amount.* Administer topically 1 mL (5 mg doramectin) per 22 lb (10 kg) of body weight.

* * * * *

(3) *Limitations.* Cattle must not be slaughtered for human consumption within 45 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.1030 [Redesignated as § 529.1004]

■ 31. Redesignate § 529.1030 as § 529.1004.

■ 32. In § 529.1940, revise paragraph (e)(1)(iii) to read as follows:

§ 529.1940 Progesterone intravaginal inserts.

* * * * *

(e) * * *

(1) * * *

(iii) *Limitations.* Do not use in beef or dairy heifers of insufficient size or age for breeding or in animals with abnormal, immature, or infected genital tracts. Do not use in anestrous lactating dairy cows less than 42 days or greater than 78 days postpartum. Do not use in lactating dairy cows less than 40 days postpartum. Do not use in beef cows that are less than 20 days postpartum. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should be disposed after a single use. Administration of vaginal inserts for periods greater than 7 days may result in reduced fertility. Dinoprost injection for use in paragraphs (e)(1)(ii)(A) and (e)(1)(ii)(B) of this section as in § 522.690 of this chapter, as provided by No. 054771 in § 510.600(c) of this chapter.

* * * * *

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 33. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 34. In § 556.710, revise paragraph (c) to read as follows:

§ 556.710 Testosterone.

* * * * *

(c) *Related conditions of use.* See § 522.2343 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 36. In § 558.59, redesignate paragraph (d) as paragraph (e) and add new paragraph (d) to read as follows:

§ 558.59 Apramycin.

* * * * *

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for apramycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for apramycin shall not be refilled.

* * * * *

■ 37. In § 558.205, revise paragraphs (d)(1) and (2) to read as follows:

§ 558.205 Diclazuril.

* * * * *

(d) * * *

(1) *Chickens.* For chickens it is used as follows:

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91	.....	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis (mivati),* and *E. maxima.* Because diclazuril is effective against *E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with *E. maxima*.	Feed continuously as the sole ration. Do not feed to birds producing eggs for human consumption.	058198

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(ii) 0.91	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis (mivati),* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency. Because diclazuril is effective against *E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with *E. maxima*.	Feed continuously as the sole ration. Do not feed to birds producing eggs for human consumption. Bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.	058198
(iii) 0.91	Bambermycins, 1 to 2 ..	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis (mivati),* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency. Because diclazuril is effective against *E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with *E. maxima*.	Feed continuously as the sole ration. Do not feed to birds producing eggs for human consumption. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.	058198

(2) *Turkeys.* For turkeys it is used as follows:

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91	.....	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis,* and *E. meleagrimitis*.	Feed continuously as the sole ration. Do not feed to breeding turkeys. Do not feed to birds producing eggs for human consumption.	058198
(ii) 0.91	Bacitracin methylenedisalicylate, 4 to 50.	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis,* and *E. meleagrimitis,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Do not feed to breeding turkeys. Do not feed to birds producing eggs for human consumption. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	058198
(iii) 0.91	Bambermycins 1 to 2 ...	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis,* and *E. meleagrimitis,* and for improved feed efficiency.	Feed continuously as the sole ration. Do not feed to breeding turkeys. Do not feed to birds producing eggs for human consumption. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	058198
(iv) 0.91	Bambermycins 2	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis,* and *E. meleagrimitis,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Do not feed to breeding turkeys. Do not feed to birds producing eggs for human consumption. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	058198

§ 558.254 [Amended]

■ 38. In § 558.254, in paragraph (e) introductory text, remove ''Table 2—Size Proxies for SRCs in 2016''.

■ 39. In § 558.261, revise paragraph (e)(2)(ii) to read as follows:

§ 558.261 Florfenicol.

* * * * *

(e) * * *

(2) * * *

Florfenicol in grams/ton of feed	Indications for use	Limitations
*	*	*
(ii) 182 to 1,816	Freshwater-reared salmonids: For the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum* and furunculosis associated with *Aeromonas salmonicida*.	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be re-evaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.
*	*	*

* * * * *

■ 39. In § 558.311, add paragraph (e)(3)(ix) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(e) * * *

(3) * * *

Lasalocid amount	Indications for use	Limitations	Sponsor
*	*	*	*
(ix) 60 to 300 mg of lasalocid per head per day.	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter) and replacement beef and dairy heifers on pasture: For increased rate of weight gain.	Feed continuously as a Type C free-choice medicated feed at a rate of 60 to 300 mg of lasalocid per head per day. Daily intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	054771

* * * * *

■ 40. In § 558.450, revise paragraph (e)(5)(ii), redesignate paragraphs (e)(5)(iii) through (vii) as paragraphs (e)(5)(iv) through (viii), and add new paragraph (e)(5)(iii) to read as follows:

§ 558.450 Oxytetracycline.

* * * * *

(e) * * *

(5) * * *

Oxytetracycline amount	Indications for use	Limitations	Sponsor
*	*	*	*
(ii) 200 mg/colony as a dust (200 mg/oz) or syrup (200 mg/5 lb).	Honey bees: For control of American foulbrood caused by *Paenibacillus larvae* and European foulbrood caused by *Melissococcus plutonius* susceptible to oxytetracycline.	Apply every 4 to 5 days for a total of three applications. Remove at least 6 weeks prior to main honey flow.	066104 069254
(iii) 800 mg/colony as an extender patty (800 mg/patty).	Honey bees: For control of American foulbrood caused by *Paenibacillus larvae* and European foulbrood caused by *Melissococcus plutonius* susceptible to oxytetracycline.	Use as a single application. Remove at least 6 weeks prior to main honey flow.	066104 069254
*	*	*	*

* * * * *

■ 41. In § 558.633, revise paragraph (d)(3) to read as follows:

§ 558.633 Tylvalosin.

* * * * *

(d) * * *

(3) An expiration date of 1 week is required for tylvalosin Type C medicated swine feeds in pelleted or crumbled form. Pelleted Type C medicated feeds must bear an expiration date of 30 days after the date of manufacture. Crumbled Type C medicated feeds must bear an expiration date of 7 days after the date of manufacture.

* * * * *

■ 42. In § 558.635, revise paragraph (e)(1)(iv) to read as follows:

§ 558.635 Virginiamycin.

* * * * *

(e) * * *

(1) * * *

Virginiamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	* * *	*	*
(iv) 20	Diclazuril, 0.91	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis* (*mivati),* and *E. maxima.* Because diclazuril is effective against *E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesions scores and improve performance and health of birds challenged with *E. maxima*.	Feed continuously as the sole ration. Do not feed to birds producing eggs for human consumption. Diclazuril as provided by No. 058198 in § 510.600(c) of this chapter.	058198
*	*	* * *	*	*

* * * * *

Dated: February 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03538 Filed 2–25–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0084]

RIN 1625–AA87

Security Zone; Lower Mississippi River, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone for all navigable waters within 400 yards of the Left Descending Bank (LDB) of the Lower Mississippi River (LMR) MM 94.4 and MM 95.1, Above Head of Passes (AHP), New Orleans, LA. This security zone is necessary to provide security and protection for visiting personnel during the events related to the Mardi Gras Celebrations. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port New Orleans (COTP) or a designated representative.

DATES: This rule is effective from 6 p.m. on February 25, 2022, through 11:59 p.m. on March 1, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0084 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 on this rule, call or email Lieutenant Commander, William A. Stewart, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2246, email *William.A.Stewart@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector New Orleans
DHS Department of Homeland Security
FR Federal Register
TFR Temporary Final Rule
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it would be impracticable. We must establish this security zone by February 25, 2022 in order to provide proper security for these visiting personnel, and we do not have sufficient time to request and respond to comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to provide adequate security to protect the public.

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 Captain of the Port New Orleans (COTP) has determined that the increased number of personnel anticipated to be visiting the city during the Mardi Gras Celebration requires certain security measures to ensure that the persons and property are kept secure during the events. The Coast Guard determined that a temporary security zone is needed for this and related events that will be taking place adjacent to a portion of Lower Mississippi River (LMR).

IV. Discussion of the Rule

This rule establishes a security zone from 6 p.m. on February 25, 2022 through 11:59 p.m. on March 1, 2022. The security zone will cover all navigable waters within 400 yards of the Left Descending Bank (LDB) of the LMR from MM 94.4 and MM 95.1, Above Head of Passes (AHP), New Orleans, LA. This zone is necessary in order to provide to provide waterside security for the protection of visitors attending the events related to the Mardi Gras Celebrations. No vessel or person will be permitted to enter the security zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans. They may be contacted on VHF–FM Channel 16 or 67 or by telephone at 504–365–2545.

Persons and vessels permitted to enter this security zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

The COTP or a designated representative will inform the public of the enforcement times and date for this regulated area through Broadcast Notices to Mariners (BNMs), Local

Notice to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

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, location, and duration of the security zone. Vessel traffic will be able to safely transit around this security zone which would impact a small designated area of the Mississippi River near New Orleans, LA for a limited number of days and will not overly impede vessel traffic during the period in effect. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

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 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 establishing a security zone to protect the public in a small designated area of the Mississippi River near New Orleans, LA for a limited number of days. It is categorically excluded from further review under paragraph L60 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. 0170.1.

■ 2. Add § 165.T08–0084 to read as follows:

§ 165.T08–0084 Security Zone; Mississippi River, New Orleans, LA.

(a) *Location.* The following area is a security zone: All navigable waters of Mississippi River, New Orleans, LA within 400 yards of the Left Descending Bank (LDB) of the Lower Mississippi River (LMR) between Mile Marker (MM) 94.4 and MM 95.1, Above Head of Passes (AHP), New Orleans, Louisiana.

(b) *Definitions.* As used in this section, *designated representative* means a designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.33 of this part, entry into or remaining within this regulated area is prohibited unless authorized by the Captain of the Port Sector New Orleans (COTP) or designated representative.

(2) Vessel requiring entry into this regulated area must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67 or by telephone at 504–365–2545.

(3) Persons and vessels permitted to enter this security zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(d) *Enforcement period.* This section will be enforced 6 p.m. on February 25, 2022, through 11:59 p.m. on March 1, 2022.

(e) *Informational broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this regulated area through Broadcast Notices to Mariners (BNMs), Local Notice to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

Dated: February 18, 2022.

W.E. Watson,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2022–04170 Filed 2–25–22; 8:45 am]

BILLING CODE 9110–04–P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1155

[Docket No. ATBCB–2022–0003]

RIN 3014–AA46

Procedures for Issuing Guidance Documents; Rescission; Correction

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Direct final rule; correction.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (''Access Board,'' or ''Board'') published a direct final rule in the **Federal Register** on Feb. 2, 2022, rescinding its regulation that details internal procedures for issuance, public availability, modification, and withdrawal of agency guidance documents. The document contained the incorrect docket number.

DATES: This final rule is effective February 28, 2022, and is applicable beginning February 2, 2022.

FOR FURTHER INFORMATION CONTACT: General Counsel Christopher Kuczynski, (202) 272–0042, *generalcounsel@access-board.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** on Feb. 2, 2022, 87 FR 5692, on page 5692, in the second column, correct the Docket No. caption to read: ''Docket No. ATBCB–2022–0003''.

Christopher Kuczynski,

General Counsel.

[FR Doc. 2022–04087 Filed 2–25–22; 8:45 am]

BILLING CODE 8150–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0055; FRL–8986–02–R4]

Air Plan Approval; North Carolina: Mecklenburg Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision to the Mecklenburg County portion of the North Carolina SIP, hereinafter referred to as the Mecklenburg Local Implementation Plan (LIP). The changes were submitted by the State of North Carolina, through the North Carolina Division of Air Quality (NCDAQ), on behalf of Mecklenburg County Air Quality (MCAQ), via a letter dated April 24, 2020, and were received by EPA on June 19, 2020. The SIP revision updates several Mecklenburg County Air Pollution Control Ordinance (MCAPCO) rules incorporated into the LIP, removes several rules, and adds several rules. The rules addressed in this final approval action relate to volatile organic compound (VOC) emissions and include several VOC Reasonably Available Control Technology (RACT) rules. EPA is finalizing the approval of these changes pursuant to the Clean Air Act (CAA or Act).

DATES: This rule is effective March 30, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2021–0055. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information 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 either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jane Spann, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9029. Ms. Spann can also be reached via electronic mail at *spann.jane@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Overview

The Mecklenburg County LIP was submitted to EPA on June 14, 1990, and EPA approved the plan on May 2, 1991. *See* 56 FR 20140. Mecklenburg County prepared three submittals in order to update the LIP and reflect regulatory and administrative changes that NCDAQ made to the North Carolina SIP [1] since EPA's 1991 LIP approval.[2] The three submittals were submitted as follows: NCDAQ transmitted the October 25, 2017, submittal to EPA but later withdrew it from review through a letter dated February 15, 2019. On April 24, 2020, NCDAQ resubmitted the October 25, 2017, update to EPA and also submitted the January 21, 2016, and January 14, 2019, updates. Due to an inconsistency with public notices at the local level, these submittals were withdrawn from EPA through a letter dated February 15, 2019. Mecklenburg County corrected this error, and NCDAQ submitted the updates to EPA in a submittal dated April 24, 2020.[3]

The April 24, 2020, submittal updates several MCAPCO rules incorporated into the LIP, removes two rules, and adds three rules to better align the LIP with the North Carolina SIP. The January 21, 2016, changes include updates to MCAPCO Rules 2.0926, *Bulk Gasoline Plants;* 2.0927, *Bulk Gasoline Terminals;* 2.0928, *Gasoline Service Stations Stage 1;* and 2.0958, *Work Practice for Sources of Volatile Organic Compounds.* The submittal also seeks to remove MCAPCO Rules 2.0910, *Alternative Compliance Schedules* and 2.0929, *Petroleum Refinery Sources* and add MCAPCO Rules 2.0947, *Manufacture of Synthesized Pharmaceutical Products;* 2.0948, *VOC Emissions from Transfer Operations;* and 2.0949, *Storage of Miscellaneous Volatile Organic Compounds.*[4]

The January 21, 2016, submittal also asks EPA to reincorporate the following rules with no changes or very few minor grammatical edits into the LIP with a new effective date: MCAPCO Rules 2.0906, *Circumvention;* 2.0918, *Can Coating;* 2.0919, *Coil Coating;* 2.0924, *Magnet Wire Coating;* 2.0925, *Petroleum Liquid Storage in Fixed Roof Tanks;* 2.0930, *Solvent Metal Cleaning;* 2.0931, *Cutback Asphalt;* 2.0933, *Petroleum Liquid Storage in External Floating Roof Tanks;* 2.0937, *Manufacture of Pneumatic Rubber Tires;* and 2.0944, *Manufacture of Polyethylene, Polypropylene and Polystyrene.*[5]

On November 17, 2021, EPA published a notice of proposed rulemaking (NPRM) proposing to approve the April 24, 2020, SIP revision regarding updates to Mecklenburg's VOC rules. *See* 86 FR 64101. The November 17, 2021, NPRM provides additional detail regarding the background and rationale for EPA's action. Comments on the November 17, 2021, NPRM were due on or before December 17, 2021, and EPA received one comment.

II. Response to Comment

As mentioned above, EPA received one comment on the November 17, 2021, NPRM. EPA's comment summary and response are provided below.

Comment: The commenter limits their comment to the removal of Rule 2.0929—*Petroleum Refinery Sources* from the LIP and reiterates the fact that removal is based, in part, on the absence of refineries in Mecklenburg County. The commenter notes that the ''surrounding bi-state metro area is comprised of more than six different counties in two different states'' and that the ''petition to remove the Rule 2.0929 does not clarify if Rock Hill or Gastonia have refineries that pose a leak hazard to the nearby inhabitants.'' The commenter goes on to state that when Rule 2.0929 was implemented, there were more local areas in the United States that did not have refineries than local areas that did have refineries and that each local area does not have to petition the CAA for removal of Rule 2.0929. The commenter provides population data for Mecklenburg County and expresses concern that removal might encourage an entrepreneur to construct a refinery in the Charlotte local area to ''avoid implementing the provisions of the [CAA] rather than building a refinery in an area that strictly reaches attainment of the refinery leak Rule 2.0929.''

Response: Rule 2.0929 was first adopted into the MCAPCO in 1979, establishing requirements to meet the 1978 Petroleum Refinery Leaks Control Technique Guidelines (CTG) for controlling VOC emissions from petroleum refinery equipment,[6] and incorporated into the LIP on May 2, 1991. *See* 56 FR 20140. Mecklenburg County was designated as a Moderate ozone nonattainment area for the 1979 1-hour ozone national ambient air quality standards (NAAQS) and the 1997 8-hour ozone NAAQS.[7] CAA section 182(b)(2) requires each state with an ozone nonattainment area classified as Moderate or higher to include requirements in its SIP implementing RACT for certain VOC sources within the area, including for all VOC sources in the nonattainment area that are covered by a CTG.

The April 24, 2020, SIP revision, submitted by North Carolina on behalf of MCAQ, seeks to remove Rule 2.0929 from the LIP because there are no petroleum refineries in Mecklenburg County [8] and because MCAQ would like the LIP to better align with the SIP.[9] EPA's role, with respect to a SIP revision, is focused on reviewing the submission to determine whether it meets the minimum criteria of the CAA. Where it does, EPA must approve the submission. EPA has reviewed the SIP revision and determined that removal of Rule 2.0929 is consistent with the CAA because, among other things, the rule does not apply to any facilities in Mecklenburg County and, therefore, removal will not impact air quality and because Mecklenburg County is designated as attainment or attainment/unclassifiable for all ozone NAAQS and, therefore, CAA section 182 no longer requires the LIP to implement the Petroleum Refinery CTG.

The commenter correctly notes that the SIP revision does not discuss whether petroleum refineries exist in Rock Hill, South Carolina or Gastonia, North Carolina. It was not necessary for the SIP revision or the November 17, 2021, NPRM to discuss whether

[1] Hereinafter, the terms ''North Carolina SIP'' and ''SIP'' refer to the North Carolina regulatory portion of the North Carolina SIP (*i.e.,* the portion that contains SIP-approved North Carolina regulations).

[2] The Mecklenburg County, North Carolina SIP revision that is dated April 24, 2020, and received by EPA on June 19, 2020, is comprised of three previous submittals—one dated January 21, 2016; one dated October 25, 2017; and one dated January 14, 2019.

[3] EPA received the April 24, 2020, submittal on June 19, 2020.

[4] EPA received other updates to the Mecklenburg County portion of the North Carolina SIP transmitted with the same April 24, 2020, cover letter. EPA has addressed or will address these other updates, including changes to certain Section 2.2600 and Section 2.0900 rules, in separate rulemakings.

[5] Hereinafter, the MCAPCO Rules will be identified by ''Rule'' and the accompanying number, *e.g.,* Rule 2.0901.

[6] The Petroleum Refinery Leaks CTG is available at *https://www3.epa.gov/airquality/ctg_act/197806_voc_epa450_2-78-036_leaks_refineery_equipment.pdf.*

[7] Mecklenburg County was part of the Charlotte-Gastonia NC 1979 Moderate ozone NAAQS nonattainment area, comprised of Mecklenburg and Gastonia Counties in North Carolina, and part of the Charlotte-Gastonia-Rock Hill, NC–SC 1997 Moderate ozone NAAQS nonattainment area, comprised of Cabarrus, Gaston, Lincoln, Mecklenburg, Rowan and Union Counties and a portion of Iredell County in North Carolina and a portion of York County in South Carolina. EPA redesignated these areas to attainment in 1995 and 2013, respectively. *See* 60 FR 34859 (July 5, 1995) and 78 FR 72036 (December 2, 2013).

[8] The term ''petroleum refinery'' is defined at Rule 2.0929(a)(6).

[9] EPA removed the corresponding state rule, 15A NCAC 02D .0929—Petroleum Refinery Sources, from the SIP on August 1, 1997. *See* 62 FR 41277.

petroleum refineries are located in those areas because Rule 2.0929 only applies within Mecklenburg County.

Since Rule 2.0929 is limited to Mecklenburg County, EPA does not find the statement regarding the number of local areas in the United States with and without refineries to be relevant for this rulemaking. It is also not clear what the commenter means by stating that each local area does not have to petition the CAA for removal of Rule 2.0929 or how this statement is relevant. The scope of this action is limited to Mecklenburg County. To the extent that other areas of the country need to address RACT for sources covered by the Petroleum Refinery CTG, EPA would evaluate the RACT requirement in the context of other rulemakings for those other areas. As discussed above, a SIP must include RACT for sources covered by the Petroleum Refinery CTG only when the state contains an ozone nonattainment area classified as Moderate or higher, and implementation is only required within the nonattainment area.

The commenter is concerned that removal might encourage a refinery to locate in the Charlotte local area to ''avoid implementing the provisions of the CAA rather than building a refinery in an area that strictly reaches attainment of the refinery leak Rule 2.0929'' and provides population data for Mecklenburg County. However, this comment is unclear because Rule 2.0929 does not apply in areas outside of Mecklenburg County and the population of Mecklenburg County is irrelevant. Furthermore, only those areas in the country that are designated as a Moderate or higher ozone nonattainment area must have SIPs that implement the Petroleum Refinery CTG and there are no ozone nonattainment areas in North Carolina or South Carolina. If a petroleum refinery wants to locate in the Charlotte area, it would have to meet all relevant CAA requirements, including new source review permitting requirements that apply before construction and are designed to protect the NAAQS. Should the Charlotte area become an ozone nonattainment area with a Moderate or higher classification in the future, the area would be required to address RACT for all sources covered by all CTGs applicable at that time.

III. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of MCAPCO Rules 2.0906, *Circumvention;* 2.0918, *Can Coating;* 2.0919, *Coil Coating;* 2.0924, *Magnet Wire Coating;* 2.0925, *Petroleum Liquid Storage in Fixed Roof Tanks;* 2.0926, *Bulk Gasoline Plants;* 2.0927, *Bulk Gasoline Terminals;* 2.0928, *Gasoline Service Stations Stage I;* 2.0930, *Solvent Metal Cleaning;* 2.0931, *Cutback Asphalt;* 2.0933, *Petroleum Liquid Storage in External Floating Roof Tanks;* 2.0937, *Manufacture of Pneumatic Rubber Tires;* 2.0944, *Manufacture of Polyethylene, Polypropylene and Polystyrene;* 2.0947, *Manufacture of Synthesized Pharmaceutical Products;* 2.0948, *VOC Emissions from Transfer Operations;* 2.0949, *Storage of Miscellaneous Volatile Organic Compounds;* and 2.0958, *Work Practice for Sources of Volatile Organic Compounds,* all of which have an effective date of December 15, 2015, into the Mecklenburg County portion of the North Carolina SIP to update the rules to more closely align with their analog North Carolina rules in the SIP. Also in this document, EPA is finalizing the removal of Rules 2.0910, *Alternative Compliance Schedules* and 2.0929, *Petroleum Refinery Sources* from the Mecklenburg portion of the North Carolina SIP, which were incorporated by reference in accordance with the requirements of 1 CFR part 51. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, the revised materials as stated above, have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[10]

IV. Final Action

EPA is approving the aforementioned changes to the Mecklenburg LIP. Specifically, EPA is approving changes to MCAPCO Rules 2.0926, *Bulk Gasoline Plants;* 2.0927, *Bulk Gasoline Terminals;* 2.0928, *Gasoline Service Stations Stage 1;* and 2.0958, *Work Practice for Sources of Volatile Organic Compounds.* EPA is finalizing the removal of Rules 2.0910, *Alternative Compliance Schedules* and 2.0929, *Petroleum Refinery Sources* and the addition of Rules 2.0947, *Manufacture of Synthesized Pharmaceutical Products;* 2.0948, *VOC Emissions from Transfer Operations;* and 2.0949, *Storage of Miscellaneous Volatile Organic Compounds.* EPA is taking final action to approve these changes to the LIP because they are consistent with the CAA.

EPA is also taking final action to reincorporate the following rules with no changes or very few minor grammatical edits with a new effective date into the LIP: MCAPCO Rules 2.0906, *Circumvention;* 2.0918, *Can Coating;* 2.0919, *Coil Coating;* 2.0924, *Magnet Wire Coating;* 2.0925, *Petroleum Liquid Storage in Fixed Roof Tanks;* 2.0930, *Solvent Metal Cleaning;* 2.0931, *Cutback Asphalt;* 2.0933, *Petroleum Liquid Storage in External Floating Roof Tanks;* 2.0937, *Manufacture of Pneumatic Rubber Tires;* and 2.0944, *Manufacture of Polyethylene, Polypropylene and Polystyrene.*

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. 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);

[10] *See* 62 FR 27968 (May 22, 1997).

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• 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 CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where 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 as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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. 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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 29, 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: February 17, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 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 II—North Carolina

■ 2. In § 52.1770(c)(3), amend the table under ''Section 2.0900 Volatile Organic Compounds'' by:

■ a. Removing the entries for ''Section 2.0906'', ''Section 2.0918'', ''Section 2.0919'', ''Section 2.0924'', ''Section 2.0925'', ''Section 2.0926'', ''Section 2.0927'', ''Section 2.0928'', ''Section 2.0930'', ''Section 2.0931'', ''Section 2.0933'', ''Section 2.0937'', ''Section 2.0944'', and ''Section 2.0958'', and adding in their place entries for ''Rule 2.0906'', ''Rule 2.0918'', ''Rule 2.0919'', ''Rule 2.0924'', ''Rule 2.0925'', ''Rule 2.0926'', ''Rule 2.0927'', ''Rule 2.0928'', ''Rule 2.0930'', ''Rule 2.0931'', ''Rule 2.0933'', ''Rule 2.0937'', ''Rule 2.0944'', and ''Rule 2.0958'';

■ b. Removing the entries for ''Section 2.0910'' and ''Section 2.0929''; and

■ c. Adding entries for ''Rule 2.0947'', ''Rule 2.0948'' and ''Rule 2.0949'' below the entry for ''Section 2.0945''.

The additions read as follows:

§ 52.1770 Identification of plan.

* * * * *

(c) * * *

(3) EPA Approved Mecklenburg County Regulations

State citation	Title/subject	State effective date	EPA approval date	Explanation
* *	*	*	* *	*
Section 2.0900 Volatile Organic Compounds				
* *	*	*	* *	*
Rule 2.0906	Circumvention	12/15/2015	2/28/2022, [Insert citation of publication].	
* *	*	*	* *	*
Rule 2.0918	Can Coating	12/15/2015	2/28/2022, [Insert citation of publication].	
Rule 2.0919	Coil Coating	12/15/2015	2/28/2022, [Insert citation of publication].	
* *	*	*	* *	*
Rule 2.0924	Magnet Wire Coating	12/15/2015	2/28/2022, [Insert citation of publication].	
Rule 2.0925	Petroleum Liquid Storage in Fixed Roof Tanks.	12/15/2015	2/28/2022, [Insert citation of publication].	
Rule 2.0926	Bulk Gasoline Plants	12/15/2015	2/28/2022, [Insert citation of publication].	
Rule 2.0927	Bulk Gasoline Terminals	12/15/2015	2/28/2022, [Insert citation of publication].	

(3) EPA APPROVED MECKLENBURG COUNTY REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
Rule 2.0928	Gasoline Service Stations Stage 1.	12/15/2015	2/28/2022, [Insert citation of publication].	
Rule 2.0930	Solvent Metal Cleaning	12/15/2015	2/28/2022, [Insert citation of publication].	
Rule 2.0931	Cutback Asphalt	12/15/2015	2/28/2022, [Insert citation of publication].	
* *	* *	*	* *	*
Rule 2.0933	Petroleum Liquid Storage in External Floating Roof Tanks.	12/15/2015	2/28/2022, [Insert citation of publication].	
* *	* *	*	* *	*
Rule 2.0937	Manufacture of Pneumatic Rubber Tires.	12/15/2015	2/28/2022, [Insert citation of publication].	
* *	* *	*	* *	*
Rule 2.0944	Manufacture of Polyethylene, Polypropylene and Polystyrene.	12/15/2015	2/28/2022, [Insert citation of publication].	
* *	* *	*	* *	*
Rule 2.0947	Manufacture of Synthesized Pharmaceutical Products.	12/15/2015	2/28/2022, [Insert citation of publication].	
Rule 2.0948	VOC Emissions from Transfer Operations.	12/15/2015	2/28/2022, [Insert citation of publication].	
Rule 2.0949	Storage of Miscellaneous Volatile Organic Compounds.	12/15/2015	2/28/2022, [Insert citation of publication].	
* *	* *	*	* *	*
Rule 2.0958	Work Practice for Sources of Volatile Organic Compounds.	12/15/2015	2/28/2022, [Insert citation of publication].	

* * * * *

[FR Doc. 2022–04113 Filed 2–25–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0337; FRL–9459–01–OCSPP]

Fluridone; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the herbicide fluridone including its degradates and metabolites in or on peanut and peanut, hay. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on peanut. This regulation establishes a maximum permissible level for residues of fluridone in or on these commodities. The time-limited tolerances expire on December 31, 2024.

DATES: This regulation is effective February 28, 2022. Objections and requests for hearings must be received on or before April 29, 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–2021–0337, 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 OPP docket is (202) 566–1744.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; 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 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 section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 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–2021–0337 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 April 29, 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–2021–0337, 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, is available at *https://www.epa.gov/dockets.*

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(l)(6), is establishing time-limited tolerances for residues of fluridone, in or on peanut at 0.1 parts per million (ppm) and peanut, hay at 0.1 ppm. These time-limited tolerances expire on December 31, 2024.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement of a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18-related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, *i.e.,* without having received any petition from an outside party.

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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Fluridone on Peanut and Peanut, Hay and FFDCA Tolerances

The Arkansas and Missouri Departments of Agriculture submitted specific emergency exemptions for the use of fluridone on peanut to control Palmer amaranth, *Amaranthus palmeri,* populations in peanut fields where glyphosate-resistant Palmer amaranth biotypes are present. According to the States, peanut growers in Arkansas and Missouri are experiencing widespread multiple herbicide-resistant populations of Palmer amaranth. These States reported that an urgent and non-routine situation exists because a registered effective soil residual herbicide is currently unavailable to reduce the impact and prevent the expansion of this destructive weed species. Significant economic losses are expected for peanut growers due to yield and quality decreases without a suitable pesticide control.

After having reviewed the submission, EPA determined that an emergency condition exists for these States, and that the criteria for approval of these emergency exemptions have been met.

As part of its evaluation of these emergency exemption applications, EPA assessed the potential risks presented by residues of fluridone in or on peanut at 0.1 ppm and peanut, hay at 0.1 ppm. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on these emergency exemptions in order to address an urgent non-routine situation in these States and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2024, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on peanut after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether fluridone meets FIFRA's registration requirements for use on peanut or whether permanent tolerances for this use would be

appropriate. Under these circumstances, EPA does not believe that these time-limited tolerance decisions serve as a basis for registration of fluridone by a State for special local needs under FIFRA section 24(c). Nor do these tolerances by themselves serve as the authority for persons in States other than Arkansas and Missouri to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemptions for fluridone, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. 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 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 expected as a result of these emergency exemption requests and the time-limited tolerances for residues of fluridone on peanut at 0.1 ppm and peanut, hay at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing these time-limited tolerances 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 rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considers in making its safety determination for the new rulemaking.

In the **Federal Register** of May 18, 2020 (85 FR 29633) (FRL–10007–09), EPA published a final rule that established tolerances for residues of fluridone in or on multiple commodities based on the Agency's determination that aggregate exposure to fluridone resulting from the residues subject to those tolerances is safe for the U.S. general population, including infants and children. EPA is incorporating sections from that final rule as described further in this rulemaking, as they remain unchanged.

Toxicological profile. The toxicological profile for fluridone has not changed since the May 18, 2020, final rule was published; therefore, EPA is relying upon the discussion of that profile in Unit III. A. as part of this rulemaking.

Toxicological points of departure/Levels of concern. The toxicological points of departure and levels of concern for fluridone have not changed since the May 18, 2020, final rule was published; therefore, EPA is relying upon the discussion in Unit III. B. as part of this rulemaking.

Exposure assessment. Much of the exposure assessment for fluridone remains unchanged from the discussion in Unit III. C. of the May 18, 2020, final rule, except that EPA considered the additional dietary exposure from the time-limited tolerances established by this action. Specifically, EPA conducted acute and chronic dietary exposure assessments to determine if the emergency use on peanut increases the dietary exposure to fluridone. Updated acute and chronic Dietary Exposure Evaluation Model (DEEM) runs were conducted with peanut included at a 0.1 ppm residue level. These results compared to the most recent dietary assessment supporting the May 18, 2020, final rule showed no exposure changes to two significant figures. Therefore, the previous assessment is protective of dietary exposure potential from the emergency use of fluridone on peanut.

Safety factor for infants and children. EPA continues to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the Food Quality Protection Act (FQPA) safety factor were reduced from 10X to 1X. The reasons for that determination are articulated in Unit III. D. of the May 18, 2020, final rule.

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 population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists.

The results of the acute and chronic analyses for fluridone do not exceed the Agency's level of concern (LOC). That is, all risk estimates were <100% of the aPAD or <100 of the cPAD and are not of concern for the general U.S. population and all population subgroups. The acute dietary exposure from food and water will occupy 2.3% of the aPAD for all infants (1-year old), the population with the highest estimated risk. Chronic exposure to fluridone from food and water will utilize 7% of the cPAD for children aged 1 to 2, the population with the highest estimated risk.

The short-term aggregate exposure assessment for fluridone is based on food and drinking water as well as residential uses. For short-term aggregate risk assessment, potential residential exposures (dermal, inhalation, and incidental ingestion from swimming in treated waters for children; dermal and inhalation from applications via pouring into recreational ponds for adults) were combined with background dietary exposures. The combined short-term food, water, and residential exposures result in aggregate MOEs for of 1,300 for adults and 1,600 for children, which are greater than the LOC of 100. Because EPA's level of concern for fluridone is an MOE of 100 or below, these MOEs are not of concern. Fluridone is not registered for any use patterns that would result in intermediate-term residential exposure.

Further, since there is no evidence of carcinogenicity in the toxicological database for fluridone, EPA concluded that fluridone is not carcinogenic and is classified as ''not likely'' to be a human carcinogen.

Therefore, based on the risk assessments and information described above, EPA concludes that there is reasonable certainty that no harm will result to the U.S. general population, or to infants and children from aggregate exposure to fluridone residues. More detailed information on the subject

action to establish time-limited tolerances in or on peanut and peanut, hay can be found at *https://www.regulations.gov* in the document entitled, ''Fluridone: ID# 21AR03 Section 18 Specific Exemption for Use on Peanut in Arkansas.'' This document can be found in docket ID number EPA–HQ–OPP–2021–0337.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (high performance liquid chromatography (HPLC) method (originally submitted as method AM–AA–CA–RO52–AA–755)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov*.

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 is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for fluridone.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of fluridone, in or on peanut at 0.1 ppm and peanut, hay at 0.1 ppm. These tolerances expire on December 31, 2024.

VII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA sections 408(e) and 408(l)(6). 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 in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances 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, but does not regulate 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, or 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).

VIII. 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: February 17, 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. Amend § 180.420, by adding paragraph (b) to read as follows:

§ 180.420 Fluridone; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the herbicide fluridone, including its metabolites and degradates, in or on the specified agricultural commodities in the table, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified in the following table is to be determined by measuring only fluridone, (1-methyl-3-phenyl-5-[3-trifluoromethyl)phenyl]-4(1H)-pyridinone). The tolerances expire on the date specified in table 3.

TABLE 3 TO PARAGRAPH (b)

Commodity	Parts per million	Expiration date
Peanut	0.1	12/31/2024
Peanut, hay	0.1	12/31/2024

* * * * *

[FR Doc. 2022–03924 Filed 2–25–22; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0364; FRL–9534–01–OCSPP]

Fatty Acids, Esters With Ethoxylated Triethanolamine; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of fatty acids, tall-oil, esters with triethanolamine, ethoxylated (CAS Reg No. 68605–38–9) and fatty acids, $C_{8–18}$ and C_{18}-unsatd., esters with polyethylene glycol ether with triethanolamine (3:1) (CAS Reg No. 2464873–19–4) (herein referred to 20ETO and 10ETO, respectively) when used as inert ingredients (surfactant) in pesticide formulations applied to growing crops pre- and post-harvest, not to exceed 10% in the final pesticide formulation. Exponent, Inc. on behalf of Lamberti USA, Incorporated submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 20ETO and 10ETO.

DATES: This regulation is effective February 28, 2022. Objections and requests for hearings must be received on or before April 29, 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–2021–0364, 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 is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; 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 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–2021–0364 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 April 29, 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–2021–0364, 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. Petition for Exemption

In the **Federal Register** of August 3, 2021 (86 FR 41809) (FRL–8792–01), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11506) by Exponent, Inc. (1150 Connecticut Ave., Suite 1100, Washington, DC 20036) on behalf of Lamberti USA, Incorporated (P.O. Box 1000, Hungerford, TX 77448). The petition requested that the 40 CFR be amended by establishing an exemption from the requirement of a tolerance for residues of 20ETO (CAS Reg No. 68605–38–9) and 10ETO (CAS Reg No. 2464873–19–4) when used as inert ingredients (surfactant) in pesticide formulations applied to growing crops pre- and post-harvest under 40 CFR 180.910. That document referenced a summary of the petition prepared by Exponent, Inc. on behalf of Lamberti USA, Incorporated, the petitioner, which is available in the docket, *https://www.regulations.gov.* No comments were received on the notice of filing.

Based upon review of the data supporting the petition, EPA has limited the maximum concentration of 20ETO or 10ETO to not more than 10% in pesticide formulations for use under 40 CFR 180.910. This limitation is based on the Agency's risk assessment which can be found at *https://www.regulations.gov* in the document titled ''Fatty acids, Tall-Oil, Esters with Triethanolamine, Ethoxylated (20ETO) and Fatty Acids, $C_{8–18}$ or C_{18}-Unsatd., Esters with

Polyethylene Glycol Ether with Triethanolamine (3:1) (10ETO); Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations'' in docket ID number EPA–HQ–OPP–2021–0364.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for 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 . . . .''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), 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 20ETO and 10ETO including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 20ETO and 10ETO follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by 20ETO and 10ETO as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

EPA considered studies on either substance to evaluate the toxicity of both substances. Based on the available data, the acute oral toxicity is expected to be low for 20ETO and 10ETO because the oral LD_{50} (lethal dose) for 20ETO is greater than 2,000 milligrams/kilogram (mg/kg). Both substances are also not expected to be acutely toxic via dermal exposure, as the LD_{50} for 20ETO is greater than 2,000 mg/kg in rats. The substances are also not expected to be irritating to the skin in the rat and rabbit nor sensitizing to the guinea pig. However, the substances are expected to be minimally irritating to the rabbit eye.

No repeated-dose toxicity studies are available for 10ETO or 20ETO. Therefore, data for triethanolamine (TEA) and fatty acids, tall oil were used, based on the predicted degradation pathways of 20ETO and 10ETO. Subchronic oral toxicity studies in guinea pigs via gavage (TEA) and rats (fatty acids, tall oil) via the diet resulted in hepatocellular cloudy swelling and fatty change in the liver and cloudy swelling of the convoluted tubules and Henle's loop in the kidney at 400 and 450 mg/kg/day, respectively, following 60- and 120-day exposures. The no observed adverse effect level (NOAEL) in these studies is 200 and 225 mg/kg/day for the guinea pig and rat, respectively. Increased liver and kidney weights and histological lesions are observed at 730 mg/kg/day in a 90-day oral toxicity study in rats. The NOAEL in this study is 170 mg/kg/day. Chronic exposure via drinking water (TEA) resulted in an increased incidence and severity of chronic nephropathy at 455 mg/kg/day in rats. No LOAEL was established in this study. In mice, decreased body weight was observed at 1,688 mg/kg/day following chronic exposure via drinking water (TEA).

In subchronic dermal toxicity studies, no systemic toxicity was observed up to 1,000 mg/kg/day, the limit dose, in rats. However, in the same study, an increased incidence of hypertrophy of the pituitary gland pars intermedia was observed at 2,000 mg/kg/day and dermal effects manifested as increased incidence and severity of acanthosis and inflammation at 500 mg/kg/day. In mice, no systemic toxicity was observed up to 4,000 mg/kg/day following 13 weeks of exposure. Mild dermal hyperplasia was observed at 140 mg/kg/day and an increased incidence and severity of acanthosis was seen at 250 mg/kg/day.

Following chronic dermal exposure in rats, an increased incidence of acanthosis and inflammation along with ulcers and dermal erosion was observed at 63 mg/kg/day.

A developmental toxicity study showed no maternal or developmental toxicity up to 1,125 mg/kg/day in mice. Another developmental toxicity study via the dermal exposure showed no toxicity up to 30 mg/kg/day, which was the highest dose tested in rats. Further, no parental, offspring, or reproduction toxicity was observed in a 2-generation reproduction toxicity study in rats (fatty acid, tall oil) up to 5,000 mg/kg/day. In a combined reproduction/developmental toxicity test, a decrease in the number of implantation sites and litter size, and an increase in the number of post-implantation loss were observed at 1,000 mg/kg/day. The NOAEL is 300 mg/kg/day. However,

there is no concern for fetal susceptibility or reproduction toxicity since the cRfD (0.455 mg/kg/day) is protective of effects seen at 1,000 mg/kg/day.

Several mutagenicity studies with TEA and fatty acids, tall oil (*e.g.,* Ames, chromosome aberration, micronucleus assay, sister chromatid exchange, and cell dominant lethal assay) were reviewed and the results for these studies are negative.

Two chronic/carcinogenicity studies in which the test substance was administered via drinking water were also reviewed. In mice, decreased bodyweight was observed at 1,688 mg/kg/day. The NOAEL is 673 mg/kg/day. No evidence of an increased incidence of tumors was seen in this study. In rats, chronic nephropathy is observed in female rats at 455 mg/kg/day. A NOAEL was not established in this study. An increased incidence of hepatocellular adenomas was observed at doses greater than 1,000 mg/kg/day. The chronic reference dose (cRfD) is based on this study.

Neurotoxicity and immunotoxicity studies are not available for review. However, evidence of neurotoxicity and immunotoxicity was not observed in the submitted studies.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for 20ETO and 10ETO used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR 20ETO AND 10ETO FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13 to 50 years of age, General population including infants and children).	An acute effect was not found in the database therefore an acute dietary assessment is not necessary.		
Chronic dietary (All populations)	LOAEL= 455 mg/kg/day UF_A = 10x UF_H = 10x UF_L = 10x FQPA SF = 1x	Chronic RfD = 0.455 mg/kg/day. cPAD = 0.455 mg/kg/day.	Chronic/Carcinogenicity Study (TEA). LOAEL = 455 mg/kg/day based on chronic nephropathy in female rats.
Incidental oral intermediate-term (1 to 6 months).	NOAEL= 300 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Combined Reproduction/Developmental (TEA). LOAEL = 1,000 mg/kg/day based on decreased number of implantation sites and litter size, and an increased number of post-implantation loss.
Inhalation short-term (1 to 30 days) ..	Inhalation study NOAEL = 43.39 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	16-Day Inhalation Toxicity Study (TEA). LOAEL = 86.77 mg/kg/day based on laryngeal inflammation.
Inhalation intermediate-term (1 to 6 months).	Inhalation study NOAEL = 43.39 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x UFs = 10x FQPA SF = 1x	LOC for MOE = 1000 ...	16-Day Inhalation Toxicity Study (TEA) LOAEL = 86.77 mg/kg/day based on laryngeal inflammation.
Cancer (Oral, dermal, inhalation)	There is no evidence of carcinogenicity in the available database. The RfD approach is protective of any potential carcinogenic effects.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 20ETO and 10ETO, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 20ETO and 10ETO in food as follows:

In conducting the chronic dietary exposure assessment using the Dietary

Exposure Evaluation Model DEEM–FCIDTM, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's (USDA's) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for 10ETO and 20ETO. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts,'' (D361707, S. Piper, 2/25/09) and can be found at *https://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

Generally, in the dietary exposure assessments for inert ingredients, the Agency assumes that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest levels of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50 percent of the product and often can be much higher. However, in assessing this petition request, the Agency assumed that a product consisted of 10% percent 10ETO and 20ETO. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity.

Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, this conservative assumption will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for 10ETO and 20ETO, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, for lawn and garden pest control, indoor pest control, termiticides, flea and tick control on pets, and hard surface disinfection on walls, floors, tables).

20ETO and 10ETO may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. For residential handlers, the Agency assumed handlers may receive short-term dermal and inhalation exposure to 20ETO and 10ETO from formulations containing the inert ingredient in outdoor and indoor scenarios. Short- and intermediate-term dermal exposures were not quantitated since no systemic toxicity is observed in dermal toxicity studies. Also, intermediate- and long-term inhalation exposures are not expected because applications are not expected to occur daily or for more than 30 days. Therefore, only short-term inhalation exposures were estimated and were based on the NOAEL of 43.39 mg/kg/day and a LOC for an MOE of 100. The short-term residential handler MOE is 36000, which is not a risk of concern because EPA considers MOEs of 100 or less to be of concern. The Agency also considered intermediate-term incidental oral exposures to children due to residential exposure associated with contact with treated surfaces (dermal and hand-to-mouth exposures). The MOE is 1964 for children, which is not a risk of concern because EPA considers MOEs of 100 or less to be of concern.

As introduced above, 10ETO and 20ETO are expected to biodegrade into TEA and fatty acids, tall oil. Residential exposure to TEA may occur from existing pesticide uses as well as from non-pesticide products that may be used in and around the home, such as cosmetics. Dermal contact is the primary route of exposure to TEA in cosmetics. However, a dermal endpoint of concern was not identified, and therefore a quantitative dermal exposure assessment is not necessary. TEA can be used in products that may be sprayed, however, so there is the potential for inhalation exposure. The Cosmetic Ingredient Review (CIR) Expert Panel has noted that 95% to 99% of TEA particles produced in cosmetic aerosols are not respirable. This assumption, coupled with the small actual exposure in the breathing zone and the concentrations at which TEA is used, suggests that inhalation would not be a significant route of exposure that might lead to local respiratory or systemic toxic effects (Fiume et. al., 2013). Small amounts of TEA may also be ingested (oral exposure) from lipsticks as they are reported to potentially contain up to 1% TEA. However, any contribution to the estimated oral pesticide exposure resulting from cosmetic uses is likely to

be insignificant in comparison to the estimates for exposure from the pesticide use.

4. *Cumulative effects from substances with a common mechanism of toxicity.* 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.''

EPA has not found 20ETO and 10ETO to share a common mechanism of toxicity with any other substances, and 20ETO and 10ETO do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 20ETO and 10ETO do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

The Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1X for the chronic dietary assessment for the following reasons. The toxicity database for 20ETO and 10ETO contains developmental, 2-generation reproduction, combined reproduction/developmental toxicity and mutagenicity studies. There is no indication of immunotoxicity or neurotoxicity in the available studies; therefore, there is no need to require an immunotoxicity or neurotoxicity study. Additionally, no fetal susceptibility or reproduction toxicity was observed in the available studies. Based on the adequacy of the toxicity database, the conservative nature of the exposure assessment and the lack of concern for prenatal and postnatal sensitivity, the Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1X.

E. 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.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, 20ETO and 10ETO is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to 20ETO and 10ETO from food and water will utilize 32.6% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure generally takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

20ETO and 10ETO may be used as inert ingredients in pesticide products that could result in short-term residential exposure. The Agency has determined that it is not appropriate to aggregate chronic exposure through food and water with short-term residential exposures to 20ETO and 10ETO since toxicological effects were different depending on the route of exposure.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term residential exposures result in aggregate MOEs of 36000 for adult males and females. Because EPA's level of concern for 20ETO and 10ETO is an MOE of 100 or below, this MOE is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

20ETO and 10ETO may be used as inert ingredients in pesticide products that could result in intermediate-term residential exposure, and the Agency has determined that it is not appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to 20ETO and 10ETO since toxicological effects were different depending on the route of exposure.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 1964 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). Because EPA's level of concern for children's residential exposure (incidental oral exposure) to 20ETO and 10ETO is an MOE of 100 or below, this MOE is not of concern.

5. *Long-term risk.* Long-term aggregate exposure takes into account long-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Long-term residential exposures are not expected from the use of 20ETO and 10ETO in pesticides used in and around the home. Therefore, long-term aggregate exposure considers chronic food and water. The MOE is 10833 based on the cPAD of 0.455 mg/kg/day. As the level of concern is for an MOE that is lower than 1000, this MOE is not of concern.

TEA, a metabolite of 10ETO and 20ETO, may be used as inert ingredients in non-pesticide products that could result in long-term residential exposure. Based on the exposure assumptions described in unit IV. C. 3, the Agency anticipates that the contribution to the estimated oral non-pesticide exposure due to its use in cosmetics is likely to be insignificant in comparison to the estimates for exposure from the pesticide use. Therefore, the Agency believes the assessments of aggregate exposures due to pesticide uses more than adequately protect for exposure from uses in cosmetics products.

6. *Aggregate cancer risk for U.S. population.* Based on the lack of tumors in the carcinogenicity studies in rats and mice and the lack of mutagenicity, 20ETO and 10ETO are not expected to pose a cancer risk to humans.

7. *Determination of safety.* Taking into consideration all available

information on 20ETO and 10ETO, EPA concludes that there is a reasonable certainty that no harm will result to the general population, including infants and children, from aggregate exposure to 20ETO and 10ETO residues.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of 20ETO and 10ETO in or on any food commodities. EPA is establishing a limitation on the amount of 20ETO and 10ETO that may be used in pesticide formulations. This limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 *et seq*. EPA will not register any pesticide formulation for food use that exceeds 10% in the final pesticide formulations for indoor and outdoor residential use.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of 20ETO (CAS Reg No. 68605–38–9) and 10ETO (CAS Reg No. 2464873–19–4) when used as inert ingredients (surfactant) in pesticide formulations applied to growing crops pre- and post-harvest under 40 CFR 180.910.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance exemption 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), EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. As such, to the extent that information is publicly available or was submitted in comments to EPA, the Agency considered whether groups or segments of the population, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

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).

VIII. 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: February 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 part 180 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 § 180.910, amend Table 1 to 180.910 by adding in alphabetical order the inert ingredients ''Fatty acids, tall-oil, esters with triethanolamine, ethoxylated'' and ''Fatty acids, $C_{8–18}$ and C_{18}-unsatd., esters with polyethylene glycol ether with triethanolamine (3:1)'' to reads as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.910

Inert ingredients	Limits (%)	Uses
* * * * * * *		
Fatty acids, tall-oil, esters with triethanolamine, ethoxylated (CAS Reg. No. 68605–38–9)	10	Surfactant.
Fatty acids, $C_{8–18}$ and C_{18}-unsatd., esters with polyethylene glycol ether with triethanolamine (3:1) (CAS Reg. No. 2464873–19–4).	10	Surfactant.
* * * * * * *		

[FR Doc. 2022–04123 Filed 2–25–22; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 206

[Docket DARS–2019–0051]

RIN 0750–AK67

Defense Federal Acquisition Regulation Supplement: Exception to Competition for Certain Follow-On Production Contracts (DFARS Case 2019–D031)

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 implement a section of the National Defense Authorization Act for Fiscal Year 2016 that modifies the criteria required to exempt from competition certain follow-on production contracts.

DATES: Effective February 28, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly R. Ziegler, telephone 571–372–6095.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 84 FR 50811 on September 26, 2019, to amend DFARS 206.001 to implement section 815 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016 (Pub. L. 114–92). Section 815 repeals and replaces section 845 of the NDAA for FY 1994 (Pub. L. 103–160; 10 U.S.C. 2371 note) with 10 U.S.C. 2371b, which modifies the authority of DoD to carry out other transaction (OT) agreements for prototype projects, as well as the criteria required to award an associated follow-on production contract to the participants in the other transaction agreement without the use of competitive procedures. One respondent submitted comments on the proposed rule.

II. Discussion and Analysis

A. Summary of Significant Changes

The purpose of this rule is to provide contracting officers with updated internal guidance when awarding a follow-on production contract that is exempt from the competitive procedures of Federal Acquisition Regulation part 6, as set forth in 10 U.S.C. 2371b. The rule is not intended to implement policy, regulation, or guidance on DoD's authority to enter into OT prototype agreements at 10 U.S.C. 2371b. As such, this final rule changes the rule text to specify that the agreements officer for the OT agreement for the prototype project is responsible for providing to the contracting officer information that confirms the requirements to award a noncompetitive follow-on production contract, as specified in 10 U.S.C. 2371b and DoD OT agreement policy, have been met.

B. Analysis of Public Comments

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided, as follows:

Comment: The respondent advised that DoD should provide clear guidance on what constitutes ''successful completion'' of a prototype transaction; the rule text should be clarified to explain what it means to award a follow-on production contract to ''the participants in the transaction,'' as contracts are usually made between the Government and a single entity; the rule should clarify what a ''participant'' is, given that not all parties to a transaction necessarily participate in the project.

The respondent also advised that the rule should be revised to clarify the prerequisites for awarding the OT for the prototype project and the prerequisites for awarding a follow-on production contract. Specifically, one of the criteria for awarding a follow-on production contract is that the OT for the prototype project is based on specific determinations made by certain acquisition officials according to different threshold values. The proposed rule, however, applies these determination requirements only to the follow-on production contract, when they should instead apply only to the initial OT agreement.

Response: This rule is not intended to implement policy, regulation, or guidance on DoD's authority to enter into OT prototype agreements at 10 U.S.C. 2371b. Instead, the Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)) is the organization responsible for promulgation of policy for OT agreements, which can be viewed at *https://aaf.dau.edu/aaf/ot-guide/.* As a result, this rule is modified to clarify that the contracting officer does not make the determination that the prototype project was successfully completed and, instead, should receive that information from the agreements officer for the OT agreement.

Comment: The respondent advised that 32 CFR part 3 should be updated to reflect the current authority at 10 U.S.C. 2371b.

Response: This comment is outside the scope of this rule, which amends 48 CFR chapter 2.

C. Other Changes

The proposed numbering of the DFARS text is redesignated as DFARS 206.001–70 from 206.001(S–70) to align with FAR system drafting conventions.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold, for Commercial Products Including Commercially Available Off-the-Shelf Items, and for Commercial Services

This rule only impacts the internal operating procedures of the agency. The rule does not impose any new requirements on contracts at or below

the simplified acquisition threshold, for commercial products including commercially available off-the-shelf items, or for commercial services.

IV. Executive Orders 12866 and 13563

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

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

The Department of Defense is amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement section 815 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016 (Pub. L. 114–92), which repeals and replaces section 845 of the NDAA for FY 1994 (Pub. L. 103–160; 10 U.S.C. 2371 note) with 10 U.S.C. 2371b.

The objective of this rule is to provide contracting officers with updated internal guidance when awarding a follow-on production contract that is exempt from the competitive procedures of Federal Acquisition Regulation part 6, as set forth in 10 U.S.C. 2371b.

No public comments were received in response to the initial regulatory flexibility analysis.

DoD does not collect data on the number of follow-on production contracts that are awarded annually and associated with a prototype project transaction agreement made under the authority of 10 U.S.C. 2371b; therefore, DoD is unable to estimate the number of small entities that will be impacted by this rule. However, DoD does not expect small entities to be significantly impacted by this rule, because the rule does not change any existing processes or impose any additional burdens. Instead, the rule simply clarifies instructions to contracting officers on the criteria that must be met in order to award an associated follow-on production contract without using competitive procedures.

This rule does not include any new reporting, recordkeeping, or other compliance requirements for small entities. This rule does not duplicate, overlap, or conflict with any other Federal rules. There are no known alternative approaches to the rule that would meet the stated objectives.

VII. Paperwork Reduction Act

The 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 206

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, 48 CFR part 206 is amended as follows:

PART 206—COMPETITION REQUIREMENTS

■ 1. The authority citation for 48 CFR part 206 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

206.001 [Amended]

■ 2. Amend section 206.001 by removing paragraph (S–70).

■ 3. Add section 206.001–70 to read as follows:

206.001–70 Exception for prototype projects for follow-on production contracts.

(a) Also excepted from this part are follow-on production contracts for products developed pursuant to the ''other transactions'' authority of 10 U.S.C. 2371b for prototype projects when—

(1) The other transaction solicitation and agreement included provisions for a follow-on production contract; and

(2) The contracting officer receives sufficient documentation from the agreements officer of the other transaction agreement for the prototype project that the requirements of 10 U.S.C. 2371b sections (f)(2)(A) and (B) and, when applicable, section (a)(2), have been met.

(b) See PGI 206.001–70(b) for additional guidance.

[FR Doc. 2022–04011 Filed 2–25–22; 8:45 am]

BILLING CODE 5001–06–P

Proposed Rules

Federal Register
Vol. 87, No. 39
Monday, February 28, 2022

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0078; Airspace Docket No. 22–AAL–2]

RIN 2120–AA66

Proposed Revocation of Colored Federal Airway Amber 4 (A–4); Anaktuvuk Pass, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to revoke Colored Federal airway Amber 4 (A–4) in the vicinity of Anakatuvuk Pass, AK due to the pending decommissioning of the Anaktuvuk Pass, AK, (AKP) Non-directional Beacon (NDB).

DATES: Comments must be received on or before April 14, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1(800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2022–0078; Airspace Docket No. 22–AAL–2 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Christopher McMullin, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2022–0078; Airspace Docket No. 22–AAL–2) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2022–0078; Airspace Docket No. 22–AAL–2.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Western Service Center, Federal Aviation Administration, 2200 South 216th St., Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

In 2019, the FAA received a request from North Slope Burrough, Alaska to

decommission Anaktuvuk Pass, AK, (AKP) NDB. North Slope Burrough owns and operates AKP and has raised concerns related to the high cost of maintenance and needed repairs. The FAA conducted a non-rulemaking study in response to their request in accordance with FAA Order JO 7400.2, Procedures for Handling Airspace Matters. As a result of the study, the FAA did not receive any objections to the removal of the NDB along with the supported airway. The FAA concurs with the request and plans to remove AKP from service.

Colored Federal airway Amber 4 (A–4) is a short route that utilizes the Evansville, AK, (ENO) NDB and AKP. The decommissioning of AKP would result in A–4 being unusable. The current alternative to navigate between Bettles Airport, Alaska and Anaktuvuk Pass Airport, Alaska, would be to utilize VHF Omnidirectional Radar (VOR) Federal airways V–444 and V–504; and United States Area Navigation (RNAV) routes T–232, and T–240. The FAA proposes to revoke A–4 due to the decommissioning of AKP.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to revoke Colored Federal airway A–4 due to the decommissioning of AKP. A–4 currently navigates between ENO and AKP. The FAA proposes to revoke Colored Federal airway A–4 in its entirety.

Colored Federal airways are published in paragraph 6009(c) of FAA Order JO 7400.11F dated August 10, 2021 and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Colored Federal airway listed in this document would be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6009(c) Colored Federal Airway.

* * * * *

A–4 [Remove]

* * * * *

Issued in Washington, DC, on February 22, 2022.

Michael R. Beckles,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2022–04119 Filed 2–25–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0109; Airspace Docket No. 22–AAL–10]

RIN 2120–AA66

Proposed Revocation of Colored Federal Airway Blue 79 (B–79); Annette Island, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to revoke Colored Federal airway Blue 79 (B–79) in the vicinity of Annette Island, AK due to the pending decommissioning of the Nichols, AK, (ICK) Non-directional Beacon (NDB).

DATES: Comments must be received on or before April 14, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1(800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2022–0109; Airspace Docket No. 22–AAL–10 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Christopher McMullin, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in

Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2022–0109; Airspace Docket No. 22–AAL–10) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2022–0109; Airspace Docket No. 22–AAL–10.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Western Service Center, Federal Aviation Administration, 2200 South 216th St., Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The Nichols, AK, (ICK) NDB in Annette Island, AK has been scheduled for decommissioning, effective February 23, 2023 due to ongoing and high cost maintenance and repairs. The FAA conducted a non-rulemaking study in 2021 in accordance with FAA Order JO 7400.2, Procedures for Handling Airspace Matters. As a result of the study, the FAA did not receive any objections to the removal of the NDB along with the supported airway.

Colored Federal airway B–79 is dependent upon ICK and navigates between Sandpit, BC, (CYZP) Canada, NDB and ICK. The airspace in Canada is not included in the route, so it terminates at the Canada border just south of ICK. The decommissioning of ICK would result in B–79 being unusable. VHF Omnidirectional Radar (VOR) Federal airway V–137 overlies B–79 and would mitigate the loss of B–79, therefore, the FAA proposes to revoke B–79.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to revoke Colored Federal airway B–79 due to the decommissioning of ICK. B–79 currently navigates between ICK and CYZP, excluding the airspace within Canada. The FAA proposes to revoke Colored Federal airway B–79 in its entirety.

Colored Federal Airways are published in paragraph 6009(d) of FAA Order JO 7400.11F dated August 10, 2021 and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Blue Federal Airway listed in this document would be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6009(d) Colored Federal Airway.

* * * * *

B–79 [Remove]

* * * * *

Issued in Washington, DC, on February 22, 2022.

Michael R. Beckles,

Manager, Rules and Regulations Group.

[FR Doc. 2022–04068 Filed 2–25–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0048; Airspace Docket No. 22–ASO–01]

RIN 2022–AA66

Proposed Amendment of Class D Airspace, and Class E Airspace; Gulf Shores, AL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class D airspace and Class E airspace extending upward from 700 feet above the surface for Gulf Shores International Airport/Jack Edwards Field, Gulf Shores, AL, by updating the airport name and adding necessary verbiage to the descriptions. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before April 14, 2022.

ADDRESSES: Send comments on this proposal to: The U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify Docket No. FAA–2022–0048; Airspace Docket No. 22–ASO–1 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would amend airspace in the Gulf Shores, AL area, to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2022–0048 and Airspace Docket No. 22–ASO–01) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2022–0048; Airspace Docket No. 22–ASO–01.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to Title 14 CFR part 71 to amend Class D airspace and Class E airspace extending upward from 700 feet above the surface for Gulf Shores International Airport/Jack Edwards Field (formerly Jack Edwards National Airport), Gulf Shores, AL, by updating the airport name, and amending the descriptions, by adding ''when active'' in reference to Restricted Area R–2908.

Class D and Class E airspace designations are published in Paragraphs 5000 and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO AL D Gulf Shores, AL [Amended]

Gulf Shores International Airport/Jack Edwards Field, AL
(Lat. 30°17′23″W″N, long. 87°40′18″W)

That airspace extending upward from the surface to and including 2,000 feet MSL, within a 4.3-mile radius of Gulf Shores International Airport/Jack Edwards Field, excluding that airspace within Restricted Area R–2908, when active. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO AL E5 Gulf Shores, AL [Amended]

Gulf Shores International Airport/Jack Edwards Field, AL
(Lat. 30°17′23′W″N, long. 87°40′18″W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Gulf Shores International Airport/Jack Edwards Field, excluding that airspace within Restricted Area R–2908, when active.

Issued in College Park, Georgia, on February 22, 2022.

Matthew N. Cathcart,

Manager, Operations Support Group Eastern Service Center, AJV–E2.

[FR Doc. 2022–04081 Filed 2–25–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0108; Airspace Docket No. 22–AAL–5]

RIN 2120–AA66

Proposed Revocation of Colored Federal Airway Blue 5 (B–5); Point Hope, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to revoke Colored Federal airway Blue 5 (B–5) in the vicinity of Point Hope, AK due to the pending decommissioning of the Point Hope, AK, (PHO) Non-directional Beacon (NDB).

DATES: Comments must be received on or before April 14, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1(800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2022–0108; Airspace Docket No. 22–AAL–5 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Christopher McMullin, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in

Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System (NAS).

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2022–0108; Airspace Docket No. 22–AAL–5) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2022–0108; Airspace Docket No. 22–AAL–5.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Western Service Center, Federal Aviation Administration, 2200 South 216th St., Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The North Slope Borough, AK has requested that the FAA decommission the Point Hope, AK, (PHO) NDB due to the high cost of continuous maintenance and repairs. The FAA conducted a non-rulemaking study in 2021 in accordance with FAA Order JO 7400.2, Procedures for Handling Airspace Matters. As a result of the study, the FAA did not receive any objections to the removal of the NDB along with the supported airway. PHO has been scheduled for decommissioning, effective February 23, 2023.

Colored Federal airway B–5 is dependent upon PHO and navigates between the Cape Lisburne, AK, (LUR) NDB and PHO. The decommissioning of PHO would result in B–5 being unusable. The loss of the airway would have little impact on the flying public and the FAA has plans to replace this route with a United States Area Navigation Route in the near future. Therefore, the FAA proposes to revoke B–5.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to revoke Colored Federal airway B–5 due to the decommissioning of PHO. B–5 currently navigates between LUR and PHO. The FAA proposes to revoke Colored Federal airway B–5 in its entirety.

Colored Federal airways are published in paragraph 6009(d) of FAA Order JO 7400.11F dated August 10, 2021 and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Blue Federal Airway listed in this document would be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6009(d) Colored Federal Airway.

* * * * *

B–5 [Remove]

* * * * *

Issued in Washington, DC, on February 22, 2022.

Michael R. Beckles,

Manager, Rules and Regulations Group.

[FR Doc. 2022–04067 Filed 2–25–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1079; Airspace Docket No. 21–ASO–15]

RIN 2120–AA66

Proposed Amendment and Removal of Air Traffic Service (ATS) Routes; Eastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental Notice of proposed rulemaking (SNPRM).

SUMMARY: This action adds the proposed amendment of jet route J–73 that was inadvertently omitted from the NPRM for Docket No. FAA–2021–1079. This action supports the VHF Omnidirectional Range (VOR) Minimum Operational Network (MON) program to improve the efficiency of the National Airspace System (NAS) and reduce dependency on ground-based navigational systems.

DATES: Comments must be received on or before April 14, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1(800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2021–1079; Airspace Docket No. 21–ASO–15 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC, 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the NAS.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2021–1079; Airspace Docket No. 21–ASO–15) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2021–1079; Airspace Docket No. 21–ASO–15.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists

Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–1079 in the **Federal Register** (86 FR 70771; December 13, 2021) to amend jet routes J–20, J–31, J–41, and J–73; and to remove J–69, and high altitude RNAV route Q–63. However, the details of the J–73 amendment were inadvertently left out of the NPRM. This SNPRM adds the amendment of J–73 to Docket No. FAA–2021–1079.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend jet route J–73 in the eastern United States. This action supports the FAA's VOR MON program.

The proposed route change is as follows:

J–73: J–73 currently extends between the La Grange, GA, (LGC) VOR and Tactical Air Navigational System (VORTAC) and the Northbrook, IL, (OBK) VOR/Distance Measuring Equipment (VOR/DME). This action proposes to remove the La Grange VORTAC, and the segment between La Grange and Nashville, TN, from the route. As amended, J–73 would extend from Nashville, TN; Pocket City, IN; to Northbrook, IL.

Jet routes are published in paragraph 2004 of FAA Order JO 7400.11F dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The jet route listed in this document would be subsequently amended in FAA Order JO 7400.11

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 14 CFR 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–73 [Amended]

From Nashville, TN; Pocket City, IN; to Northbrook, IL.

* * * * *

Issued in Washington, DC, on February 16, 2022.

Michael R. Beckles,

Manager, Rules and Regulations Group.

[FR Doc. 2022–04066 Filed 2–25–22; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0395; FRL–9563–01–R4]

Air Plan Approval; Kentucky; Emissions Statement Requirements for the 2015 8-Hour Ozone Standard Nonattainment Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted to EPA by the Commonwealth of Kentucky through the Kentucky Division for Air Quality (KDAQ) on October 15, 2020. The proposed changes were submitted by KDAQ to address the emissions statement requirements for the 2015 8-hour ozone national ambient air quality standards (NAAQS) for Kentucky counties in the Cincinnati, Ohio-Kentucky 2015 8-hour ozone NAAQS nonattainment area (Cincinnati, OH-KY Area), and for some of the Kentucky counties in the Louisville, Kentucky-Indiana 2015 8-hour ozone NAAQS nonattainment area (Louisville, KY-IN Area). Specifically, EPA is proposing to approve the emissions statement requirements for portions of Boone, Campbell, and Kenton Counties in the Cincinnati, OH-KY Area, and Bullitt and Oldham Counties in the Louisville, KY-IN Area. EPA will consider and take action, or has considered and taken action, on submissions addressing the emissions statement requirements for the remaining counties in these two nonattainment areas, including the Jefferson County, Kentucky portion of the Louisville, KY-IN Area, in separate rulemakings. EPA is proposing approval pursuant to the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before March 30, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2021–0395 at *www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written

comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Tiereny Bell, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9088. Ms. Bell can also be reached via electronic mail at *bell.tiereny@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On October 1, 2015, EPA promulgated a revised 8-hour primary and secondary ozone NAAQS, strengthening both from 0.075 parts per million (ppm) to 0.070 ppm (the 2015 8-hour Ozone NAAQS). *See* 80 FR 65292. The 2015 8-hour ozone NAAQS is set at 0.070 ppm based on an annual fourth-highest daily maximum 8-hour average concentration averaged over three years. Under EPA's regulations at 40 CFR part 50, the 2015 8-hour ozone NAAQS is attained when the 3-year average of the annual fourth-highest daily maximum 8-hour average ambient air quality ozone concentration is less than or equal to 0.070 ppm. *See* 40 CFR 50.19. Ambient air quality monitoring data for the 3-year period must meet a data completeness requirement. The ambient air quality monitoring data completeness requirement is met when the average percentage of days with valid ambient monitoring data is greater than 90 percent, and no single year has less than 75 percent data completeness as determined using Appendix U of part 50.

Upon promulgation of a new or revised ozone NAAQS, the CAA requires EPA to designate as nonattainment any area that is violating the NAAQS based on the three most recent years of ambient air quality data at the conclusion of the designation process. On June 4, 2018 (effective August 3, 2018), EPA designated the 7-county Cincinnati, OH-KY Area as a Marginal ozone nonattainment area for the 2015 8-hour ozone NAAQS.[1] Also on June 4, 2018 (effective August 3, 2018), EPA designated the 5-county Louisville, KY-IN Area as a Marginal ozone nonattainment area for the 2015 8-hour ozone NAAQS.[2] The Cincinnati, OH-KY Area and the Louisville, KY-IN Area were designated nonattainment for the 2015 8-hour Ozone NAAQS using 2014–2016 ambient air quality data. *See* 83 FR 25776.

On December 6, 2018, EPA finalized a rule entitled ''Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements'' (SIP Requirements Rule) that establishes the requirements that state, tribal, and local air quality management agencies must meet as they develop implementation plans for areas where air quality exceeds the 2015 8-hour ozone NAAQS.[3] *See* 83 FR 62998. This rule establishes nonattainment area attainment dates based on Table 1 of section 181(a) of the CAA, including an attainment date three years after the August 3, 2018, designation effective date, for areas classified as Marginal for the 2015 8-hour ozone NAAQS.

Ground level ozone is not emitted directly into the air but is created by chemical reactions between oxides of nitrogen (NO_X) and volatile organic compounds (VOC) in the presence of sunlight. Emissions from industrial facilities and electric utilities, motor vehicle exhaust, gasoline vapors, and chemical solvents are some of the major sources of NO_X and VOC. Section 182(a)(3)(B) of the CAA requires states with ozone nonattainment areas to submit a SIP revision requiring annual emissions statements to be submitted to the state by the owner or operator of each NO_X and VOC stationary source. However, a state may waive the emissions statement requirement for any class or category of stationary sources which emit less than 25 tons per year (tpy) of VOC or NO_X if the state provides an inventory of emissions as required by CAA section 182 that accounts for emissions from those sources. *See* CAA section 182(a)(3)(B)(ii). The first statement is due three years from the area's nonattainment designation, and subsequent statements are due at least annually thereafter.

Based on the nonattainment designation, Kentucky was required to develop a SIP revision satisfying, among other things, CAA section 182(a)(3)(B). On October 15, 2020,[4] Kentucky submitted a SIP revision addressing the emissions statement requirements related to the 2015 8-hour ozone NAAQS for the Kentucky portion of the Cincinnati, OH-KY Area and for Bullitt and Oldham Counties in the Kentucky portion of the Louisville, KY-IN Area. EPA is proposing to approve the October 15, 2020, SIP submittal as meeting the requirements of section 182(a)(3)(B) of the CAA and associated federal regulations. EPA's analysis of the SIP revision and how it addresses the emissions statement requirements is discussed in the next section of this notice.

II. Analysis of the Commonwealth's Submittal

As discussed above, section 182(a)(3)(B) of the CAA requires states to submit a SIP revision requiring the owner or operator of each NO_X and VOC stationary source located in an ozone nonattainment area to submit to the state annual emissions statements. The first statement is due three years from the area's nonattainment designation, and subsequent statements are due at least annually thereafter.

Due to previous nonattainment ozone designations, Kentucky has an existing emissions statement program. The October 15, 2020, SIP revision includes Kentucky's certification that the following SIP-approved regulations contain provisions that meet the emissions statement requirements of CAA section 182(a)(3)(B) for the 2015 8-hour ozone NAAQS and that the Commonwealth continues to operate under these approved provisions: 401 Kentucky Administrative Regulations (KAR) 52:020, Sections 22 and 23; 401

[1] The Cincinnati, OH-KY Area consists of the following counties: Boone (Partial), Campbell (Partial), Kenton (Partial), in Kentucky and the entire counties of Butler, Clermont, Hamilton, and Warren in Ohio. EPA has taken action on the 2015 8-hour ozone NAAQS nonattainment area emissions statement requirements for the entire counties of Butler, Clermont, Hamilton, and Warren in Ohio in a separate action. *See* 86 FR 12270 (March 3, 2021).

[2] The Louisville, KY-IN Area consists of Bullitt, Jefferson, and Oldham Counties in Kentucky and Clark and Floyd Counties in Indiana. EPA has proposed action on the 2015 8-hour ozone NAAQS emissions statement requirements for the Jefferson County, Kentucky portion of the Louisville, KY-IN area in a separate proposed rulemaking, *see* 87 FR 2101 (January 13, 2022), and will take action on the emissions statement requirements for Clark and Floyd Counties in Indiana in a separate rulemaking.

[3] The SIP Requirements Rule addresses a range of nonattainment area SIP requirements for the 2015 ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further progress, reasonably available control technology, reasonably available control measures, major new source review, emission inventories, and the timing of SIP submissions and compliance with emission control measures in the SIP.

[4] KDAQ's transmittal letter for the October 15, 2020, SIP revision was dated October 15, 2020, and submitted to EPA on October 16, 2020.

KAR 52:030, Sections 3 and 22; 401 KAR 52:040 Section 3; and 401 KAR 52:070 Section 3.[5] On January 28, 2016, EPA approved Kentucky's emissions statement program, which applies to sources located in ozone nonattainment areas.[6] *See* 81 FR 4896. The regulatory sections identified in the October 15, 2020 submittal require sources that emit 25 tons per year or more of VOC or NO_X within the Kentucky portion of the Cincinnati, OH-KY Area and the Kentucky portion of the Louisville, KY-IN Area, not including Jefferson County, to submit annual certified statements showing actual VOC and NO_X emissions. EPA has preliminarily determined that the specific regulatory sections identified in the October 15, 2020, submittal, collectively, coupled with the waiver for stationary sources emitting less than 25 tpy of NO_X or VOC discussed in the two paragraphs below, meet the emissions statement requirements of section 182(a)(3)(B).

As allowed by CAA section 182(a)(3)(B)(ii), Kentucky waived the emissions statement requirements for stationary sources emitting less than 25 tpy of NO_X or VOC. CAA section 182(a)(3)(B)(ii) allows a state to waive the application of emissions statements requirements to any class or category of stationary sources which emit less than 25 tons per year of VOC or NO_X if the state, in its submissions under section 182(a)(1) or 182(a)(3)(A), provides an inventory of emissions from such class or category of sources, based on the use of the emission factors established by the Administrator or other methods acceptable to the Administrator.

Pursuant to CAA section 182(a)(3)(A), Kentucky is required to submit a revised inventory meeting the requirements of section 182(a)(1) at the end of each 3-year period after submission of the inventory under section 182(a)(1) until the Cincinnati, OH-KY Area and the Louisville, KY-IN Area are redesignated to attainment. CAA section 182(a)(1) requires the submission of a comprehensive, accurate, current inventory of actual emissions from all sources, as described in CAA section 172(c)(3), in accordance with guidance provided by EPA.[7] To comply with CAA section 182(a)(3)(A)'s requirement to submit periodic emissions inventories, Kentucky submits NO_X and VOC emissions data to EPA's National Emissions Inventory (NEI)[8] consistent with 83 FR 62998, ''Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements,'' and 40 CFR 51.1315. That emissions data includes small stationary sources (namely, those emitting less than 25 tpy of NO_X or VOC) in accordance with CAA section 182(a)(3)(B)(ii).

For the reasons discussed above, EPA has preliminarily determined that Kentucky's emissions statement regulations meet the requirements under CAA section 182(a)(3)(B) and the SIP Requirements Rule for the 2015 8-hour ozone NAAQS for the entire Kentucky portion of the Cincinnati, OH-KY Area and the Bullitt County, Kentucky and Oldham County, Kentucky portion of the Louisville, KY-IN Area.

III. Proposed Action

EPA is proposing to approve Kentucky's October 15, 2020, SIP revision addressing the emissions statement requirements for the 2015 8-hour ozone NAAQS for portions of Boone, Campbell, and Kenton Counties in the Cincinnati, OH-KY 2015 8-hour ozone nonattainment area, and Bullitt and Oldham Counties in the Louisville, KY-IN 2015 8-hour ozone nonattainment area. EPA is proposing to find that the Commonwealth's submission meets the requirements of sections 110 and 182 of the CAA.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided they meet the criteria of the CAA. This action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed 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);
- 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 CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where 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 as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

[5] EPA notes that, in addition to the provisions identified in Kentucky's October 15, 2020, SIP revision, the following are also SIP-approved and apply to ozone nonattainment areas: the entirety of 401 KAR 52:030; and relevant provisions of 401 KAR 52:040, Sections 20 and 21. *See* 81 FR 4896 (January 28, 2016).

[6] EPA's 2016 approval of Kentucky's emissions statement program pertained to the Kentucky portion of the 2008 Cincinnati, OH-KY Area, but the Kentucky regulations approved in that 2016 action apply to all ozone nonattainment areas in Kentucky's jurisdiction, which include the counties and partial counties in the 2015 Cincinnati, OH-KY and Louisville, KY-IN Areas that are within Kentucky's jurisdiction.

[7] CAA section 172(c)(3) states, ''Such plan provisions shall include a comprehensive, accurate, current inventory of actual emissions from all sources of the relevant pollutant or pollutants in such area including such periodic revisions as the Administrator may determine necessary to assure that the requirements of this part are met.''

[8] To access EPA's NEI, please visit: U.S. EPA, *National Emissions Inventory (NEI), https://www.epa.gov/air-emissions-inventories/national-emissions-inventory-nei.*

Dated: February 17, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

[FR Doc. 2022–04112 Filed 2–25–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 3

[Docket Number—NIH–2020–0002]

RIN 0925–AA67

Conduct of Persons and Traffic on the National Institutes of Health Federal Enclave

AGENCY: National Institutes of Health, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or Department), through the National Institutes of Health (NIH), proposes to amend the existing regulation for the conduct of persons and traffic on the NIH enclave in Bethesda, Maryland, in order to update certain provisions of the regulation.

DATES: Comments must be received on or before April 29, 2022.

ADDRESSES: You may send comments, identified by Docket Number NIH–2020–0002 and/or RIN 0925–AA67 by any of the following methods:

Electronic Submissions

You may send comments electronically in the following way:

- *Federal rulemaking Portal: www.regulations.gov.* Follow the instructions for sending comments.

Written Submissions

You may send written comments in the following ways:

Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *Mail (for paper or CD–ROM submissions):* Daniel Hernandez, NIH Regulations Officer, National Institutes of Health, Office of Management Assessment, Rockledge 1, 6701 Rockledge Drive, Suite 601, Room 601–T, MSC 7901, Bethesda, Maryland 20817–7901.
- *Hand delivery/courier (for paper or CD–ROM submissions):* Daniel Hernandez, NIH Regulations Officer, National Institutes of Health, Office of Management Assessment, Rockledge 1, 6705 Rockledge Drive, Suite 601, Room 601–T, Room 601–T, MSC 7901, Bethesda, Maryland 20892–7901.

Instructions: All submissions received must include the agency name and docket number or Regulatory Identifier Number (RIN) for this Rulemaking. All comments will be posted without change to *www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to the eRulemaking Portal at *www.regulations.gov* and insert the docket number provided in brackets in the heading on page one of this document into the ''search'' box and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Daniel Hernandez, NIH Regulations Officer, Office of Management Assessment, NIH, Rockledge 1, 6705 Rockledge Drive, Suite 601, Room 601–T, Bethesda, MD 20817—MSC 7901, by email at *dhernandez@mail.nih.gov,* or by telephone at 301–435–3343 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

1. Background

On November 16, 2020, the Department of Health and Human Services (HHS or Department) issued a direct final rule (85 FR 72899–72912) amending certain regulations, as part of its Regulatory Clean Up Initiative, to make miscellaneous corrections, including correcting references to other regulations, misspellings and other typographical errors. These corrections included changes to the regulation codified at 45 CFR part 3 concerning the conduct of persons and traffic on the National Institutes of Health Federal Enclave. With this notice of proposed rulemaking (NPRM), the Department proposes to make several additional changes to 45 CFR part 3 that are necessary to further update the regulation. These additional changes were determined to be necessary following the review of the regulation conducted by NIH in 2019.

2. Summary of Proposed Changes

With this NPRM, we propose to make several changes to the regulation at 45 CFR part 3 concerning the conduct of persons and traffic on the National Institutes of Health Federal Enclave that are necessary to ensure the regulation is up-to-date.

Specifically, in Subpart A of the regulation, we propose to amend section 3.4 by removing the last sentence that specifies the Police Office's main location and telephone number. The NIH Police Department may be relocated in the future under the current campus master plan. Removing the sentence will eliminate the need in the future to amend the regulation any time the NIH Police Department is relocated.

In Subpart C of the regulation, we propose to amend section 3.42 by revising the last sentence of paragraph (b) to update several terms. The existing last sentence states that the use of a dog by a handicapped person to assist that person is authorized. NIH proposes to update this sentence by replacing the term ''dog'' with the term ''service animal''. NIH also proposes to update this sentence by removing the term ''handicapped person'' and replacing it with the term ''a person with a disability'' to reflect current and accepted use of the term. The proposed revised sentence is ''The use of a service animal by a person with a disability to assist that person is authorized.''

Additionally, in Subpart C, we propose to amend section 3.42 by revising paragraph (f) to state that except as part of an approved medical research protocol a person may not smoke on the enclave. The existing language does not prohibit smoking outside of buildings on the enclave. As a tobacco-free campus, NIH does not allow smoking inside or outside buildings. The proposed change makes this clear in the regulation.

In Subpart D, we propose to amend section 3.61 by revising paragraph (a) to state that a person found guilty of violating any provision of the regulations in this part is subject to a fine or imprisonment of not more than thirty days or both, for each violation (U.S. Pub. L. 107–296, Homeland Security Act of 2002). The existing language states that a person found guilty of violating any provision of the regulation is subject to a fine of not more that $50 or imprisonment, or both for each violation. The dollar amount of fines can increase at any time. In fact, the current fine amount is more than $50. Not stating a specific dollar amount for the fine in paragraph (a) will eliminate any future need to amend the regulation when incremental increases in the fine amount occur. Information about fines is publicly available.

The purpose of this NPRM is to invite comment concerning these proposed actions. We provide the following as public information,

Regulatory Impact Analysis

We have examined the impacts of this proposed rule under Executive Order (E.O.) 12866, Regulatory Planning and Review; E.O. 13563, Improving Regulation and Regulatory Review; and E.O. 13132, Federalism; 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

E.O. 12866, Regulatory Planning and Review, and E.O. 13563, Improving Regulation and Regulatory Review, direct Federal 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) for all significant regulatory actions. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). Based on our analysis, we believe the proposed rulemaking does not constitute a significant or economically significant regulatory action.

Executive Order 13132

Executive Order 13132, Federalism, requires Federal agencies to consult with State and local government officials in the development of regulatory policies and with federalism implications. We have reviewed the proposed rule as required under the Order and have determined that it will not have a significant potential negative impact on States, in the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government does not have any federalism implications. The Secretary asserts that this proposed rule will not have effect on the States or on the distribution of power and responsibilities among the various levels of government.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Federal agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. For the purpose of this analysis, small entities include small business concerns as defined by the Small Business Administration (SBA), usually businesses with fewer than 500 employees. The Secretary asserts that the proposed rule will not create a significant economic impact on a substantial number of small entities, and therefore a regulatory flexibility analysis, is not required.

Unfunded Mandates Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires Federal agencies 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 organizations, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation with base year of 1995) in any one year.'' The current inflation-adjusted statutory threshold is approximately $156 million based on the Bureau of Labor Statistics inflation calculator. This rule will not result in a one-year expenditure that would meet or exceed that amount.

Paperwork Reduction Act

This proposed rule does not contain any information collection requirements which are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

List of Subjects in 45 CFR Part 3

Conduct, Federal buildings and facilities, Government property, Traffic regulations, Firearms.

For reasons presented in the preamble, it is proposed to amend title 45 of the Code of Federal Regulations by revising Part 3, as set forth below.

PART 3—CONDUCT OF PERSONS AND TRAFFIC ON THE NATIONAL INSITUTES OF HEALTH FEDERAL ENCLAVE

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

Authority: 40 U.S.C. 318–318d. 486; Delegation of Authority, 33 FR 604.

§ 3.4 [Amended]

■ 2. Amend § 3.4 by removing the last sentence of the paragraph.

■ 3. Amend § 3.42 by revising the last sentence in paragraph (b) and paragraph (f) to read as follows:

§ 3.42 Restricted activities.

* * * * *

(b) * * * The use of a service animal by a person with a disability to assist that person is authorized.

* * * * *

(f) *Smoking.* Except as part of an approved medical research protocol, a person may not smoke on the enclave.

* * * * *

■ 4. Amend § 3.61 by revising paragraph (a) to read as follows:

§ 3.61 Penalties.

(a) A person found guilty of violating any provision of the regulations in this part is subject to a fine or imprisonment of not more than thirty days or both, for each violation (U.S. Pub. L. 107–296, Homeland Security Act of 2002).

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–02859 Filed 2–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 225, and 252

[Docket DARS–2022–0003]

RIN 0750–AL18

Defense Federal Acquisition Regulation Supplement: United States-Mexico-Canada Agreement (DFARS Case 2020–D032)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement the United States-Mexico-Canada Agreement Implementation Act.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before May 27, 2022, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2020–D032, using any of the following methods:

○ *Federal eRulemaking Portal: https://www.regulations.gov.* Search for ''DFARS Case 2020–D032.'' Select ''Comment'' and follow the instructions to submit a comment. Please include ''DFARS Case 2020–D032'' on any attached documents.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2020–D032 in the subject line of the message.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Bass, telephone 571–372–6174.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is issuing a proposed rule to amend the DFARS to implement the United States-Mexico-Canada Agreement Implementation Act (Pub. L. 116–113). On November 30, 2018, the Governments of the United States, Mexico, and Canada (the parties) signed the protocol replacing the North American Free Trade Agreement (NAFTA) with the United States-Mexico-Canada Agreement (USMCA). On December 10, 2019, the parties signed the protocol of amendment to the USMCA. On January 29, 2020, the President signed into law the United States-Mexico-Canada Agreement Implementation Act, through which Congress approved the USMCA. On July 1, 2020, the USMCA entered into effect.

II. Discussion and Analysis

A. Chapter 13 of the USMCA

The USMCA supersedes the NAFTA. Chapter 13 (Government Procurement) of the USMCA applies only to the United States and Mexico. Therefore, Canada is no longer a Free Trade Agreement country, although Canada is still a designated country under the World Trade Organization Government Procurement Agreement (WTO GPA). Chapter 13 of the USMCA sets forth certain obligations between the United States and Mexico with respect to government procurement of goods and services, as specified in Annex 13–A of the USMCA.

This proposed rule is required to meet the United States trade obligations to Mexico and remove any trade benefits that no longer should accrue to Canada. Therefore, all references in the DFARS to Canada as a Free Trade Agreement country are revised to delete Canada and its associated Free Trade Agreement threshold of $25,000. The new minimum Free Trade Agreement threshold is now $92,319. Mexico thresholds remain unchanged.

B. Chapter 20 of the USMCA

Chapter 20 of the USMCA addresses intellectual property rights. The requirements of Federal Acquisition Regulation (FAR) 27.204–1, Patented technology under the NAFTA, and the associated emergency acquisition flexibility at FAR 18.120 are no longer applicable or authorized. FAR case 2020–014, United States-Mexico-Canada Agreement, is currently in process to address required changes to the FAR to implement the USMCA. DoD contracting officers should consult with legal counsel concerning questions that may arise with regard to the use of patented technology under the USMCA. Any potential impacts with regard to the USMCA to DFARS part 218, Emergency Acquisitions, and DFARS part 227, Patents, Data, and Copyrights, will be addressed with further rulemaking.

C. Implementation of the USMCA in the DFARS

Part 212

The proposed rule deletes all references to 19 U.S.C. 3301 note associated with the implementation of NAFTA in DFARS 212.301.

Part 225

The $25,000 Free Trade Agreement threshold for Canada is no longer applicable. The proposed rule deletes all references to the $25,000 threshold in its entirety in the clause prescriptions at DFARS 225.1101, Acquisition of supplies.

Part 252

All references to Free Trade Agreement countries are revised to delete Canada and remove the $25,000 threshold, replacing it with the Free Trade Agreement minimum threshold of $92,319. Contracting officers will be required to use the revised provisions and clauses as prescribed that reflect the USMCA requirements. Proposed revisions are as follows:

DFARS 252.225–7013, Duty-Free Entry. Revises the definition of ''eligible product'' to delete the reference to Canadian end products or devices.

DFARS 252.225–7017, Photovoltaic Devices, and DFARS 252.225–7018, Photovoltaic Devices—Certificate. Removes the definition of ''Canadian photovoltaic device'' as it no longer applies in both the clause and provision. Deletes Canada as a Free Trade Agreement country from the definition of ''designated country'' and from the definition of ''Free Trade Agreement country'' in DFARS 252.225–7017. Conforming changes made to remove the associated $25,000 threshold for Canada, replacing it with the Free Trade Agreement minimum threshold of $92,319 in both the clause and provision.

DFARS 252.225–7021, Trade Agreements. In the basic clause and in alternate II, removes Canada as a Free Trade Agreement country from the definition of ''designated country''. Editorial change made to redesignate paragraph numbers in paragraph (a) definitions to conform to current drafting conventions.

DFARS 252.225–7035, Buy American—Free Trade Agreements—Balance of Payments Program Certificate. In the basic provision and alternates I, II, III, IV, and V, removes all references to Canadian end products and the ''Canadian end product'' definition in alternates I and III with conforming changes.

DFARS 252.225–7036, Buy American—Free Trade Agreements—Balance of Payments Program. In the basic clause and alternates I, II, III, IV, and V, removes Canada from the definition of ''Free Trade Agreement country'' and removes the definition for ''Canadian end product'' from alternates I and II, with conforming changes. Editorial changes made to redesignate paragraph numbers in paragraph (a) definitions to conform to current drafting conventions.

DFARS 252.225–7045, Balance of Payments Program—Construction Material Under Trade Agreements. In the basic clause and alternates I, II, and III, removes references to Canada in the ''designated country'' definition as a ''Free Trade Agreement country''; removes ''NAFTA'' and replaces it with references to ''USMCA'' in alternates I and III in accordance with the implementation of the Balance of Payments Program. Editorial changes made to redesignate paragraph numbers in paragraph (a) definitions to conform to current drafting conventions.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products Including Commercially Available Off-the-Shelf (COTS) Items, and for Commercial Services

This rule amends the clauses at DFARS 252.225–7013, Duty-Free Entry; DFARS 252.225–7017, Photovoltaic Devices; DFARS 252.225–7021, Trade Agreements (Basic and Alternate II); DFARS 252.225–7036, Buy American—Free Trade Agreements—Balance of Payments Program (Basic and Alternates I (with the prescription), II, III (with the prescription), IV, V); 252.225–7045, Balance of Payments Program—Construction Material Under Trade Agreements (Basic and Alternates I, II, and III); and provisions at DFARS 252.225–7018 Photovoltaic Devices—Certificate; 252.225–7035 Buy American—Free Trade Agreements—Balance of Payments Program Certificate (Basic and Alternate I, II, III (with the prescription). This rule does not impose any new requirements on contracts at or below the simplified acquisition threshold, for commercial products including commercially available off-the-shelf items, or for commercial services.

IV. Expected Impact of the Rule

The rule implements the United States-Mexico-Canada Agreement Implementation Act. The USMCA supersedes the NAFTA. Canada is still a designated country under the World Trade Organization Government Procurement Agreement; however, Canada is no longer a Free Trade Agreement country, because chapter 13 (Government Procurement) of the USMCA applies only to the United States and Mexico. References to Canada as a Free Trade Agreement country in the DFARS are deleted, including the $25,000 threshold. Canadian end products will still receive nondiscriminatory treatment with respect to the Buy American statute but starting at $183,000 rather than $25,000. Impacts are anticipated to be negligible, since Canada remains a WTO GPA designated country, and a qualifying country, with a threshold of $183,000. The Mexico thresholds remain unchanged.

V. 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.

VI. 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 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**. This rule is not anticipated to be a major rule under 5 U.S.C. 804.

VII. Regulatory Flexibility Act

DoD does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq*. Nevertheless, an initial regulatory flexibility analysis has been performed consistent with 5 U.S.C. 603 and summarized as follows:

The proposed rule implements the United States-Mexico-Canada Agreement Implementation Act (Pub. L. 116–113). On November 30, 2018, the Governments of the United States, Mexico, and Canada (the parties) signed the protocol replacing NAFTA with the United States-Mexico-Canada Agreement (USMCA). On December 10, 2019, the parties signed the protocol of amendment to the USMCA. On January 29, 2020, the President signed into law the United States-Mexico-Canada Agreement Implementation Act, through which Congress approved the USMCA. On July 1, 2020, the USMCA entered into effect.

The objective of this rule is to implement the USMCA Implementation Act. The proposed rule includes changes in the Defense Federal Acquisition Regulation Supplement (DFARS) to conform to chapter 13 of the USMCA, which sets forth certain obligations between the United States and Mexico with respect to government procurement of goods and services, as specified in Annex 13–A of the USMCA. Chapter 13 of the USMCA applies only between Mexico and the United States and does not cover Canada.

Although Canada is still a designated country under the World Trade Organization Government Procurement Agreement (WTO GPA), Canada is no longer a Free Trade Agreement country, because chapter 13 of the USMCA applies only to the United States and Mexico. Therefore, references to Canada as a Free Trade Agreement country in the DFARS are deleted, including the $25,000 threshold. Canadian end products will still receive nondiscriminatory treatment with respect to the Buy American statute but starting at $183,000 rather than the threshold of $25,000. Mexico thresholds remain unchanged.

The proposed rule removes all references to the NAFTA, replacing them with the new USMCA language, including statutory references. All references to Canadian end products or Canadian photovoltaic devices also are removed.

The legal basis for the rule is Public Law 116–113.

This rule is not expected to have a significant economic impact on small entities. Although the rule removes Canada as a Free Trade Agreement designated country and deletes the associated $25,000 threshold, replacing it with the free trade agreement minimum threshold of $92,319, Canada remains a WTO GPA designated country, and a qualifying country, with a threshold of $183,000. The Mexico thresholds remain unchanged. Contracting officers will be required to use the revised provisions and clauses as prescribed that reflect the USMCA requirements.

Based on fiscal year 2019 data from the Federal Procurement Data System, 22,050 unique small entities were awarded DoD contracts. Impacts to small businesses are anticipated to be negligible, since Canada remains a WTO GPA designated country, and a qualifying country, with a threshold of $183,000, and the Mexico thresholds remain unchanged.

This proposed rule does not include any new reporting, recordkeeping, or other compliance requirements for small entities. The rule does not impose additional information collection requirements to the paperwork burden previously approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. chapter 35), Control Number 0704–0229, DFARS part 225, Foreign Acquisition, and Related Clauses at 252.225; DD Form 2139.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known significant alternative approaches to the rule that would meet the requirements of the USMCA Implementation Act.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2020–D032), in correspondence.

VIII. Paperwork Reduction Act

The rule affects information collection requirements in the provisions at 252.225–7018, Photovoltaic Devices—Certificate, and 252.225–7035, Buy American—Free Trade Agreements—Balance of Payments Program Certificate; and the clauses at 252.225–7013, Duty-Free Entry, and 252.225–7021, Alternate II, Trade Agreements, currently approved under OMB Control Number 0704–0229 in accordance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The impact, however, is negligible because the rule merely removes Canada as a Free Trade Agreement country.

List of Subjects in 48 CFR Parts 212, 225, and 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212, 225, and 252 are proposed to be amended as follows:

■ 1. The authority citation for 48 CFR parts 212, 225, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

212.301 [Amended]

■ 2. Amend section 212.301 in paragraphs (f)(ix)(M) introductory text, (f)(ix)(N) introductory text, (f)(ix)(V) introductory text, and (f)(ix)(W) introductory text by removing ''3301 note'' and adding ''4501–4732'' wherever it appears.

PART 225—FOREIGN ACQUISITION

225.1101 [AMENDED]

■ 3. Amend section 225.1101 in paragraphs (10)(i) introductory text and (10)(i)(B) and (D) by removing the term ''equals or exceeds $25,000, but''.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Amend section 252.225–7013 by—
■ a. Revising the section heading and date of the clause; and
■ b. In paragraph (a), revising the definition of ''Eligible product''.

The revisions read as follows:

252.225–7013 Duty-Free Entry.

* * * * *

Duty-Free Entry (Date)

(a) * * *

Eligible product means—

(1) *Designated country end product,* as defined in the Trade Agreements (either basic or alternate) clause of this contract;

(2) *Free Trade Agreement country end product,* other than a *Bahrainian end product,* a *Moroccan end product,* a *Panamanian end product,* or a *Peruvian end product,* as defined in the Buy American—Free Trade Agreements—Balance of Payments Program (either basic or alternate II) clause of this contract; or

(3) *Free Trade Agreement country end product* other than a *Bahrainian end product, Korean end product, Moroccan end product, Panamanian end product,* or *Peruvian end product,* as defined in the Buy American—Free Trade Agreements—Balance of Payments Program (either alternate IV or alternate V) clause of this contract.

* * * * *

■ 5. Amend section 252.225–7017 by—
■ a. Revising the date of the clause;
■ b. In paragraph (a)—
■ i. Removing the definition of ''Canadian photovoltaic device''; and
■ ii. In the definitions of ''Designated country'', paragraph (2), and ''Free Trade Agreement country'' removing ''Canada,'';
■ c. In paragraph (c)(1), removing ''$25,000'' and adding ''$92,319'' in its place;
■ d. Removing paragraph (c)(2); and
■ e. Redesignating paragraphs (c)(3), (4), and (5) as paragraphs (c)(2), (3), and (4).

The revision reads as follows:

252.225–7017 Photovoltaic Devices.

* * * * *

Photovoltaic Devices (Date)

* * * * *

252.225–7018 [Amended]

■ 6. Amend section 252.225–7018 by—
■ a. Revising the date of the provision;
■ b. In paragraph (a), removing ''Canadian photovoltaic device,'';
■ c. In paragraph (c), removing ''$25,000'' and adding ''$92,319'' in its place;
■ d. In paragraph (d)(2) introductory text, removing ''$25,000'' and adding ''$92,319'' in its place; and
■ e. Revising paragraph (d)(3).

The revisions read as follows:

252.225–7018 Photovoltaic Devices—Certificate.

* * * * *

Photovoltaic Devices—Certificate (Date)

* * * * *

(d) * * *

(3) If less than $92,319—

____(i) The offeror certifies that each photovoltaic device to be utilized in performance of the contract is a domestic photovoltaic device;

____(ii) The offeror certifies that each photovoltaic device to be utilized in performance of the contract is a qualifying country photovoltaic device *[Offeror to specify country of origin ____];* or

____(iii) The foreign photovoltaic devices to be utilized in performance of the contract are the product of ____. *[Offeror to specify country of origin, if known, and provide documentation that the cost of a domestic photovoltaic device would be unreasonable in comparison to the cost of the proposed foreign photovoltaic device, i.e. that the price of the foreign photovoltaic device plus 50 percent is less than the price of a comparable domestic photovoltaic device.]*

* * * * *

■ 7. Amend section 252.225–7021 by—
■ a. Revising the section heading and date of the clause;
■ b. In paragraph (a)—
■ i. In the definition of ''Caribbean Basin Country end product'', redesignating paragraphs (i) introductory text, (i)(A) and (B), (ii) introductory text, and (ii)(A), (B), and (C) as paragraphs (1) introductory text, (1)(i) and (ii), (2) introductory text, and (2)(i), (ii), and (iii), respectively;
■ ii. In the definition of ''Commercially available off-the-shelf (COTS) item'', redesignating paragraphs (i) introductory text, (i)(A), (B), and (C), and (ii) as paragraphs (1) introductory text, (1)(i), (ii), and (iii), and (2), respectively;
■ iii. In the definition of ''Designated country'', redesignating paragraphs (i) through (iv) as paragraphs (1) through (4), respectively; and in the newly redesignated paragraph (2), removing ''Canada,'';
■ iv. In the definitions of ''Free Trade Agreement country end product'' and ''Least developed country end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ v. In the definition of ''Qualifying country end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*), (*2*), and (*3*), and (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A), (B), and (C), and (2)(ii), respectively; and
■ vi. In the definitions of ''U.S.-made end product'' and ''WTO GPA country end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ c. In paragraph (e) introductory text, removing ''on the Internet''; and
■ d. In Alternate II—
■ i. Revising the date of the clause;
■ ii. In paragraph (a)—
■ A. In the definition of ''Caribbean Basin Country end product'', redesignating paragraphs (i) introductory text, (i)(A) and (B), (ii) introductory text, and (ii)(A), (B), and (C) as paragraphs (1) introductory text, (1)(i) and (ii), (2) introductory text, and (2)(i), (ii), and (iii), respectively;
■ B. In the definition of ''Commercially available off-the-shelf (COTS) item'', redesignating paragraphs (i) introductory text, (i)(A), (B), and (C), and (ii) as paragraphs (1) introductory text, (1)(i), (ii), and (iii), and (2), respectively;

■ C. In the definition of ''Designated country'', redesignating paragraphs (i) through (iv) as paragraphs (1) through (4), respectively; and in the newly redesignated paragraph (2), removing ''Canada,'';
■ D. In the definitions of ''Free Trade Agreement country end product'' and ''Least developed country end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ E. In the definition of ''Qualifying country end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*), (*2*), and (*3*), and (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A), (B), and (C), and (2)(ii), respectively; and
■ F. In the definitions of ''South Caucasus/Central and South Asian (SC/CASA) state end product'', ''U.S.-made end product'', and ''WTO GPA country end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively; and
■ iii. In paragraph (f) introductory text, removing ''on the Internet''.

The revisions read as follows:

252.225–7021 Trade Agreements.

* * * * *

Trade Agreements—Basic (Date)

* * * * *

Trade Agreements–Alternate II (Date)

* * * * *

■ 8. Amend section 252.225–7035 by—
■ a. Revising the provision date;
■ b. In paragraph (b)(1), removing ''Part'' and adding ''part'' in its place;
■ c. In paragraph (c)(2)(i), removing ''or Canadian'';
■ d. In Alternate I—
■ i. Revising the introductory text and the provision date;
■ ii. In paragraph (a)—
■ A. Removing ''Canadian end product,'';
■ B. Removing ''commercially available off-the-shelf (COTS) item'' and adding ''Commercially available off-the-shelf (COTS) item'' in its place;
■ iii. In paragraph (b)(2), removing ''or Canadian end products''; and
■ iv. Revising paragraph (c)(2);
■ e. In Alternate II—
■ i. Revising the provision date; and
■ ii. In paragraph (c)(2)(i), removing ''or Canadian'';
■ f. In Alternate III—
■ i. Revising the provision date;
■ ii. In paragraph (a)—
■ A. Removing ''Canadian end product,'';
■ B. Removing ''commercially available off-the-shelf (COTS) item'' and adding ''Commercially available off-the-shelf (COTS) item'' in its place;
■ iii. In paragraph (b)(2), removing ''or Canadian end products''; and
■ iv. In paragraph (c)(2)(i), removing ''(except Canadian)'';
■ g. In Alternate IV—
■ i. Revising the provision date; and
■ ii. In paragraph (c)(2)(i), removing ''or Canadian''; and
■ h. In Alternate V—
■ i. Revising the provision date; and
■ ii. In paragraph (c)(2)(i), removing ''or Canadian''.

The revisions read as follows:

252.225–7035 Buy American—Free Trade Agreements—Balance of Payments Program Certificate.

* * * * *

Buy American—Free Trade Agreements—Balance of Payments Program Certificate—Basic (Date)

* * * * *

Alternate I. As prescribed in 225.1101(9) and (9)(ii), use the following provision, which does not use the phrases *Bahrainian end product, Free Trade Agreement country, Free Trade Agreement country end product, Moroccan end product, Panamanian end product,* and *Peruvian end products* in paragraph (a) of the basic provision; does not use ''Free Trade Agreement country end products other than Bahrainian end products, Moroccan end products, Panamanian end products, or Peruvian end products'' in paragraphs (b)(2) and (c)(2)(ii) of the basic provision; and does not use ''Australian or'' in paragraph (c)(2)(i):

Buy American—Free Trade Agreements—Balance of Payments Program Certificate—Alternate I (Date)

* * * * *

(c) * * *

(2) The offeror shall identify all end products that are not domestic end products.

(i) The offeror certifies that the following supplies are qualifying country end products:

(*Line Item Number*) (*Country of Origin*)

(ii) The following supplies are other foreign end products, including end products manufactured in the United States that do not qualify as domestic end products, *i.e.,* an end product that is not a COTS item and does not meet the component test in paragraph (ii) of the definition of ''domestic end product'':

(*Line Item Number*) (*Country of Origin (If known)*)

* * * * *

Buy American—Free Trade Agreements—Balance of Payments Program Certificate—Alternate II (Date)

* * * * *

Buy American—Free Trade Agreements—Balance of Payments Program Certificate—Alternate III (Date)

* * * * *

Buy American—Free Trade Agreements—Balance of Payments Program Certificate—Alternate IV (Date)

* * * * *

Buy American—Free Trade Agreements—Balance of Payments Program Certificate—Alternate V (Date)

* * * * *

■ 9. Amend section 252.225–7036 by—
■ a. Revising the clause date;
■ b. In paragraph (a)—
■ i. In the definition of ''Bahrainian end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ ii. In the definition of ''Commercially available off-the-shelf (COTS) item'', redesignating paragraphs (i) introductory text, (i)(A), (B), and (C), and (ii) as paragraphs (1) introductory text, (1)(i), (ii), and (iii), and (2), respectively;
■ iii. In the definition of ''Domestic end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*) and (*2*), (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A) and (B), and (2)(ii);
■ iv. In the definition of ''Free Trade Agreement country'', removing ''Canada,'';
■ v. In the definitions of ''Free Trade Agreement country end product'', ''Moroccan end product'', ''Panamanian end product'', and ''Peruvian end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively; and
■ vi. In the definition of ''Qualifying country end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*), (*2*), and (*3*), and (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A), (B), and (C), and (2)(ii), respectively;
■ c. In Alternate I—
■ i. Revising the introductory text and the clause date;
■ ii. In paragraph (a)—
■ A. In the definition of ''Bahrainian end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;

■ B. Removing the definition of ''Canadian end product'';
■ C. In the definition of ''Commercially available off-the-shelf (COTS) item'', redesignating paragraphs (i) introductory text, (i)(A), (B), and (C), and (ii) as paragraphs (1) introductory text, (1)(i), (ii), and (iii), and (2), respectively;
■ D. In the definition of ''Domestic end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*) and (*2*), (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A) and (B), and (2)(ii);
■ E. In the definition of ''Free Trade Agreement country'', removing ''Canada,'';
■ F. In the definitions of ''Free Trade Agreement country end product'', ''Moroccan end product'', ''Panamanian end product'', and ''Peruvian end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively; and
■ G. In the definition of ''Qualifying country end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*), (*2*), and (*3*), and (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A), (B), and (C), and (2)(ii), respectively; and iii. In paragraph (c), removing '', Canadian'', ''or a Canadian end product'', and '', a Canadian end product,'';
■ d. In Alternate II—
■ i. Revising the clause date; and
■ ii. In paragraph (a)—
■ A. In the definition of ''Bahrainian end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ B. In the definition of ''Commercially available off-the-shelf (COTS) item'', redesignating paragraphs (i) introductory text, (i)(A), (B), and (C), and (ii) as paragraphs (1) introductory text, (1)(i), (ii), and (iii), and (2), respectively;
■ C. In the definition of ''Domestic end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*) and (*2*), (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A) and (B), and (2)(ii);
■ D. In the definition of ''Free Trade Agreement country'', removing ''Canada,'';
■ E. In the definitions of ''Free Trade Agreement country end product'', ''Moroccan end product'', ''Panamanian end product'', and ''Peruvian end product'' redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ F. In the definition of ''Qualifying country end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*), (*2*), and (*3*), and (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A), (B), and (C), and (2)(ii), respectively; and
■ G. In the definition of ''South Caucasus/Central and South Asian (SC/CASA) state end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ e. In Alternate III—
■ i. Revising the introductory text and the clause date;
■ ii. In paragraph (a)—
■ A. In the definition of ''Bahrainian end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ B. Removing the definition of ''Canadian end product'';
■ C. In the definition of ''Commercially available off-the-shelf (COTS) item'', redesignating paragraphs (i) introductory text, (i)(A), (B), and (C), and (ii) as paragraphs (1) introductory text, (1)(i), (ii), and (iii), and (2), respectively;
■ D. In the definition of ''Domestic end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*) and (*2*), (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A) and (B), and (2)(ii);
■ E. In the definition of ''Free Trade Agreement country'', removing ''Canada,'';
■ F. In the definitions of ''Free Trade Agreement country end product'', ''Moroccan end product'', ''Panamanian end product'', and ''Peruvian end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ G. In the definition of ''Qualifying country end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*), (*2*), and (*3*), and (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A), (B), and (C), and (2)(ii), respectively; and
■ H. In the definition of ''South Caucasus/Central and South Asian (SC/CASA) state end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively; and
■ iii. Revising paragraph (c);
■ f. In Alternate IV—
■ i. Revising the clause date; and
■ ii. In paragraph (a)—
■ A. In the definition of ''Bahrainian end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ B. In the definition of ''Commercially available off-the-shelf (COTS) item'', redesignating paragraphs (i) introductory text, (i)(A), (B), and (C), and (ii) as paragraphs (1) introductory text, (1)(i), (ii), and (iii), and (2), respectively;
■ C. In the definition of ''Domestic end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*) and (*2*), (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A) and (B), and (2)(ii);
■ D. In the definition of ''Free Trade Agreement country'', removing ''Canada,'';
■ E. In the definitions of ''Free Trade Agreement country end product'', ''Korean end product'', ''Moroccan end product'', ''Panamanian end product'', and ''Peruvian end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively; and
■ F. In the definition of ''Qualifying country end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*), (*2*), and (*3*), and (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A), (B), and (C), and (2)(ii), respectively; and
■ g. In Alternate V—
■ i. Revising the clause date; and
■ ii. In paragraph (a)—
■ A. In the definition of ''Bahrainian end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ B. In the definition of ''Commercially available off-the-shelf (COTS) item'', redesignating paragraphs (i) introductory text, (i)(A), (B), and (C), and (ii) as paragraphs (1) introductory text, (1)(i), (ii), and (iii), and (2), respectively;
■ C. In the definition of ''Domestic end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*) and (*2*), and (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A) and (B), and (2)(ii), respectively;
■ D. In the definition of ''Free Trade Agreement country'', removing ''Canada,'';
■ E. In the definitions of ''Free Trade Agreement country end product'', ''Korean end product'', ''Moroccan end product'', ''Panamanian end product'', and ''Peruvian end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ F. In the definition of ''Qualifying country end product'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) introductory text, (ii)(A)(*1*), (*2*), and (*3*), and (ii)(B) as paragraphs (1), (2) introductory text, (2)(i) introductory text, (2)(i)(A), (B), and (C), and (2)(ii), respectively; and

■ G. In the definition of ''South Caucasus/Central and South Asian (SC/CASA) state end product'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively.

The revisions read as follows:

252.225–7036 Buy American—Free Trade Agreements—Balance of Payments Program.

* * * * *

Buy American—Free Trade Agreements—Balance of Payments Program—Basic (Date)

* * * * *

Alternate I. As prescribed in 225.1101(10)(i) and (10)(i)(B), use the following clause, which uses a different paragraph (c) than the basic clause:

Buy American—Free Trade Agreements—Balance of Payments Program—Alternate I (Date)

* * * * *

Buy American—Free Trade Agreements—Balance of Payments Program—Alternate II (Date)

* * * * *

Alternate III. As prescribed in 225.1101(10)(i) and (10)(i)(D), use the following clause, which adds *South Caucasus/Central and South Asian (SC/CASA) state* and *South Caucasus/Central and South Asian (SC/CASA) state end product* to paragraph (a) and uses a different paragraph (c) than the basic clause:

Buy American—Free Trade Agreements—Balance of Payments Program—Alternate III (Date)

* * * * *

(c) The Contractor shall deliver under this contract only domestic end products unless, in its offer, it specified delivery of qualifying country end products, SC/CASA state end products, or other foreign end products in the Buy American—Free Trade Agreements—Balance of Payments Program Certificate—Alternate III provision of the solicitation. If the Contractor certified in its offer that it will deliver a qualifying country end product or SC/CASA state end products, the Contractor shall deliver a qualifying country end product, an SC/CASA state end product, or, at the Contractor's option, a domestic end product.

* * * * *

Buy American—Free Trade Agreements—Balance of Payments Program—Alternate IV (Date)

* * * * *

Buy American—Free Trade Agreements—Balance of Payments Program—Alternate V (Date)

* * * * *

■ 10. Amend section 252.225–7045 by—
■ a. Revising the clause date;
■ b. In paragraph (a)—
■ i. In the definition of ''Caribbean Basin country construction material'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ ii. In the definition of ''Commercially available off-the-shelf (COTS) item'', redesignating paragraphs (i) introductory text, (i)(A), (B), and (C), and (ii) as paragraphs (1) introductory text, (1)(i), (ii), and (iii), and (2), respectively;
■ iii. In the definition of ''Cost of components'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ iv. In the definition of ''Designated country'', redesignating paragraphs (i), (ii), (iii), and (iv) as paragraphs (1), (2), (3), and (4), respectively; and in the newly redesignated paragraph (2), removing ''Canada,'';
■ iv. In the definition of ''Domestic construction material'', redesignating paragraphs (i), (ii) introductory text, and (ii)(A) and (B) as paragraphs (1), (2) introductory text, and (2)(i) and (ii), respectively; and
■ v. In the definitions of ''Free Trade Agreement country construction material'', ''Least developed country construction material'', and ''WTO GPA country construction material'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ c. In Alternate I—
■ i. Revising the clause date;
■ ii. In paragraph (a)—
■ A. In the definitions of ''Bahrainian or Mexican construction material'' and ''Caribbean Basin country construction material'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ B. In the definition of ''Commercially available off-the-shelf (COTS) item'', redesignating paragraphs (i) introductory text, (i)(A), (B), and (C), and (ii) as paragraphs (1) introductory text, (1)(i), (ii), and (iii), and (2), respectively;
■ C. In the definition of ''Cost of components'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ D. In the definition of ''Designated country'', redesignating paragraphs (i), (ii), (iii), and (iv) as paragraphs (1), (2), (3), and (4), respectively; and in the newly redesignated paragraph (2), removing ''Canada,'';
■ E. In the definition of ''Domestic construction material'', redesignating paragraphs (i), (ii) introductory text, and (ii)(A) and (B) as paragraphs (1), (2) introductory text, and (2)(i) and (ii), respectively; and
■ F. In the definitions of ''Free Trade Agreement country construction material'', ''Least developed country construction material'', and ''WTO GPA country construction material'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively; and
■ iii. In paragraph (b), removing ''NAFTA'' and adding ''United States-Mexico-Canada Agreement'' in its place;
■ d. In Alternate II—
■ i. Revising the clause date; and
■ ii. In paragraph (a)—
■ A. In the definition of ''Caribbean Basin country construction material'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ B. In the definition of ''Commercially available off-the-shelf (COTS) item'', redesignating paragraphs (i) introductory text, (i)(A), (B), and (C), and (ii) as paragraphs (1) introductory text, (1)(i), (ii), and (iii), and (2), respectively;
■ C. In the definition of ''Cost of components'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ D. In the definition of ''Designated country'', redesignating paragraphs (i), (ii), (iii), and (iv) as paragraphs (1), (2), (3), and (4), respectively; and in the newly redesignated paragraph (2), removing ''Canada,'';
■ E. In the definition of ''Domestic construction material'', redesignating paragraphs (i), (ii) introductory text, and (ii)(A) and (B) as paragraphs (1), (2) introductory text, and (2)(i) and (ii), respectively; and
■ F. In the definitions of ''Free Trade Agreement country construction material'', ''Least developed country construction material'', ''SC/CASA state construction material'', and ''WTO GPA country construction material'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively; and
■ e. In Alternate III—
■ i. Revising the clause date;
■ ii. In paragraph (a)—
■ A. In the definition of ''Caribbean Basin country construction material'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;
■ B. In the definition of ''Commercially available off-the-shelf (COTS) item'', redesignating paragraphs (i) introductory text, (i)(A), (B), and (c), and (ii) as paragraphs (1) introductory text, (1)(i), (ii), and (iii), and (2), respectively;
■ C. In the definition of ''Cost of components'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively;

■ D. In the definition of ''Designated country'', redesignating paragraphs (i), (ii), (iii), and (iv) as paragraphs (1), (2), (3), and (4), respectively; and in the newly redesignated paragraph (2), removing ''Canada,'';

■ E. In the definition of ''Domestic construction material'', redesignating paragraphs (i), (ii) introductory text, (ii)(A) and (B) as paragraphs (1), (2) introductory text, and (2)(i) and (ii), respectively; and

■ F. In the definitions of ''Free Trade Agreement country construction material'', ''Least developed country construction material'', ''SC/CASA state construction material'', and ''WTO GPA country construction material'', redesignating paragraphs (i) and (ii) as paragraphs (1) and (2), respectively; and

■ iii. In paragraph (b) removing ''NAFTA'' and adding ''United States-Mexico-Canada Agreement'' in its place.

The revisions read as follows:

252.225–7045 Balance of Payments Program—Construction Material Under Trade Agreements.

* * * * *

Balance of Payments Program—Construction Material Under Trade Agreements—Basic (Date)

* * * * *

Balance of Payments Program—Construction Material Under Trade Agreements—Alternate I (Date)

* * * * *

Balance of Payments Program—Construction Material Under Trade Agreements—Alternate II (Date)

* * * * *

Balance of Payments Program—Construction Material Under Trade Agreements—Alternate III (Date)

* * * * *

[FR Doc. 2022–04009 Filed 2–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Chapter 2

[Docket DARS–2022–0002]

RIN 0750–AK96

Defense Federal Acquisition Regulation Supplement: Reauthorization and Improvement of Mentor-Protégé Program (DFARS Case 2020–D009)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2020 that reauthorizes and modifies the DoD Mentor-Protégé Program.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before April 29, 2022 to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS 2020–D009, using any of the following methods:

○ *Federal eRulemaking Portal: https://www.regulations.gov.* Search for ''DFARS Case 2020–D009'' in the search box and select ''Search.'' Select ''Comment'' and follow the instructions to submit a comment. Please include your name, company name (if any), and ''DFARS Case 2020–D009'' on any attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2020–D009 in the subject line of the message.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Ms. Jeanette Snyder, 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to implement section 872 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020 (Pub. L. 116–92). Section 872 modifies subsection (j) of section 831 of the NDAA for FY 1991 (Pub. L. 101–510; 10 U.S.C. 2302 note) to reauthorize and improve the DoD Mentor-Protégé Program. Section 872 extends the date for entering into a mentor-protégé agreement, extends the date for reimbursement of mentors, limits the term for program participation, extends the date for a mentor to receive credit toward the attainment of small business subcontracting goals, and expands eligibility for protégé firms.

II. Discussion and Analysis

This proposed rule includes changes to DFARS subpart 219.71 and DFARS appendix I to implement section 872 of the NDAA for FY 2020 to reauthorize and improve the DoD Mentor-Protégé Program (the Program). This proposed rule—

—Reauthorizes the Program by extending the date for entering into a mentor-protégé agreement from September 30, 2018, to September 30, 2024;

—Extends the date for mentor reimbursements to be paid for developmental assistance costs incurred under the Program from September 30, 2021, to September 30, 2026;

—Extends the date for a mentor to receive, for developmental assistance costs incurred under the Program, credit toward attainment of the subcontracting goals in its small business subcontracting plan from September 30, 2021, to September 30, 2026;

—Limits the program participation term to two years, unless approval is otherwise obtained for an additional period not to exceed three years;

—Expands the eligibility of a protégé by aligning its size with the size standard of its primary North American Industry Classification System (NAICS) code; and

—Adds a DoD Office of Small Business Programs cybersecurity readiness assessment that will be provided to protégés.

In addition, proposed amendments to appendix I include—

—Updated definitions to align with the statute;

—Addition of DoD's right to terminate agreements for convenience; and

—Other administrative and conforming changes.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold, for Commercial Products Including Commercially Available Off-the-Shelf Items, and for Commercial Services

This rule does not create any new solicitation provisions or contract clauses. It does not impact any existing provisions or clauses or their applicability to contracts at or below the simplified acquisition threshold, acquisitions of commercial products including commercially available off-the-shelf items, and acquisitions of commercial services.

IV. Expected Impact of the Rule

This rule reauthorizes and improves the DoD Mentor-Protégé program. The purpose of the program is to provide incentives to major DoD contractors to furnish eligible small business concerns with assistance designed to—

(1) Enhance the capabilities of small business concerns to perform as subcontractors and suppliers under DoD contracts and other contracts and subcontracts; and

(2) Increase the participation of such business concerns as subcontractors and suppliers under DoD contracts, other Federal Government contracts, and commercial contracts.

Therefore, this rule will benefit small business concerns by extending the opportunity to enter into DoD mentor-protégé agreements. In addition, the eligibility of small business concerns is expanded as this rule removes prior restrictions for eligibility by aligning the size of the small business with the size standard associated with its primary NAICS code. This rule is expected to benefit large entities and the Government, as well, by expanding the defense industrial base.

V. 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.

VI. 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**. This rule is not anticipated to be a major rule under 5 U.S.C. 804.

VII. Regulatory Flexibility Act

DoD does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because this rule is expected to impact a limited number of small entities. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This proposed rule is necessary in order to implement section 872 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020 (Pub. L. 116–92). Section 872 modifies subsection (j) of section 831 of the NDAA for FY 1991 (Pub. L. 101–510; 10 U.S.C. 2302 note) to reauthorize and improve the DoD Mentor-Protégé Program (the Program).

The objective of this rule is to implement the reauthorization and improvements to the Program authorized by section 872. The authority for entering into new agreements expired on September 30, 2018. This rule extends the date for new mentor-protégé agreements to September 30, 2024. In addition, the date for reimbursement of incurred costs under the Program is extended to September 30, 2026, as is the date for costs to be applied to a mentor's subcontracting goals under its small business subcontracting plan. The eligibility of a small business concern, as related to the Program, is modified to align with the size standard associated with its primary NAICS code. The legal basis for the rule is section 872 of the NDAA for FY 2020.

The number of ongoing DoD mentor-protégé agreements in FY 2018 and FY 2019 was 90, four of which expired in FY 2019. No new agreements were entered into in FY 2019 since the authority to enter into agreements expired on September 30, 2018. The number of ongoing agreements in FY 2020 was 86, 29 of which expired. As of June 2021, there were 57 ongoing agreements, 50 new agreements, and 12 expiring agreements, with a total of 95. DoD estimates 66 new agreements will be entered into in FY 2022, 82 in FY 2023, and 98 in FY 2024.

This rule does not impose any new reporting, recordkeeping, or other compliance requirements for small entities.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

DoD did not identify any significant alternatives that would minimize or reduce the impact on small entities. Any impact is expected to be beneficial.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2020–D009), in correspondence.

VIII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does apply; however, these changes to the DFARS do not impose additional information collection requirements to the paperwork burden previously approved under OMB Control Number 0704–0332.

List of Subjects in 48 CFR part 219 and Appendix I to Chapter 2

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, 48 CFR part 219 and appendix I to chapter 2 are proposed to be amended as follows:

PART 219—SMALL BUSINESS PROGRAMS

■ 1. The authority citation for 48 CFR part 219 is revised to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Revise section 219.7100 to read as follows:

219.7100 Scope.

This subpart implements the Pilot Mentor-Protégé Program (referred to as the Program) established under section 831 of the National Defense Authorization Act for Fiscal Year 1991 (Pub. L. 101–510; 10 U.S.C. 2302 note). The purpose of the Program is to provide incentives for DoD contractors to assist protégé firms in enhancing

their capabilities and to increase participation of such firms in Government and commercial contracts.

■ 3. Amend section 219.7102 by—

■ a. In paragraphs (a) and (b), removing the periods and adding semicolons in their places;

■ b. Redesignating paragraph (c) as paragraph (d);

■ c. Adding a new paragraph (c); and

■ d. Revising newly redesignated paragraphs (d) introductory text and (d)(1)(ii).

The addition and revisions read as follows:

219.7102 General.

* * * * *

(c) A preliminary assessment of the protégé firm's cybersecurity readiness. The DoD Office of Small Business Programs (OSBP), Office of the Under Secretary of Defense, Acquisition and Sustainment (OUSD (A&S)), provides this preliminary assessment, which is a benefit of program participation; and

(d) Incentives that DoD may provide to mentor firms, which include—

(1) * * *

(ii) A separate contract, upon written determination by the Director, OSBP, of the cognizant military department or defense agency that unusual circumstances justify reimbursement using a separate contract; or

* * * * *

■ 4. Revise section 219.7103–1 to read as follows:

219.7103–1 General.

The procedures for application, acceptance, and participation in the Program are in appendix I, Policy and Procedures for the DoD Pilot Mentor-Protégé Program. The Mentor-Protégé Program Director, OSBP, OUSD (A&S), has the authority to approve contractors as mentor firms. The Director, OSBP, of each military department or defense agency has the authority to approve mentor-protégé agreements and forward approved mentor-protégé agreements to the contracting officer when funding is available.

5. Amend section 219.7103–2 by—

■ a. In the introductory text, removing ''must'' and adding ''shall'' in its place; and

■ b. Revising paragraphs (d)(1), (e)(3), (f), and (h).

The revisions read as follows:

219.7103–2 Contracting officer responsibilities.

* * * * *

(d) * * *

(1) A DoD program manager or the Director, OSBP, of the cognizant military department or defense agency has made funds available for that purpose; and

* * * * *

(e) * * *

(3) The Director, OSBP, of the military department or defense agency has made a determination in accordance with 219.7102(d)(1)(ii).

(f) Not authorize reimbursement for costs of assistance furnished to a protégé firm in excess of $1 million in a fiscal year unless a written determination from the Director, OSBP, of the military department or defense agency is obtained.

* * * * *

(h) Provide a copy of the approved mentor-protégé agreement to the Defense Contract Management Agency (DCMA) small business professional responsible for conducting the annual performance review (see appendix I, section I–113).

219.7104 [Amended]

■ 6. Amend section 219.7104 in paragraphs (b) and (d) by removing ''September 30, 2021'' and adding ''September 30, 2026'' in its place.

219.7106 [Amended]

■ 7. Amend section 219.7106 by removing ''The Defense Contract Management Agency'' and adding ''DCMA'' in its place.

Appendix I to Chapter 2—Policy and Procedures for the DoD Pilot Mentor-Protégé Program

■ 9. Add an authority citation at the end of appendix I to chapter 2 to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 10. Amend appendix I to chapter 2 by—

■ a. In section I–100—

■ i. Revising paragraph (a) introductory text;

■ ii. In paragraph (c)(1), removing ''2 years'' and adding ''5 years'' in its place;

■ iii. Revising paragraph (c)(3); and

■ iv. Adding paragraph (c)(4).

■ b. Revising section I–101.

■ c. In section I–102—

■ i. In paragraph (a)(2)(ii), removing the word ''and'' at the end of the paragraph;

■ ii. Adding paragraph (a)(2)(iv);

■ iii. Revising paragraph (a)(3);

■ iv. In paragraph (b)(3), removing ''Less than half'' and adding ''Not more than'' in its place;

■ v. In paragraph (e), removing ''Office of Small Business Programs (OSBP)'' and adding ''OSBP'' in its place;

■ vi. In paragraph (g)(1), removing ''pursuant to approved mentor-protégé agreements'' and adding ''in accordance with the approved mentor-protégé agreement'' in its place;

■ vii. In paragraph (g)(3), removing ''cognizant Component Director, SBP'' and adding ''Director, OSBP, of the cognizant military department or defense agency'' in its place; and

■ viii. Adding paragraph (h).

■ d. In section I–103—

■ i. In paragraph (a), removing ''September 30, 2018'' and adding ''September 30, 2024'' in its place;

■ ii. In paragraph (b) introductory text, removing ''prior to September 30, 2021'' and adding ''through September 30, 2026'' in its place; and

■ iii. In paragraph (b)(3), removing ''cognizant Component Director, SBP,'' and adding ''Director, OSBP, of the cognizant military department or defense agency'' in its place.

■ e. In section I–104, revising paragraph (c).

■ f. In section I–105, revising paragraphs (a) and (c).

■ g. In section I–106—

■ i. In paragraph (d)(1)(i), removing ''marketing'' and adding ''marketing and technology commercialization, compliance systems'' in its place;

■ ii. In paragraph (d)(1)(ii), removing ''quality assurance'' and adding ''quality assurance; acquisition or transfer of hardware, tooling, or software; and technology transfer and transition'' in its place;

■ iii. In paragraph (d)(2), removing ''firmunder'' and adding ''firm under'' in its place;

■ iv. In paragraph (d)(4), removing ''Subpart'' and adding ''subpart'' in its place; and

■ v. Adding paragraph (g).

■ h. In section I–107—

■ i. In paragraph (a), removing ''email'' and adding ''email'' in its place;

■ ii. In paragraph (j), removing ''2 years'' and adding ''5 years'' in its place; and

■ iii. Revising paragraph (k).

■ i. In section I–108—

■ i. In paragraph (a) introductory text, removing ''DoD component'' and adding ''military department or defense agency'' in its place;

■ ii. In paragraph (a)(5), removing ''3 years (Term of agreements may not exceed 5 years)'' and adding ''2 years (agreements may not exceed 5 years) (see I–107(k))'' in its place;

■ iii. In paragraph (a)(6), removing ''$1,000,000'' and adding ''$1 million'' in its place;

■ iv. In paragraph (b), removing ''cognizant DoD components'' and adding ''the military department or defense agency'' in its place;

■ v. In paragraph (c), removing ''cognizant Component Director, SBP, prior'' and adding ''Director, OSBP, of

the military department or defense agency prior'' in its place;
■ vi. In paragraph (d), removing ''cognizant DoD component'' and adding ''military department or defense agency'' in its place;
■ vii. In paragraph (e), removing ''component'' and ''Director, SBP'' and adding ''military department or defense agency'' and ''the Director, OSBP'' in their places, respectively; and
■ viii. In paragraph (f), removing ''cognizant Component Director, SBP,'' and adding ''Director, OSBP, of the military department or defense agency'' in its place.
■ j. In section I–109—
■ i. In the introductory text, removing ''agreements'' and adding ''agreements including agreements that provide for both reimbursement and subcontracting credit'' in its place;
■ ii. In paragraph (c), removing ''Component Directors, SBP'' and adding ''Directors, OSBP, of the military departments or defense agencies'' in its place; and
■ iii. In paragraph (d), removing ''$1,000,000'' and ''cognizant Component Director, SBP'' wherever they appear and adding ''$1 million'' and ''Director, OSBP, of the military department or defense agency'' in their places, respectively.
■ k. In section I–110, adding introductory text.
■ l. In section I–110.1, paragraph (a), removing ''Plans .'' and adding ''Plans.'' in its place.
■ m. In section I–110.2, paragraphs (a) introductory text, (b) introductory text, and (c), removing ''SBP'' and adding ''OSBP'' in its place.
■ n. In section I–111—
■ i. In paragraph (a), removing ''cognizant Component Director, SBP,'' and ''administrative contracting officer'' and adding ''Director, OSBP, of the cognizant military department or defense agency'' and ''small business professional'' in their places, respectively; and
■ ii. Adding paragraph (f).
■ o. In section I–112.2—
■ i. In paragraph (a)(2)(xii)(A), removing ''success assistance'' and adding ''success developmental assistance'' in its place;
■ ii. In paragraph (a)(2)(xii)(B), removing ''contracts'' and adding ''contracts, including but not limited to the transition of innovative technology into a program of record'' in its place;
■ iii. In paragraph (a)(4), removing ''at: *http://www.acq.osd.mil/osbp/sb/programs/mpp/resources.shtml*'' and adding ''at *https://business.defense.gov/Programs/Mentor-Protégé-Program/MPP-Resources/*'' in its place;
■ iv. In paragraph (b)(2), removing ''2 fiscal years'' and adding ''5 fiscal years'' in its place;
■ v. In paragraph (d)(1), removing ''cognizant Component Director, SBP,'' and adding ''Director, OSBP, of the military department or defense agency'' in its place; and
■ vi. In paragraph (d)(2), removing ''cognizant Component Director, SBP,'' and adding ''Director, OSBP, of the military department or defense agency,'' in its place.
■ p. Revising section I–113.

The revisions and additions read as follows:

Appendix I to Chapter 2—Policy and Procedures for the DoD Pilot Mentor-Protégé Program

I–100 Purpose

(a) This appendix implements the Pilot Mentor-Protégé Program (the Program) established under section 831 of the National Defense Authorization Act for Fiscal Year 1991 (Pub. L. 101–510; 10 U.S.C. 2302 note). The purpose of the Program is to provide incentives to major DoD contractors to furnish eligible small business concerns with assistance designed to—

* * * * *

(c) * * *

(3) An increase in protégé participation in DoD science and technology programs; and

(4) An increase in job creation of protégé firms from the date of execution of the mentor-protégé agreement until 5 years after completion of the mentor-protégé agreement.

* * * * *

I–101 Definitions

As used in this appendix—

Affiliation means, with respect to a relationship between a mentor firm and a protégé firm, a relationship described under 13 CFR 121.103.

Eligible entity employing the severely disabled means a business entity operated on a for-profit or nonprofit basis that—

(1) Uses rehabilitative engineering to provide employment opportunities for severely disabled individuals and integrates severely disabled individuals into its workforce;

(2) Employs severely disabled individuals at a rate that averages not less than 20 percent of its total workforce;

(3) Employs each severely disabled individual in its workforce generally on the basis of 40 hours per week; and

(4) Pays not less than the minimum wage prescribed pursuant to section 6 of the Fair Labor Standards Act (29 U.S.C. 206) to those employees who are severely disabled individuals.

Minority institution of higher education means an institution of higher education with a student body that reflects the composition specified in sections 312(b)(3), (4), and (5) of the Higher Education Act of 1965 (20 U.S.C. 1058(b)(3), (4), and (5)).

Service-disabled veteran-owned small business means a small business concern owned and controlled by service-disabled veterans as defined in section 8(d)(3) of the Small Business Act (15 U.S.C. 637(d)(3)).

Severely disabled individual means an individual who is blind or severely disabled as defined in 41 U.S.C. 8501.

Women-owned small business means a small business concern owned and controlled by women as defined in section 8(d)(3)(D) of the Small Business Act (15 U.S.C. 637(d)(3)(D)).

I–102 Participant Eligibility

(a) * * *

(2) * * *

(iv) Is an other than small business concern, unless approved by the Director of the Office of Small Business Programs (OSBP), Office of the Under Secretary of Defense, Acquisition and Sustainment (OUSD (A&S)), in accordance with 13 CFR 121.103 regarding ''affiliation and relationship''; and

(3) Be capable of imparting value to a protégé firm because of experience gained as a DoD contractor or through knowledge of general business operations and Government contracting, as demonstrated by evidence that such entity—

(i) Received DoD contracts and subcontracts equal to or greater than $100 million during the previous fiscal year;

(ii) Is a prime contractor to DoD with an active subcontracting plan; or

(iii) Has graduated from the 8(a) Business Development Program and provides documentation of its ability to serve as a mentor.

* * * * *

(h) Within 30 days of any change in status affecting eligibility, mentors and protégés must give notice and explanation of pertinent facts to each other, the Director of OSBP, OUSD (A&S), and the Director, OSBP, of the military department or defense agency.

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I–104 Selection of Protégé Firms

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(c) Any interested party may file a protest of the selection of a protégé firm directly with the Director, OSBP, OUSD

(A&S) or the Director, OSBP, of the cognizant military department or defense agency. In the event of a protest regarding the size or status of an entity selected to be a protégé firm, the Director, OSBP, OUSD (A&S), or the Director, OSBP, of the military department or defense agency must refer the protest to the SBA to resolve in accordance with 13 CFR part 121 (with respect to size) or other parts of title 13 of the CFR or this appendix (with respect to the protégé's socioeconomic status). The Director, OSBP, OUSD (A&S), or the Director, OSBP, of the military department or defense agency shall decide protests concerning all other aspects of a protégé's eligibility for the Program (*e.g.,* nontraditional defense contractor or entity employing the severely disabled).

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I–105 Mentor Approval Process

(a) An entity seeking to participate as a mentor must apply to the Mentor-Protégé Program Director, OSBP, OUSD (A&S), to establish its initial eligibility as a mentor.

* * * * *

(c) A template of the mentor application is available at *https://business.defense.gov/Programs/Mentor-Protégé-Program/MPP-Resources/.*

* * * * *

I–106 Development of Mentor-Protégé Agreements

* * * * *

(g) The agreement shall demonstrate, through its execution, how it will contribute to the overall mission of DoD and/or fill or address an identified critical gap or vulnerability. Focus areas include, but are not limited to, manufacturing, research and development, and knowledge-based services.

I–107 Elements of a Mentor-Protégé Agreement

* * * * *

(k) A program participation term for the agreement that does not exceed 2 years. Requests for an extension of the agreement for a period not to exceed an additional 3 years are subject to the approval of the Director, OSBP, of the cognizant military department or defense agency. The justification must detail the unusual circumstances that warrant a term in excess of 2 years;

* * * * *

I–110 Credit Agreements

Sections I–110.1 and I–110.2 apply to all credit agreements, including agreements that provide for both credit and reimbursement.

* * * * *

I–111 Agreement Terminations

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(f) The Director, OSBP, OUSD (A&S) or the Director, OSBP, of the military department or defense agency is authorized to terminate the mentor-protégé agreement for the convenience of the Government (to include national security grounds, funding limits, statutory requirements, or other considerations), as well as for cause upon written findings (*e.g.,* either of the participants' failure to perform or provide adequate assurance of performance; failure to comply with laws, regulations, and policies; conflicts of interest; or default under any provisions of a DoD contract or agreement).

* * * * *

I–113 Performance Reviews

DCMA will conduct annual performance reviews of the progress and accomplishments realized under approved mentor-protégé agreements. These reviews must verify data provided on the semiannual reports and must provide information as to—

(a) Whether all costs reimbursed to the mentor firm under the agreement were reasonably incurred to furnish assistance to the protégé in accordance with the mentor-protégé agreement and applicable regulations and procedures; and

(b) Whether the mentor and protégé accurately reported progress made by the protégé in employment, revenues, and participation in DoD contracts during the Program participation term and for 5 fiscal years following the expiration of the Program participation term.

[FR Doc. 2022–04012 Filed 2–25–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2021–0108; FF09E21000 FXES1111090FEDR 223]

RIN 1018–BE90

Endangered and Threatened Wildlife and Plants; Foothill Yellow-Legged Frog; Threatened Status With Section 4(d) Rule for Two Distinct Population Segments and Endangered Status for Two Distinct Population Segments

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; extension of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are extending the comment period on our December 28, 2021, proposed rule to list four distinct population segments (DPSs) of the foothill yellow-legged frog (*Rana boylii*), a stream-dwelling amphibian from Oregon and California, under the Endangered Species Act of 1973, as amended (Act). We are extending the proposed rule's comment period for 30 days to give all interested parties an additional opportunity to comment. Comments previously submitted need not be resubmitted as they are already incorporated into the public record and will be fully considered in the final rule.

DATES: The comment period on the proposed rule that published December 28, 2021, at 86 FR 73914, is extended. We will accept comments received or postmarked on or before March 30, 2022.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–R8–ES–2021–0108, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate the document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R8–ES–2021–0108, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *https://www.regulations.gov.* This generally

means that we will post any personal information you provide us (see Public Comments, below, for more information).

FOR FURTHER INFORMATION CONTACT: Michael Fris, Field Supervisor, Sacramento Fish and Wildlife Office, 2800 Cottage Way, Sacramento, CA 95825; telephone 916–414–6700. 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:

Background

On December 28, 2021, we published a proposed rule (86 FR 73914) to list the South Sierra and South Coast DPSs of the foothill yellow-legged frog as endangered and the North Feather and Central Coast DPSs of the foothill yellow-legged frog as threatened with rules issued under section 4(d) of the Act. The proposed rule opened a 60-day comment period, ending February 28, 2022. On January 31, 2022, we received a request to extend the public comment period. With this document, we extend the public comment period for an additional 30 days, as specified above in **DATES**.

Public Comments

We will accept written comments and information during the extended comment period on our proposed rule to list the South Sierra, South Coast, North Feather, and Central Coast DPSs of the foothill yellow-legged frog. We will consider information and recommendations from all interested parties. We intend that any final action resulting from the proposal will be based on the best scientific and commercial data available. Our final determination will take into consideration all comments and any additional information we receive during the open comment period on the proposed rule.

Because we will consider all comments and information we receive during the open comment period, our final determinations may differ from our December 28, 2021, proposed rule (86 FR 73914). In addition, we may change the parameters of the prohibitions or the exceptions to those prohibitions in the proposed rule issued under section 4(d) of the Act (*i.e.,* the ''proposed 4(d) rule'') for the North Feather or Central Coast DPS if we conclude it is appropriate in light of comments and new information received. For example, we may expand the prohibitions in the proposed 4(d) rule for the North Feather or Central Coast DPS to include prohibiting additional activities if we conclude that those additional activities are not compatible with conservation of either DPS. Conversely, we may establish additional exceptions to the prohibitions in the final rule if we conclude that the activities would facilitate or are compatible with the conservation and recovery of either DPS.

If you already submitted comments or information on the December 28, 2021, proposed rule, please do not resubmit them. Any such comments are incorporated as part of the public record of the rulemaking proceeding, and we will fully consider them in the preparation of our final determinations.

Comments should be as specific as possible. Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you assert.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, do not provide substantial information necessary to support our determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered species or a threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

We request that you send comments and materials only by one of the methods listed in **ADDRESSES**. If you submit information via *https://www.regulations.gov,* your entire submission—including your personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, 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. We will post all hardcopy submissions on *https://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rule, will be available for public inspection on *https://www.regulations.gov* at Docket No. FWS–R8–ES–2021–0108.

Authors

The primary authors of this document are the staff members of the Fish and Wildlife Service's Species Assessment Team and the California Great Basin Regional Office (Interior Region 10).

Authority

The Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), is the authority for this action.

Martha Williams,

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–04257 Filed 2–25–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No.: 220214–0046]

RIN 0648–BK17

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Amendment 23

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to approve, and implement through regulations, measures included in Amendment 23 to the Northeast Multispecies Fishery Management Plan, which the New England Fishery Management Council adopted and submitted to NMFS for approval. This action would adjust the existing industry-funded at-sea monitoring program for groundfish sectors to improve the accuracy of collected catch data (landings and discards) and catch accounting. The measures selected by the New England Fishery Management Council in Amendment 23 are intended to ensure there is a precise and accurate representation of catch to set catch limit levels that prevent overfishing and determine when catch limits are exceeded.

DATES: Comments must be received by March 30, 2022.

ADDRESSES: The New England Fishery Management Council (Council) has prepared an Environmental Impact Statement (EIS) for this action that describes the proposed measures in

Amendment 23 to the Northeast Multispecies Fishery Management Plan (FMP) and other considered alternatives, and analyzes the impacts of the proposed measures and alternatives. The Council submitted the amendment to NMFS, including the EIS, a description of the Council's preferred alternatives, the Council's rationale for selecting each alternative, and a Regulatory Impact Review (RIR). Copies of supporting documents used by the Council, including the EIS and RIR, are available from: Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Newburyport, MA 01950 and accessible via the internet in documents available at: *https://www.nefmc.org/library/amendment-23*.

You may submit comments, identified by NOAA–NMFS–2020–0144, by the following method:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov* and enter NOAA–NMFS–2020–0144 in the Search box. Click the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted 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: Mark Grant, Fishery Policy Analyst, (978) 281–9145.

SUPPLEMENTARY INFORMATION:

Amendment 23 Summary

The Council initiated Amendment 23 to consider changes to the groundfish monitoring and reporting system to ensure it is providing accurate catch information necessary to manage the fishery effectively. The alternatives considered in this action focus on measures that adjust the existing industry-funded sector monitoring program to improve the accuracy of collected catch data (landings and discards) and catch accounting. To address these issues, the Council adopted Amendment 23 to make a number of changes to the industry-funded sector monitoring program in order to:

• Replace the current process for calculating an annual monitoring coverage target for at-sea monitoring (ASM) with a fixed monitoring coverage target as a percentage of trips, dependent on Federal funding. The coverage target would be 100 percent of trips for 4 years, but could be set at less than 100 percent at the maximum level for which there are sufficient Federal funds to support all agency and industry costs. Beginning in year 5, the ASM coverage target would be 40 percent of trips but NMFS could increase ASM coverage above the 40-percent target when Federal funding is available to support all industry costs. For years with a 40-percent coverage target, Federal funding would be used to first pay NMFS costs and then support as much of industry costs as possible. Sectors would be responsible for paying only the industry costs above the portion supported by Federal funding.

• Approve additional electronic monitoring (EM) technologies as an alternative to human at-sea monitors;

• Exclude from the monitoring requirement all trips in geographic areas with low groundfish catch;

• Require periodic evaluation of the monitoring program and exclusions from the monitoring requirement;

• Remove the management uncertainty buffer from the portion of the ABC allocated to the sector catch share when the monitoring coverage target is 100 percent; and

• Grant authority to the Northeast Regional Administrator to revise sector reporting requirements to streamline reporting for the industry.

The proposed measures are discussed in detail below under Discussion of Proposed Rule Measures. Under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), we are required to publish proposed rules for comment after preliminarily determining that they are consistent with applicable law. The Magnuson-Stevens Act allows us to approve, partially approve, or disapprove measures proposed by the Council based only on whether the measures are consistent with the fishery management plan, plan amendment, the Magnuson-Stevens Act and its National Standards, and other applicable law. Otherwise, we must defer to the Council's policy choices. We are seeking comment on the Council's proposed measures in Amendment 23 and whether they are consistent with the Northeast Multispecies FMP, the Magnuson-Stevens Act and its National Standards, and other applicable law.

Discussion of Proposed Rule Measures

ASM Coverage Target

Amendment 23 would replace the current method for determining the ASM coverage target for deploying human at-sea monitors, including the coefficient of variation (CV) standard, stock status criteria, and the need for an annual determination by NMFS, with a fixed coverage target as a percentage of trips, dependent on Federal funding. Currently, NMFS is required to determine an ASM coverage target that at least meets the 30-percent CV specified in the Standardized Bycatch Reporting Methodology at the overall stock level for each stock of regulated species and ocean pout; and to monitor sector operations, to the extent practicable, in order to reliably estimate overall catch by sector vessels. Analyses included in the Amendment 23 EIS (see **ADDRESSES**) demonstrated the CV standard was no longer an effective basis for determining coverage due to bias that results from differences between trips that are monitored and trips that are not monitored.

To address bias, the coverage target would be 100 percent of trips for 4 years, provided Federal funding can support agency and industry costs. The ASM coverage target in years 1–4 could be less than 100 percent, and would be set at the maximum level for which there are sufficient Federal funds to support all agency and industry costs. The at-sea monitoring coverage target would default to 40 percent in years 1–4 if Federal funding cannot completely support all industry costs for a coverage target greater than 40 percent. In year 5 and beyond, the coverage target would be 40 percent unless replaced by a subsequent Council action. However, Amendment 23 would also allow for increased coverage in year 5 and beyond, when Federal funding is available to support industry costs. For years with a 40-percent ASM coverage target, Federal funding would be used to first pay NMFS costs and then support as much of industry costs as possible. The current method used to set ASM target coverage levels is not effective to estimate catch because observed trips

are not representative of unobserved trips. As a result, biased catch data undermines management of the fishery. It is not possible at this time to calculate an ASM coverage target less than 100 percent that would eliminate or minimize bias sufficiently to ensure catch accountability because the current catch data are not representative of the entirety of the sector fishery. The Council chose a fixed ASM coverage target of 100 percent to address bias by establishing a baseline of accurate and precise catch information for the fishery. The 100-percent coverage target would increase the accuracy of catch estimates and reduce the potential for bias more than any other coverage target considered. Setting the coverage target at 100 percent also simplifies compliance and enforceability of the monitoring program by removing a complex system of stratified random sampling. In addition, while improved monitoring would not solve all of the issues facing the fishery, a 100-percent coverage target is expected to provide more information to support better management of this fishery. Making the coverage target contingent on Federal funding for industry costs balances the need for improved monitoring with the economic effects to the fishery. Combined with the option for vessels to use EM (see ''*Electronic Monitoring*'' below) and removing the management uncertainty buffers from the sector portion of the annual catch limit (ACL) (see ''*Elimination of Management Uncertainty Buffer for Sector ACLs*'' below), the increased cost to industry is reduced. ASM coverage targets of at least 40-percent on a consistent basis would be an increase from attained coverage levels to date. Higher ASM coverage, even for a limited time, along with data from EM, could improve the cost-effectiveness of the monitoring system by providing a baseline of accurate and precise catch information to be used in the evaluation of the program that is planned (see ''*Review Process for Monitoring Coverage Rates*'' below).

The Council also selected a minimum ASM coverage target of 40 percent in the event that Federal funds are not available in a given year in order to ensure accurate catch information is still provided while addressing concerns about industry costs. The minimum target level of 40 percent will be funded either by sectors (if no Federal funds are available) or a combination of sectors and Federal funds.

The availability of EM also provides a potential option for sector monitoring programs to ensure catch accountability. The EM models address bias by requiring cameras to monitor fishing activity during the entirety of all sector groundfish trips. The availability and use of EM will also provide additional data to compare to ASM coverage and inform NMFS and the Council on the Amendment 23 coverage target's performance. NMFS proposes several administrative procedural changes to implement the revised ASM coverage target, but would retain other aspects of the current requirements. All vessels would continue to provide advanced notice to NMFS through the pre-trip notification systems (PTNS) for the purposes of selecting vessels for ASM and observer deployment. The agency would continue to issue waivers from ASM for selected trips in specific circumstances, including if an observer or at-sea monitor is not available to cover the trip, or for other logistical reasons (*e.g.,* late observer, safety), consistent with its current practice.

Each year, NMFS would evaluate available Federal funding. Consistent with the Magnuson-Stevens Act and other applicable laws, NMFS would determine how much Federal funding is available for the groundfish sector monitoring program and then use that in conjunction with other available information (*e.g.,* recent monitoring costs, estimate of the number of vessels choosing EM) to calculate the ASM coverage target between 40 and 100 percent for the coming fishing year. This funding-based determination would replace the current annual process for determining the ASM coverage target for the sector monitoring program.

NMFS would announce the ASM coverage target at least 3 weeks before the annual sector enrollment deadline set by NMFS, if Federal funding information is available (see ''*Determining Total Monitoring Coverage at a Time Certain*'' below). NMFS currently anticipates that existing available Federal funding would be sufficient to fund at least 2 years with a 100-percent ASM coverage target.

Electronic Monitoring

Amendment 23 would approve the Audit Model and the maximized retention model of EM (MREM) for sector vessels to use, in place of ASM, to satisfy the sector monitoring requirement. EM is expected to provide important information for NMFS and the Council to consider during the first 4 years and to provide a suitable basis for sector monitoring programs to ensure catch accountability. A vessel using EM would still be subject to Northeast Fishery Observer Program (NEFOP) coverage, which is set at a level to meet the standardized bycatch reporting methodology requirements of the FMP and the Magnuson-Stevens Act. Amendment 23 does not remove or alter the existing authority for the Regional Administrator to deem types of EM technology sufficient to be used in place of human at-sea monitors. However, the two EM models in Amendment 23 would be available for sectors to include in their operations plans without requiring a separate determination by the Regional Administrator. Additional forms of EM would still be subject to approval or disapproval by NMFS.

The audit model is one of the EM models included in Amendment 23. NMFS previously determined the EM audit model is sufficient to verify a vessel's submission of information on groundfish discards and other relevant information (*e.g.,* date and time, gear category, location) for the purpose of catch accounting, provided that the vessel's captain and crew adhere to catch handling and reporting requirements as described in the vessel-specific monitoring plan (VMP) (86 FR 16686; March 31, 2021). The VMP details specific fish handling protocols, policies, and procedures; as well as the number and location of cameras. VMPs are reviewed and approved by NMFS prior to a vessel enrolling in EM to ensure the set-up is adequate to support data collection needs and requirements. Under the audit model, the vessel operator and crew hold groundfish discards on a measuring board and under a camera prior to discarding, and discard other species in view of cameras at designated discard control points. The vessel operator estimates the total weight of groundfish discards on an electronic vessel trip report (eVTR), and submits the video footage to the EM service provider. The EM service provider reviews trips selected for audit and develops an independent estimate of groundfish discards for the trip. The EM data are compared to verify the eVTR-reported catch and discards. NMFS sets the video review rates for audit model trips and conducts a secondary review of some trips to evaluate EM provider performance. NMFS may revise audit rates to ensure accurate reporting and minimize costs. For instance, vessels that demonstrate higher performance in terms of compliance with the VMP and accuracy of discard reporting could have lower review rates than vessels that do not perform as well. Additional detail of the audit model requirements are contained in the Fishing Years 2021–2022 Sector Operations Plan, Contract, and

Environmental Assessment Requirements guide (*https://bit.ly/3pdau1L*).

Amendment 23 would also approve the MREM model. The goal of MREM is to verify compliance with catch retention requirements and use dockside monitoring (DSM) to collect information on allocated groundfish discards at the dock that otherwise would be collected at sea. Under the MREM model, on all sector EM trips, the vessel operator and crew are required to retain and land all catch of allocated groundfish, including fish below the minimum size, specified at 50 CFR § 648.83, that they would otherwise be required to discard. Unallocated regulated species, ocean pout, and non-groundfish species must be handled in accordance with standard commercial fishing operations. Any allowable discards must occur at designated discard control points on the vessel, described in the vessel's VMP. EM data from the trip would be reviewed by the EM service provider to verify that the vessel operator and crew complied with the catch retention requirements. A human dockside monitor would meet the vessel at port upon its return from each trip to observe the offload and collect information on the catch (particularly fish below the minimum size). Landings of all fish by MREM vessels, including fish below the minimum size in the regulations, would be reported to NMFS by the dealer.

Approving EM models as alternatives to human ASM provides each sector the flexibility to choose the monitoring options (ASM, audit model EM, MREM) that best meet the needs of its members and ensure catch accountability. Through their operations plans, sectors would develop monitoring plans that describe how the sector would use the chosen monitoring tools. The intent of implementing the audit model and MREM through Amendment 23 is to make alternatives to human ASM available now while also retaining authority for the Regional Administrator to approve additional tools in the future. The goal is to provide sectors with additional tools to monitor catch that ensure precise and accurate catch estimation and minimize the potential for bias because EM is active on 100 percent of sector groundfish trips. These EM options are expected to eliminate bias and eliminate the coordination of human logistics for trips not assigned NEFOP coverage. Both EM models increase flexibility for sectors and their vessels to choose the monitoring option that best suits their business and operational needs while offering potential reductions in monitoring costs. The audit model may be most suitable for lower volume groundfish trips because it requires extra catch handling. MREM may be better suited for larger volume vessels where the catch handling protocols of the audit model present logistical challenges. DSM is a required component of MREM and may be easier to facilitate at dealers that are prepared to handle large volume offloads. The economic analyses in the EIS suggest that when both the audit model and MREM are available to vessels, as alternatives to ASM, the costs of 100-percent monitoring may be reduced for individual vessels and the fishery as a whole.

A vessel may only use the audit model or MREM to meet the sector monitoring requirement if its sector includes that EM model in its approved operations plan. A vessel must opt into an EM program for an entire fishing year, with two exceptions. First, a sector may allow a vessel a single opportunity to opt in/out of EM at any time during a fishing year if the sector operations plan includes both an approved ASM and EM plan. Second, if a vessel changes to a gear type not covered in the VMP, the vessel may temporarily become an ASM vessel until the VMP authorizing the use of the new gear type is approved. Vessels using EM must have their EM system operational and running on every sector groundfish trip, including trips that would be excluded from the ASM requirement (see ''*Exclusion from Monitoring Requirements for Certain Vessel Under Certain Conditions*'' below), unless issued a waiver by NMFS or assigned an ASM. During each sector EM trip taken by a vessel, the EM system records all fishing activity onboard the vessel. The vessel operator and crew sort fish and make any allowable discards within view of the cameras in accordance with the catch handling protocols described in the VMP.

NMFS proposes to implement the audit model consistent with the operational program implemented in fishing year 2021. Amendment 23 specified that vessels using audit model EM in place of ASM would be required to report discards at the haul level. However, the current operational audit model allows vessels to report discards at the sub-trip level, rather than the haul level. Haul-level reporting would require the vessel to fill out a new eVTR for each haulback of a trawl net, each haul of a string of gillnets, and each haul of fixed hook gear while sub-trip-level reporting requires a new eVTR only when a vessel changes gear type or mesh size, or physically changes location to a different statistical area. As part of implementing Amendment 23, NMFS proposes to allow vessels using the audit model to continue reporting discards at the sub-trip level, rather than the haul level, and is soliciting comment on this proposal (see ''*Sector Reporting*'' below).

NMFS proposes to implement MREM consistent with the NOAA Fisheries MREM program detailed in the draft Sector Operations Plan, Contract, and Environmental Assessment Requirements guide for fishing year 2022 available at: *https://media.fisheries.noaa.gov/2022-01/210826_SectorOpsEAGuidanceFY2021_2022_Revised.pdf.* Under MREM, the vessel operator and crew must adhere to the following catch handling requirements: Retain and land all catch of allocated groundfish, including any sublegal-size catch and unmarketable fish; discard unallocated groundfish stocks (*i.e.,* windowpane flounder, ocean pout, wolffish, Atlantic halibut) at designated discard control points; handle all other species in accordance with standard commercial fishing operations, including adhering to possession limits for halibut and non-groundfish species; and sort unmarketable fish separately from fish below the minimum legal size.

MREM vessels must also participate in a DSM program. NMFS proposes to initially continue to operate a DSM program for MREM vessels while working with partners to pilot a third-party DSM program. Subsequently, an industry-funded DSM model would be implemented and sectors would be required to contract with approved DSM providers to cover their MREM vessels. The vessel operator must notify the DSM program of its intention to sail prior to beginning a sector EM trip. Either the vessel operator or dealer must provide an offload time to the DSM program in advance of landing. The advance notice of landing and offload schedule will be dependent on the nature of the vessel's activity (*e.g.,* day boat vs trip boat vessels) and will be defined in the vessel's VMP. The vessel operator, crew, and dealer must offload all allocated groundfish in the presence of the dockside monitor. The vessel operator and crew may not begin offloading unless a dockside monitor is present or they have received a waiver from the DSM program. The vessel operator must allow the dockside monitor access to the fish hold immediately following the offload in order to confirm all allocated groundfish were offloaded. The vessel operator and crew or dealer personnel must separate sublegal allocated groundfish catch by species, except in instances where the

sublegal component of a high-volume target species (*i.e.,* redfish, haddock, and pollock) is combined with fish in the terminal legal-sized market category. The vessel operator and crew or dealer personnel must also separate unmarketable fish from fish below the minimum size.

NMFS also proposes requirements for Northeast multispecies dealers to facilitate DSM for MREM vessels. Federally permitted Northeast multispecies dealers would be required to allow dockside monitors access to their premises, scales, and any fish received from vessels participating in the MREM program for the purpose of collecting fish species and weights of fish received by the dealer, fish length measurements, and the collection of age structures such as otoliths or scales. The primary dealer would be required to retain all sublegal allocated groundfish catch in order to be weighed and sampled by the dockside monitor. Dealers would be required to clearly mark all containers containing sublegal catch to facilitate tracking, and would be required to provide settlement documents to the DSM program for any allocated groundfish forwarded to secondary dealers. This is intended to provide a ready means for dealers to show when they possess undersized fish landed from MREM vessels. The implementing regulations deemed by the Council inadvertently omitted this requirement, but it is included in the regulations proposed in this rule. We highlight this change from the deeming requirements to ensure the Council and the public have an opportunity to comment on this addition to the implementing regulations.

Dealers would also be required to provide dockside monitors with access to facilities equivalent to what is provided to the dealer's staff, including: A safe sampling station, with shelter from weather, for dockside monitors to conduct their duties and process catch; access to bathrooms; and access to facilities for washing equipment with fresh water. The intent of the dealer requirements is not to require dealers to create or provide facilities that do not already exist, but to ensure dockside monitors have access to facilities equivalent to what is available to the dealer's staff.

The proposed EM programs raise several implementation issues that NMFS is highlighting for comment. First, as noted above, NMFS proposes that vessels using EM must have their EM system operational and running on every sector groundfish trip, including trips that would be excluded from the ASM requirement, unless issued a waiver by NMFS or assigned an ASM. Throughout the development of EM, we have found that vessels are most successful at complying with their VMP when it is followed on all groundfish trips. Further, this requirement is consistent with the Council's intent that EM tools meet or exceed the ASM coverage target to ensure catch accountability. Vessels that are interested in fishing in ways that would be excluded from ASM (see ''*Exclusion from Monitoring Requirements for Certain Vessel Under Certain Conditions*'' below) may choose to use ASM, rather than adopting EM, and be excluded from the sector monitoring requirement on trips with low groundfish catch. Second, some discards of allocated groundfish occur on MREM trips and the Council should consider how to account for those fish. This would include operational discards (fish that drop out of the gear into the ocean, fish taken by birds), accidental discards, and intentional discards. These discards cannot always be estimated using EM technology. Third, vessels must discard any red hake in excess of the possession limit, but those fish cannot be distinguished from white hake using cameras. The Council may want to consider this interaction between the NE Multispecies FMP and the small-mesh fishery and potential methods for fully accounting for catch of these two stocks by MREM vessels.

Determining Total Monitoring Coverage at a Time Certain

Amendment 23 would require the Regional Administrator to determine the ASM coverage target at least 3 weeks prior to the annual sector enrollment deadline set by NMFS. The date NMFS announces the annual ASM coverage target in past years has varied from January 25 to March 26 and has sometimes been later than the sector roster deadline for that fishing year (see Table 65 in the EIS, see **ADDRESSES**). This action sets a fixed ASM coverage target; however, the monitoring coverage target is dependent on available Federal funding (see ''*ASM Coverage Target*'' above and ''*Higher Monitoring Coverage Levels if NMFS Funds Are Available*'' below). The Council identified the importance for industry to know the ASM coverage target at a time certain in advance of the start of the fishing year because the ASM coverage target may have industry costs when Federal funding cannot at least support NMFS and industry costs for a 40-percent ASM coverage target. Therefore, this rule proposes NMFS will announce the ASM coverage target at least 3 weeks before the annual sector enrollment deadline set by NMFS, if Federal funding information is available. In years when Federal funding information is not available prior to the sector enrollment deadline, the ASM coverage target will be announced as soon as practicable.

Review Process for Monitoring Coverage Rates

As part of the revisions to the groundfish sector monitoring program, Amendment 23 includes a Council review process to evaluate the effectiveness of the increased ASM coverage target. The Council would undertake the review once two full fishing years of data are available (likely in year 3 following implementation), and periodically thereafter. The Council review process is intended to be flexible and somewhat general, but would include establishing metrics and indicators of how well the monitoring program improved accuracy while maximizing value and minimizing costs. As a priority for 2021, the Council recommended that the Groundfish Plan Development Team develop the review process metrics based on the Council's final preferred alternatives in Amendment 23. The Council discussed that the scope of the review would be different if 100 percent coverage levels are selected compared to lower coverage levels. The Council selected a fixed ASM coverage target 100 percent of trips, but also selected a default ASM coverage target of 40-percent coverage in the event that Federal funds are not available to support industry costs for higher monitoring coverage. The review process if the ASM coverage target is 100 percent could include metrics such as discard estimate CVs and a measure of how catch (discards and landings) changed following implementation of comprehensive monitoring. For lower ASM coverage targets, the review may include additional metrics to ensure monitoring targets were met and were effective, and might include analyses of whether the program is operating in a way the Council intended, whether catch is being measured accurately, or whether there is evidence of bias.

The intent of the review process is to evaluate whether the revised groundfish sector monitoring program, and particularly the increased ASM coverage target, is meeting the Council's goal of improved accuracy of catch data and catch monitoring while maximizing the value of the data collected and minimizing the costs of the monitoring program. The Council would be responsible for the review and the results would support potential future Council action to refine the groundfish

sector monitoring program or revise the ASM coverage target. NMFS may also review the sector monitoring program to assist the Council in its review and to ensure the sector monitoring program meets requirements of the Magnuson-Stevens Act, particularly the requirement to specify ACLs at a level that prevents overfishing, including measures to ensure accountability.

Waivers From Monitoring Requirements

Amendment 23 includes a provision to allow waivers exempting individual vessels from industry-funded monitoring requirements, for either a trip or the fishing year, if coverage would be unavailable due to insufficient funding for NMFS administrative costs to meet the ASM coverage target. The waivers would include coverage for ASM and EM, including DSM for MREM vessels. Allowing the potential to issue these waivers preserves the Council's intent to increase monitoring in the groundfish fishery without creating a requirement that could prevent vessels from participating in the groundfish fishery if monitoring coverage was not available.

As described above, NMFS would evaluate available Federal funding each year (see ''*ASM Coverage Target*'' above). If NMFS determines that there is insufficient funding to pay for its cost responsibilities, as defined in § 648.11(g)(3), for an ASM coverage target of at least 40 percent, then vessels would continue to be required to notify NMFS of all trips through the PTNS, but NMFS would issue a waiver for a sector trip exempting the vessel from the sector monitoring program coverage requirements. If NMFS waives monitoring requirements due to insufficient funding, as part of its review the Council would consider whether changes to the FMP were necessary to ensure effective management if the ASM coverage target was less than 40 percent.

Exclusion From Monitoring Requirements for Certain Vessel Under Certain Conditions

Amendment 23 excludes sector fishing trips fished in their entirety west of 71°30′ W Longitude from the ASM requirement. The Council included this provision to minimize the costs of the overall increase in monitoring because the majority of groundfish are caught in waters east of this boundary. The catch composition includes little to no catch of many groundfish stocks, with substantial catch of a few groundfish stocks, for sector vessels fishing exclusively west of 71°30′ W Longitude (see Table 73 of the EIS). However, the proportion of commercial catches for some stocks (Southern New England yellowtail flounder and winter flounder, southern windowpane flounder, and ocean pout) caught in this area has been over 25 percent in recent years.

Vessels would continue to be required to notify NMFS of all trips through the PTNS, but NMFS would issue a waiver for a sector trip exempting the vessel from ASM on a trip fishing exclusively west of 71°30′ W Longitude. Vessels on a trip excluded from the ASM requirement under this provision would be required to comply with the VMS declaration requirements at § 648.10(g)(3), and the transiting requirements at § 648.81(e) when east of 71°30′ W Longitude. Vessels using EM to satisfy the sector monitoring requirement would be required to have their system turned on and comply with their vessel monitoring plan on all trips, including trips fishing exclusively west 71°30′ W Longitude.

This proposed exclusion from the ASM requirements raises several implementation issues and concerns that NMFS is highlighting for comment and future Council consideration. First, as discussed in more detail above (see ''*Electronic Monitoring*'' above), NMFS proposes that vessels using EM must have their EM system operational and running on every sector groundfish trip, including trips that would otherwise be excluded from the ASM requirement under this provision, unless issued a waiver by NMFS or assigned an ASM. Therefore, this exclusion would not apply to EM vessels. Second, any catch of groundfish on these trips would not be monitored and because the 71°30′ W Longitude line splits three statistical areas (533, 537, and 539), some trips in those statistical areas will have ASM coverage and others will not, complicating any attempt to use observed trips to estimate catch on unobserved trips in those areas, including during the Council's review (see ''*Review Process for Monitoring Coverage Rates*'' above). The Council should consider these issues when considering uncertainty buffers in future actions setting specifications.

Review Process for Vessels Excluded Exempted From Commercial Groundfish Monitoring Program Requirements

The monitoring revisions in Amendment 23 establish a process for reviewing measures that exclude certain vessels from the groundfish monitoring program requirements based on catch composition. This includes the existing gear-based exclusion from the ASM requirement, implemented by Framework 55, for sector trips that exclusively fish using gillnets of 10-inch (24.5-cm) or larger mesh in the Inshore Georges Bank and/or the Southern New England Broad Stock Areas; and the Amendment 23 provision excluding sector fishing trips taken in their entirety west of 71°30′ W Longitude (see ''*Exclusion from Monitoring Requirements for Certain Vessel Under Certain Conditions*'' above). The Council will conduct this review after two years of fishing data are available and every three years after that.

The intent of the review process is to evaluate whether the trips excluded from the ASM requirement continue to catch small amounts of groundfish. The Council raised a concern that it did not want vessels to change their fishing behavior and target groundfish on trips excluded from the ASM requirement. The review would also be important to evaluate whether exclusions from the ASM requirement undermine the monitoring program or other measures of the FMP. The Council would be responsible for the review and the results would support potential future Council action.

Higher Monitoring Coverage Levels if NMFS Funds Are Available

Amendment 23 would allow for ASM at higher coverage levels than the ASM coverage target selected by the Council, up to 100 percent, if NMFS determines funding is available to cover the additional administrative costs to NMFS and sampling costs to industry in a given year. This measure would apply to year 5 and later, when the ASM coverage target would otherwise be 40 percent of sector trips.

Monitoring coverage of 100 percent of trips, or as close to 100 percent as achievable increases the accuracy of catch estimates and at least reduces, if not eliminates, the potential for bias. Higher coverage levels, even for a limited time, could inform understanding of the magnitude of bias, and inform future actions on the value of higher monitoring coverage levels. ASM coverage of 100 percent of trips is currently considered to remove or reduce bias to the greatest extent practicable; however, it may be impracticable for industry or NMFS to fund costs associated with complete ASM coverage, resulting in a lower ASM coverage level. Higher levels of ASM coverage would substantially increase costs to NMFS and sectors. Making the ASM coverage target contingent on Federal funding for industry costs balances the need for improved monitoring with the economic impacts on the fishery.

Each year, NMFS would evaluate available Federal funding and determine how much Federal funding is available for the groundfish sector monitoring program and then use that in conjunction with other available information (*e.g.,* recent monitoring costs, estimate of the number of vessels choosing EM) to calculate the ASM coverage target for the coming fishing year.

Elimination of Management Uncertainty Buffer for Sector ACLs

Amendment 23 includes an option to revise the management uncertainty buffer for the sector portion of the ACL for each allocated groundfish stock to be set to zero. The NE Multispecies includes a process for setting an overfishing limit (OFL) for groundfish stocks. The OFL represents the maximum amount of fish that can be caught in a year without resulting in overfishing. The Council typically recommends an acceptable biological catch (ABC) for a groundfish stock that is lower than the OFL to account for scientific uncertainty. The Council sets an ACL at a level below the ABC to account for management uncertainty, and this serves as a buffer to prevent the fishery from exceeding the ABC. The management uncertainty buffer accounts for the possibility that management measures will result in a level of catch greater than expected. The Council evaluates the management uncertainty buffers in each specification-setting action.

The revised management uncertainty buffers would apply only to sectors, and not to the common pool component of the fishery, or other sub-ACLs or sub-components for any stocks. The management uncertainty buffer may be removed only in years in which the ASM coverage target is 100 percent. The process by which the Council evaluates and sets management uncertainty buffers remains unchanged and the Council could adjust management uncertainty buffers in future actions. The need for a management uncertainty buffer for the sector sub-ACL would continue to be evaluated as part of each specification action.

Monitoring adequacy, precision, and enforceability of management measures are three of the elements considered in setting the management uncertainty buffer. An ASM coverage target of 100 percent could minimize all of those sources of management uncertainty for the sector fishery. The full accountability associated with comprehensive monitoring could remove uncertainty about whether management measures successfully restrain catch by sector vessels to the sector quotas. Eliminating uncertainty in quantifying true sector catch could make the management uncertainty buffer unnecessary for the sector program. Removing the buffer provides direct benefits to the fishery by providing opportunity for additional catch and revenue. Increased catch and revenue may reduce the net costs of increased monitoring.

NMFS would make an annual determination prior to the start of the fishing year as to whether the buffers would be eliminated based on the ASM coverage target set for the fishing year. If Federal funds are not available for 100 percent ASM coverage and a lower target coverage level is set, the management uncertainty buffers would be in place for that fishing year, subject to the Council's review as part of each specification action. If 100-percent monitoring coverage is determined not to be effective, or if any additional elements evaluated when setting the management uncertainty buffers have the potential to result in catches that could exceed ACLs, the PDT would recommend an appropriate management uncertainty buffer for the sector sub-ACLs as part of actions setting specifications.

This proposed elimination of the uncertainty buffer for sectors raises several issues that NMFS is highlighting for comment and future Council consideration. First, as discussed above, Amendment 23 excludes sector fishing trips taken in their entirety west of 71°30′ W Longitude from the ASM requirement, but for some stocks (southern New England yellowtail flounder and winter flounder, southern windowpane flounder, and ocean pout) catch in this area has been over 25 percent in recent years. Further, 71°30′ W Longitude splits three statistical areas (533, 537, and 539), making estimation of catch on those trips more complicated. Second, some operational discards (*e.g.,* fish fall from the net, birds steal fish) of allocated groundfish occur on MREM trips and the Council should consider how to account for those fish. Third, eliminating the uncertainty buffer from the sector allocations would result in negligible sector carryover because sector carryover from one year to the next is limited by the management uncertainty buffer between the ACL and ABC in year 2. These issues arose after the Council made its final decision on Amendment 23. We highlight these issues to ensure the Council and the public have an opportunity to comment on how NMFS proposes to address these issues.

Sector Reporting

Amendment 23 would authorize the Regional Administrator to modify the sector monitoring requirements at § 648.87(b)(1)(v) and the sector reporting requirements at § 648.87(b)(1)(vi) to streamline the sector reporting process. Each week, each sector must submit to NMFS a summary catch report, including quota balances; a detailed catch report with catch for each trip; and a trip issue report detailing any enforcement or reporting compliance issues, violations of sector operations and regulations, and general problems with monitoring or sector operations. When a sector has caught 90 percent of any quota, that sector must submit daily catch reports. Each sector must also submit an annual report that summarizes the fishing activities of participating vessels.

More efficient methods might be developed that would still involve timely monitoring and reconciliation of data sources between sectors and NMFS. For example, NMFS could eliminate the requirement for sectors to submit weekly and daily reports and instead provide monitoring summaries for the sectors to use for catch accounting and managing annual catch entitlements, while continuing the process where NMFS and sectors reconcile catch data to confirm accuracy. Authorizing the Regional Administrator to streamline the sector reporting process could help to reduce reporting redundancies, provide flexibility to sectors and sector managers, and improve timeliness of data processing.

As discussed above (see ''*Electronic Monitoring*''), Amendment 23 specified that vessels using Audit Model EM in place of ASM would be required to report discards at the haul level. However, the current operational Audit Model allows vessels to report discards at the sub-trip level, rather than the haul level. As part of implementing Amendment 23, NMFS proposes using the authority to streamline sector reporting requirements to allow vessels using the Audit Model to continue reporting discards at the sub-trip level, rather than the haul level, and is soliciting comment on this proposal.

Addition to List of Framework Items

The regulations at § 648.90 list management measures that may be changed or implemented through specifications or framework actions. During the development of Amendment 23, the Council identified a list of specific issues that may be addressed through future specifications actions or

framework adjustments. All alternatives considered in Amendment 23 would be added to the list of FMP items that may be considered in a future framework. Specifically, this includes:

- The addition of new sector monitoring tools (*e.g.,* EM, other technologies or approaches) that meet or exceed the Council's selected monitoring standard;
- Setting vessel-specific coverage targets instead of coverage targets applicable at the sector level; and
- All the Amendment 23 measures discussed in detail above.

Amendment 23 includes two options for electronic monitoring that would be available for sectors to include in their operations plans without requiring a separate determination of sufficiency by NMFS. Further evolution of technology or development of analytical methods could lead to additional or better tools for achieving the goals of the monitoring program. It is not possible to forecast technology changes, but it is expected that in the future there may be additional technologies that would benefit the monitoring program that the Council could adopt through a framework.

A vessel-specific coverage level would require each vessel to meet the target coverage level, rather than evaluating the target at the sector level. The intent would be to reduce the variation in the amount of industry-funded monitoring coverage applicable to each vessel.

The intent of adding all alternatives considered in Amendment 23 to the list of framework items is to allow adjustments to groundfish monitoring program to be considered in a framework action. This would support a Council response to the new review requirements that would be implemented as part of Amendment 23. The regulations at § 648.90(a)(2)(iii) would be revised to specify that the Council could consider these items in a future framework adjustment.

Regulatory Adjustments and Corrections Under Regional Administrator Authority

NMFS is proposing several changes to the regulations consistent with section 305(d) of the Magnuson-Stevens Act, which provides that the Secretary of Commerce may promulgate regulations necessary to ensure that amendments to an FMP are carried out in accordance with the FMP and the Magnuson-Stevens Act. These adjustments do not make any substantive changes to the current regulations, but are intended to improve the clarity of the regulations.

First, NMFS would revise § 648.2 to add definitions of terms related to EM that are used in the implementing regulations for Amendment 23 and clarify and consolidate definitions related to individuals that collect data for NMFS. Second, NMFS would move the sector monitoring program regulations from § 648.87 to § 648.11. Third, NMFS would revise § 648.11 to update the names of divisions within NMFS. Fourth, NMFS would revise §§ 648.2, 648.10, 648.11, 648.14, 648.51, 648.80, 648.86, and 648.202 to clarify that individuals undergoing observer training are included in regulatory provisions that apply to certified observers. Finally, NMFS would revise § 648.14(k) to correct a typographical error where text is missing and to clarify application of the prohibitions to EM.

Finally, due to the extensive regulatory changes in this action, we are updating references throughout the groundfish regulations that will change based on the proposed regulatory adjustments. We have included a summary of all of the proposed regulatory changes in this rule in Table 1.

TABLE 1—SUMMARY OF PROPOSED REGULATORY CHANGES TO 50 CFR PART 648

Section	Authority	Summary of proposed changes
§ 648.2	Amendment 23 and 305(d).	The existing definition of ''electronic monitoring'' is revised and new definitions for ''electronic monitoring audit model'' and ''electronic monitoring maximized retention model'' are added to address the EM models included in Amendment 23. A new definition for ''electronic monitoring provider staff'' is added to accommodate monitoring staff that are not involved in at-sea or dockside monitoring tasks. The existing definition of ''observer/sea sampler'' is deleted and the existing definition of ''observer or monitor'' is revised to cover any person, including trainees, who collects observer information, operational fishing data, biological data, or economic data for conservation and management purposes, whether they work on a vessel or on shore. The definitions of ''slippage in the Atlantic herring fishery,'' ''slip(s) or slipping catch in the Atlantic herring fishery,'' and ''video reviewer'' are revised to include staff in training.
§ 648.10	305(d)	Paragraph (f)(4)(i) is revised to include staff in training.
§ 648.11	Amendment 23 and 305(d).	The monitoring coverage regulations are revised to include the groundfish sector monitoring program regulations currently codified in § 648.87. The newly added groundfish sector monitoring program regulations include revisions and additions to the text formerly codified in § 648.87 to incorporate the proposed measures to implement Amendment 23. This section is also revised to clarify the insurance requirements for monitoring providers, to clarify that individuals undergoing observer training are included in regulatory provisions that apply to certified observers, and to update the names of divisions within NMFS.
§ 648.14	Amendment 23 and 305(d).	The prohibitions are revised to address new regulations implementing Amendment 23 and to revise citations associated with moving the groundfish sector monitoring program regulations currently codified in § 648.87 to § 648.11. The prohibitions are also revised to address changes to the definitions in § 648.2 that include monitoring staff that are not involved in at-sea or dockside monitoring tasks and trainees. Prohibitions are added to address the dockside monitoring requirements applicable to dealers at § 648.11 that implement Amendment 23. Section 648.14(k)(3) is revised to incorporate missing text stating it is prohibited to engage in the behaviors listed in sub-paragraphs. Sections 648.14(i)(1)(ix)(B) and (r)(2)(iv) are also revised to include staff in training.
§ 648.51	305(d)	§§ 648.51(c)(4) and (e)(3)(iii) are revised to include staff in training.
§ 648.80	305(d)	§§ 648.80(d)(3) and (e)(2)(ii) are revised to include staff in training.
§ 648.83(a)(1)	Amendment 23	The text regarding minimum fish sizes for commercial vessels is revised to exclude fish landed by MREM vessels from the minimum sizes to implement Amendment 23.
§ 648.85	Amendment 23 and 305(d).	Section 648.85(e)(1)(viii)(C) is revised to address the participation of MREM vessels in the universal sector exemption for targeting redfish.
§ 648.86	Amendment 23	The text regarding NE multispecies possession limits for commercial vessels is revised to exclude fish landed by MREM vessels to implement Amendment 23. Section 648.86(a)(3)(ii)(A)(*1*) is also revised to include staff in training.
§ 648.87	Amendment 23	Section 648.87 is revised by removing the groundfish sector monitoring program regulations that are being moved to § 648.11, redesignating the remaining paragraphs, and updating citations to the new locations of the monitoring regulations.
§ 648.90	Amendment 23	Section 648.90 is revised to include all Amendment 23 measures as frameworkable items. The potential to implement vessel-specific ASM coverage targets was also added to the list of frameworkable items consistent with Amendment 23. New regulatory text was added specifying that the sector portion of the management uncertainty buffer for allocated stocks would be set to zero when the coverage target is 100 percent, unless the Council chooses to incorporate a different amount of management uncertainty for sectors.

TABLE 1—SUMMARY OF PROPOSED REGULATORY CHANGES TO 50 CFR PART 648—Continued

Section	Authority	Summary of proposed changes
§ 648.202	305(d)	Section 648.202(b)(1) is revised to include staff in training.

Classification

NMFS is issuing this rule pursuant to sections 304(b)(1)(A) and 305(d) of the Magnuson-Stevens Act, which provide specific authority for implementing this action. Pursuant to Magnuson-Stevens Act section 305(d), this action is necessary to carry out the NE Multispecies FMP, through administrative changes revising the existing implementing regulations for the groundfish sector monitoring program to be consistent with the industry-funded monitoring program regulations, moving the groundfish monitoring program implementing regulations to the same chapter as other industry-funded monitoring programs, and improving the clarity of the existing regulations. Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has made a preliminary determination that this proposed rule is consistent with the NE Multispecies FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

The New England Fishery Management Council prepared a final environmental impact statement for Amendment 23 to the NE Multispecies FMP; a notice of availability was published on January 21, 2022 (87 FR 3298). A target ASM coverage rate of 100 percent, higher than past and current coverage levels, will be in place, if sufficient Federal funds are available, which should result in more accurate information on catch (landings and discards) of target and non-target species, and fully account for discard mortality. In the short term, improved catch accounting is expected to reduce fishing effort and fishing mortality, which in the long term should allow for rebuilding of overfished stocks. In the longer-term analytical assessments should improve with better catch data. If the proposed coverage level target of 100 percent results in reduced groundfish fishing activity, then it may provide some minor short-term benefits to habitat. Over the long term, if 100-percent coverage contributes to higher catch limits, fishing effort could increase in the future, which could have negative impacts to habitat. The modifications in management measures may indirectly affect protected resources, but are not expected to have substantial impacts on protected resources. This action is expected to have a range of potential socioeconomic impacts, depending on the availability of Federal funding for monitoring and the ultimate ASM coverage target. A target at-sea monitoring coverage rate of 100 percent will be in place, if sufficient Federal funds are available, which will result in relatively neutral impacts on operating costs compared to those under past and current coverage levels. However, if no Federal funding is available, the ASM coverage rate target would be 40 percent, which would increase fleet wide operating costs by an estimated $2.09 million per year. Economic effects could be lower if any subsidy is available to offset the cost of monitoring, or depending on the number of vessels that use electronic monitoring (EM) in lieu of human at-sea monitoring. Initial costs of installing and purchasing EM equipment may be high which may have negative impacts in the short term, if not subsidized, but over the long term EM may be more cost effective than human at-sea monitors. EM is expected to be more cost effective for vessels who fish more in the groundfish fishery (*i.e.,* greater than 20 days per year). Based on the amount of available funds that have been allocated to reimburse sectors for monitoring as of 2021, there appears to be sufficient funds for at least 2 years of 100-percent monitoring starting in fishing year 2022. In addition, 100-percent at-sea monitoring coverage may be seen as overly burdensome by fishing communities. However, under 100-percent monitoring coverage the enforceability of the FMP and the risk of non-compliance both improve, which should improve the fairness and equitability of management measures. In the short term, economic impacts of 100-percent at-sea monitoring coverage on human communities would be reduced while Federal reimbursements for monitoring costs are available. Impacts over the long term will vary depending on whether Federal reimbursements of monitoring costs continue into the future.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

An initial regulatory flexibility analysis (IRFA) was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A copy of the IRFA, contained in the Environmental Impact Statement, is available from the Council (see **ADDRESSES**). A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. No relevant Federal rules duplicate, overlap, or conflict with this proposed rule. A summary of the analysis follows.

Description of the Reasons Why Action by the Agency Is Being Considered and Statement of the Objectives of, and Legal Basis for, This Proposed Rule

This action is taken under the authority of the Magnuson-Stevens Act and regulations at 50 CFR part 648.

The primary purpose of this action is to improve accounting of landings and discards in the commercial groundfish fishery, while also taking into account the costs of such monitoring. Catch of commercial groundfish in the sector component of the fishery is managed via a quota system, where pounds of each groundfish species are allocated annually to sectors (essentially cooperatives) and all fish caught, including discards, must be accounted against these shares of quota. Quota shares (pounds) are ''leased'' (traded) among sectors, with each sector agreeing to a lease price prior to executing the trade. Catch that is discarded or landed without accounting would save sectors and the businesses that comprise those sectors the value of the leased quota pounds. To ensure that all sectors are accountable to their annual allocations, various monitoring methods were considered in Amendment 23.

Description and Estimate of the Number of Small Entities to Which This Proposed Rule Would Apply

This action would regulate all commercial fishing businesses issued a Federal limited access NE multispecies vessel permit and/or a NE multispecies dealer permit. As of June 1, 2020, NMFS had issued 828 commercial limited access groundfish permits associated with vessels and 148 permits associated with dealers. Therefore, 976 permits are regulated by this action. Each vessel or dealer may be individually owned or part of a larger corporate ownership

structure, and for RFA purposes, it is the ownership entity that ultimately would be regulated by the proposed action. Ownership entities are identified on June 1 of each year, based on the list of all permit numbers, for the most recent complete calendar year, that have applied for any type of Northeast Federal fishing permit. The current ownership data set is based on calendar year 2019 permits and contains gross sales associated with those permits for calendar years 2017 through 2019.

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. The determination as to whether the entity is large or small is based on the average annual revenue for the three years from 2017 through 2019. Ownership data collected from vessel permit holders indicate that there are 667 distinct business entities that hold at least one vessel permit regulated by the proposed action. Of these, all are engaged primarily in commercial fishing, and 80 did not have any revenues (were inactive) in 2019. Of these distinct business entities, 661 are categorized as small entities and 6 are categorized as large entities, per the NMFS guidelines. Ownership data collected from dealer permit holders indicate there are 148 distinct business entities that hold at least one dealer permit regulated by this action. Of these, 135 distinct businesses are categorized as small entities and 13 are categorized as large entities, per the NMFS guidelines.

Federal Rules Which May Duplicate, Overlap, or Conflict With This Proposed Rule

The proposed action does not duplicate, overlap, or conflict with any other Federal rules.

Description of Significant Alternatives to the Proposed Action Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact on Small Entities

The New England Fishery Management Council selected all alternatives that met the objectives of the action, and minimized costs, to provide regulated businesses the ability to choose the monitoring options that best suit their operations while meeting the catch accounting requirements.

Description of the Projected Reporting, Record-Keeping, and Other Compliance Requirements of This Proposed Rule

A description of the projected reporting, recordkeeping, and other compliance requirements of this proposed action, including an estimate of the classes of small entities that will be subject to the requirements is contained in the Notice of Information Collection published December 17, 2021 (86 FR 71624), and summarized below.

This proposed rule contains a collection-of-information requirement subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). This rule revises, and renews, the existing requirements for the collection of information 0648–0605, titled ''Northeast Multispecies Amendment 16.'' These revisions are due to an increased monitoring and reporting burden from higher ASM coverage targets; additional reporting and data collection through voluntary options for sector monitoring tools (audit model EM and MREM); potential for increases or decreases in monitoring and reporting burden as a result of coverage level changes from funding provisions; and an additional VMS declaration required for vessels fishing on a trip exclusively west of 71°30′ W longitude to be excluded from the ASM requirement.

In 2010, we implemented a new suite of regulations for the NE multispecies fishery through Amendment 16 to the NE Multispecies FMP. Amendment 16 required sectors to develop and fund an independent third-party ASM program. Amendment 16 allowed sectors to use EM instead of human monitors to meet ASM requirements, provided that the Greater Atlantic Regional Administrator deemed EM sufficient. Using the authority and process granted to it in Amendment 16, NMFS announced its determination that sectors may use EM to meet monitoring requirements (86 FR 16686; March 31, 2021). To implement this change, we are proposing to collect additional data elements necessary to support an EM program. Specifically, we propose to require the development and submission of VMPs and trip-level feedback reports, both of which are critical for accurate catch data and management of ACLs. We also propose to require the collection of information related to the purchase and installation of EM equipment. This is necessary for NMFS to reimburse industry's ASM costs as directed and funded by Congressional appropriations.

We estimate 1,309 entities will be subject to the existing and new elements of the information collection. The estimated total annual burden hours are 73,198. The estimated total annual cost to the public is $10,632,454 in recordkeeping and reporting costs. These estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The estimated time per response varies by item within the suite of information collected, as follows: Sector operations plan and membership list updates, 110 hours; monitoring service provider initial application, 10 hours; monitoring service provider response to application disapproval, 10 hours; data entry for sector discard monitoring system, 3 minutes; sector weekly catch report, 4 hours; sector annual report, 10 hours; notification of expulsion from a sector, 30 minutes; request to transfer sector annual catch entitlement, 5 minutes; request to lease DAS, 5 minutes; request to downgrade DAS baseline, 5 minutes; VMS area and DAS declaration, 5 minutes; VMS trip-level catch report; VMS daily catch reports when fishing in multiple broad stock areas, 15 minutes; daily VMS catch reports when fishing in the U.S./Canada Management Area and Closed Area II Special Access Programs, 15 minutes; daily VMS catch reports when fishing in the Regular B DAS Program, 15 minutes; pre-trip hail report, 2 minutes; trip-end hail report, 15 minutes; pre-trip notification system notification, 2 minutes; vessel notification of selection for ASM coverage, 5 minutes; at-sea monitor deployment report, 10 minutes; ASM and EM service provider catch report to NMFS upon request, 5 minutes; at-sea monitor or EM staff report of harassment, safety concerns, and other issues, 30 minutes; ASM and EM service provider contracts upon request, 30 minutes; ASM and EM service provider information materials upon request, 30 minutes; EM VMP development and submission, 2 hours; EM vessel feedback letters, 30 minutes; EM equipment installation, 16 hours; EM equipment purchase and installation reimbursement form, 30 minutes; Office of Law Enforcement debriefing of at-sea monitors and EM staff, 2 hours; ASM database and data entry requirements, 0 minutes; DAS Transfer Program, 5minutes; submission of proposed special access programs, 20 hours; and

NAFO Reporting Requirements, 23 hours.

Public comment is sought regarding: Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Submit comments on these or any other aspects of the collection of information at *www.reginfo.gov/public/do/PRAMain.*

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 of information displays a currently valid OMB Control Number.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: February 14, 2022.

Samuel D. Rauch, III

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. Section 648.2 is amended by:
■ a. Revising the definition for ''Electronic monitoring'';
■ b. Adding the definition for ''Electronic monitoring audit model'';
■ c. Adding the definition for ''Electronic monitoring maximized retention model'';
■ d. Adding the definition for ''Electronic monitoring provider staff'';
■ e. Revising the definition for ''Observer or monitor'';
■ f. Removing the definition for ''Observer/sea sampler'';
■ g. Republishing in alphabetical order the definition of ''Ocean quahog''.
■ h. Revising the definition for ''Slippage in the Atlantic herring fishery'';
■ i. Revising the definition for ''Slip(s) or slipping catch in the Atlantic herring fishery''; and
■ j. Revising the definition for ''Video reviewer''.

The revisions and additions read as follows:

§ 648.2 Definitions.

* * * * *

Electronic monitoring means a network of equipment that uses a software operating system connected to one or more technology components, including, but not limited to, cameras and recording devices to collect data on catch and vessel operations. With respect to the groundfish sector monitoring program, electronic monitoring means any equipment that is used to meet sector monitoring requirements in lieu of at-sea monitors as part of an approved sector at-sea monitoring program, including the audit model and maximized retention model.

Electronic monitoring audit model with respect to the groundfish sector monitoring program means a program in which all eligible trips must be electronically monitored; discards are reported at the haul level; fish must be handled in view of cameras; species identification and length must be collected for regulated species and ocean pout discards for catch estimation; allowed discarding must occur at controlled points in view of cameras; and electronic monitoring data are compared to the area fished, regulated species and ocean pout discards, and other information reported on the vessel trip report on a subset of trips for validation.

* * * * *

Electronic monitoring maximized retention model with respect to the groundfish sector monitoring program, means a program in which all eligible trips are electronically monitored; fish must be handled in view of cameras; allowed discarding must occur at controlled points in view of cameras; all allocated regulated species stocks must be retained; electronic monitoring is used to verify compliance; and offloads are subject to observation by dockside monitors.

* * * * *

Electronic monitoring provider staff means any video reviewer, or any person employed or contracted by an electronic monitoring service provider to provide electronic monitoring services to vessels.

* * * * *

Observer or monitor means any person authorized by NMFS to collect observer information, operational fishing data, biological data, or economic data for conservation and management purposes on or from fishing vessels or federally permitted dealers as required by the regulations, including, but not limited to, observers, at-sea monitors, observer/sea samplers, portside samplers, or dockside monitors.

Ocean quahog means the species *Arctica islandica.*

* * * * *

Slippage in the Atlantic herring fishery means discarded catch from a vessel issued an Atlantic herring permit that is carrying an observer or monitor prior to the catch being brought on board or prior to the catch being made available for sampling and inspection by an observer or monitor after the catch is on board. Slippage also means any catch that is discarded during a trip prior to it being sampled portside by a portside sampler on a trip selected for portside sampling coverage by NMFS. Slippage includes releasing catch from a codend or seine prior to the completion of pumping the catch aboard and the release of catch from a codend or seine while the codend or seine is in the water. Fish that cannot be pumped and remain in the codend or seine at the end of pumping operations are not considered slippage. Discards that occur after the catch is brought on board and made available for sampling and inspection by an observer or monitor are also not considered slippage.

* * * * *

Slip(s) or slipping catch in the Atlantic herring fishery means discarded catch from a vessel issued an Atlantic herring permit that is carrying an observer or monitor prior to the catch being brought on board or prior to the catch being made available for sampling and inspection by an observer or monitor after the catch is on board. Slip(s) or slipping catch also means any catch that is discarded during a trip prior to it being sampled portside by a portside sampler on a trip selected for portside sampling coverage by NMFS. Slip(s) or slipping catch includes releasing fish from a codend or seine prior to the completion of pumping the fish on board and the release of fish from a codend or seine while the codend or seine is in the water. Slippage or slipped catch refers to fish that are slipped. Slippage or slipped catch does not include operational discards, discards that occur after the catch is brought on board and made available for sampling and inspection by an observer or monitor, or fish that inadvertently fall out of or off fishing gear as gear is being brought on board the vessel.

* * * * *

Video reviewer means any electronic monitoring service provider staff

approved/certified or training to be approved/certified by NMFS for providing electronic monitoring video review services consistent with electronic monitoring program requirements.

* * * * *

■ 3. Section 648.10 is amended by revising paragraph (f)(4)(i) to read as follows:

§ 648.10 VMS and DAS requirements for vessel owners/operators.

* * * * *

(f) * * *

(4) * * *

(i) For trips greater than 24 hours, the owner or operator of a limited access or LAGC scallop vessel with an IFQ permit that fishes for, possesses, or retains scallops, and is not fishing under a NE Multispecies DAS or sector allocation, must submit reports through the VMS, in accordance with instructions to be provided by the Regional Administrator, for each day fished, including open area trips, access area trips as described in § 648.59(b)(9), Northern Gulf of Maine RSA trips, and trips accompanied by an observer. The reports must be submitted for each day (beginning at 0000 hr and ending at 2400 hr) and not later than 0900 hr of the following day. Such reports must include the following information:

(A) VTR serial number;

(B) Date fish were caught;

(C) Total pounds of scallop meats kept; and

(D) Total pounds of all fish kept.

* * * * *

■ 4. Section 648.11 is amended by:

■ a. Revising paragraphs (a), (b), (d), (h)(1), (h)(3)(vii), (h)(3)(ix) and (x), (h)(5)(i) through (iv), (h)(5)(vi) and (vii), (h)(7), (i)(1) and (2), (i)(3)(i), (i)(4)(ii), (i)(5) and (6);

■ b. Adding paragraph (i)(7); and

■ c. Revising paragraphs (j), (k)(4)(i) and (ii), (l), (m)(1)(i) and (v), (m)(2)(iii)(A), (m)(4)(i), (m)(6) introductory text, and (n)(2) introductory text.

The revisions and addition read as follows:

§ 648.11 Monitoring coverage.

(a) *Coverage.* The Regional Administrator may request any vessel holding a permit for Atlantic sea scallops, NE multispecies, monkfish, skates, Atlantic mackerel, squid, butterfish, scup, black sea bass, bluefish, spiny dogfish, Atlantic herring, tilefish, Atlantic surfclam, ocean quahog, or Atlantic deep-sea red crab; or a moratorium permit for summer flounder; to carry a fisheries observer. A vessel holding a permit for Atlantic sea scallops is subject to the additional requirements specific in paragraph (g) of this section. Also, any vessel or vessel owner/operator that fishes for, catches or lands hagfish, or intends to fish for, catch, or land hagfish in or from the exclusive economic zone must carry a fisheries observer when requested by the Regional Administrator in accordance with the requirements of this section. The requirements of this section do not apply to vessels with only a Federal private recreational tilefish permit.

(b) *Facilitating coverage.* If requested by the Regional Administrator or their designees, including observers, monitors, and NMFS staff, to be sampled by an observer or monitor, it is the responsibility of the vessel owner or vessel operator to arrange for and facilitate observer or monitor placement. Owners or operators of vessels selected for observer or monitor coverage must notify the appropriate monitoring service provider before commencing any fishing trip that may result in the harvest of resources of the respective fishery. Notification procedures will be specified in selection letters to vessel owners or permit holder letters.

* * * * *

(d) *Vessel requirements associated with coverage.* An owner or operator of a vessel on which an observer or monitor is embarked must:

(1) Provide accommodations and food that are equivalent to those provided to the crew.

(2) Allow the observer or monitor access to and use of the vessel's communications equipment and personnel upon request for the transmission and receipt of messages related to the observer's or monitor's duties.

(3) Provide true vessel locations, by latitude and longitude or loran coordinates, as requested by the observer or monitor, and allow the observer or monitor access to and use of the vessel's navigation equipment and personnel upon request to determine the vessel's position.

(4) Notify the observer or monitor in a timely fashion of when fishing operations are to begin and end.

(5) Allow for the embarking and debarking of the observer or monitor, as specified by the Regional Administrator, ensuring that transfers of observers or monitors at sea are accomplished in a safe manner, via small boat or raft, during daylight hours as weather and sea conditions allow, and with the agreement of the observers or monitors involved.

(6) Allow the observer or monitor free and unobstructed access to the vessel's bridge, working decks, holding bins, weight scales, holds, and any other space used to hold, process, weigh, or store fish.

(7) Allow the observer or monitor to inspect and copy any the vessel's log, communications log, and records associated with the catch and distribution of fish for that trip.

* * * * *

(h) * * *

(1) *General.* An entity seeking to provide monitoring services, including services for IFM Programs described in paragraph (g) of this section, must apply for and obtain approval from NMFS following submission of a complete application. Monitoring services include providing observers, monitors (at-sea monitors and portside samplers), and/or electronic monitoring. A list of approved monitoring service providers shall be distributed to vessel owners and shall be posted on the NMFS Fisheries Sampling Branch (FSB) website: *https://www.fisheries.noaa.gov/resource/data/observer-providers-northeast-and-mid-atlantic-programs.*

* * * * *

(3) * * *

(vii) Evidence of holding adequate insurance to cover injury, liability, and accidental death for any observers, monitors (at-sea or dockside/roving monitors), or electronic monitoring provider staff who provide electronic monitoring services onboard vessels, whether contracted or directly employed by the service provider, during their period of employment (including during training).

(A) A monitoring service provider must hold Workers' Compensation and Maritime Employer's Liability for observers, monitors, vessel owners, and their operations. The minimum combined coverage required is $5 million.

(B) An electronic monitoring service provider must hold Worker's Compensation and commercial general liability coverage for electronic monitoring provider staff. The minimum combined coverage required is $1 million.

(C) Upon request by a vessel owner, operator, or vessel manager, a monitoring service provider must provide a certificate of insurance, or other evidence, that demonstrates they have the required coverages under (A) and (B) of this paragraph as appropriate.

* * * * *

(ix) The names of its fully equipped certified observers, monitors, or video reviewers on staff; or a list of its training candidates (with resumes) and a request for an appropriate NMFS-certified

Training class. All training classes have a minimum class size of eight individuals, which may be split among multiple vendors requesting training. Requests for training classes with fewer than eight individuals will be delayed until further requests make up the full training class size.

(x) An Emergency Action Plan (EAP) describing its response to an emergency with an observer, monitor, or electronic monitoring provider staff on a vessel at sea or in port, including, but not limited to, personal injury, death, harassment, or intimidation. The EAP shall include communications protocol and appropriate contact information in an emergency.

* * * * *

(5) *Responsibilities of monitoring service providers.* To maintain an approved monitoring service provider status, a monitoring service provider, including electronic monitoring service providers, must demonstrate an ability to provide or support the following monitoring services:

(i) *Certified observers or monitors.* Provide observers or monitors that have passed a NMFS-certified Observer or Monitor Training class pursuant to paragraph (i) of this section for deployment in a fishery when contacted and contracted by the owner, operator, or vessel manager of a fishing vessel, unless the monitoring service provider refuses to deploy an observer or monitor on a requesting vessel for any of the reasons specified at paragraph (h)(5)(viii) of this section.

(ii) *Support for observers, monitors, or electronic monitoring provider staff.* Ensure that each of its observers, monitors, or electronic monitoring provider staff procures or is provided with the following:

(A) All necessary transportation, lodging costs and support for arrangements and logistics of travel for observers, monitors, or electronic monitoring provider staff to and from the initial location of deployment, to all subsequent vessel assignments, to any debriefing locations, and for appearances in Court for monitoring-related trials as necessary;

(B) Lodging, per diem, and any other services necessary for observers, monitors, or electronic monitoring provider staff assigned to a fishing vessel or to attend an appropriate NMFS training class;

(C) The required observer, monitor, or electronic monitoring equipment, in accordance with equipment requirements, prior to any deployment and/or prior to certification training; and

(D) Individually assigned communication equipment, in working order, such as a mobile phone, for all necessary communication. A monitoring service provider may alternatively compensate observers or monitors for the use of the observer's or monitor's personal mobile phone, or other device, for communications made in support of, or necessary for, the observer's or monitor's duties.

(iii) *Deployment logistics.* (A) Assign an available observer or monitor to a vessel upon request. For service providers contracted to meet the requirements of the NE multispecies monitoring program in paragraph (l) of this section, assign available at-sea monitors, electronic monitoring provider staff, and other approved at-sea monitoring mechanisms fairly and equitably in a manner that represents fishing activities within each sector throughout the fishing year without regard to any sector manager or vessel representative preference.

(B) Enable an owner, operator, or manager of a vessel to secure monitoring coverage or electronic monitoring technical support when requested, 24 hours per day, 7 days per week via a telephone or other notification system that is monitored a minimum of four times daily to ensure rapid response to industry requests.

(iv) *Observer deployment limitations.* (A) A candidate observer's first several deployments and the resulting data shall be immediately edited and approved after each trip by NMFS prior to any further deployments by that observer. If data quality is considered acceptable, the observer would be certified.

(B) For the purpose of coverage to meet SBRM requirements, unless alternative arrangements are approved by NMFS, a monitoring service provider must not deploy any observer on the same vessel for more than two consecutive multi-day trips, and not more than twice in any given month for multi-day deployments.

(C) For the purpose of coverage to meet IFM requirements, a monitoring service provider may deploy any observer or monitor on the same vessel for more than two consecutive multi-day trips and more than twice in any given month for multi-day deployments.

* * * * *

(vi) *Observer and monitor training requirements.* Ensure all observers and monitors attend and complete a NMFS-certified Observer or Monitor Training class. Requests for training must be submitted to NMFS 45 calendar days in advance of the requested training. The following information must be submitted to NMFS at least 15 business days prior to the beginning of the proposed training: A list of observer or monitor candidates; candidate resumes, cover letters and academic transcripts; and a statement signed by the candidate, under penalty of perjury, that discloses the candidate's criminal convictions, if any. A medical report certified by a physician for each candidate is required 7 business days prior to the first day of training. CPR/First Aid certificates and a final list of training candidates with candidate contact information (email, phone, number, mailing address and emergency contact information) are due 7 business days prior to the first day of training. NMFS may reject a candidate for training if the candidate does not meet the minimum qualification requirements as outlined by NMFS minimum eligibility standards for observers or monitors as described on the National Observer Program website: *https://www.fisheries.noaa.gov/topic/fishery-observers#become-an-observer.*

(vii) *Reports and Requirements.* (A) *Deployment reports.*

(*1*) Report to NMFS when, where, to whom, and to what vessel an observer or monitor has been deployed, as soon as practicable, and according to requirements outlined by NMFS. The deployment report must be available and accessible to NMFS electronically 24 hours a day, 7 days a week.

(*2*) Ensure that the raw (unedited) data collected by the observer or monitor is provided to NMFS at the specified time per program. Electronic data submission protocols will be outlined in training and may include accessing government websites via personal computers/devices or submitting data through government issued electronics.

(B) *Safety refusals.* Report to NMFS any trip or landing that has been refused due to safety issues (*e.g.,* failure to hold a valid USCG Commercial Fishing Vessel Safety Examination Decal or to meet the safety requirements of the observer's or monitor's safety checklist) within 12 hours of the refusal.

(C) *Biological samples.* Ensure that biological samples, including whole marine mammals, sea turtles, sea birds, and fin clips or other DNA samples, are stored/handled properly and transported to NMFS within 5 days of landing. If transport to NMFS Observer Training Facility is not immediately available then whole animals requiring freezing shall be received by the nearest NMFS freezer facility within 24 hours of vessel landing.

(D) *Debriefing.* Ensure that the observer, monitor, or electronic

monitoring provider staff remains available to NMFS, either in-person or via phone, at NMFS' discretion, including NMFS Office of Law Enforcement, for debriefing for at least 2 weeks following any monitored trip/offload or electronic monitoring trip report submission. If requested by NMFS, an observer or monitor that is at sea during the 2-week period must contact NMFS upon his or her return. Monitoring service providers must pay for travel and land hours for any requested debriefings.

(E) *Availability report.* The monitoring service provider must report to NMFS any inability to respond to an industry request for observer or monitor coverage due to the lack of available observers or monitors as soon as practicable. Availability report must be available and accessible to NMFS electronically 24 hours a day, 7 days a week.

(F) *Incident reports.* Report possible observer, monitor, or electronic monitoring provider staff harassment, discrimination, concerns about vessel safety, or marine casualty; concerns with possible electronic monitoring system tampering, data loss, or catch handling protocols; or observer or monitor illness or injury; or other events as specified by the Regional Administrator; and any information, allegations, or reports regarding observer, monitor, or electronic monitoring provider staff conflict of interest or breach of the standards of behavior, to NMFS within 12 hours of the event or within 12 hours of learning of the event.

(G) *Status report.* (*1*) Provide NMFS with an updated list of contact information for all observers or monitors that includes the identification number, name, mailing address, email address, phone numbers, homeports or fisheries/trip types assigned, and must include whether or not the observer or monitor is ''in service,'' indicating when the observer or monitor has requested leave and/or is not currently working for an industry-funded program.

(*2*) Place any Federally contracted observer not actively deployed on a vessel for 30 days on Leave of Absence (LOA) status (or as specified by NMFS) according to most recent Information Technology Security Guidelines.

(*3*) Ensure Federally contracted observers on LOA for 90 days or more conduct an exit interview with NMFS and return any NMFS issued gear and Common Access Card (CAC), unless alternative arrangements are approved by NMFS. NMFS requires 2-week advance notification when a Federally contracted observer is leaving the program so that an exit interview may be arranged and gear returned.

(H) *Vessel contract.* Submit to NMFS, if requested, a copy of each type of signed and valid contract (including all attachments, appendices, addendums, and exhibits incorporated into the contract) between the monitoring service provider and those entities requiring monitoring services.

(I) *Observer, monitor, or video reviewer contract.* Submit to NMFS, if requested, a copy of each type of signed and valid contract (including all attachments, appendices, addendums, and exhibits incorporated into the contract) between the monitoring service provider and specific observers, monitors, or video reviewers.

(J) *Additional information.* Submit to NMFS, if requested, copies of any information developed and/or used by the monitoring service provider and distributed to vessels, observers, monitors, or electronic monitoring provider staff such as informational pamphlets, payment notification, daily rate of monitoring or review services, description of observer or monitor duties, etc.

(K) *Discard estimates.* Estimate discards for each trip and provide such information to the sector manager and NMFS when providing monitoring services to meet catch estimation and/or at-sea or electronic monitoring service requirements in paragraph (l) of this section.

(L) *Data system.* If contracted to meet the groundfish sector monitoring program in paragraph (l) of this section, maintain an electronic monitoring system to record, retain, and distribute to NMFS upon request for a minimum of 12 months after receiving notice from NMFS that catch data are finalized for the fishing year, the following information:

(*1*) The number of at-sea monitor deployments and other approved monitoring equipment deployments or video reviews, including any refusal to provide service when requested and reasons for such refusals;

(*2*) Incident/non-compliance reports (*e.g.,* failure to offload catch);

(*3*) Vessel hail reports and landings records;

(*4*) Electronic monitoring data and reports; and

(*5*) A means to protect the confidentiality and privacy of data submitted by vessels, as required by the Magnuson-Stevens Act.

(M) *Data retention.* Ensure that electronic monitoring data and reports are retained for a minimum of 12 months after catch data are finalized for the fishing year. NMFS will notify monitoring service providers of the catch data finalization date each year. The electronic monitoring service provider must provide NMFS access to electronic monitoring data or reports upon request.

(N) *Software requirements.* Provide NMFS with all software necessary for accessing, viewing, and interpreting the data generated by the electronic monitoring system, including submitting the agency's secondary review data to the application programming interface and maintenance releases to correct errors in the software or enhance software functionality. The software must:

(*1*) Support a ''dual user'' system that allows NMFS to complete and submit secondary reviews to the application programming interface.

(*2*) Allow for the export or download of electronic monitoring data in order for the agency to make a copy if necessary.

(O) *Software training.* Provide software training for NMFS staff.

(P) *Facilitation.* Provide the following to NMFS upon request:

(*1*) Assistance in electronic monitoring system operations, diagnosing/resolving technical issues, and recovering lost or corrupted data;

(*2*) Responses to inquiries related to data summaries, analyses, reports, and operational issues;

(*3*) Access to video reviewers for debriefing sessions;

(Q) *Litigation support.* Provide technical and expert information substantiating electronic monitoring system data, testing procedures, error rates, peer review or other issues raised in litigation, including but not limited to, a brief summary of the litigation and any court findings on the reliability of the technology.

* * * * *

(7) *Removal of monitoring service provider from the list of approved service providers.* A monitoring service provider that fails to meet the requirements, conditions, and responsibilities specified in paragraphs (h)(5) and (6) of this section shall be notified by NMFS, in writing, that it is subject to removal from the list of approved monitoring service providers. Such notification shall specify the reasons for the pending removal. A monitoring service provider that has received notification that it is subject to removal from the list of approved monitoring service providers may submit written information to rebut the reasons for removal from the list. Such rebuttal must be submitted within 30 days of notification received by the

monitoring service provider that the monitoring service provider is subject to removal and must be accompanied by written evidence rebutting the basis for removal. NMFS shall review information rebutting the pending removal and shall notify the monitoring service provider within 15 days of receipt of the rebuttal whether or not the removal is warranted. If no response to a pending removal is received by NMFS, the monitoring service provider shall be automatically removed from the list of approved monitoring service providers. The decision to remove the monitoring service provider from the list, either after reviewing a rebuttal, or if no rebuttal is submitted, shall be the final decision of NMFS and the Department of Commerce. Removal from the list of approved monitoring service providers does not necessarily prevent such monitoring service provider from obtaining an approval in the future if a new application is submitted that demonstrates that the reasons for removal are remedied. Observers and monitors under contract with observer monitoring service provider that has been removed from the list of approved service providers must complete their assigned duties for any fishing trips on which the observers or monitors are deployed at the time the monitoring service provider is removed from the list of approved monitoring service providers. A monitoring service provider removed from the list of approved monitoring service providers is responsible for providing NMFS with the information required in paragraph (h)(5)(vii) of this section following completion of the trip. NMFS may consider, but is not limited to, the following in determining if a monitoring service provider may remain on the list of approved monitoring service providers:

(i) Failure to meet the requirements, conditions, and responsibilities of monitoring service providers specified in paragraphs (h)(5) and (6) of this section;

(ii) Evidence of conflict of interest as defined under paragraph (h)(6) of this section;

(iii) Evidence of criminal convictions related to:

(A) Embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property; or

(B) The commission of any other crimes of dishonesty, as defined by state law or Federal law, that would seriously and directly affect the fitness of an applicant in providing monitoring services under this section; and

(iv) Unsatisfactory performance ratings on any Federal contracts held by the applicant; and

(v) Evidence of any history of decertification as either an observer, monitor, or monitoring service provider.

(i) *Observer, monitor, or video reviewer certification.* (1) *Requirements.* To be certified as an observer, or monitor, or video reviewer, a monitoring service provider employee or contractor must meet the criteria in paragraphs (i)(1) through (3) of this section for observers, or paragraphs (i)(1), (2), and (4) of this section for monitors, and paragraphs (i)(1), (2), and (5) of this section for video reviewers, respectively. In addition, observers must meet NMFS National Minimum Eligibility Standards for observers specified at the National Observer Program website: *https://www.fisheries.noaa.gov/topic/fishery-observers#become-an-observer.*

(2) *Training.* In order to provide observer or monitor services and be deployed on any fishing vessel, a candidate observer or monitor must have passed an appropriate NMFS-certified Observer or Monitor Training course and must adhere to all NMFS program standards and policies. In order to perform electronic monitoring video review, a candidate video reviewer must have passed an appropriate NMFS-certified Video Review Training course and must adhere to all NMFS program standards and policies. NMFS will immediately notify any candidate that fails training and the monitoring service provider. Observer or monitor training may include an observer training trip, as part of the observer's training, aboard a fishing vessel with a trainer. Contact NMFS for the required number of program specific observer and monitor training certification trips for full certification following training.

(3) * * *

(i) Have a valid NMFS fisheries observer certification pursuant to paragraph (i)(1) of this section;

* * * * *

(4) * * *

(ii) Have a valid NMFS certification pursuant to paragraph (i)(1) of this section;

* * * * *

(5) *Video reviewer requirements.* All video reviewers must:

(i) Hold a high school diploma or legal equivalent;

(ii) Have a valid NMFS certification pursuant to paragraph (i)(1) of this section; and

(iii) Accurately record sampling data, write complete reports, and report accurately any observations relevant to conservation of marine resources or their environment.

(6) *Probation and decertification.* NMFS may review observer, monitor, and video reviewer certifications and issue observer, monitor, and video reviewer certification probations and/or decertifications as described in NMFS policy.

(7) *Issuance of decertification.* Upon determination that decertification is warranted under paragraph (i)(6) of this section, NMFS shall issue a written decision to decertify the observer, monitor, or video reviewer to the observer, monitor, or video reviewer and approved monitoring service provider via certified mail at the observer's, monitor's, or video reviewer's most current address provided to NMFS. The decision shall identify whether a certification is revoked and shall identify the specific reasons for the action taken. Decertification is effective immediately as of the date of issuance, unless the decertification official notes a compelling reason for maintaining certification for a specified period and under specified conditions. Decertification is the final decision of NMFS and the Department of Commerce and may not be appealed.

(j) *Coverage.* In the event that a vessel is requested by the Regional Administrator to carry a fisheries observer pursuant to paragraph (a) of this section and is also selected to carry an at-sea monitor as part of an approved sector at-sea monitoring program specified in paragraph (l) of this section for the same trip, only the fisheries observer is required to go on that particular trip. Vessels using electronic monitoring to satisfy the groundfish sector monitoring program requirement must comply with their vessel monitoring plan on all trips, including a trip that has been selected to carry, or a trip that carries, a fisheries observer.

(k) * * *

(4) * * *

(i) An owner of a scallop vessel required to carry an observer under paragraph (k)(3) of this section must arrange for carrying an observer that has passed a NMFS-certified Observer Training class certified by NMFS from an observer service provider approved by NMFS under paragraph (h) of this section. The owner, operator, or vessel manager of a vessel selected to carry an observer must contact the observer service provider and must provide at least 48-hr notice in advance of the fishing trip for the provider to arrange for observer deployment for the specified trip. The observer service provider will notify the vessel owner,

operator, or manager within 18 hr whether they have an available observer. A list of approved observer service providers shall be posted on the NMFS/FSB website: *https://www.fisheries.noaa.gov/resource/data/observer-providers-northeast-and-mid-atlantic-programs.* The observer service provider may take up to 48 hr to arrange for observer deployment for the specified scallop trip.

(ii) An owner, operator, or vessel manager of a vessel that cannot procure an observer within 48 hr of the advance notification to the provider due to the unavailability of an observer may request a waiver from NMFS from the requirement for observer coverage for that trip, but only if the owner, operator, or vessel manager has contacted all of the available observer service providers to secure observer coverage and no observer is available. NMFS shall issue such a waiver within 24 hr, if the conditions of this paragraph (k)(4)(ii) are met. A vessel may not begin the trip without being issued a waiver.

* * * * *

(l) * * *

(1) *Groundfish sector monitoring program goals and objectives.* The primary goal of the at-sea/electronic monitoring program is to verify area fished, as well as catch and discards by species and gear type, in the most cost-effective means practicable. The following goals and objectives of groundfish monitoring programs are equally-weighted secondary goals by which monitoring programs established for the NE multispecies are to be designed to be consistent with:

(i) Improve documentation of catch:

(A) Determine total catch and effort, for each sector and common pool, of target or regulated species and ocean pout; and

(B) Achieve coverage level sufficient to minimize effects of potential monitoring bias to the extent possible while maintaining as much flexibility as possible to enhance fleet viability.

(ii) Reduce the cost of monitoring:

(A) Streamline data management and eliminate redundancy;

(B) Explore options for cost-sharing and deferment of cost to industry; and

(C) Recognize opportunity costs of insufficient monitoring.

(iii) Incentivize reducing discards:

(A) Determine discard rate by smallest possible strata while maintaining cost-effectiveness; and

(B) Collect information by gear type to accurately calculate discard rates.

(iv) Provide additional data streams for stock assessments:

(A) Reduce management and/or biological uncertainty; and

(B) Perform biological sampling if it may be used to enhance accuracy of mortality or recruitment calculations.

(v) Enhance safety of monitoring program.

(vi) Perform periodic review of monitoring program for effectiveness.

(2) *Sector monitoring programs.* A sector must develop and implement an at-sea and/or electronic monitoring program that may be approved by NMFS as both sufficient to monitor catch, discards, and use of sector ACE; and as consistent with the sector monitoring program goals and objectives. The details of any at-sea or electronic monitoring program must be specified in the sector's operations plan, pursuant to paragraph § 648.87(b)(2)(xi), and must meet the operational standards specified in paragraph (l)(10) of this section. Maximized retention electronic monitoring and audit electronic monitoring models, meeting the requirements in paragraph (l)(10) of this section, may be used in place of at-sea monitoring to ensure a sector's monitoring programs may be approved. Other types of electronic monitoring may be used in place of at-sea monitors if the technology is deemed sufficient by NMFS, in a manner consistent with the Administrative Procedure Act, for a specific trip type based on gear type and area fished. The Regional Administrator will approve or disapprove at-sea/electronic programs, including vessel monitoring plans, as part of a sector's operations plans in a manner consistent with the Administrative Procedure Act.

(3) *Pre-trip notification.* For the purpose of selecting vessels for observer or at-sea monitor deployment, as instructed by the Regional Administrator, the owner, operator, or manager of a vessel (*i.e.,* vessel manager or sector manager) issued a limited access NE multispecies permit that is fishing under a NE multispecies DAS or on a sector trip, as defined in this part, must provide advance notice to NMFS at least 48 hr prior to departing port on any trip declared into the NE multispecies fishery pursuant to § 648.10 or § 648.85 of the following: The vessel name, permit number, and sector to which the vessel belongs, if applicable; contact name and telephone number for coordination of observer or at-sea monitor deployment; date, time, and port of departure; and the vessel's trip plan, including area to be fished, whether a monkfish DAS will be used, and gear type to be used, unless otherwise specified in this paragraph (l) or notified by the Regional Administrator. For trips lasting 48 hr or less in duration from the time the vessel leaves port to begin a fishing trip until the time the vessel returns to port upon the completion of the fishing trip, the vessel owner, operator, or manager may make a weekly notification rather than trip-by-trip calls. For weekly pre-trip notification, a vessel must notify NMFS by 0001 hr of the Friday preceding the week (Sunday through Saturday) that it intends to complete at least one NE multispecies DAS or sector trip during the following week and provide the vessel's trip-plans for that week, including each trip's date, time, port of departure, area to be fished, whether a monkfish DAS will be used, and gear type to be used. Pre-trip notification calls must be made no more than 10 days in advance of each fishing trip. The vessel owner, operator, or manager must notify NMFS of any trip plan changes at least 24 hr prior to vessel departure from port. A vessel may not begin the trip without being issued either an observer notification, an at-sea monitor notification, or a waiver by NMFS.

(4) *Vessel selection for observer or at-sea monitor coverage.* NMFS shall notify the vessel owner, operator, or manager whether the vessel must carry an observer or at-sea monitor for the specified trip within 24 hr of the vessel owner's, operator's or manager's pre-trip notification of the prospective trip, as specified in paragraph (l)(2) of this section. All pre-trip notifications shall be issued a unique confirmation number. A vessel may not fish on a NE multispecies DAS or sector trip with an observer waiver confirmation number that does not match the vessel's trip plan that was called in to NMFS. Confirmation numbers and the vessel's observer or observer waiver status for pre-trip notification calls remain valid for 48 hr from the intended sail date. After a trip begins, that trip's confirmation number and observer or observer waiver status remains valid until the trip ends. If a trip is interrupted and the vessel returns to port due to bad weather or other circumstance beyond the operator's control, the vessel's observer or observer waiver status and confirmation number for the interrupted trip remains the same if the vessel departs within 48 hr from the vessel's return to port. If the layover time is greater than 48 hr, the vessel owner, operator, or manager must provide a new pre-trip notification. If an observer or at-sea monitor is assigned to a particular trip, a vessel may not leave port without the at-sea monitor on board, unless NMFS issues a waiver. If a vessel is using electronic monitoring to comply with the monitoring requirements of this part, it may not leave port without an operational

electronic monitoring system on board, unless NMFS issues a waiver, or assigned other at-sea monitoring coverage.

(5) *Sector monitoring coverage levels.* Coverage levels for an at-sea or electronic monitoring program, including video review requirements, shall be specified by NMFS, pursuant to paragraph (l)(5)(i) of this section.

(i) *At-sea monitoring coverage target.* The at-sea monitoring coverage target for the sector monitoring program will be set as a percentage of all eligible sector trips based on available federal funding for NMFS and industry cost responsibilities as defined in paragraph (g)(3) of this section. Sectors are responsible for industry costs for at-sea monitoring coverage up to the coverage target for all trips not observed by a Northeast Fishery Observer Program observer. In fishing years 2022, 2023, 2024, and 2025, the ASM coverage target will be set at the highest level that available federal funding for NMFS and industry cost responsibilities supports, up to 100 percent of trips. Beginning in fishing year 2026, the target coverage will be set at 40 percent of trips, unless replaced by the Council after a review, as detailed in paragraph (l)(5)(v) of this section. In the absence of available federal funds sufficient to fund both NMFS costs and industry costs associated with a coverage target of at least 40 percent of all sector trips, sectors must pay the industry's costs for coverage necessary to achieve a 40-percent coverage target. As an example, if, after paying NMFS costs, available federal funding is sufficient only to fund industry costs for 15-percent coverage, sectors must pay the industry costs for the remaining 25-percent coverage to achieve a 40-percent coverage target. Any coverage provided by the Northeast Fisheries Observer Program through deployment of an observer would be deducted from the industry's cost responsibility. To ensure coverage is both sufficient to monitor sector catch, discards, and sector ACE; and consistent with sector monitoring goals and objectives, at-sea monitoring coverage may be higher than the at-sea monitoring coverage target, up to 100 percent of all eligible trips, if available federal funding is sufficient for NMFS and industry cost responsibilities, respectively. NMFS will announce the coverage target at least 3 weeks before the annual sector enrollment deadline set by NMFS, if federal funding information is available.

(ii) *Gear-based exclusion from the at-sea monitoring program.* A sector vessel that notifies NMFS of its intent to exclusively fish using gillnets with a mesh size of 10-inch (25.4-cm) or greater in either the Inshore GB Stock Area, as defined at § 648.10(k)(3)(ii), and/or the SNE Broad Stock Area, as defined at § 648.10(k)(3)(iv), is not subject to the coverage level for at-sea monitoring specified in § 648.11(l)(5)(i) provided that the trip is limited to the Inshore GB and/or SNE Broad Stock Areas and that the vessel only uses gillnets with a mesh size of 10-inches (25.4-cm) or greater. When on such a trip, other gear may be on board provided that it is stowed and not available for immediate use as defined in § 648.2. A sector trip fishing with 10-inch (25.4-cm) mesh or larger gillnets will still be subject to at-sea monitoring coverage if the trip declares its intent to fish in any part of the trip in the GOM Stock area, as defined at § 648.10(k)(3)(i), or the Offshore GB Stock Area, as defined at § 648.10(k)(3)(iii). Vessels using electronic monitoring to satisfy the sector monitoring requirement must have their system turned on and comply with their vessel monitoring plan on all trips, including a trip that is limited to the Inshore GB and/or SNE Broad Stock Areas where the vessel only uses gillnets with a mesh size of 10-inches (25.4-cm) or greater.

(iii) *Geographic exclusion from the at-sea monitoring program.* Vessels fishing exclusively west of 71 degrees 30 minutes west longitude on a sector trip are excluded from the requirement to carry an at-sea monitor. Vessels on a trip excluded from the at-sea monitoring requirement under this provision must comply with the VMS declaration requirements at § 648.10(g)(3), and the transiting requirements at § 648.81(e) when east of 71 degrees 30 minutes. Vessels using electronic monitoring to satisfy the sector monitoring requirement must have their system turned on and comply with their vessel monitoring plan on all trips, including trips fishing exclusively west of 71 degrees 30 minutes west longitude.

(iv) *Waivers.* In addition to the safety waivers in § 648.11(c), NMFS may issue a waiver for a sector trip exempting the vessel from the sector monitoring program coverage requirements for the following reasons.

(A) *Funding waivers.* NMFS will issue a waiver for a sector trip exempting the vessel from the sector monitoring program coverage requirements if coverage is unavailable due to insufficient funding for NMFS cost responsibilities as defined in paragraph (g)(3) of this section.

(B) *Logistics waivers.* NMFS may issue a waiver for a sector trip exempting the vessel from the sector monitoring program coverage requirements for logistical and technical reasons, including, but not limited to: No monitor is available; the assigned observer is unable to make the trip; the trip will have no fishing effort; and electronic monitoring system technical problems.

(C) *Set-only trip waivers.* Vessels on a set-only trip, as defined at § 648.2, are excluded from the groundfish sector monitoring program requirements in § 648.11(l). If a vessel is using electronic monitoring to comply with the monitoring requirements of this part, that vessel may turn off its cameras on a set-only trip.

(v) *Review of exclusions from the at-sea monitoring program.* A Council review of the exclusions from the at-sea monitoring program in § 648.11(l)(5)(ii) and (iii) will evaluate whether the exclusions continue to meet the intent of the Council to exclude trips with little catch of regulated species and ocean pout. The review will be conducted using complete data from 2 fishing years once the data are available (fishing years 2022 and 2023) and every 3 years after the initial review.

(6) *Groundfish sector monitoring program review.* A Council review of the NE multispecies monitoring program will evaluate whether the monitoring program is meeting the goal of improved accuracy of catch data, while maximizing value and minimizing costs of the program, using complete data from 2 fishing years once the data are available (fishing years 2022 and 2023) and periodically after the initial review. The review process should be flexible and general, and include establishing metrics and indicators of how well the monitoring program improved accuracy while maximizing value and minimizing costs.

(7) *Hail reports.* For the purposes of the monitoring requirements specified in paragraph (l)(2) of this section, sector vessels must submit all hail reports for a sector trip in which the NE multispecies catch applies against the ACE allocated to a sector, as specified in this part, to their respective contracted monitoring service providers. The mechanism and timing of the transmission of such hail reports must be consistent with instructions provided by the Regional Administrator for any at-sea or electronic monitoring program required by paragraph (l)(2) of this section, or specified in the annual sector operations plan, consistent with § 648.87(b)(5).

(8) *Notification of monitoring service provider change.* If, for any reason, a sector decides to change approved service providers used to provide at-sea or electronic monitoring services

required in paragraph (l)(2) of this section, the sector manager must first inform NMFS in writing in advance of the effective date of the change in approved monitoring service providers in conjunction with the submission of the next weekly sector catch report specified in § 648.87(b)(1)(v)(B). A sector may use more than one monitoring service provider at any time, provided any monitoring service provider employed by or contracted with a sector meets the standards specified in paragraph (b)(4) of this section.

(9) *Discards.* A sector vessel may not discard any legal-sized regulated species or ocean pout allocated to sectors pursuant to § 648.87(b)(1)(i), unless otherwise required pursuant to § 648.86(l). Discards of undersized regulated species or ocean pout by a sector vessel must be reported to NMFS consistent with the reporting requirements specified in § 648.87(b)(1)(v). Discards shall not be included in the information used to calculate a vessel's PSC, as described in § 648.87(b)(1)(i)(E), but shall be counted against a sector's ACE for each regulated species allocated to a sector.

(10) *Sector monitoring program operational standards.* In addition to the monitoring service provider standards specified in paragraph (h)(5) of this section, any at-sea/electronic monitoring program developed as part of a sector's yearly operations plan pursuant to paragraph (l)(2) of this section must meet the following operational standards to be approved by NMFS:

(i) *Vessel requirements.* (A) *Electronic monitoring system requirements.* A vessel owner or operator using electronic monitoring to meet sector monitoring requirements must do the following:

(*1*) Ensure that the electronic monitoring system is fully operational for every sector trip, which means it is operating, recording, and retaining the recording for the duration of every trip. A vessel may not fish without a fully operational electronic monitoring system, unless issued a waiver by NMFS for that trip;

(*2*) Conduct a system check of the electronic monitoring system prior to departing on a fishing trip. An electronic monitoring system check must show that the electronic monitoring system is fully operational and there is sufficient video storage capacity to retain the recording of the entire fishing trip;

(*3*) Maintain clear and unobstructed camera views at all times. Ensure lighting is sufficient in all circumstances to illuminate catch so that catch and discards are visible and may be identified and quantified as required; and

(*4*) Ensure no person tampers with, disconnects, or destroys any part of the electronic monitoring system, associated equipment, or recorded data.

(B) *Vessel monitoring plan requirements for electronic monitoring vessels.* A vessel must have a NMFS-approved vessel monitoring plan to use electronic monitoring to meet sector monitoring requirements. The vessel monitoring plan describes how an electronic monitoring system is configured on a particular vessel and how fishing operations must be conducted to effectively monitor catch.

(*1*) The vessel monitoring plan must be onboard the vessel at all times.

(*2*) The vessel owner, operator and crew must comply with all catch handling protocols and other requirements described in the vessel monitoring plan, including sorting catch and processing any discards within view of the cameras and consistent with the vessel monitoring plan.

(*3*) Modifications to any vessel monitoring plan must be approved by NMFS prior to such vessel fishing under the conditions of the new vessel monitoring plan.

(*4*) A vessel owner or operator using electronic monitoring to meet sector monitoring requirements must submit all electronic monitoring data to the monitoring service provider in accordance with the electronic monitoring program requirements in § 648.11, or as otherwise instructed by the Regional Administrator.

(*5*) A vessel owner or operator must make the electronic monitoring system, associated equipment, electronic monitoring data, or vessel monitoring plan available to NMFS for inspection, upon request.

(*6*) A vessel owner or operator using electronic monitoring to meet sector monitoring requirements must turn on its camera for 100 percent of sector trips.

(*7*) A vessel owner or operator using electronic monitoring to meet sector monitoring requirements must comply with the requirements in § 648.11(l)(10)(ii)(B) or the Regional Administrator may withdraw approval for the vessel to use electronic monitoring.

(*8*) The Regional Administrator may revise vessel monitoring plan requirements and approval standards consistent with the Administrative Procedure Act. Any revisions will be published on the agency's website.

(C) *Safety hazards.* The operator of a sector vessel must detail and identify any safety hazards to any at-sea monitor assigned pursuant to paragraph (b)(5)(iii)(B)(*1*) of this section prior to leaving port. A vessel may not begin a trip if it has failed a review of safety issues pursuant to paragraph (b)(5)(iv)(B) of this section, until the identified safety deficiency has been resolved, pursuant to § 600.746(i).

(D) *Dockside monitoring.* Vessels using maximized retention electronic monitoring must participate in either an independent third party dockside monitoring program approved by NMFS, or the dockside monitoring program operated by NMFS, as instructed by NMFS.

(E) *Retention of fish.* Vessels using maximized retention electronic monitoring must retain all fish from each allocated regulated species, regardless of length.

(ii) *Sector monitoring plan monitoring service provider requirements.* In addition to the monitoring service provider standards in paragraph (h) of this section, sector monitoring plans must include the following operational requirements for any monitoring provider contracted to meet sector monitoring program requirements in this paragraph (l):

(A) *At-sea monitoring report.* Within 48 hours of the completion of a trip, or as otherwise instructed by the Regional Administrator, electronic submission to NMFS and the sector a report detailing the area fished and the amount of each species kept and discarded. A standard format for submission shall be specified by NMFS and distributed to all monitoring service providers and sectors. NMFS will accept only monitoring data that passes automated NMFS data quality checks.

(B) *Electronic monitoring report.* A report detailing area fished and the amount of each species discarded must be submitted electronically in a standard acceptable form to the appropriate sector and NMFS within 10 business days of a trip being selected for video review, or as otherwise instructed by the Regional Administrator. The format for submission shall be specified by NMFS and distributed to all monitoring service providers and sectors. NMFS will accept only monitoring data that passes automated NMFS data quality checks.

(C) *Vessel feedback report.* A report must be submitted to the vessel owner following a trip with detailed feedback on the vessel operator's and crew's catch handling, camera maintenance, and vessel monitoring plan compliance.

A copy must be submitted to NMFS upon request.

(D) *Safety hazards.* Completion by an at-sea monitor of a pre-trip vessel safety checklist provided by NMFS before an at-sea monitor can leave port onboard a vessel on a sector trip. If the vessel fails a review of safety issues pursuant to this paragraph (l)(10)(ii)(E), an at-sea monitor cannot be deployed on that vessel for that trip.

(E) *Gear.* Provision of all equipment specified by the Northeast Fisheries Science Center to each at-sea monitor before the at-sea monitor may be deployed on a vessel. A list of such equipment is available from the Northeast Fisheries Science Center upon request. This gear shall be inspected by NMFS upon the completion of training required pursuant to paragraph (i)(2) of this section.

(F) *Adjustment to service provider requirements and approval standards.* The Regional Administrator may revise monitoring service provider requirements and approval standards consistent with the Administrative Procedure Act.

(iii) *Sector requirements.* Each sector shall monitor catch by participating sector vessels to ensure that ACEs are not exceeded during the fishing year, as specified in this paragraph (l)(10)(iii). The sector shall summarize trips validated by dealer reports; oversee the use of electronic monitoring equipment and review of associated data; maintain a database of VTR, dealer, observer, and electronic monitoring reports; determine all species landings by stock areas; apply discard estimates to landings; deduct catch from ACEs allocated to sectors; and report sector catch on a weekly basis to NMFS, as required in paragraph (b)(1)(v) of this section. Unless otherwise specified in this paragraph (l)(10), all catches of stocks allocated to sectors by vessels on a sector trip shall be deducted from the sector's ACE for each regulated species stock regardless of the fishery the vessel was participating in when the fish was caught. For the purposes of this paragraph (l)(10), any regulated species or ocean pout caught using gear capable of catching NE multispecies (*i.e.,* gear not listed as exempted gear under this part) would be deducted from a sector's ACE if such catch contributed to the specification of PSC, as described in § 648.87(b)(1)(i)(E), and would not apply to another ACL sub-component pursuant to § 648.90(a)(4). For example, any regulated species or ocean pout landed while fishing for or catching skates or monkfish pursuant to the regulations for those fisheries would be deducted from the sector's ACE for each stock because such regulated species or ocean pout were caught while also operating under a NE multispecies DAS. However, for example, if a sector vessel is issued a limited access General Category Atlantic Sea Scallop permit and fishes for scallops under the provisions specific to that permit, any yellowtail flounder caught by the vessel on such trips would be deducted from the appropriate non-groundfish component, such as the other sub-component or the appropriate yellowtail flounder stock's ACL specified for the Atlantic Sea Scallop fishery and not from the yellowtail flounder ACE for the sector.

(iv) *Dealer requirements.* Federally permitted NE multispecies dealers must allow dockside monitors access to their premises, scales, and any fish received from vessels participating in the maximized retention electronic monitoring program for the purpose of collecting fish species and weights of fish received by the dealer, fish length measurements, and the collection of age structures such as otoliths or scales.

(A) *Facilitation.* Federally permitted NE multispecies dealers must facilitate dockside monitoring for vessels participating in a maximized retention electronic monitoring program, including, but not limited to, the following requirements:

(*1*) Provide a safe sampling station, including shelter from weather, for dockside monitors to conduct their duties and process catch, that is equivalent to the accommodations provided to the dealer's staff.

(*2*) Allow dockside monitors access to bathrooms equivalent to the accommodations provided to the dealer's staff.

(*3*) Allow dockside monitors access to any facilities for washing equipment with fresh water that are provided to the dealer's staff.

(B) *Processing, sorting, labeling, and reporting.* Federally permitted NE multispecies dealers must process fish for vessels participating in a maximized retention electronic monitoring program consistent with and including, but not limited to, the following requirements:

(*1*) Offload from vessels participating in the maximized retention monitoring program all fish below the minimum size specified at § 648.83 before other fish that meet the minimum size, sort the undersized fish by species, and provide the dockside monitor access to those at the safe sampling station.

(*2*) Sort by species all redfish, haddock, and pollock, except that fish of the same species below the minimum size specified at § 648.83 may be mixed with the same species of fish in the smallest market category.

(*3*) Sort by species all unmarketable fish from other fish, when identifiable to species.

(*4*) Clearly identify, mark, or label all containers with fish below the minimum size specified in § 648.83 as containing undersized fish, the fishing vessel from which they were offloaded, and the date of offloading.

(*5*) Report all fish below the minimum size specified in § 648.83, and all unmarketable fish, as instructed by NMFS.

(v) *Adjustment to operational standards.* The at-sea/electronic monitoring operational standards specified in paragraph (l)(10) of this section may be revised by the Regional Administrator in a manner consistent with the Administrative Procedure Act.

(m) * * *

(1) * * *

(i) In addition to the requirement for any vessel holding an Atlantic herring permit to carry an observer described in paragraph (a) of this section, vessels issued a Category A or B Herring Permit are subject to industry-funded monitoring (IFM) requirements on declared Atlantic herring trips, unless the vessel is carrying an observer to fulfill Standard Bycatch Reporting Methodology requirements. An owner of a midwater trawl vessel, required to carry an observer when fishing in Northeast Multispecies Closed Areas at § 648.202(b), may purchase an IFM high volume fisheries (HVF) observer to access Closed Areas on a trip-by-trip basis. General requirements for IFM programs in New England Council FMPs are specified in paragraph (g) of this section. Possible IFM monitoring for the Atlantic herring fishery includes observers, at-sea monitors, and electronic monitoring and portside samplers, as defined in § 648.2.

* * * * *

(v) To provide the required IFM coverage aboard declared Atlantic herring trips, observers and monitors must hold a high volume fisheries certification from NMFS.

(2) * * *

(iii) * * *

(A) For IFM observer coverage aboard vessels fishing with midwater trawl gear to access the Northeast Multispecies Closed Areas, consistent with requirements at § 648.202(b), at any point during the trip;

* * * * *

(4) * * *

(i) An owner of an Atlantic herring vessel required to have monitoring under paragraph (m)(3) of this section

must arrange for monitoring by an observer from a monitoring service provider approved by NMFS under paragraph (h) of this section. The owner, operator, or vessel manager of a vessel selected for monitoring must contact a monitoring service provider prior to the beginning of the trip and the monitoring service provider will notify the vessel owner, operator, or manager whether monitoring is available. A list of approved monitoring service providers shall be posted on the NMFS website: *https://www.fisheries.noaa.gov/resource/data/observer-providers-northeast-and-mid-atlantic-programs.*

* * * * *

(6) *Sampling requirements for observers and monitors.* In addition to the requirements at § 648.11(d)(1) through (7), an owner or operator of a vessel issued a limited access herring permit on which an observer or monitor is embarked must provide observers or monitors:

* * * * *

(n) * * *

(2) *Sampling requirements for limited access Atlantic mackerel and longfin squid/butterfish moratorium permit holders.* In addition to the requirements in paragraphs (d)(1) through (7) of this section, an owner or operator of a vessel issued a limited access Atlantic mackerel or longfin squid/butterfish moratorium permit on which an observer is embarked must provide observers:

* * * * *

■ 5. Section 648.14 is amended by:

■ a. Revising paragraphs (a)(7), (e), and (i)(1)(ix)(B);

■ b. Adding paragraph (k)(2)(vii); and

■ c. Revising paragraphs (k)(3), (k)(14)(ix) through (xiii), and (r)(2)(v).

The revisions and addition read as follows:

§ 648.14 Prohibitions.

(a) * * *

(7) Possess, import, export, transfer, land, or have custody or control of any species of fish regulated pursuant to this part that do not meet the minimum size provisions in this part, unless such species were harvested exclusively within state waters by a vessel that does not hold a valid permit under this part, or are species included in the NE Multispecies Fishery Management Plan that were either harvested by a vessel participating in the maximized retention electronic monitoring program consistent with § 648.11(l)(10)(i)(E) or harvested by a vessel issued a valid High Seas Fishing Compliance permit that fished exclusively in the NAFO Regulatory Area.

* * * * *

(e) *Observer program.* It is unlawful for any person to do any of the following:

(1) Assault, resist, oppose, impede, harass, intimidate, or interfere with or bar by command, impediment, threat, or coercion any observer or monitor conducting his or her duties; any electronic monitoring provider staff who collects data required under this part; any authorized officer conducting any search, inspection, investigation, or seizure in connection with enforcement of this part; any official designee of the Regional Administrator conducting his or her duties, including those duties authorized in §§ 648.7(g) and 648.11(l)(10)(v).

(2) Refuse monitoring coverage by an observer or monitor if selected for monitoring coverage by the Regional Administrator or the Regional Administrator's designee.

(3) Fail to provide information, notification, accommodations, access, or reasonable assistance to either an observer, monitor, or electronic monitoring provider staff conducting his or her duties as specified in § 648.11.

(4) Submit false or inaccurate data, statements, or reports.

* * * * *

(i) * * *

(1) * * *

(ix) * * *

(B) Fail to provide information, notification, accommodations, access, or reasonable assistance to an observer conducting his or her duties aboard a vessel, as specified in § 648.11.

* * * * *

(k) * * *

(2) * * *

(vii) Fish under a waiver from the groundfish sector monitoring program issued under § 648.11(l)(5)(ii) or (iii) without complying with the VMS declaration requirements at § 648.10(g)(3) and the pre-trip notification requirements at § 648.11(l)(1).

(3) *Dealer requirements.* It is unlawful for any person to:

(i) Purchase, possess, import, export, or receive as a dealer, or in the capacity of a dealer, regulated species or ocean pout in excess of the possession limits specified in §§ 648.82, 648.85, 648.86, or 648.87 applicable to a vessel issued a NE multispecies permit, unless otherwise specified in § 648.17, or unless the regulated species or ocean pout are purchased or received from a vessel that caught them on a sector trip and such species are exempt from such possession limits in accordance with an approved sector operations plan, as specified in § 648.87(c).

(ii) Sell or transfer to another person for a commercial purpose, other than solely for transport on land, any NE multispecies harvested from the EEZ by a vessel issued a Federal NE multispecies permit, unless the transferee has a valid NE multispecies dealer permit.

(iii) Purchase, possess, import, export, or receive as a dealer, or in the capacity of a dealer, regulated species or ocean pout from a vessel participating in the maximized retention electronic monitoring program in § 648.11(l) unless the offload of catch was observed by a dockside monitor or NMFS issued a waiver from dockside monitoring for the trip.

(iv) Assault, resist, oppose, impede, harass, intimidate, or interfere with or bar by command, impediment, threat, or coercion any observer or monitor conducting his or her duties or any electronic monitoring provider staff who collects data required under this part.

(v) Impede a dockside monitors' access to their premises, scales, and any fish received from vessels participating in the maximized retention electronic monitoring program; fail to facilitate dockside monitoring for vessels participating in a maximized retention electronic monitoring program; or fail to process, sort, label, and report fish from vessels participating in the maximized retention monitoring program, as required in § 648.11(l)(10)(iv).

* * * * *

(14) * * *

(ix) Fail to comply with the reporting requirements specified in § 648.11(l)(10)(iii) and § 648.87(b)(1)(v).

(x) Leave port to begin a trip before an at-sea monitor has arrived and boarded the vessel if assigned to carry an at-sea monitor for that trip, or without an operational electronic monitoring system installed on board, as specified in §§ 648.11(l)(3) and (l)(10)(i).

(xi) Leave port to begin a trip if a vessel has failed a review of safety issues by an at-sea monitor and has not successfully resolved any identified safety deficiencies, as prohibited by § 648.11(l)(10)(i)(C).

(xii) Fail to comply with the electronic monitoring system requirements as specified in § 648.11(l)(10)(i)(A), including, but not limited to: Ensuring the electronic monitoring system is fully operational; conducting a system check of the electronic monitoring system; ensuring camera views are unobstructed and clear; and ensuring that no person tampers with the electronic monitoring system.

(xiii) Fail to comply with the vessel monitoring plan requirements as

specified in § 648.11(l)(10)(i)(B), including, but not limited to: Carrying the vessel monitoring plan onboard the vessel at all times; complying with all catch handling protocols and other requirements in the vessel monitoring plan; submitting electronic monitoring data as required; and making the electronic monitoring system available to NMFS for inspection upon request.

* * * * *

(r) * * *

(2) * * *

(v) Fish with midwater trawl gear in any Northeast Multispecies Closed Area, as defined in § 648.81(a)(3) through (5) and (c)(3) and (4), without an observer on board, if the vessel has been issued an Atlantic herring permit.

* * * * *

■ 6. Section 648.51 is amended by revising paragraphs (c)(4) and (e)(3)(iii) to read as follows:

§ 648.51 Gear and crew restrictions.

* * * * *

(c) * * *

(4) An at-sea observer is on board, as required by § 648.11(k).

* * * * *

(e) * * *

(3) * * *

(iii) An at-sea observer is on board, as required by § 648.11(k).

* * * * *

■ 7. Section 648.80 is amended by revising paragraphs (d)(3) and (e)(2)(ii) to read as follows:

§ 648.80 NE Multispecies regulated mesh areas and restrictions on gear and methods of fishing.

* * * * *

(d) * * *

(3) The vessel carries an observer, if requested by the Regional Administrator;

* * * * *

(e) * * *

(2) * * *

(ii) The vessel carries an observer, if requested by the Regional Administrator;

* * * * *

■ 8. Section 648.83 is amended by revising paragraph (a)(1) to read as follows:

§ 648.83 Multispecies minimum fish sizes.

(a) * * *

(1) Minimum fish sizes for recreational vessels and charter/party vessels that are not fishing under a NE multispecies DAS are specified in § 648.89. Except as provided in § 648.11(l)(10)(i)(E) and § 648.17, all other vessels are subject to the following minimum fish sizes, determined by total length (TL):

MINIMUM FISH SIZES (TL) FOR COMMERCIAL VESSELS

Species	Size in inches
Cod	19 (48.3 cm).
Haddock	16 (40.6 cm).
Pollock	19 (48.3 cm).
Witch flounder (gray sole)	13 (33 cm).
Yellowtail flounder	12 (30.5 cm).
American plaice (dab)	12 (30.5 cm).
Atlantic halibut	41 (104.1 cm).
Winter flounder (blackback)	12 (30.5 cm).
Redfish	7 (17.8 cm).

* * * * *

■ 9. Section 648.85 is amended by revising paragraph (e)(1)(viii)(C) to read as follows:

§ 648.85 Special management programs.

* * * * *

(e) * * *

(1) * * *

(viii) * * *

(C) *Administration of Thresholds.* (*1*) For the purpose of determining a sector's monthly redfish landings threshold performance described in paragraph (e)(1)(viii)(A)(*1*) of this section and the annual redfish landings threshold described in paragraph (e)(1)(viii)(B)(*1*) of this section, landings of allocated regulated species by vessels participating in a maximized retention electronic monitoring program consistent with § 648.11(l), including landings of allocated stocks below the minimum size at § 648.83(a)(1), will be counted as landings and not discards.

(*2*) For the purpose of determining a sector's monthly discards threshold performance described in paragraph (e)(1)(viii)(A)(*2*) of this section, a trip by a vessel participating in a maximized retention electronic monitoring program consistent with § 648.11(l) will be excluded from evaluation of the monthly discard threshold.

(*3*) If a sector fails to meet the monthly redfish landings threshold or the monthly discards threshold described in paragraphs (e)(1)(viii)(A)(*1*) and (*2*) of this section for four or more months total, or three or more consecutive months, in a fishing year, the Regional Administrator shall prohibit all vessels in that sector from fishing under the provisions of the Redfish Exemption Program for the remainder of the fishing year, and place the sector and its vessels in a probationary status for one fishing year beginning the following fishing year.

(*4*) If a sector fails to meet the annual redfish landings threshold described in paragraph (e)(1)(viii)(B)(*1*) of this section in a fishing year, the Regional Administrator shall place the sector and its vessels in a probationary status for one fishing year beginning the following fishing year.

(*5*) While in probationary status as described in paragraph (e)(1)(viii)(C)(*3*) or (*4*) of this section, if the sector fails to meet the monthly redfish landings threshold or the monthly discards threshold described in paragraphs (e)(1)(viii)(A)(*1*) and (*2*) of this section for four or more months total, or three or more consecutive months, in that fishing year, the Regional Administrator shall prohibit all vessels in that sector from fishing under the provisions of the Redfish Exemption Program for the remainder of the fishing year and the following fishing year.

(*6*) If a sector fails to meet the annual redfish landings threshold in (e)(1)(viii)(B)(*1*) of this section for any fishing year during which the sector is in a probationary status as described in paragraph (e)(1)(viii)(C)(*3*) or (*4*) of this section, the Regional Administrator shall prohibit all vessels in that sector from fishing under the provisions of the Redfish Exemption Program for the following fishing year.

(*7*) The Regional Administrator may determine a sector has failed to meet required monthly or annual thresholds described in paragraphs (e)(1)(viii)(A) and (B) of this section using available information including, but not limited to, vessel declarations and notifications, vessel trip reports, dealer reports, and observer and electronic monitoring records.

(*8*) The Regional Administrator shall notify a sector of a failure to meet the required monthly or annual thresholds and the sector's vessels prohibition or probation status consistent with the provisions in paragraphs (e)(1)(viii)(C)(*1*) through (*7*) of this section. The Regional Administrator shall also make administrative amendments to the approved sector operations plan and issue sector vessel letters of authorization consistent with the provisions in paragraphs (e)(1)(viii)(C)(*1*) through (*7*) of this section. These administrative amendments may be made during a fishing year or during the sector operations plan and sector contract approval process.

(*9*) A sector may request in writing that the Regional Administrator review and reverse a determination made under the provisions of this section within 30 days of the date of the Regional Administrator's determination. Any such request must be based on information showing the sector complied with the required thresholds, including, but not limited to, landing, discard, observer or electronic monitoring records. The Regional

Administrator will review and maintain or reverse the determination and notify the sector of this decision in writing. Any determination resulting from a review conducted under this provision is final and may not be reviewed further.

* * * * *

■ 10. Section 648.86 is amended by revising the introductory text and paragraph (a)(3)(ii)(A)(*1*) to read as follows:

§ 648.86 NE Multispecies possession restrictions.

Except as provided in § 648.11(l), § 648.17, or elsewhere in this part, the following possession restrictions apply:

(a) * * *

(3) * * *

(ii) * * *

(A) * * *

(*1*) *Haddock incidental catch cap.* When the Regional Administrator has determined that the incidental catch allowance for a given haddock stock, as specified in § 648.90(a)(4)(iii)(D), has been caught, no vessel issued an Atlantic herring permit and fishing with midwater trawl gear in the applicable stock area, *i.e.,* the Herring GOM Haddock Accountability Measure (AM) Area or Herring GB Haddock AM Area, as defined in paragraphs (a)(3)(ii)(A)(2) and (3) of this section, may fish for, possess, or land herring in excess of 2,000 lb (907.2 kg) per trip in or from that area, unless all herring possessed and landed by the vessel were caught outside the applicable AM Area and the vessel's gear is stowed and not available for immediate use as defined in § 648.2 while transiting the AM Area. Upon this determination, the haddock possession limit is reduced to 0 lb (0 kg) for a vessel issued a Federal Atlantic herring permit and fishing with midwater trawl gear or for a vessel issued a Category A or B Herring Permit fishing on a declared herring trip, regardless of area fished or gear used, in the applicable AM area, unless the vessel also possesses a NE multispecies permit and is operating on a declared (consistent with § 648.10(g)) NE multispecies trip. In making this determination, the Regional Administrator shall use haddock catches observed by observers or monitors by herring vessel trips using midwater trawl gear in Management Areas 1A, 1B, and/or 3, as defined in § 648.200(f)(1) and (3), expanded to an estimate of total haddock catch for all such trips in a given haddock stock area.

* * * * *

■ 11. Section 648.87 is amended by:

■ a. Revising paragraph (b)(1) introductory text, and (b)(1)(v) through (viii);

■ b. Removing paragraph (b)(1)(ix);

■ c. Revising paragraph (b)(2) and (3); and

■ d. Removing paragraphs (b)(4) and (5).

The revisions read as follows:

§ 648.87 Sector allocation.

* * * * *

(b) * * *

(1) All sectors approved under the provisions of paragraph (a) of this section must submit the documents specified in paragraphs (a)(1), (b)(2), and (3) of this section, comply with the conditions and restrictions of this paragraph (b)(1), and comply with the groundfish sector monitoring program in § 648.11(l).

* * * * *

(v) *Sector reporting requirements.* In addition to the other reporting/recordkeeping requirements specified in this part, a sector's vessels must comply with the reporting requirements specified in this paragraph (b)(1)(v).

(A) *VMS declarations and trip-level catch reports.* Prior to each sector trip, a sector vessel must declare into broad stock areas in which the vessel fishes and submit the VTR serial number associated with that trip pursuant to § 648.10(k). The sector vessel must also submit a VMS catch report detailing regulated species and ocean pout catch by statistical area when fishing in multiple broad stock areas on the same trip, pursuant to § 648.10(k).

(B) *Weekly catch report.* Each sector must submit weekly reports to NMFS stating the remaining balance of ACE allocated to each sector based upon regulated species and ocean pout landings and discards of vessels participating in that sector and any compliance/enforcement concerns. These reports must include at least the following information, as instructed by the Regional Administrator: Week ending date; species, stock area, gear, number of trips, reported landings (landed pounds and live pounds), discards (live pounds), total catch (live pounds), status of the sector's ACE (pounds remaining and percent remaining), and whether this is a new or updated record of sector catch for each regulated species stock allocated to that particular sector; sector enforcement issues; and a list of vessels landing for that reporting week. These weekly catch reports must be submitted no later than 0700 hr on the second Monday after the reporting week, as defined in this part. The frequency of these reports must be increased to more than a weekly submission when the balance of remaining ACE is low, as specified in the sector operations plan and approved by NMFS. If requested, sectors must provide detailed trip-by-trip catch data to NMFS for the purposes of auditing sector catch monitoring data based upon guidance provided by the Regional Administrator.

(C) *Year-end report.* An approved sector must submit an annual year-end report to NMFS and the Council, no later than 60 days after the end of the fishing year, that summarizes the fishing activities of participating permits/vessels, which must include at least the following information: Catch, including landings and discards, of all species by sector vessels; the permit number of each sector vessel that fished for regulated species or ocean pout; the number of vessels that fished for non-regulated species or ocean pout; the method used to estimate discards by sector vessels; the landing port used by sector vessels; enforcement actions; and other relevant information required to evaluate the biological, economic, and social impacts of sectors and their fishing operations consistent with confidentiality requirements of applicable law.

(D) *Streamlining sector reporting requirements.* The reporting/recordkeeping requirements specified in § 648.11(l) and this paragraph (b)(1)(v) may be revised by the Regional Administrator in a manner consistent with the Administrative Procedure Act.

(vi) *Interaction with other fisheries.*

(A) *Use of DAS.* A sector vessel must comply with all measures specified for another fishery pursuant to this part, including any requirement to use a NE multispecies DAS. If the regulations of another fishery require the use of a NE multispecies DAS, the DAS allocation and accrual provisions specified in § 648.82(d) and (e), respectively, apply to each trip by a sector vessel, as applicable. For example, if a sector vessel is also issued a limited access monkfish Category C permit and is required to use a NE multispecies DAS concurrent with a monkfish DAS under this part, any NE multispecies DAS used by the sector vessel accrues, as specified in § 648.82(e)(1)(ii) based upon the vessel's NE multispecies DAS allocation calculated pursuant to § 648.82(d)(1)(iv)(B).

(B) *Availability of ACE.* Notwithstanding the requirements in paragraph (b)(1)(vi)(A) of this section, if a sector has not been allocated or does not acquire sufficient ACE available to cover the catch of a particular stock of regulated species while participating in another fishery in which such catch would apply to the ACE allocated to a sector, vessels participating in that sector cannot participate in those other fisheries unless NMFS has approved a

sector operations plan that ensures that regulated species or ocean pout will not be caught while participating in these other fisheries.

(vii) *ACE transfers.* All or a portion of a sector's ACE for any NE multispecies stock may be transferred to another sector at any time during the fishing year and up to 2 weeks into the following fishing year (*i.e.,* through May 14), unless otherwise instructed by NMFS, to cover any overages during the previous fishing year. A sector is not required to transfer ACE to another sector. An ACE transfer only becomes effective upon approval by NMFS, as specified in paragraph (b)(1)(vii)(B) of this section.

(A) *Application to transfer ACE.* ACE may be transferred from one sector to another through written request to the Regional Administrator. This request must include the name of the sectors involved, the amount of each ACE to be transferred, the fishing year in which the ACE transfer applies, and the amount of compensation received for any ACE transferred, as instructed by the Regional Administrator.

(B) *Approval of an ACE transfer request.* NMFS shall approve/disapprove a request to transfer ACE based upon compliance by each sector and its participating vessels with the reporting requirements specified in this part. The Regional Administrator shall inform both sectors in writing whether the ACE transfer request has been approved within 2 weeks of the receipt of the ACE transfer request.

(C) *Duration of transfer.* Notwithstanding ACE carried over into the next fishing year pursuant to paragraph (b)(1)(i)(C) of this section, ACE transferred pursuant to this paragraph (b)(1)(vii) is only valid for the fishing year in which the transfer is approved, with the exception of ACE transfer requests that are submitted up to 2 weeks into the subsequent fishing year to address any potential ACE overages from the previous fishing year, as provided in paragraph (b)(1)(iii) of this section, unless otherwise instructed by NMFS.

(viii) *Trip limits.* With the exception of stocks listed in § 648.86(1) and the Atlantic halibut trip limit at § 648.86(c), a sector vessel is not limited in the amount of allocated NE multispecies stocks that can be harvested on a particular fishing trip, unless otherwise specified in the operations plan.

(2) *Operations plan and sector contract.* To be approved to operate, each sector must submit an operations plan and preliminary sector contract to the Regional Administrator no later than September 1 prior to the fishing year in which the sector intends to begin operations, unless otherwise instructed by NMFS. A final roster, sector contract, and list of Federal and state permits held by participating vessels for each sector must be submitted by December 1 prior to the fishing year in which the sector intends to begin operations, unless otherwise instructed by NMFS. The operations plan may cover a 1- or 2-year period, provided the analysis required in paragraph (b)(3) of this section is sufficient to assess the impacts of sector operations during the 2-year period and that sector membership, or any other parameter that may affect sector operations during the second year of the approved operations plan, does not differ to the point where the impacts analyzed by the supporting NEPA document are compromised. Each vessel and vessel operator and/or vessel owner participating in a sector must agree to and comply with all applicable requirements and conditions of the operations plan specified in this paragraph (b)(2) and the letter of authorization issued pursuant to paragraph (c)(2) of this section. It shall be unlawful to violate any such conditions and requirements unless such conditions or restrictions are identified in an approved operations plan as administrative only. If a proposed sector does not comply with the requirements of this paragraph (b)(2), NMFS may decline to propose for approval such sector operations plans, even if the Council has approved such sector. At least the following elements must be contained in either the final operations plan or sector contract submitted to NMFS:

(i) A list of all parties, vessels, and vessel owners who will participate in the sector;

(ii) A list of all Federal and state permits held by persons participating in the sector, including an indication for each permit whether it is enrolled and will actively fish in a sector, or will be subject to the provisions of the common pool;

(iii) A contract signed by all sector participants indicating their agreement to abide by the operations plan;

(iv) The name of a designated representative or agent of the sector for service of process;

(v) If applicable, a plan for consolidation or redistribution of ACE detailing the quantity and duration of such consolidation or redistribution within the sector;

(vi) A list of the specific management rules the sector participants will agree to abide by in order to avoid exceeding the allocated ACE for each stock, including a plan of operations or cessation of operations once the ACEs of one or more stocks are harvested and detailed plans for enforcement of the sector rules;

(vii) A plan that defines the procedures by which members of the sector that do not abide by the rules of the sector will be disciplined or removed from the sector, and a procedure for notifying NMFS of such expulsions from the sector;

(viii) If applicable, a plan of how the ACE allocated to the sector is assigned to each vessel;

(ix) If the operations plan is inconsistent with, or outside the scope of the NEPA analysis associated with the sector proposal/framework adjustment as specified in paragraph (a)(1) of this section, a supplemental NEPA analysis may be required with the operations plan;

(x) Detailed information about overage penalties or other actions that will be taken if a sector exceeds its ACE for any stock;

(xi) Detailed plans for the monitoring and reporting of landings and discards by sector participants, including, but not limited to, detailed information describing the sector's at-sea/electronic monitoring program for monitoring utilization of ACE allocated to that sector; identification of the independent third-party service providers employed by the sector to provide at-sea/electronic monitoring services; the mechanism and timing of any hail reports; a list of specific ports where participating vessels will land fish, with specific exemptions noted for safety, weather, etc., allowed, provided the sector provides reasonable notification to NMFS concerning a deviation from the listed ports; and any other information about such a program required by NMFS;

(xii) ACE thresholds that may trigger revisions to sector operations to ensure allocated ACE is not exceeded, and details regarding the sector's plans for notifying NMFS once the specified ACE threshold has been reached;

(xiii) Identification of any potential redirection of effort into other fisheries expected as a result of sector operations, and, if necessary, proposed limitations to eliminate any adverse effects expected from such redirection of effort;

(xiv) If applicable, description of how regulated species and ocean pout will be avoided while participating in other fisheries that have a bycatch of regulated species or ocean pout if the sector does not have sufficient ACE for stocks of regulated species or ocean pout caught as bycatch in those

fisheries, as specified in paragraph (b)(1)(vi)(B) of this section; and

(xv) A list of existing regulations that the sector is requesting exemption from during the following fishing year pursuant to paragraph (c)(2) of this section.

(3) *NEPA analysis.* In addition to the documents required by paragraphs (a)(1) and (b)(2) of this section, before NMFS can approve a sector to operate during a particular fishing year, each sector must develop and submit to NMFS, in conjunction with the yearly operations plan and sector contract, an appropriate NEPA analysis assessing the impacts of forming the sector and operating under the measures described in the sector operations plan.

* * * * *

■ 12. In § 648.90, revise paragraphs (a)(2)(iii) and (4)(i)(B) to read as follows:

§ 648.90 NE multispecies assessment, framework procedures and specifications, and flexible area action system.

* * * * *

(a) * * *

(2) * * *

(iii) In addition, the PDT may develop ranges of options for any of the management measures in the FMP and the following conditions that may be adjusted through a framework adjustment to achieve FMP goals and objectives including, but not limited to:

(A) Revisions to DAS measures, including DAS allocations (such as the distribution of DAS among the four categories of DAS), future uses for Category C DAS, and DAS baselines, adjustments for steaming time, etc.;

(B) Accumulation limits due to a permit buyout or buyback;

(C) Modifications to capacity measures, such as changes to the DAS transfer or DAS leasing measures;

(D) Calculation of area-specific ACLs (including sub-ACLs for specific stocks and areas (*e.g.,* Gulf of Maine cod)), area management boundaries, and adoption of area-specific management measures including the delineation of inshore/offshore fishing practices, gear restrictions, declaration time periods;

(E) Sector allocation requirements and specifications, including the establishment of a new sector, the disapproval of an existing sector, the allowable percent of ACL available to a sector through a sector allocation, an optional sub-ACL specific to Handgear A permitted vessels, management uncertainty buffers, and the calculation of PSCs;

(F) Sector administration provisions, including at-sea, electronic, dockside, and other monitoring tools, coverage requirements and processes, monitoring program review, or other measures; sector reporting requirements; vessel-specific coverage levels;

(G) State-operated permit bank administrative provisions;

(H) Measures to implement the U.S./Canada Resource Sharing Understanding, including any specified TACs (hard or target);

(I) Changes to administrative measures;

(J) Additional uses for Regular B DAS;

(K) Reporting requirements;

(L) Declaration requirements pertaining to when and what time period a vessel must declare into or out of a fishery management area;

(M) The GOM Inshore Conservation and Management Stewardship Plan;

(N) Adjustments to the Handgear A or B permits;

(O) Gear requirements to improve selectivity, reduce bycatch, and/or reduce impacts of the fishery on EFH;

(P) SAP modifications;

(Q) Revisions to the ABC control rule and status determination criteria, including, but not limited to, changes in the target fishing mortality rates, minimum biomass thresholds, numerical estimates of parameter values, and the use of a proxy for biomass may be made either through a biennial adjustment or framework adjustment;

(R) Changes to the SBRM, including the CV-based performance standard, the means by which discard data are collected/obtained, fishery stratification, the process for prioritizing observer sea-day allocations, reports, and/or industry-funded observers or observer set aside programs; and

(S) Any other measures currently included in the FMP.

* * * * *

(4) * * *

(i) * * *

(B) *ACL recommendations.* The PDT shall develop ACL recommendations based upon ABCs recommended by the SSC and the pertinent recommendations of the Transboundary Management Guidance Committee (TMGC). The ACL recommendations of the PDT shall be specified based upon total catch for each stock (including both landings and discards), if that information is available. The PDT shall describe the steps involved with the calculation of the recommended ACLs and uncertainties and risks considered when developing these recommendations, including whether different levels of uncertainties were used for different sub-components of the fishery and whether ACLs have been exceeded in recent years. Based upon the ABC recommendations of the SSC and the ACL recommendations of the PDT, the Council shall adopt ACLs that are equal to or lower than the ABC recommended by the SSC to account for management uncertainty in the fishery. In years that the coverage target for the groundfish sector monitoring program specified in § 648.11(l) is set at 100 percent, the management uncertainty buffer will default to zero for the sector sub-ACL for the allocated regulated species stocks specified at § 648.87(b)(1)(i)(A), but the need for a management uncertainty buffer for the sector sub-ACL will continue to be evaluated as part of each specification action. The PDT will recommend an appropriate management uncertainty buffer for the sector sub-ACLs if 100-percent monitoring coverage is determined not to be effective, or if any additional elements evaluated when setting the management uncertainty buffers have the potential to result in catches that could exceed ACLs.

* * * * *

■ 13. Section 648.202 is amended by revising paragraph (b)(1) to read as follows:

§ 648.202 Season and area restrictions.

* * * * *

(b) * * *

(1) No vessel issued an Atlantic herring permit and fishing with midwater trawl gear, may fish for, possess or land fish in or from the Closed Areas, including Cashes Ledge Closure Area, Western GOM Closure Area, Closed Area I North (February 1–April 15), and Closed Area II, as defined in § 648.81(a)(3), (4), and (5) and (c)(3) and (4), respectively, unless it has declared first its intent to fish in the Closed Areas as required by § 648.11(m)(1), and is carrying onboard an observer.

* * * * *

[FR Doc. 2022–03572 Filed 2–25–22; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 87, No. 39
Monday, February 28, 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

Submission for OMB Review; Notice of Request for Emergency Approval

February 22, 2022.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Department of Agriculture (USDA) has submitted a request to the Office of Management and Budget (OMB) for a six-month emergency approval of the following information collection: ICR 0596–NEW, Wildland Fire Mitigation and Management Commission Nomination. The requested approval would enable the implementation of this Commission to collect the necessary information needed to brief to Congress on future wild fire mitigation and management plans and techniques.

Forest Service

Title: Wildland Fire Mitigation and Management Commission Nomination.

OMB Control Number: 0596–NEW.

Summary of Collection: The Forest Service (FS) is requesting emergency clearance and review through 5 CFR 1320.13 for a new information collection for the Wildland Fire Mitigation and Management Commission Nomination. The United States Department of Agriculture (USDA), United States Department of Interior (DOI) and Federal Emergency Management Agency (FEMA) collaboratively established the Wildland Fire Mitigation and Management Commission in December 2021 as part of the Bipartisan Infrastructure Law.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–04099 Filed 2–25–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Natural Resources Conservation Service

[Docket ID: NRCS–2022–0003]

Information Collection Request; Partnerships for Climate-Smart Commodities

AGENCY: Commodity Credit Corporation and Natural Resources Conservation Service, United States Department of Agriculture.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Natural Resources Conservation Service (NRCS) is requesting comments from all interested individuals and organizations on a revision and an extension of a currently approved information collection request associated with the Partnerships for Climate-Smart Commodities grant activity. The purpose of the Partnerships for Climate-Smart Commodities is to support the production and marketing of climate-smart commodities through a set of pilot projects that provide voluntary incentives through partners to producers and landowners, including early adopters, to implement climate-smart production practices, activities, and systems on working lands; measure and quantify, monitor and verify the carbon and greenhouse gas (GHG) benefits associated with those practices; and develop markets and promote the resulting climate-smart commodities. Additional information on the partnerships is available at *https://www.usda.gov/climate-solutions/climate-smart-commodities.*

DATES: We will consider comments that we receive by April 29, 2022.

ADDRESSES: We invite you to submit comments on this notice. You may submit comments, identified by Docket ID: NRCS–2022–0003 in the Federal eRulemaking Portal: Go to *https://www.regulations.gov.* Follow the online instructions for submitting comments.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Copies of the information collection may be requested by contacting Allison Owens below.

FOR FURTHER INFORMATION CONTACT: Allison Owens, telephone: (202) 253–1449; email: *climate-smart-commodities@usda.gov.* Persons with disabilities who require alternative mean for communication should contact the USDA's TARGET Center at (202) 720–2600 (Voice).

SUPPLEMENTARY INFORMATION:

Description of Information Collection

Title: Partnerships for Climate-Smart Commodities.

OMB Control Number: 0578–0031.

Type of Request: Revision and Extension.

Abstract: We are requesting comments on the project narrative, proposals, support letters, progress reports, and resumes. In general, reporting for the Partnerships for Climate-Smart Commodities grants will follow the guidelines included in the General Terms and Conditions, which are available at the following website: *https://www.fpacbc.usda.gov/about/grants-and-agreements/award-terms-and-conditions/index.html.* Prior to publishing this notice, NRCS received emergency approval from OMB for 6 months to cover this collection activity. This included information collection for the application process, which includes in addition to standard government-wide grant application forms, a requirement for applicants to provide a project narrative, proposals, support letters and resumes. This will be included in this regular request after the 60 day comment period.

Partners will be required to submit progress reports after the first quarter and at least biannually on the project, including the following information:

- A list of participating producers and landowners, and demonstration of equitable enrollment, including enrollment of underserved and small producers;
- Climate-Smart Agriculture and Forestry (CSAF) practices applied;
- Outreach and training;
- Financial assistance for producers or landowners to implement CSAF practices;
- Greenhouse gas and carbon sequestration benefits accrued and verified, and other ancillary environmental benefits;
- Marketing and outreach related to climate-smart commodities as a result of

project activities, including information on impacts related to a variety of farm sizes and types;

- Technical assistance and resources provided, especially to help producers overcome barriers to adopting CSAF practices;
- Partnerships developed and leveraged, including public-private partnerships to foster and develop CSAF markets;
- Climate-smart commodity supply chain and demand impacts, as well as other economic benefits; and
- Implementation of measurement, monitoring, reporting, and verification, and supply chain traceability systems.

Additional reporting and data-sharing requirements may apply at the time of award, particularly in support of the USDA Partnerships for Climate-Smart Commodities Learning Network. Certain reporting elements will be required to be georeferenced (geospatially referenced). Further, we received Office of Management and Budget (OMB) clearance to use electronic submission form (SF–270, SF–424 and SF–425) in *Grants.gov*.

For the following estimated total annual burden on respondents, the formula used to calculate the total burden hour is the estimated average time per responses, in hours, multiplied by the estimated total annual responses.

Estimate of Annual Burden: Public reporting burden for the collection of information is estimated to average 10.5 hours per response.

Respondents: Partnerships for Climate-Smart Commodities Applicants and Awardees.

Estimated Number of Respondents: 500.

Estimated Number of Responses per Respondent: 5.

Estimated Total Annual Number of Responses: 1,610.

Estimated Average Time per Response: 10.5 hours.

Estimated Total Annual Burden Hours: 14,370 hours.

We are requesting comments on all aspects of this information collection to help us:

(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 agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Evaluate the quality, utility, and clarity of the information technology; and

(4) Minimize the burden of the information collection on those who respond through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses where provided, will be made a matter of public record. Comments will be summarized and included in the request for OMB approval of the information collection.

Robert Ibarra,

Executive Vice President, Commodity Credit Corporation.

Terry Cosby,

Chief, Natural Resources Conservation Service.

[FR Doc. 2022–04176 Filed 2–25–22; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2022–0002]

Notice of Request for a New Information Collection: Poultry Finished Product Standards

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to request a new information collection for poultry Finished Product Standards (FPS). This is a new information collection because the existing forms for FPS are in use without approval. There is an estimated annual burden of 68,899 hours.

DATES: Submit comments on or before April 29, 2022.

ADDRESSES: FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to *https://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2022–0002. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *https://www.regulations.gov.*

Docket: For access to background documents or comments received, call (202) 205–0495 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; (202) 720–5627.

SUPPLEMENTARY INFORMATION: *Title:* Poultry Finished Product Standards.

OMB Number: 0583–NEW.

Type of Request: Request for a new information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53), as specified in the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*). This statute mandates that FSIS protect the public by verifying that poultry products are safe, wholesome, unadulterated, and properly labeled and packaged.

Since 1987, FSIS regulations have required that processed birds meet FPS before and after chilling to ensure that the product being produced is consistently wholesome and unadulterated. By design, FPS provides a clear picture of the effectiveness of the dressing and evisceration process and alerts FSIS and the establishment to a need for adjustments before unacceptable product is produced. Poultry slaughter establishments that operate under the Streamlined Inspection System (SIS) or the New Line Speed Inspection System (NELS) or the New Turkey Inspection (NTI) system are required to comply with the Poultry FPS regulatory requirements (9 CFR 381.76(b)). These regulations require establishments to perform and record the results of FPS tests throughout each shift. The forms used to document FPS tests include the defects that must be counted, as well as a method to calculate the results.

Establishments use FSIS Form 6500–1, *Poultry QC Finished Product Standards,* to record poultry pre-chill processing nonconformance results; FSIS Form 6500–2, *Poultry QC Finished Product Standards,* to record poultry pre-chill trim nonconformance results, and FSIS Form 6500–3, *Poultry Finished Product Standards,* to record poultry post-chill processing nonconformance results. FSIS inspection program personnel also review all three forms to verify compliance with 9 CFR 381.76(b).

FSIS has made the following estimates based upon an information collection assessment:

Estimate of burden: FSIS estimates that it takes each respondent an average of 861.23 hours per year to complete FSIS Forms 6500–1, 6500–2, and 6500–3.

Estimated total number of respondents: 80 Poultry Slaughter establishments that operate under the SIS, NELS or NTIS inspection systems.

Estimated number of responses per respondent: 9,085.

Estimated annual number of responses: 726,800.

Estimated annual burden on respondents: 68,899 hours.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; (202) 720–5627.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS' functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *https://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *https://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

USDA Non-Discrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632–9992.

Submit your completed form or letter to USDA by: (1) Mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: *program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

Paul Kiecker,

Administrator.

[FR Doc. 2022–04121 Filed 2–25–22; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Central Idaho Resource Advisory Committee

AGENCY: Forest Service, (Agriculture) USDA.

ACTION: Notice of meeting.

SUMMARY: The Central Idaho Resource Advisory Committee (RAC) will hold two virtual meetings by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act as well as make recommendations on recreation fee proposals for sites on Salmon-Challis, Caribou Targhee, and Sawtooth National Forests within the counties of Butte, Custer, and Lemhi, consistent with the Federal Lands Recreation Enhancement Act. RAC information and virtual meeting information can be found at the following website: *https://www.fs.usda.gov/main/scnf/workingtogether/advisorycommittees.*

DATES: The virtual meetings will be held on:

- Thursday, March 24, 2022, 9:00 a.m.–5:00 p.m., Mountain Daylight Time; and

• Thursday, March 31, 2022, 9:00 a.m.–5:00 p.m., Mountain Daylight Time.

All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meetings will be held virtually via telephone and/or video conference. Details for how to join the meetings are listed in the above website link under **SUMMARY.**

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received upon request.

FOR FURTHER INFORMATION CONTACT: Charles A. Mark, Designated Federal Officer (DFO), by phone at 208–756–5100 or email at c*harles.mark@usda.gov* or Amy Baumer at 208–756–5145 or email at *amy.baumer@usda.gov.*

Individuals who use telecommunication devices for the deaf and hard of hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours per day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Hear from Title II project proponents and discuss project proposals; and

2. Make funding recomendations on Title II projects.

The meetings are open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by March 17, 2022, to be scheduled on the agenda for a particular meeting. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Amy Baumer, 1206 S Challis St.; Salmon, ID 83467 or by email to *amy.baumer@usda.gov*.

Meeting Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodation. For access to proceedings, please contact the person listed in the section titled for **FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to the RAC. To help ensure that recommendations of the RAC have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, political beliefs, income derived from a public assistance program, or reprisal or retaliation for prior civil rights activity in any program or activity conducted or funded by USDA (not all bases apply to all programs).

Dated: February 22, 2022.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2022–04024 Filed 2–25–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Monitoring Trends in Burn Severity User Satisfaction Survey

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the new information collection, *Monitoring Trends in Burn Severity User Satisfaction Survey.*

DATES: Comments must be received in writing on or before April 29, 2022 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: carl.albury@usda.gov.*
- *Mail:* Carl Albury, Geospatial Technology and Applications Center (GTAC), USDA Forest Service, 125 South State Street, Suite 7105, Salt Lake City, UT 84138.
- *Phone:* 202–205–1689.
- *Hand Delivery/Courier:* Carl Albury, Geospatial Technology and Applications Center (GTAC), USDA Forest Service, 125 South State Street, Suite 7105, Salt Lake City, UT 84138.
- *Facsimile:* 801–975–3478.

Comments submitted in response to this notice may be made available to the public through relevant websites and upon request. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

The public may inspect the draft supporting statement and/or comments received at 125 South State Street, Suite 7105, Salt Lake City, UT 84138 during normal business hours. Visitors are encouraged to call ahead to 801–975–3351 to facilitate entry to the building. The public may request an electronic copy of the draft supporting statement and/or any comments received be sent via return email. Requests should be emailed to *carl.albury@usda.gov.*

FOR FURTHER INFORMATION CONTACT: Carl Albury, USDA Forest Service, Geospatial Technology and Application Center (GTAC), 801–975–3351. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Monitoring Trends in Burn Severity User Satisfaction Survey.

OMB Number: 0596–NEW.

Expiration Date of Approval:

Type of Request: NEW.

Abstract: Monitoring Trends in Burn Severity (MTBS) is an interagency program whose goal is to consistently map the location, extent, and burn severity of large fires across all lands of the United States from 1984 to present. MTBS data is distributed in a variety of geospatial formats that are accessible by website download. This survey will allow the MTBS program to assess the needs of its users and how well the program is meeting those needs. This survey will be offered to anyone visiting the MTBS website (*www.MTBS.gov*). The survey will be delivered using the Microsoft Forms platform. Participation in the survey will be voluntary. The survey will solicit information pertaining to what data the visitor is

interested in, the ease with which those data can be accessed, how the visitor will utilize the accessed data, the visitor's satisfaction with the program and data products, and any suggestions to improvements to products/services the visitor may have. The information collected from this survey will be used to guide program development and changes to better meet the visitor needs. The survey results will be collected and analyzed by federal staff. If this information is not collected the MTBS program will be unable to tailor its products and services to the needs of its users in the government and public domains.

Affected Public: Individuals, Private Sector Business and Non-Profit Organizations, State Government, Local Government and Tribal Government.

Estimate of Burden per Response: 5 minutes.

Estimated Annual Number of Respondents: 1,500 respondents.

Estimated Annual Number of Responses per Respondent: 1 response.

Estimated Total Annual Burden on Respondents: 7,500 minutes (125 hours).

Comment Is Invited: Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden 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 to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request toward Office of Management and Budget approval.

Chris French,

Deputy Chief, National Forest Systems.

[FR Doc. 2022–04120 Filed 2–25–22; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Pennsylvania Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of 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 Pennsylvania Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold series of web-based panel discussions on Friday March 18, 2022 from 12–2:00 p.m. Eastern time; Friday April 22, 2022 from 12–2:00 p.m. Eastern time and Friday April 29, 2022 from 12–2:00 p.m. Eastern time. The purpose of these meetings is for the Committeeto hear testimony regarding civil rights and fair housing in the state.

DATES:

- *Panel I:* Friday March 18, 2022 from 12:00 p.m.–2:00 p.m. Eastern time.

Online Regisration (Audio/Visual): https://bit.ly/3Blg0UA.

Telephone (Audio Only): Dial 800–360–9505 USA Toll Free; Access code: 2764 260 7579.

- *Panel II:* Friday April 22, 2022 from 12:00 p.m.–2:00 p.m. Eastern time.

Online Regisration (Audio/Visual): https://bit.ly/3BnT4nS.

Telephone (Audio Only): Dial 800–360–9505 USA Toll Free; Access code: 2760 963 7104.

- *Panel III:* Friday April 29, 2022 from 12:00 p.m.–2:00 p.m. Eastern time.

Online Regisration (Audio/Visual): https://bit.ly/3gLybcD.

Telephone (Audio Only): Dial 800–360–9505 USA Toll Free; Access code: 2760 860 9626.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or (202) 618–4158.

SUPPLEMENTARY INFORMATION: Members of the public may listen to these discussions. Committee meetings are available to the public through the above listed online registration link or call in number. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. 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. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. 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 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 emailed to Corrine Sanders at *csanders@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 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, Pennsylvania 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 Unit at the above email or street address.

Agenda

Welcome and Roll Call
Panel Discussion: Civil Rights and Fair Housing in Pennsylvania
Public Comment
Adjournment

Dated: February 23, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–04168 Filed 2–25–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Arkansas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of 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 Arkansas Advisory Committee (Committee) will hold a virtual (online) meeting Friday, March 4, 2022 at 1:00 p.m. Central Time. The purpose of the meeting is for the Committee to hear continued testimony reegarding IDEA

compliance and implementation in Arkansas schools.

DATES: The meeting will be held on Friday, March 4, 2022 1:00 p.m.–3:00 p.m. Central time.

Web Access (Audio/Visual): Register at: *https://bit.ly/3BdiRyJ.*

Phone Access (Audio Only): 800–360–9505, Access Code: 2760 162 7443.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, Designated Federal Officer, at *mwojnaroski@usccr.gov* or (202) 618–4158.

SUPPLEMENTARY INFORMATION: Members of the public may join online or listen to this discussion through the above call-in number. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. ASL interpretation and closed captions will be provided. Individuals requiring other reasonable accomodatations should contact Corrine Sanders at *csanders@usccr.gov* in advance of the meeting to make their request.

Members of the public are 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 Melissa Wojnaroski at *mwojnaroski@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 via *www.facadatabase.gov* under the Commission on Civil Rights, Arkansas 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 Unit at the above email or street address.

Agenda

I. Welcome & Roll Call

II. Panel Discussion: IDEA Compliance and Implementation in Arkansas School

III. Public Comment

VI. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given fewer than 15 calendar days prior to the meeting because of the exceptional circumstances of pending panel testimony.

Dated: February 23, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–04165 Filed 2–25–22; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Minnesota Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual 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 Minnesota Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Webex at 12:00 p.m. CT on Tuesday, March 8, 2022. The purpose of this meeting is to discuss the Committee's project on policing practices in the state.

DATES: The meeting will take place on Tuesday, March 8, 2022, at 12:00 p.m. CT.

Link to Join (Audio/Visual): https://tinyurl.com/5xb2n94s

Telephone (Audio Only): Dial (800) 360–9505 USA Toll Free; Access Code: 2761 766 6792

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at *dbarreras@usccr.gov* or (202) 656–8937.

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 (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 *dbarreras@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 Liliana Schiller at *lschiller@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit, 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, Minnesota 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 phone number.

Agenda

I. Welcome & Roll Call
II. Civil Rights Discussion
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: February 23, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–04141 Filed 2–25–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2124]

Reorganization of Foreign-Trade Zone 218 Under Alternative Site Framework; St. Lucie County, Florida

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Act provides for ''. . . the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board adopted the alternative site framework (ASF) (15 CFR 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, St. Lucie County, Florida, grantee of Foreign-Trade Zone 218,

submitted an application to the Board (FTZ Docket B–64–2021, docketed September 17, 2021) for authority to reorganize under the ASF with a service area of St. Lucie, Indian River and Okeechobee Counties, Florida, in and adjacent to the Fort Pierce U.S. Customs and Border Protection Customs Station, and FTZ 218's existing Sites 1, 2, 3 and 4 would be categorized as magnet sites;

Whereas, notice inviting public comment was given in the **Federal Register** (86 FR 52875–52876, September 23, 2021) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiners' report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, therefore, the Board hereby orders:

The application to reorganize FTZ 218 under the ASF is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, to the Board's standard 2,000-acre activation limit for the zone, and to an ASF sunset provision for magnet sites that would terminate authority for Sites 2, 3 and 4 if not activated within five years from the month of approval.

Dated: February 22, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance, Alternate Chairperson, Foreign-Trade Zones Board.

[FR Doc. 2022–04117 Filed 2–25–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–68–2021]

Foreign-Trade Zone (FTZ) 38—Spartanburg County, South Carolina; Authorization of Production Activity; BMW Manufacturing Company, LLC; (Passenger Motor Vehicles) Spartanburg, South Carolina

On October 22, 2021, BMW Manufacturing Company, LLC submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 38A, in Spartanburg, South Carolina.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (86 FR 60201, November 1, 2022). On February 22, 2022, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: February 22, 2022.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2022–04116 Filed 2–25–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials and Equipment Technical Advisory Committee

Notice of Partially Closed Meeting

The Materials and Equipment Technical Advisory Committee will meet on March 17, 2022, 10:00 a.m., Eastern Standard Time, via teleconference. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials and related technology.

Agenda

Open Session

1. Opening Remarks and Introduction by BIS Senior Management.
2. Report from working groups.
3. Report by regime representatives.

Closed Session

4. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. App. §§ 10 (a)(1) and 10 (a)(3).

The open session will be accessible via teleconference on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov,* no later than March 10, 2022.

To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the materials should be forwarded prior to the meeting to Ms. Springer via email.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on February 14, 2022, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App. § 10(d)), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and the U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. App. §§ 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, contact Yvette Springer via email.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2022–04163 Filed 2–25–22; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–028]

Hydrofluorocarbon Blends From the People's Republic of China: Continuation of Antidumping Duty Order

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

SUMMARY: As a result of the determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC) that revocation of the antidumping duty (AD) order on hydrofluorocarbon (HFC) blends from the People's Republic of China (China) would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States, Commerce is publishing a notice of continuation of the AD order.

DATES: Applicable February 28, 2022.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Luberda, 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) 482–2185.

SUPPLEMENTARY INFORMATION:

Background

On August 19, 2016, Commerce published the AD order on HFC blends from China.[1] On July 1, 2021, the ITC instituted,[2] and Commerce initiated, the fifth sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[3] As a result of its review, Commerce determined that revocation of the *Order*

[1] *See Hydrofluorocarbon Blends from the People's Republic of China: Antidumping Duty Order,* 81 FR 55436 (August 19, 2016) (*Order*).

[2] *See Hydrofluorocarbon Blends from China; Institution of a Five-Year Review,* 86 FR 35131 (July 1, 2021).

[3] *See Initiation of Five-Year (Sunset) Reviews,* 86 FR 35070 (July 1, 2021).

would likely lead to continuation or recurrence of dumping and, therefore, notified the ITC of the magnitude of the margins likely to prevail should the *Order* be revoked.[4]

On February 11, 2022, the ITC published its determination, pursuant to section 751(c) of the Act, that revocation of the *Order* would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

Scope of the Order

The products subject to this *Order* are HFC blends. HFC blends covered by the scope are R–404A, a zeotropic mixture consisting of 52 percent 1,1,1-Trifluoroethane, 44 percent Pentafluoroethane, and 4 percent 1,1,1,2-Tetrafluoroethane; R–407A, a zeotropic mixture of 20 percent Difluoromethane, 40 percent Pentafluoroethane, and 40 percent 1,1,1,2-Tetrafluoroethane; R–407C, a zeotropic mixture of 23 percent Difluoromethane, 25 percent Pentafluoroethane, and 52 percent 1,1,1,2-Tetrafluoroethane; R–410A, a zeotropic mixture of 50 percent Difluoromethane and 50 percent Pentafluoroethane; and R–507A, an azeotropic mixture of 50 percent Pentafluoroethane and 50 percent 1,1,1-Trifluoroethane also known as R–507. The foregoing percentages are nominal percentages by weight. Actual percentages of single component refrigerants by weight may vary by plus or minus two percent points from the nominal percentage identified above.[6]

Any blend that includes an HFC component other than R–32, R–125, R–143a, or R–134a is excluded from the scope of this *Order.*

Excluded from this *Order* are blends of refrigerant chemicals that include products other than HFCs, such as blends including chlorofluorocarbons (CFCs), hydrochlorofluorocarbons (HCFCs), hydrocarbons (HCs), or hydrofluoroolefins (HFOs).

Also excluded from the *Order* are patented HFC blends, including, but not limited to, ISCEON® blends, including MO99™ (R–438A), MO79 (R–422A), MO59 (R–417A), MO49Plus™ (R–437A) and MO29™ (R–4 22D), Genetron® Performax™ LT (R–407F), Choice® R–421A, and Choice® R–421B.

HFC blends covered by the scope of this *Order* are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings 3824.78.0020 and 3824.78.0050. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope is dispositive.[7]

Continuation of the Order

As a result of the determinations by Commerce and the ITC that revocation of the *Order* would likely lead to a continuation or a recurrence of dumping, as well as material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, Commerce hereby orders the continuation of the *Order.*

U.S. Customs and Border Protection will continue to collect AD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

The effective date of the continuation of the *Order* will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, Commerce intends to initiate the next five-year review of the *Order* not later than 30 days prior to the fifth anniversary of the effective date of continuation.

Administrative Protective Order

This notice serves as the only reminder to 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), which continues to govern business proprietary information in this segment of the proceeding. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of the APO is a sanctionable violation.

Notification to Interested Parties

This five-year sunset review and this notice are in accordance with section 751(c) of the Act and published in accordance with section 777(i)(1) of the Act and 19 CFR 351.218(f)(4).

Dated: February 18, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–04122 Filed 2–25–22; 8:45 am]

BILLING CODE 3510–DS–P

[4] *See Hydrofluorocarbon Blends from the People's Republic of China: Final Results of the Expedited First Sunset Review of the Antidumping Duty Order,* 86 FR 61120 (November 5, 2021), and accompanying Issues and Decision Memorandum.

[5] *See Hydrofluorocarbon Blends from China,* 87 FR 8037 (February 11, 2022).

[6] R–404A is sold under various trade names, including Forane® 404A, Genetron® 404A, Solkane® 404A, Klea® 404A, and Suva® 404A. R–407A is sold under various trade names, including Forane® 407A, Solkane® 407A, Klea® 407A, and Suva® 407A. R–407C is sold under various trade names, including Forane® 407C, Genetron® 407C, Solkane® 407C, Klea® 407C and Suva® 407C. R–410A is sold under various trade names, including EcoFluor R410, Forane® 410A, Genetron® R410A and AZ–20, Solkane® 410A, Klea® 410A, Suva® 410A, and Puron®. R–507A is sold under various trade names, including Forane® 507, Solkane® 507, Klea® 507, Genetron® AZ–50, and Suva® 507. R–32 is sold under various trade names, including Solkane® 32, Forane® 32, and Klea® 32. R–125 is sold under various trade names, including Solkane® 125, Klea® 125, Genetron® 125, and Forane® 125. R–143a is sold under various trade names, including Solkane® 143a, Genetron® 143a, and Forane® 125.

[7] *See Order.* Certain merchandise has been the subject of affirmative anti-circumvention determinations by Commerce, pursuant to section 781 of the Tariff Act of 1930, as amended (the Act). As a result, the circumventing merchandise is included in the scope of the *Order. See Hydrofluorocarbon Blends from the People's Republic of China: Final Negative Scope Ruling on Gujarat Fluorochemicals Ltd.'s R–410A Blend; Affirmative Final Determination of Circumvention of the Antidumping Duty Order by Indian Blends Containing Chinese Components,* 85 FR 61930 (October 1, 2020); *Hydrofluorocarbon Blends from the People's Republic of China: Final Scope Ruling on Unpatented R–421A; Affirmative Final Determination of Circumvention of the Antidumping Duty Order for Unpatented R–421A,* 85 FR 34416 (June 4, 2020); and *Hydrofluorocarbon Blends from the People's Republic of China: Affirmative Final Determination of Circumvention of the Antidumping Duty Order; Unfinished R–32/R–125 Blends,* 85 FR 15428 (March 18, 2020).

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Construction Safety Team Advisory Committee Meeting

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

ACTION: Notice; correction.

SUMMARY: The National Construction Safety Team (NCST) Advisory Committee (Committee) will hold a virtual meeting via web conference on Wednesday, June 8, 2022, from 11:00 a.m. to 5:00 p.m. and Thursday, June 9, 2022, from 11:00 a.m. to 5:00 p.m. Eastern Time. The National Institute of Standards and Technology (NIST) originally published a notice regarding this meeting on February 18, 2022. The date of the meeting is being corrected, the topics discussed are being updated, and NIST is providing notice that the meeting will be recorded. The primary purpose of this meeting is to update the Committee on the progress of the NCST investigation focused on the impacts of Hurricane Maria in Puerto Rico, progress of the NCST investigation focused on the Champlain Towers South partial building collapse that

occurred in Surfside, Florida, and the implementation of recommendations from previous investigations. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST website at *https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee-meetings.*

DATES: The NCST Advisory Committee will meet on Wednesday, June 8, 2022, from 11:00 a.m. to 5:00 p.m. and Thursday, June 9, 2022, from 11:00 a.m. to 5:00 p.m. Eastern Time.

ADDRESSES: The meeting will be held via web conference. For instructions on how to participate in the meeting, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Tanya Brown-Giammanco, Disaster and Failure Studies Program, Engineering Laboratory, NIST. Tanya Brown-Giammanco's email address is *Tanya.Brown-Giammanco@nist.gov* and her phone number is (240) 267–9504.

SUPPLEMENTARY INFORMATION: The Committee was established pursuant to Section 11 of the NCST Act (Pub. L. 107–231, codified at 15 U.S.C. 7301 *et seq.*). The Committee is currently composed of seven members, appointed by the Director of NIST, who were selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting the National Construction Safety Teams. The Committee advises the Director of NIST on carrying out the NCST Act; reviews the procedures developed for conducting investigations; and reviews the reports issued documenting investigations. Background information on the NCST Act and information on the NCST Advisory Committee is available at *https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee.*

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the NCST Advisory Committee will meet on Wednesday, June 8, 2022, from 11:00 a.m. to 5:00 p.m. and Thursday, June 9, 2022, from 11:00 a.m. to 5:00 p.m. Eastern Time. NIST previously published a notice for this meeting on February 18, 2022, at 87 FR 9322. This notice repeats the same information contained in the previous notice but corrects the date of the meeting, updates the topics being discussed, and provides notice that the meeting will be recorded. The meeting will be open to the public and will be held via web conference. Interested members of the public will be able to participate in the meeting from remote locations. The primary purpose of this meeting is to update the Committee on the progress of the NCST investigation focused on the impacts of Hurricane Maria in Puerto Rico, progress of the NCST investigation focused on the Champlain Towers South partial building collapse that occurred in Surfside, Florida, and the implementation of recommendations from previous investigations. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST website at *https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee-meetings.*

Individuals and representatives of organizations who would like to offer comments and suggestions related to items on the Committee's agenda for this meeting are invited to request a place on the agenda. Approximately thirty minutes will be reserved for public comments and speaking times will be assigned on a first-come, first-served basis. This meeting will be recorded. Public comments can be provided via email or by web conference attendance. The amount of time per speaker will be determined by the number of requests received. Questions from the public will not be considered during this period. All those wishing to speak must submit their request by email to the attention of Peter Gale at *Peter.Gale@nist.gov* by 5:00 p.m. Eastern Time, Tuesday, May 31, 2022. Speakers who wish to expand upon their oral statements, those who wish to speak but cannot be accommodated on the agenda, and those who are unable to attend are invited to submit written statements electronically by email to *disaster@nist.gov.*

Anyone wishing to attend this meeting via web conference must register by 5:00 p.m. Eastern Time, Tuesday, May 31, 2022, to attend. Please submit your full name, the organization you represent (if applicable), email address, and phone number to Peter Gale at *Peter.Gale@nist.gov.*

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2022–04095 Filed 2–25–22; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB843]

Western Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meeting.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold its 143rd Scientific and Statistical Committee (SSC), Pelagic and International Standing Committee, Executive and Budget Standing Committee, and 190th Council meetings to take actions on fishery management issues in the Western Pacific Region.

DATES: The meetings will be held between March 15 and March 24, 2022. For specific times and agendas, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meetings will be held by web conference via Webex. Instructions for connecting to the web conference and providing oral public comments will be posted on the Council website at *www.wpcouncil.org.* For assistance with the web conference connection, contact the Council office at (808) 522–8220.

The Council has arranged host sites only for the 190th Council meeting at the following venues: Cliff Pointe, 304 W. O'Brien Drive, Hagatna, Guam; BRI Building Suite 205, Kopa Di Oru St., Garapan, Saipan, Commonwealth of the Northern Mariana Islands (CNMI); and, Tedi of Samoa Building Suite 208B, Fagatogo Village, American Samoa.

FOR FURTHER INFORMATION CONTACT: Contact Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; phone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: All times shown are in Hawaii Standard Time. The 143rd SSC meeting will be held between 11 a.m. and 5 p.m. on March 15–17, 2022. The Pelagic and International Standing Committee will be held between 1 p.m. and 3 p.m. on March 21, 2022. The Executive and Budget Standing Committee meeting will be held between 3:30 p.m. and 5:30 p.m. on March 21, 2022. The 190th Council meeting will be held between 11 a.m. and 5 p.m. on March 22–24, 2022.

Please note that the evolving public health situation regarding COVID–19 may affect the conduct of the March

Council and its associated meetings. At the time this notice was submitted for publication, the Council anticipated convening the meeting by web conference with host site locations in Guam, CNMI and American Samoa for the 190th Council meeting only. Council staff will monitor COVID–19 developments and will determine the extent to which in-person public participation at host sites will be allowable consistent with applicable local and federal safety and health guidelines. If public participation will be limited to web conference only or on a first-come-first-serve basis consistent with applicable guidelines, the Council will post notice on its website at *www.wpcouncil.org.*

Agenda items noted as ''Final Action'' refer to actions that may result in Council transmittal of a proposed fishery management plan, proposed plan amendment, or proposed regulations to the U.S. Secretary of Commerce, under Sections 304 or 305 of the MSA. In addition to the agenda items listed here, the Council and its advisory bodies will hear recommendations from Council advisors. An opportunity to submit public comment will be provided throughout the agendas. The order in which agenda items are addressed may change and will be announced in advance at the Council meeting. The meetings will run as late as necessary to complete scheduled business.

Background documents for the 190th Council meeting will be available at *www.wpcouncil.org.* Written public comments on final action items at the 190th Council meeting should be received at the Council office by 5 p.m. HST, March 18, 2022, and should be sent to Kitty M. Simonds, Executive Director; Western Pacific Fishery Management Council, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813, phone: (808) 522–8220 or fax: (808) 522–8226; or email: *info@wpcouncil.org.* Written public comments on all other agenda items may be submitted for the record by email throughout the duration of the meeting. Instructions for providing oral public comments during the meeting will be posted on the Council website. This meeting will be recorded (audio only) for the purposes of generating the minutes of the meeting.

Agenda for the 143rd SSC Meeting

Tuesday, March 15, 2022, 11 a.m. to 5 p.m.

1. Introductions
2. Approval of Draft Agenda and Assignment of Rapporteurs
3. Status of the 142nd SSC Meeting Recommendations
4. Pacific Islands Fisheries Science Center (PIFSC) Director Report
5. Island Fisheries
   - A. Review of the Acceptable Biological Catch for the Main Hawaiian Island Deepwater Shrimp and Precious Corals (Action Item)
   - B. Revision of the Territorial Bottomfish Management Unit Species (BMUS) Complex
     1. Multivariate Analysis of the Territorial BMUS
     2. Options for Revising the Territorial BMUS Complex
   - C. Outcomes of the American Samoa Bottomfish Fisherman Data Workshop
   - D. Public Comment
   - E. SSC Discussion and Recommendations
6. Protected Species
   - A. False Killer Whale Hook Study Implications
   - B. Meta-synthesis of Marine Turtle Post-release Mortality
   - C. Endangered Species Act (ESA) Consultations for the Hawaii Deep-set Longline Fishery, American Samoa Longline Fishery, and Bottomfish Fisheries
   - D. ESA and Marine Mammal Protection Act Updates
   - E. Public Comment
   - F. SSC Discussion and Recommendations

Wednesday, March 16, 2022, 11 a.m. to 5 p.m.

7. Pelagic and International Fisheries
   - A. 2021 American Samoa Longline Fishery Report
   - B. 2021 Hawaii Longline Fishery Report
   - C. Area Based Management
     1. Assessing the Population-level Conservation Effects of Marine Protected Areas
     2. The Trade-off Between Biodiversity and Sustainable Fish Harvest with Area-Based Management
     3. SSC Working Group on Area-Based Management
   - D. International Fisheries
     1. South Pacific Regional Fisheries Management Organization (SPRFMO) Annual Meeting
     2. New Strategy for Addressing Western-Central Pacific Fisheries Commission (WCPFC) Issues
     3. Biodiversity Beyond National Jurisdiction
   - E. Public Comment
   - F. SSC Discussion and Recommendations

Thursday, March 17, 2022, 11 a.m. to 5 p.m.

8. Other Business
   - A. June 14–16, 2022 SSC Meeting Dates
9. Summary of SSC Recommendations to the Council

Agenda for the Pelagic and International Standing Committee

Monday, March 21, 2022, 1 p.m. to 3 p.m.

1. Status of ESA Biological Opinions
2. MSA304(i) Obligations for Western and Central Pacific Silky Sharks
3. International Fisheries
   - A. Update from PIRO on WCPFC Matters
   - B. New Pacific Strategy & Information Paper
4. Advisory Group Report and Recommendations
5. Other Business
6. Public Comment
7. Discussion and Recommendations

Agenda for the Executive and Budget Standing Committee

Monday, March 21, 2022, 3:30 p.m. to 5:30 p.m.

1. Financial Reports
2. Administrative Reports
3. Regional Operating Agreement Update
4. Council Family Changes
5. Meetings and Workshops
6. Other Issues
7. Public Comment
8. Discussion and Recommendations

Agenda for the 190th Council Meeting

Tuesday, March 22, 2022, 11 a.m. to 5 p.m.

1. Welcome and Introductions
2. Approval of the 190th Agenda
3. Approval of the 189th Meeting Minutes
4. Executive Director's Report
5. Agency Reports
   - A. NMFS
     1. Pacific Islands Regional Office
     2. PIFSC
   - B. NOAA Office of General Counsel Pacific Islands Section
   - C. Enforcement
     1. U.S. Coast Guard
     2. NOAA Office of Law Enforcement
     3. NOAA Office of General Counsel Enforcement Section
   - D. U.S. State Department
   - E. U.S. Fish and Wildlife Service
   - F. Public Comment
   - G. Council Discussion and Action
6. Mariana Archipelago
   - A. Guam
     1. Department of Agriculture/Division Aquatic and Wildlife Resources Report
     2. Isla Informe
   - B. CNMI

1. Arongol Falú
2. Department of Lands Natural Resources/Division of Fish and Wildlife Report
3. Proposed Marianas Sanctuary Nomination Discussion

C. Advisory Group Report and Recommendations
1. Advisory Panel
2. Fishing Industry Advisory Committee
3. Scientific and Statistical Committee

D. Public Comment
E. Council Discussion and Action

7. Hawaii Archipelago and Pacific Remote Island Areas
A. Moku Pepa
B. Department of Land and Natural Resources/Division of Aquatic Resources Report (Legislation, Enforcement)
C. Green Turtle Management Update
D. Northwestern Hawaiian Islands Proposed National Marine Sanctuary 304(a)(5) Council Response
E. Specification of the Main Hawaiian Island Deepwater Shrimp and Precious Coral Annual Catch Limits for Fishing Year 2022–2025 (Final Action)
F. Advisory Group Report and Recommendations
1. Advisory Panel
2. Fishing Industry Advisory Committee
3. Scientific and Statistical Committee

G. Public Comment
H. Council Discussion and Action

Tuesday, March 22, 2022, 4:30 p.m. to 5 p.m.

Public Comment on Non-Agenda Items

Wednesday, March 23, 2022, 11 a.m. to 5 p.m.

8. Pelagic and International Fisheries
A. 2021 American Samoa Longline Fishery Report
B. 2021 Hawaii Longline Fishery Report
C. Area-Based Management Working Group Reports
1. Assessing the Population-level Conservation Effects of Marine Protected Areas
2. The Trade-off Between Biodiversity and Sustainable Fish Harvest with Area-Based Management
3. SSC Working Group on Area-Based Management

D. International Fisheries
1. SPRFMO Annual Meeting
2. New Strategy for Addressing WCPFC Issues
3. Biodiversity Beyond National Jurisdiction

E. Advisory Group Report and Recommendations
1. Advisory Panel
2. Fishing Industry Advisory Committee
3. Scientific and Statistical Committee

F. Pelagic and International Standing Committee
G. Public Comment
H. Council Discussion and Action

9. Protected Species
A. False Killer Whale Hook Study Implications
B. ESA Section 7 Mapper Overview
C. ESA Consultations for the Hawaii Deep-set Longline Fishery, American Samoa Longline Fishery, and Bottomfish Fisheries
D. ESA and Marine Mammal Protection Act Updates
E. Advisory Group Report and Recommendations
1. Advisory Panel
2. Fishing Industry Advisory Committee
3. Scientific and Statistical Committee

F. Public Comment
G. Council Discussion and Action

10. American Samoa Archipelago
A. Motu Lipoti
B. DMWR Report
C. Outcomes of the American Samoa Bottomfish Fisherman Data Workshop
D. Advisory Group Report and Recommendations
1. Advisory Panel
2. Fishing Industry Advisory Committee
3. Scientific and Statistical Committee

E. Public Comment
F. Council Discussion and Action

Thursday, March 24, 2022, 11 a.m.–5 p.m.

11. Program Planning and Research
A. National Legislative Report
B. Multivariate Analysis of the Territorial Bottomfish Management Unit Species
C. Options for Revising the Territorial BMUS Complex
D. Report of the Pilot Implementation of Catchit Logit
E. Aquaculture Management Final Programmatic Environmental Impact Statement and Future Action
F. Report on the Environmental Justice Workshop
G. Regional Communications and Outreach Report
H. Advisory Group Report and Recommendations
1. Advisory Panel
2. Fishing Industry Advisory Committee
3. Archipelagic Plan Team
4. Scientific and Statistical Committee

I. Public Comment
J. Council Discussion and Action

12. Administrative Matters
A. Financial Reports
B. Administrative Reports
C. Regional Operating Agreement Update
D. Council Family Changes
E. Meetings and Workshops
F. Standing Committee Report
G. Public Comment
H. Council Discussion and Action

13. Other Business

Non-emergency issues not contained in this agenda may come before the Council for discussion and formal Council action during its 190th meeting. However, Council action on regulatory issues will be restricted to those issues specifically listed in this document and any regulatory issue arising after publication of this document that requires emergency action under section 305(c) of the MSA, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

These meetings are accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: February 23, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–04137 Filed 2–25–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB841]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public joint meeting of its Habitat Committee via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Thursday, March 17, 2022, at 1 p.m.

Webinar registration URL information: *https://attendee.gotowebinar.com/register/2538856332393707790.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will review alternatives to designate a Habitat Area of Particular Concern in Southern New England and identify a preferred alternative for Council consideration at the April meeting. As needed, recommend additional analysis or information to be developed by the Plan Development Team to support Council final action in April. They will also receive an update on the discussions that have occurred between the Plan Development Team and Coonamessett Farm Foundation staff related to development of a final report for their Exempted Fishing Permit study in the Great South Channel Habitat Management Area. The Committee will receive updates on offshore energy, cable, and aquaculture projects of interest to the Council and provide feedback as appropriate. They will also discuss and recommend updates to habitat-related Council research priorities. Also on the agenda is a progress update on habitat-related Council work priorities. Other business may be discussed as necessary.

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

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the date. This meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

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

Dated: February 23, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–04135 Filed 2–25–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB825]

Caribbean Fishery Management Council; Public Meeting; Correction

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

ACTION: Notice; correction.

SUMMARY: The National Marine Fisheries Service published a document in the **Federal Register** of February 23, 2022, regarding a meeting of the Caribbean Fishery Management Council's (Council) Ecosystem-Based Fishery Management Technical Advisory Panel (EBFM TAP). The document omitted a meeting location.

FOR FURTHER INFORMATION CONTACT: Graciela García-Moliner, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918–1903, telephone: (787) 403–8337.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 23, 2022, in FR Doc. 2022–03810, on page 10173, in the second column, add the following information to the **ADDRESSES** caption:

ADDRESSES:

Meeting address: The meeting will be held at the Courtyard by Marriott Isla Verde Beach Resort, 7012 Boca de Cangrejos Avenue, Carolina, Puerto Rico 00979.

All previously published information remains unchanged.

Special Accommodations

For any additional information on this hybrid meeting, please contact Dr. Graciela García-Moliner, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico, 00918–1903, telephone: (787) 403–8337.

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

Dated: February 23, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–04134 Filed 2–25–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Determination Regarding Review of Nomination for Hudson Canyon National Marine Sanctuary

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice.

SUMMARY: In January 2022, the National Oceanic and Atmospheric Administration (NOAA) requested written comments to facilitate the five-year review of the nomination for Hudson Canyon National Marine Sanctuary (NMS). NOAA requested relevant and new information pertaining to its 11 sanctuary nomination evaluation criteria. In particular, NOAA sought any additional details about the area's natural or cultural resources, emerging threats to these resources, and evolving management efforts or human uses in the proposed area (*e.g.,* wind energy proposals). After reviewing the information gathered through the public process and completing an internal analysis of readily-available and relevant information on the proposed area, NOAA has determined the Hudson Canyon NMS nomination will remain on the inventory until at least February 23, 2027.

DATES: This determination is applicable on February 23, 2022.

ADDRESSES: Matt Brookhart, Eastern Regional Director, NOAA Sanctuaries Eastern Region, 1305 East West Highway, N/NMS, Silver Spring, MD 20910, or at *Matt.Brookhart@noaa.gov,* and at *https://nominate.noaa.gov/nominations/.*

FOR FURTHER INFORMATION CONTACT: LeAnn Hogan, Regional Operations Coordinator, NOAA Sanctuaries Eastern Region, 1305 East-West Highway, N/NMS, Silver Spring, MD 20910, or at *LeAnn.Hogan@noaa.gov,* or at 202–731–0678.

SUPPLEMENTARY INFORMATION:

Background Information

In June 2014, NOAA issued a final rule establishing the sanctuary

nomination process (SNP), which details how communities may submit nominations to NOAA for consideration of national marine sanctuary designation (79 FR 33851). NOAA moves successful nominations to an inventory of areas that could be considered for national marine sanctuary designation. The final rule establishing the SNP included a five-year limit on any nomination added to the inventory that NOAA does not advance for designation.

In November 2019, NOAA issued a notice (84 FR 61546) to clarify procedures for evaluating and updating a nomination as it approaches the five-year mark on the inventory of areas that could be considered for national marine sanctuary designation. The clarified procedure is intended to ensure the inventory contains nominations that remain relevant and responsive to the 11 national significance criteria and management considerations. The 11 criteria can be found at *https://nominate.noaa.gov.* The process to update a nomination that is about to expire includes the following steps:

1. ONMS notifies the nominating party prior to the five-year mark of the nominated area's time on the inventory to give the nominator an opportunity to provide updates on the nominated area's relevance to the 11 sanctuary nomination evaluation criteria.

2. ONMS works with partners and the public to gather information on the nominated area's relevance to the 11 sanctuary nomination evaluation criteria.

3. ONMS reviews the information received from the original nominating party, partners, the public, Indigenous communities, and other relevant sources to update any information on the 11 criteria, assess the level of community-based support for the nomination from a broad range of interests, and determine if that support has increased or decreased since the time of nomination. Based on this information, ONMS assesses if the nomination is still accurate and relevant.

4. ONMS produces a report for the ONMS Director that presents an analysis of the information that has been collected, and recommends whether to maintain the nomination on the inventory, or remove it once the five-year mark is reached.

On January 21, 2022, NOAA issued a request for public comments on the Hudson Canyon NMS nomination (87 FR 3283). NOAA requested relevant information pertaining to the 11 sanctuary nomination evaluation criteria for inclusion in the national inventory. Five public comment letters were submitted during this public comment process. The public comment letters can be found at *regulations.gov* (search for docket number NOAA–NOS–2022–0010). In analyzing these public comment letters, particular attention was given to new scientific information about the national significance of natural and cultural resources, increases or decreases in the threats to resources originally proposed for protection, and evolving management efforts or human uses in the proposed area.

NOAA reviewed the information contained in the public comment letters and has determined that the new information shows that there are changes to the threats to the resources in Hudson Canyon, Hudson Canyon remains an area of national significance, the area has special cultural significance to the Indigenous people of the region, and the natural resources and ecological qualities continue to contribute to the biological productivity of the area. Therefore, this notice serves to inform the public of NOAA's decision to extend the nomination of the Hudson Canyon NMS on the inventory for another five-year period. With this action, NOAA is not proposing to designate Hudson Canyon as a national marine sanctuary.

Authority: 16 U.S.C. 1431 *et seq.*

John Armor,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2022–04076 Filed 2–25–22; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB847]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of webconference.

SUMMARY: The North Pacific Fishery Management Council (Council)'s Executive Committee will hold a webconference March 14, 2022.

DATES: The Executive Committee will begin at 8 a.m. on Monday, March 14, 2022, from 8 a.m. to 4 p.m., Alaska Time.

ADDRESSES: The meeting will be by webconference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/2857.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave, Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting via webconference are given under Connection Information, below.

FOR FURTHER INFORMATION CONTACT: Diana Evans, Council staff; email: *diana.evans@noaa.gov,* telephone: (907) 271–2809. For technical support please contact our administrative staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Monday, March 14, 2022

The Executive Committee and AP and SSC leadership will review a staff paper on reflections on the Council process and Ideas for Change, and develop recommendations for the Council. The Agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2857* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2857.* For technical support please contact our administrative staff, email: *npfmc.admin@noaa.gov.*

Public Comment

Public comment letters will be accepted and should be submitted electronically through the links at *https://meetings.npfmc.org/Meeting/Details/2857* by 5 p.m. Alaska time, March 13, 2022. The Committee will also hear oral testimony, sign-up information will be posted at *https://meetings.npfmc.org/Meeting/Details/2857.*

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

Dated: February 23, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–04138 Filed 2–25–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB842]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of webconference.

SUMMARY: The North Pacific Fishery Management Council (Council) Bering Sea Fishery Ecosystem Plan Climate Change Taskforce will meet March 15, 2022 through March 17, 2022.

DATES: The meeting will be held on Tuesday, March 15, 2022, through Thursday, March 17, 2022, from 8 a.m. to 4 p.m., Alaska Time.

ADDRESSES: The meeting will be a webconference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/2853.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave, Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Dr. Diana Stram, Council staff; phone: (907) 271–2809 and email: *diana.stram@noaa.gov.* For technical support, please contact our administrative staff; email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, March 15, 2022 Through Thursday, March 17, 2022

The agenda will include: (a) Review and revise draft Climate synthesis report; (b) review and discuss proposed Ecosystem matrix; (c) outline Climate Briefing report; and (d) contined work on process and other business. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2853* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2853.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/2853.*

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

Dated: February 23, 2022.

Tracey L. Thompson,

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

[FR Doc. 2022–04136 Filed 2–25–22; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meetings

TIME AND DATE: Monday, February 28, 2022; 10:00 a.m.

PLACE: This meeting will be conducted by remote means.

STATUS: Commission meeting—closed to the public.*

MATTERS TO BE CONSIDERED: Briefing matter.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Secretary, Division of the Secretariat, Office of the General Counsel, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, (301) 504–7479 (Office) or 240–863–8938 (cell).

* The Commission unanimously determined by recorded vote to close the meeting and that agency business requires calling the meeting without seven calendar days advance public notice.

Dated: February 23, 2022.

Alberta E. Mills,

Secretary.

[FR Doc. 2022–04216 Filed 2–24–22; 11:15 am]

BILLING CODE 6355–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2022–SCC–0023]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application for Grants Under the Veterans Upward Bound Program (1894–0001)

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a reinstatement with change of a previously approved collection.

DATES: Interested persons are invited to submit comments on or before March 30, 2022.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kenneth Foushee, (202) 453–7417.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application for Grants under the Veterans Upward Bound Program (1894–0001).

OMB Control Number: 1840–0823.

Type of Review: Reinstatement with change of a previously approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 200.

Total Estimated Number of Annual Burden Hours: 6,480.

Abstract: The Department of Education is requesting a reinstatement with change of the application for grants under the Veterans Upward Bound (VUB) Program. The Department is requesting a reinstatement with change because the previous VUB application expired in April 2020 and the application will be needed for a Fiscal Year (FY) 2022 competition for new awards. The Department expects an increase in respondents for the FY 2022 competition. The FY 2022 application incorporates three competitive preference priorities.

This collection is being submitted under the Streamlined Clearance Process for Discretionary Grant Information Collections (1894–0001). Therefore, the 30-day public comment period notice will be the only public comment notice published for this information collection.

Dated: February 23, 2022.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–04140 Filed 2–25–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0022]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Package for TRIO Training Program for Federal TRIO Programs (1894–0001)

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a reinstatement with change of a previously approved collection.

DATES: Interested persons are invited to submit comments on or before March 30, 2022.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Suzanne Ulmer, (202) 453–7691.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application package for TRIO Training Program for Federal TRIO Programs (1894–0001).

OMB Control Number: 1840–0814.

Type of Review: Reinstatement with change of a previously approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 46.

Total Estimated Number of Annual Burden Hours: 1,452.

Abstract: This information collection provides the U.S. Department of Education with information needed to evaluate, score and rank the quality of the projects proposed by institutions of higher education and public or private nonprofit agencies and organizations applying for a TRIO Training grant, in accordance with Title IV, Part A, Subpart 2, Section 402G of the Higher Education Act of 1965, as amended (HEA), which requires the collection of specific information and data necessary for applicants to receive an initial competitive grant and a non-competing grant for the second year.

This collection is being submitted under the Streamlined Clearance Process for Discretionary Grant Information Collections (1894–0001). Therefore, the 30-day public comment period notice will be the only public comment notice published for this information collection.

Dated: February 23, 2022.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–04142 Filed 2–25–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; National Professional Development Program

AGENCY: Office of English Language Acquisition, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2022 for the National Professional Development (NPD) program, Assistance Listing Number 84.365Z. This notice relates to the approved information collection under OMB control number 1894–0006.

DATES:

Applications Available: February 28, 2022.

Deadline for Notice of Intent to Apply: March 21, 2022.

Deadline for Transmittal of Applications: April 29, 2022.

Deadline for Intergovernmental Review: June 28, 2022.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 27, 2021 (86 FR 73264) and available at *www.federalregister.gov/d/2021-27979.* Please note that these Common Instructions supersede the version published on February 13, 2019, and, in part, describe the transition from the requirement to register in *SAM.gov* a Data Universal Numbering System (DUNS) number to the implementation of the Unique Entity Identifier (UEI). More information on the phase-out of DUNS numbers is available at *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

FOR FURTHER INFORMATION CONTACT: Francisco J. López, Jr., U.S. Department of Education, 400 Maryland Ave. SW, Room H3215, Potomac Center Plaza, Washington, DC 20202. Telephone: (202) 401–1433. Email: *NPD2022@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: Under the NPD program, authorized by sections 3111(c)(1)(C) and 3131 of the Elementary and Secondary Education Act of 1965, as amended (ESEA), the Department awards grants to institutions of higher education (IHEs) or public or private entities with relevant experience and capacity, in consortia with State educational agencies (SEAs) or local educational agencies (LEAs). The purpose of these grants is to provide professional development activities that will improve classroom instruction for English learners (ELs) and assist educational personnel working with such children to meet high professional standards, including standards for certification and licensure as teachers who work in language instruction educational programs or serve ELs.

Grants awarded under this program may be used—

(1) For effective pre-service or in-service professional development programs that will improve the qualifications and skills of educational personnel involved in the education of ELs, including personnel who are not certified or licensed and educational paraprofessionals, and for other activities to increase teacher and school leader effectiveness in meeting the needs of ELs;

(2) For the development of program curricula appropriate to the needs of the consortia participants involved;

(3) To support strategies that strengthen and increase parent, family, and community member engagement in the education of ELs;

(4) To develop, share, and disseminate effective practices in the instruction of ELs and in increasing the academic achievement of ELs, including the use of technology-based programs;

(5) In conjunction with other Federal need-based student financial assistance programs, for financial assistance, including costs related to tuition, fees, and books for enrolling in courses required to complete the degree involved, to meet certification or licensing requirements for teachers who work in language instruction educational programs or serve ELs; and

(6) As appropriate, to support strategies that promote school readiness of ELs and their transition from early childhood education programs, such as Head Start or State-run preschool programs, to elementary school programs.

Background: Educator effectiveness is the most important in-school factor affecting student achievement and success.[1] To improve the academic achievement of ELs, the NPD program supports pre-service and in-service instruction for teachers and other staff, including school leaders, working with ELs.

The NPD program has funded a range of grantees that are currently implementing 142 projects across the country. As the EL population continues to grow, it has become increasingly important to identify and expand the use of evidence-based instructional practices that improve EL learning outcomes.

The body of evidence on effective language, literacy, and content instruction for ELs, including specific instructional practices for English language acquisition, is growing steadily, as documented by the 2014 What Works Clearinghouse (WWC) Practice Guide for teaching ELs, available at: *http://ies.ed.gov/ncee/wwc/PracticeGuide.aspx?sid=19.* To encourage the use of evidence to increase the effectiveness of projects funded by the NPD program, the Department has included Competitive Preference Priority 1 for projects designed to improve academic outcomes for ELs using strategies supported by moderate evidence (as defined in this notice).

While we are encouraged by the growing body of evidence supporting effective EL instruction, this competition is designed to promote further study of pre- and in-service professional development models for EL educators. We encourage NPD program applicants to design rigorous evaluations of their proposed activities that, if well-implemented, would meet the WWC Evidence Standards With Reservations. We believe that such evaluations will help ensure that projects funded under the NPD program help expand the knowledge base on effective EL instructional practice.

Supporting ELs begins with their having access to high-quality early learning programs, including those that are designed to improve their early learning and development outcomes across one or more of the Essential Domains of School Readiness for children from birth through third grade (or for any age group within this range). The knowledge and skills of early learning educators is also critical to EL success in early learning programs. Early learning educators without adequate knowledge and skills can contribute to inequities in educational opportunities for ELs and result in long-term negative consequences for EL students.[2] We therefore encourage applicants to propose projects that improve access to culturally and linguistically responsive early learning environments for multilingual learners, and that increase public awareness about the benefits of proficiency in more than one language. Further, we encourage applicants to include in their projects professional learning to equip educators for providing culturally and linguistically responsive early learning programs for ELs.

The Department is also interested in supporting projects that promote elementary school readiness of ELs in early learning environments. Supporting ELs' transitions from early childhood education programs can be a challenge for schools. We believe projects with a focus in this area will advance efforts

[1] Calderón, M., Slavin, R., and Sánchez, M. (2011). Effective instruction for English learners. *Future of Children,* 21(1), 103–127.

[2] Samson, J.F., & Lesaux, N.K. (2015). Disadvantaged language minority students and their teachers: A national picture. *Teachers College Record,* 117, 1–26.

that increase the field's understanding of how schools can effectively respond to ELs' needs as they relate to school readiness.

The Department is also interested in supporting projects that improve parental, family, and community engagement. Professional development that enhances educators' capacity to build meaningful relationships with students' families may also support students' learning at home. Accordingly, we have included two invitational priorities in this competition for projects that promote school readiness of ELs and encourage family and community involvement.

Priorities: This notice includes one absolute priority, two competitive preference priorities, and two invitational priorities. In accordance with 34 CFR 75.105(b)(2)(iv), the absolute priority is from section 3131 of the ESEA (20 U.S.C. 6861). Competitive Preference Priority 1 is from 34 CFR 75.226(d)(2). Competitive Preference Priority 2 is from the Secretary's Supplemental Priorities and Definitions for Discretionary Grants Programs (Supplemental Priorities), published in the **Federal Register** on December 10, 2021 (86 FR 70612).

Absolute Priority: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

Providing Professional Development to Improve Instruction for ELs.

Projects that provide professional development activities that will improve classroom instruction for ELs and assist educational personnel working with ELs to meet high professional standards, including standards for certification and licensure as teachers who work in language instruction educational programs or serve ELs.

Competitive Preference Priorities: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2), we award an additional five points to an application that meets Competitive Preference Priority 1, and we award up to an additional five points to an application, depending on how well the application meets Competitive Preference Priority 2. An application may be awarded up to a maximum of 10 additional points under these competitive preference priorities. Applicants may address none, one, or both of the competitive preference priorities. An applicant must clearly identify in the project abstract and the project narrative section of its application the competitive preference priority or priorities it wishes the Department to consider for purposes of earning competitive preference priority points.

These priorities are:

Competitive Preference Priority 1—Moderate Evidence (0 or 5 points).

Projects supported by evidence that meets the conditions in the definition of ''moderate evidence'' (as defined in this notice).

Note: The Department will consider only the first citation in an applicant's proposal.

Competitive Preference Priority 2—Promoting Equity in Student Access to Educational Resources and Opportunities (up to 5 points).

Projects designed to promote educational equity and adequacy in resources and opportunity for underserved students in early learning programs that examine the sources of inequity and inadequacy and implement responses, and that may include establishing, expanding, or improving learning environments for multilingual learners, and increasing public awareness about the benefits of fluency in more than one language and how the coordination of language development in the school and the home improves student outcomes for multilingual learners.

Invitational Priorities: For FY 2022 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are invitational priorities. Under 34 CFR 75.105(c)(1) we do not give an application that meets these invitational priorities a competitive or absolute preference over other applications.

These priorities are:

Invitational Priority 1—School Readiness.

Projects that support strategies that assist educational personnel working with ELs to promote school readiness of ELs and their transition from early childhood education programs, such as Head Start or State-run preschool programs, to elementary school programs.

Invitational Priority 2—Family Engagement.

Projects to develop or implement evidence-based policies or strategies that assist educational personnel working with ELs in implementing ongoing, robust family or community involvement.

Definitions: The following definitions are from 34 CFR 77.1, the Supplemental Priorities, and sections 3201 and 8101 of the ESEA (20 U.S.C. 7011 and 7801), and they apply to the priorities, selection criteria, and performance measures in this notice. The source of each definition is noted in parentheses following the text of the definition.

Ambitious means promoting continued, meaningful improvement for program participants or for other individuals or entities affected by the grant, or representing a significant advancement in the field of education research, practices, or methodologies. When used to describe a performance target, whether a performance target is ambitious depends upon the context of the relevant performance measure and the baseline for that measure. (34 CFR 77.1)

Baseline means the starting point from which performance is measured and targets are set. (34 CFR 77.1)

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes. (34 CFR 77.1)

English learner, when used with respect to an individual, means an individual—

(a) Who is aged 3 through 21;

(b) Who is enrolled or preparing to enroll in an elementary school or secondary school;

(c)(i) Who was not born in the United States or whose native language is a language other than English;

(ii)(I) Who is a Native American or Alaska Native, or a Native resident of the outlying areas; and

(II) Who comes from an environment where a language other than English has had a significant impact on the individual's level of English language proficiency; or

(iii) Who is migratory, whose native language is a language other than English, and who comes from an environment where a language other than English is dominant; and

(d) Whose difficulties in speaking, reading, writing, or understanding the English language may be sufficient to deny the individual—

(i) The ability to meet the challenging State academic standards;

(ii) The ability to successfully achieve in classrooms where the language of instruction is English; or

(iii) The opportunity to participate fully in society. (Section 8101 of the ESEA)

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise

equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbooks:

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment. (34 CFR 77.1)

Institution of higher education has the meaning given that term in section 101(a) of the Higher Education Act of 1965. (Section 8101(29) of the ESEA)

Language instruction educational program means an instruction course—

(a) In which an English learner is placed for the purpose of developing and attaining English proficiency while meeting challenging State academic standards; and

(b) That may make instructional use of both English and a child's native language to enable the child to develop and attain English proficiency, and may include the participation of English proficient children if such course is designed to enable all participating children to become proficient in English and a second language. (Section 3201 of the ESEA)

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes. (34 CFR 77.1.)

Note: Applicants may use resources such as the Pacific Education Laboratory's Education Logic Model Application (*http://relpacific.mcrel.org/resources/elm-app*) to help design their logic models.

Moderate evidence means that there is evidence of effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations or settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study or quasi-experimental design study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbooks, as appropriate, and that—

(A) Meets WWC standards with or without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy the requirement in this paragraph (iii)(D). (34 CFR 77.1.)

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers). (34 CFR 77.1)

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbooks. (34 CFR 77.1)

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program. (34 CFR 77.1)

What Works Clearinghouse (WWC) Handbooks (WWC Handbooks) means the standards and procedures set forth in the WWC Standards Handbook, Versions 4.0 or 4.1, and WWC Procedures Handbook, Versions 4.0 or 4.1, or in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (all incorporated by reference, see § 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the WWC Handbooks documentation. (34 CFR 77.1)

Program Authority: 20 U.S.C. 6861.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The Supplemental Priorities.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $25,500,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $350,000–600,000.

Estimated Average Size of Awards: $464,000.

Maximum Award: $600,000 per year.

Estimated Number of Awards: 42.

Note: The Department is not bound by any estimates in this notice.

Project Period: 60 months.

III. Eligibility Information

1. *Eligible Applicants:* IHEs, or public or private entities with relevant experience and capacity, in consortia with LEAs or SEAs.

To maximize student population needs and geographic diversity, the number of awards per single entity will be limited to one per DUNS or UEI number. For information on the transition from DUNS numbers to UEIs, see *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

2. a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses a training indirect cost rate. This limits indirect cost reimbursement to an entity's actual indirect costs, as determined in its negotiated indirect cost rate agreement, or eight percent of a modified total direct cost base, whichever amount is less. For more information regarding training indirect cost rates, see 34 CFR 75.562. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 27, 2021 (86 FR 73264) and available at *www.federalregister.gov/d/2021-27979,* which contain requirements and information on how to submit an application. Please note that these Common Instructions supersede the version published on February 13, 2019, and, in part, describe the transition from the requirement to register in SAM.gov a DUNS number to the implementation of the UEI. More information on the phase-out of DUNS numbers is available at *https://www2.ed.gov/about/offices/list/ofo/docs/unique-entity-identifier-transition-fact-sheet.pdf.*

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the NPD competition, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Consistent with the process followed in the prior NPD competitions, we may post the project narrative section of funded NPD applications on the Department's website so you may wish to request confidentiality of business information. Identifying proprietary information in the submitted application will help facilitate this public disclosure process.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application.

We recommend that you (1) limit the application narrative to no more than 35 pages and (2) use the following standards:

- A ''page'' is 8.5'' x 11'', on one side only, with 1'' margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit for the application does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the bibliography, or the letters of support of the application. However, the recommended page limit does apply to the entire narrative section of the application. An application will not be disqualified if it exceeds the recommended page limit.

6. *Notice of Intent To Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants that intend to apply. Therefore, we strongly encourage each potential applicant to notify us of their intent to submit an application. To do so, please email the program contact person listed under **FOR FURTHER INFORMATION CONTACT** with the subject line ''Intent to Apply,'' and include the applicant's name and a contact person's name and email address. Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from section 34 CFR 75.210. The maximum score for all of these criteria is 100 points (not including competitive preference priority points). The maximum score for each criterion is indicated in parentheses.

(a) *Quality of the project design.* (up to 40 points)

(1) The Secretary considers the quality of the design of the proposed project.

(2) In determining the quality of the design of the proposed project, the

Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(ii) The extent to which the design for implementing and evaluating the proposed project will result in information to guide possible replication of project activities or strategies, including information about the effectiveness of the approach or strategies employed by the project.

(iii) The extent to which the proposed project demonstrates a rationale (as defined in this notice).

(b) *Quality of project personnel.* (up to 10 points)

(1) The Secretary considers the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator.

(ii) The qualifications, including relevant training and experience, of key project personnel.

(c) *Quality of the management plan.* (up to 25 points)

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(ii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(d) *Adequacy of resources.* (up to 5 points)

(1) The Secretary considers the adequacy of resources for the proposed project.

(2) In determining the adequacy of resources for the proposed project, the Secretary considers the following factors:

(i) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

(ii) The extent to which the costs are reasonable in relation to the number of persons to be served and to the anticipated results and benefits.

(e) *Quality of the project evaluation.* (up to 20 points)

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(ii) The extent to which the methods of evaluation will, if well implemented, produce evidence about the project's effectiveness that would meet the What Works Clearinghouse standards with or without reservations as described in the What Works Clearinghouse Handbook (as defined in this notice).

(iii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(iv) The extent to which the methods of evaluation will provide valid and reliable performance data on relevant outcomes.

Note: The following are technical assistance resources on evaluation: (1) WWC Procedures and Standards Handbook: *http://ies.ed.gov/ncee/wwc/references/idocviewer/doc.aspx?docid=19&tocid=1;* and (2) IES/NCEE Technical Methods papers: *http://ies.ed.gov/ncee/tech_methods.*

In addition, we invite applicants to view two webinar recordings that were hosted by the Institute of Education Sciences. The first webinar addresses strategies for designing and executing well-designed quasi-experimental design studies. This webinar is available at: *http://ies.ed.gov/ncee/wwc/Multimedia.aspx?sid=23.* The second webinar focuses on more rigorous evaluation designees, including strategies for designing and executing randomized controlled trials. This webinar is available at: *http://ies.ed.gov/ncee/wwc/Multimedia.aspx?sid=18.*

2. *Review and Selection Process:* The Department will screen applications that are submitted for NPD grants in accordance with the requirements in this notice and determine which applications meet the eligibility and other requirements. Peer reviewers will review all eligible applications for NPD grants that are submitted by the established deadline.

Applicants should note, however, that we may screen for eligibility at multiple points during the competition process, including before and after peer review; applicants that are determined to be ineligible will not receive a grant award regardless of peer reviewer scores or comments. If we determine that an application does not meet an NPD requirement, the application will not be considered for funding.

For NPD grant applications, the Department intends to conduct a two-part review process to review and score all eligible applications. Content reviewers will review and score all eligible applications on the following selection criteria: (a) Quality of the project design; (b) Quality of project personnel; (c) Quality of the management plan; and (d) Adequacy of resources. These reviewers will also review and score Competitive Preference Priority 2. Peer reviewers with evaluation expertise will review and score selection criterion (e) Quality of the project evaluation. The Department will review and score the Competitive Preference Priority 1 relying on expertise from the Institute of Education Sciences.

We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this program the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2

CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *http://www.ed.gov/fund/grant/apply/appforms.html.*

(c) The Secretary may provide a grantee with additional funding for data collection, analysis, and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* The Department has established the following performance measures for the purpose of Department reporting under 34 CFR 75.110:

Measure 1: The percentage of project-specific annual goals the program met.

Measure 2: The number of pre-service program participants enrolled annually.

Measure 3: The unduplicated number of in-service program participants served annually.

Measure 4: Under measures 2 and 3, the number of participants who are making progress toward becoming fully State certified, licensed, or endorsed in EL instruction and the number of participants who have become fully State certified, licensed, or endorsed by the end of the five-year project period.

(b) *Baseline data.* Applicants must provide baseline (as defined in this notice) data in their applications for each of the project performance measures listed in (a) and explain how each proposed baseline data is related to program outcomes; or, if the applicant has determined that there are no established baseline data for a particular performance measure, explain why there is no established baseline and explain how and when, during the project period, the applicant will establish a baseline for the performance measure.

(c) *Performance measure targets.* In addition, the applicant must propose in its application annual targets for the measures listed in paragraph (a). Applications must also include the following information as directed under 34 CFR 75.110(b):

(1) Why each proposed performance target is ambitious (as defined in this notice) yet achievable compared to the baseline for the performance measure.

(2) The data collection and reporting methods the applicant would use and why those methods are likely to yield reliable, valid, and meaningful performance data; and

(3) The applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data

collection, analysis, and reporting in other projects or research.

Note: If the applicant does not have experience with collection and reporting of performance data through other projects or research, the applicant should provide other evidence of capacity to successfully carry out data collection and reporting for its proposed project.

(d) *Performance Reports.* All grantees must submit an annual performance report and final performance report with information that is responsive to these performance measures. The Department will consider this data in making annual continuation awards.

(e) *Department Evaluations.* Consistent with 34 CFR 75.591, grantees funded under this program must comply with the requirements of any evaluation of the program conducted by the Department or an evaluator selected by the Department.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Supreet Anand,

[Acting] Assistant Deputy Secretary and Director, Office of English Language Acquisition.

[FR Doc. 2022–04175 Filed 2–25–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[Docket No. 18–70–LNG]

Mexico Pacific Limited LLC; Application To Amend Export Term Through December 31, 2050, for Existing Non-Free Trade Agreement Authorization

AGENCY: Office of Fossil Energy and Carbon Management, Department of Energy.

ACTION: Notice of application.

SUMMARY: The Office of Fossil Energy and Carbon Management (FECM) (formerly the Office of Fossil Energy) of the Department of Energy (DOE) gives notice (Notice) of receipt of an application (Application), filed on January 24, 2022, by Mexico Pacific Limited LLC (MPL). MPL seeks to amend the export term set forth in its current authorization, DOE/FE Order No. 4312, to a term ending on December 31, 2050. Under Order No. 4312, MPL is authorized to re-export U.S.-sourced natural gas in the form of liquefied natural gas (LNG) from the proposed MPL Facility to be located in Mexico to non-free trade agreement countries. MPL filed the Application under the Natural Gas Act (NGA) and DOE's policy statement entitled, ''Extending Natural Gas Export Authorizations to Non-Free Trade Agreement Countries Through the Year 2050'' (Policy Statement). Protests, motions to intervene, notices of intervention, and written comments on the requested term extension are invited.

DATES: Protests, motions to intervene, or notices of intervention, as applicable, and written comments are to be filed electronically as detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, March 15, 2022.

ADDRESSES:

Electronic Filing by email: fergas@hq.doe.gov.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, DOE has found it necessary to make temporary modifications to the comment submission process in light of the ongoing Covid–19 pandemic. DOE is currently accepting only electronic submissions at this time. If a commenter finds that this change poses an undue hardship, please contact Office of Resource Sustainability staff at (202) 586–4749 or (202) 586–7893 to discuss the need for alternative arrangements. Once the Covid–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

FOR FURTHER INFORMATION CONTACT:

Jennifer Wade or Peri Ulrey, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability, Office of Fossil Energy and Carbon Management, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–4749 or (202) 586–7893, *jennifer.wade@hq.doe.gov* or *peri.ulrey@hq.doe.gov.*

Cassandra Bernstein, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Energy Delivery and Resilience, Forrestal Building, Room 6D–033, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9793, *cassandra.bernstein@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On December 14, 2018, in Order No. 4312, DOE authorized MPL to re-export U.S.-sourced natural gas in the form of LNG in a volume equivalent to 621 billion cubic feet per year of natural gas, pursuant to NGA section 3(a), 15 U.S.C. 717b(a).[1] MPL is authorized to re-export this LNG by vessel from the proposed MPL Facility, to be located in the State of Sonora, Mexico, to any country with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in

[1] *Mexico Pacific Limited LLC,* DOE/FE Order No. 4312, Docket No. 18–70–LNG, Opinion and Order Granting Long-Term, Multi-Contract Authorization to Export U.S.-Sourced Natural Gas by Pipeline to Mexico for Liquefaction and Re-export in the Form of Liquefied Natural Gas to Non-Free Trade Agreement Nations (Dec. 14, 2018).

natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries) for a 20-year term. In the Application,[2] MPL asks DOE to extend its current export term to a term ending on December 31, 2050, as provided in the Policy Statement.[3] Additional details can be found in the Application, posted on the DOE website at: *https://www.energy.gov/sites/default/files/2022-01/2022.01.24%20MPL%20DOE%20Term%20Extension%20Application.pdf.*

DOE Evaluation

In the Policy Statement, DOE adopted a term through December 31, 2050 (inclusive of any make-up period), as the standard export term for long-term non-FTA authorizations.[4] As the basis for its decision, DOE considered its obligations under NGA section 3(a), the public comments supporting and opposing the proposed Policy Statement, and a wide range of information bearing on the public interest.[5] DOE explained that, upon receipt of an application under the Policy Statement, it would conduct a public interest analysis of the application under NGA section 3(a). DOE further stated that ''the public interest analysis will be limited to the application for the term extension—meaning an intervenor or protestor may challenge the requested extension but not the existing non-FTA order.'' [6]

Accordingly, in reviewing MPL's Application, DOE will consider any issues required by law or policy under NGA section 3(a), as informed by the Policy Statement. To the extent appropriate, DOE will consider the study entitled, *Macroeconomic Outcomes of Market Determined Levels of U.S. LNG Exports* (2018 LNG Export Study),[7] DOE's response to public comments received on that Study,[8] and the following environmental documents:

- *Addendum to Environmental Review Documents Concerning Exports of Natural Gas From the United States,* 79 FR 48132 (Aug. 15, 2014); [9]
- *Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States,* 79 FR 32260 (June 4, 2014); [10] and
- *Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States: 2019 Update,* 84 FR 49278 (Sept. 19, 2019), and DOE/FE's response to public comments received on that study.[11]

Parties that may oppose the Application should address these issues and documents in their comments and/or protests, as well as other issues deemed relevant to the Application.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.,* requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its environmental responsibilities.

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable, addressing the Application. Interested parties will be provided 15 days from the date of publication of this Notice in which to submit comments, protests, motions to intervene, or notices of intervention. The public previously was given an opportunity to intervene in, protest, and comment on MPL's long-term non-FTA application. Therefore, DOE will not consider comments or protests that do not bear directly on the requested term extension.

Any person wishing to become a party to the proceeding must file a motion to intervene or notice of intervention. The filing of comments or a protest with respect to the Application will not serve to make the commenter or protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by the regulations in 10 CFR part 590.

As noted, DOE is only accepting electronic submissions at this time. Please email the filing to *fergas.hq.doe.gov.* All filings must include a reference to ''Docket No. 18–70–LNG'' or ''Mexico Pacific Limited LLC Term Extension'' in the title line.

Please Note: Please include all related documents and attachments (*e.g.,* exhibits) in the original email correspondence. Please do not include any active hyperlinks or password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner. Any hardcopy filing submitted greater in length than 50 pages must also include, at the time of the filing, a digital copy on disk of the entire submission.

The Application and any filed protests, motions to intervene, notices of interventions, and comments will also be available electronically by going to the following DOE web address: *https://www.energy.gov/fecm/division-natural-gas-regulation.*

A decisional record on the Application will be developed through responses to this Notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Opinion and Order may be issued based on the official record, including the Application and responses filed by parties pursuant to this Notice, in accordance with 10 CFR 590.316.

Signed in Washington, DC, on February 22, 2022.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability.

[FR Doc. 2022–04074 Filed 2–25–22; 8:45 am]

BILLING CODE 6450–01–P

[2] Mexico Pacific Limited LLC, Application to Amend Export Term for Existing Long-Term Authorization Through December 31, 2050, Docket No. 18–70–LNG (Jan. 24, 2022). MPL is currently authorized under a separate order (DOE/FE Order No. 4248) to export domestically produced natural gas to Mexico and to re-export the natural gas in the form of LNG to FTA countries. MPL's request regarding its FTA authorization is not subject to this Notice. *See* 15 U.S.C. 717b(c).

[3] U.S. Dep't of Energy, Extending Natural Gas Export Authorizations to Non-Free Trade Agreement Countries Through the Year 2050; Notice of Final Policy Statement and Response to Comments, 85 FR 52237 (Aug. 25, 2020) [hereinafter Policy Statement].

[4] *See id.,* 85 FR 52247.

[5] *See id.,* 85 FR 52247.

[6] *Id.,* 85 FR 52247.

[7] *See* NERA Economic Consulting, Macroeconomic Outcomes of Market Determined Levels of U.S. LNG Exports (June 7, 2018), *available at: https://www.energy.gov/sites/prod/files/2018/06/f52/Macroeconomic%20LNG%20Export%20Study%202018.pdf.*

[8] U.S. Dep't of Energy, Study on Macroeconomic Outcomes of LNG Exports: Response to Comments Received on Study; Notice of Response to Comments, 83 FR 67251 (Dec. 28, 2018).

[9] The Addendum and related documents are available at: *http://energy.gov/fe/draft-addendum-environmental-review-documents-concerning-exports-natural-gas-united-states.*

[10] The 2014 Life Cycle Greenhouse Gas Report is available at: *http://energy.gov/fe/life-cycle-greenhouse-gas-perspective-exporting-liquefied-natural-gas-united-states.*

[11] U.S. Dep't of Energy, Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States: 2019 Update—Response to Comments, 85 FR 72 (Jan. 2, 2020). The 2019 Update and related documents are available at: *https://fossil.energy.gov/app/docketindex/docket/index/21.*

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG22–57–000.
Applicants: Panorama Wind, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Panorama Wind, LLC.
Filed Date: 2/18/22.
Accession Number: 20220218–5257.
Comment Date: 5 p.m. ET 3/11/22.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL19–58–012.
Applicants: PJM Interconnection, L.L.C.
Description: Compliance filing: Reserve Compliance Filing Docket Nos. EL19–58, ER19–1486 to be effective 5/1/2022.
Filed Date: 2/22/22.
Accession Number: 20220222–5262.
Comment Date: 5 p.m. ET 3/14/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–2402–002.
Applicants: UGI Utilities Inc.
Description: Compliance filing: UGI Utilities Inc. Compliance Filing to be effective 9/1/2021.
Filed Date: 2/18/22.
Accession Number: 20220218–5216.
Comment Date: 5 p.m. ET 3/11/22.

Docket Numbers: ER21–1130–002.
Applicants: ISO New England Inc., Central Maine Power Company, The United Illuminating Company, Maine Electric Power Company, Inc., Versant Power, Eversource Energy Service Company (as agent), The Connecticut Light and Power Company, NSTAR Electric Company, Public Service Company of New Hampshire, Green Mountain Power Corporation, New England Power Company, New Hampshire Transmission, LLC, Unitil Energy Systems, Inc., Fitchburg Gas and Electric Light Company.
Description: Compliance filing: ISO New England Inc. submits tariff filing per 35: NETOs; ER20–2572–001, ER21–1130–001 & ER22—Compliance Filing to be effective 1/27/2020.
Filed Date: 2/18/22.
Accession Number: 20220218–5219.
Comment Date: 5 p.m. ET 3/11/22.

Docket Numbers: ER21–1709–002.
Applicants: ISO New England Inc., Vermont Transco LLC.
Description: Compliance filing: ISO New England Inc. submits tariff filing per 35: Vermont Transco LLC; Docket ER21–1709 *et al.* Revised Eff Date for Order No. 864 to be effective 1/27/2020.
Filed Date: 2/22/22.
Accession Number: 20220222–5001.
Comment Date: 5 p.m. ET 3/15/22.

Docket Numbers: ER22–290–001.
Applicants: Oakland Power Company LLC.
Description: Compliance filing: Notice of Implementation of Capital Items to be effective 1/1/2022.
Filed Date: 2/22/22.
Accession Number: 20220222–5218.
Comment Date: 5 p.m. ET 3/15/22.

Docket Numbers: ER22–1086–000.
Applicants: ISO New England Inc., Central Maine Power Company, The United Illuminating Company, Maine Electric Power Company, Inc., Versant Power, Eversource Energy Service Company (as agent), Green Mountain Power Corporation, New England Power Company, New Hampshire Transmission, LLC, Unitil Energy Systems, Inc., Fitchburg Gas and Electric Light Company, Vermont Electric Power Company, Inc., Vermont Transco LLC.
Description: Compliance filing: ISO New England Inc. submits tariff filing per 35: NETOs; ER20–2572–001; ER21–1130–001 & ER22—to be effective 1/1/2022.
Filed Date: 2/22/22.
Accession Number: 20220222–5000.
Comment Date: 5 p.m. ET 3/15/22.

Docket Numbers: ER22–1087–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: Powerex Construction and Security Agreement to be effective 2/22/2022.
Filed Date: 2/22/22.
Accession Number: 20220222–5011.
Comment Date: 5 p.m. ET 3/15/22.

Docket Numbers: ER22–1088–000.
Applicants: BIF II Safe Harbor Holdings, LLC.
Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 2/23/2022.
Filed Date: 2/22/22.
Accession Number: 20220222–5063.
Comment Date: 5 p.m. ET 3/15/22.

Docket Numbers: ER22–1089–000.
Applicants: Jackson Generation, LLC.
Description: Initial rate filing: Reactive Power Rate Schedule and Request for Waiver and Expedited Action to be effective 4/1/2022.
Filed Date: 2/22/22.
Accession Number: 20220222–5070.
Comment Date: 5 p.m. ET 3/15/22.

Docket Numbers: ER22–1090–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 2486R1 ITC Great Plains/NPPD/Midwest Interconnection Agr to be effective 5/1/2022.
Filed Date: 2/22/22.
Accession Number: 20220222–5079.
Comment Date: 5 p.m. ET 3/15/22.

Docket Numbers: ER22–1091–000.
Applicants: AEP Texas Inc.
Description: § 205(d) Rate Filing: AEPTX–BRP Carina BESS 1st A&R Generation Interconnection Agreement to be effective 2/11/2022.
Filed Date: 2/22/22.
Accession Number: 20220222–5121.
Comment Date: 5 p.m. ET 3/15/22.

Docket Numbers: ER22–1092–000.
Applicants: Southern California Edison Company.
Description: Tariff Amendment: Notice of Cancellation EDP Ltr Agreement SCE and Falcon Energy SA No. 1143 to be effective 4/25/2022.
Filed Date: 2/22/22.
Accession Number: 20220222–5137.
Comment Date: 5 p.m. ET 3/15/22.

Docket Numbers: ER22–1093–000.
Applicants: PacifiCorp.
Description: Tariff Amendment: Termination of RS 740 LVE Const Agmt for Threemile Knoll—Hooper Springs to be effective 4/23/2022.
Filed Date: 2/22/22.
Accession Number: 20220222–5247.
Comment Date: 5 p.m. ET 3/15/22.

Docket Numbers: ER22–1094–000.
Applicants: California Independent System Operator Corporation.
Description: § 205(d) Rate Filing: 2022–02–22 Intertie Deviation Settlements—Clarification to be effective 12/31/9998.
Filed Date: 2/22/22.
Accession Number: 20220222–5255.
Comment Date: 5 p.m. ET 3/15/22.

Docket Numbers: ER22–1095–000.
Applicants: KCE NY 6, LLC.
Description: Baseline eTariff Filing: Baseline new to be effective 2/22/2022.
Filed Date: 2/22/22.
Accession Number: 20220222–5268.
Comment Date: 5 p.m. ET 3/15/22.

Take notice that the Commission received the following electric reliability filings.

Docket Numbers: RD22–3–000.
Applicants: North American Electric Reliability Corporation.
Description: Application of the North American Electric Reliability Corporation for Approval of Modification to the Compliance Section of Reliability Standard CIP–014.
Filed Date: 2/16/22.
Accession Number: 20220216–5230.
Comment Date: 5 p.m. ET 3/15/22.

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: February 22, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–04129 Filed 2–25–22; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF22–3–000; Docket No. PF22–4–000]

Columbia Gas Transmission, LLC; Transcontinental Gas Pipe Line Company, LLC; Notice of Scoping Period Requesting Comments on Environmental Issues for the Planned Virginia Reliability Project and Commonwealth Energy Connector Project, and Notice of Public Scoping Session

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document that will discuss the environmental impacts of the Virginia Reliability Project and Commonwealth Energy Connector Project involving construction and operation of facilities by Columbia Gas Transmission, LLC (Columbia) and Transcontinental Gas Pipe Line Company, LLC (Transco), respectively. Columbia's project would be located in Greensville, Prince George, Sussex, Surry, Southampton, and Isle of Wight Counties, Virginia and in the cities of Suffolk and Chesapeake, Virginia. Transco's project would be located in Mecklenburg, Brunswick, and Greensville Counties, Virginia. Because of planned operational connections between the Virginia Reliability Project and the Commonwealth Energy Connector Project, the Commission will prepare a single environmental document as part of the National Environmental Policy Act (NEPA) review process. The Commission will use this environmental document in its decision-making process to determine whether the projects are in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the projects. As part of the NEPA review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. This gathering of public input is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission's NEPA process is described below in the *NEPA Process and Environmental Document* section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on March 24, 2022. Comments may be submitted in written or oral form. Further details on how to submit comments are provided in the *Public Participation* section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all written or oral comments during the preparation of the environmental document.

If you submitted comments on either of these projects to the Commission before the opening of the dockets on December 1, 2021, you will need to file those comments in Docket Nos. PF22–3–000 (Virginia Reliability Project) or PF22–4–000 (Commonwealth Energy Connector Project) to ensure they are considered.

This notice is being sent to the Commission's current environmental mailing list for these projects. State and local government representatives should notify their constituents of these planned projects and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a representative from Columbia or Transco may contact you about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the project, the Natural Gas Act conveys the right of eminent domain to the company. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law. The Commission does not subsequently grant, exercise, or oversee the exercise of that eminent domain authority. The courts have exclusive authority to handle eminent domain cases; the Commission has no jurisdiction over these matters.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' addresses typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (*www.ferc.gov*) under the links to Natural Gas Questions or Landowner Topics.

Public Participation

There are four methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.*

(1) You can file your comments electronically using the eComment feature, which is located on the Commission's website (*www.ferc.gov*) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to FERC Online. 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; a comment on a particular project is considered a ''Comment on a Filing,'' or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (PF22–3–000 for Virginia Reliability Project or PF22–4–000 for Commonwealth Energy Connector Project) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

(4) In lieu of sending written comments, the Commission invites you to attend the virtual public scoping session its staff will conduct by telephone, scheduled as follows:

Date and Time

Tuesday, March 15, 2022, 5:00 p.m. to 7:00 p.m., Call in number: 800–779–8625, Passcode: 3472916

Although there will not be a formal presentation, Commission staff will be available to answer questions you may have about the environmental review process. The primary goal of this scoping session is to have you identify the specific environmental issues and concerns that should be considered in the environmental document. Individual oral comments will be taken on a one-on-one basis with a court reporter present on the line. This format is designed to receive the maximum amount of oral comments, in a convenient way during the timeframe allotted, and is in response to the ongoing COVID–19 pandemic.

The scoping session is scheduled from 5:00 p.m. to 7:00 p.m. eastern time. You may call at any time after 5:00 p.m. at which time you will be placed on mute and hold. Calls will be answered in the order they are received. Once answered, you will have the opportunity to provide your comment directly to a court reporter with FERC staff or representative present on the line. A time limit of three minutes will be implemented for each commentor.

Transcripts of all comments received during the scoping session will be publicly available on FERC's eLibrary system (see the last page of this notice for instructions on using eLibrary).

It is important to note that the Commission provides equal consideration to all comments received, whether filed in written form or provided orally at a virtual scoping session.

Additionally, the Commission offers a free service called eSubscription, which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Summary of the Planned Projects

Virginia Reliability Project

Columbia plans to replace and expand existing facilities associated with its VM–107 and VM–108 pipelines in southeast Virginia. The Virginia Reliability Project would increase the capability of Columbia's existing pipeline facilities to provide incremental firm transportation service of 100,000 dekatherms per day (Dth/d), while increasing the reliability of Columbia's system by replacing 1950s vintage pipeline. According to Columbia, its project would meet the increasing market demand of residential, commercial, and industrial consumers in southeast Virginia.

The Virginia Reliability Project would consist of the following:

- Replacement of approximately 47.7 miles of existing, 1950s vintage 12-inch-diameter VM–107 and VM–108 pipelines with 24-inch-diameter pipeline mostly within Columbia's existing right-of-way, in the Counties of Sussex, Surry, Southampton, and Isle of Wight, as well as the cities of Suffolk and Chesapeake, Virginia;
- installation of one new 5,500 horsepower (HP) electric-drive compressor unit at the existing Emporia Compressor Station in Greensville County, Virginia;
- a facility upgrade involving additional gas cooling and an increase of 2,700 HP at the existing Petersburg Compressor Station in Prince George County, Virginia;
- expansion of the Emporia Point of Receipt in Greensville County, Virginia; RS–7423 Regulator Station in Prince George County, Virginia; and the MS–831010 Point of Delivery in the City of Chesapeake, Virginia; and
- eight mainline valve replacements, five new launcher/receiver installations, and other minor appurtenant facilities.

The general location of the project facilities is shown in appendix 1.[1]

Commonwealth Energy Connector Project

Transco plans to expand its existing natural gas transmission system to provide 105,000 Dth/d of incremental firm transportation capacity from its Compressor Station 165 in Pittsylvania County, Virginia to the existing Emporia delivery point in Greensville County, Virginia on the existing South Virginia Lateral B-Line Pipeline.

The Commonwealth Energy Connector Project would consist of the following:

- Construction of a 6.35-mile-long, 24-inch-diameter pipeline loop[2] (referred to as the Commonwealth Loop), including valve and launcher/receiver facilities, in Brunswick and Greensville Counties, Virginia;
- installation of a 30,500 HP electric motor-drive compressor unit at the existing Compressor Station 168 in Mecklenburg County, Virginia; and
- expansion of the existing Emporia Metering and Regulator Station in Greensville County, Virginia.

The general location of the project facilities is shown in appendix 1.

Land Requirements for Construction

Virginia Reliability Project

As a preliminary estimate, construction of the planned facilities for the Virginia Reliability Project would disturb about 814 acres of land for the aboveground facilities and the pipeline. Following construction, Columbia would maintain about 195 acres for permanent operation of the project's facilities; the remaining acreage would be restored. These acreages are subject to change pending further pipeline route refinement. All of the planned pipeline route parallels Columbia's existing VM–107 and VM–108 pipelines.

Commonwealth Energy Connector Project

Construction of the planned facilities for the Commonwealth Energy Connector would disturb about 168 acres of land for the compressor station modifications and the pipeline. An additional amount, as yet to be quantified, would be disturbed for

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary.'' For instructions on connecting to eLibrary, refer to the last page of this notice. 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 FERC at *FERCOnlineSupport@ferc.gov* or call toll free, (886) 208–3676 or TTY (202) 502–8659.

[2] A pipeline loop is a segment of pipe constructed parallel to an existing pipeline to increase capacity.

aboveground facilities. Following construction, Transco would maintain about 2.8 acres of new pipeline right-of-way for permanent operation of the project's facilities; the remaining acreage is either part of its existing permanent right-of-way or would be restored. The acreage that would be permanently affected by aboveground facilities outside of Transco's existing facilities has yet to be quantified. All of the planned pipeline route parallels Transco's existing South Virginia Lateral A-Line.

NEPA Process and the Environmental Document

Any environmental document issued by Commission staff will discuss impacts that could occur as a result of the construction and operation of the planned projects under the relevant general resource areas:

- Geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- socioeconomics and environmental justice;
- land use;
- air quality and noise;
- climate change; and
- reliability and safety.

Commission staff have already identified several issues that deserve attention based on a preliminary review of the planned facilities and the environmental information provided by Columbia and Transco for their respective projects. This preliminary list of issues may change based on your comments and our analysis:

- Lands administered by the Great Dismal Swamp National Wildlife Refuge;
- the Sunray Historic District in the city of Chesapeake, Virginia; and
- residential, commercial, and industrial areas;
- agricultural lands;
- wetlands and waterbodies; and
- forested areas.

Commission staff will also evaluate reasonable alternatives to the planned projects or portions of the projects and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Although no formal application has been filed for either project, Commission staff have already initiated a NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the Commission receives an application. As part of the pre-filing review, Commission staff will contact federal and state agencies to discuss their involvement in the scoping process and the preparation of the environmental document.

If formal applications are filed, Commission staff will then determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff's independent analysis of the environmental issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its determination on the proposed projects. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/ Notice of Schedule* will be issued once the applications are filed, which will open an additional public comment period. Staff will then prepare a draft EIS that will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS, and revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the public record through eLibrary [3] and the Commission's natural gas environmental documents web page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to these projects to formally cooperate in the preparation of the environmental document.[4] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the *Public Participation* section of this notice.

[3] For instructions on connecting to eLibrary, refer to the last page of this notice.

[4] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.8.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the Virginia Department of Historic Resources, and to solicit its views and those of other government agencies, interested Indian tribes, and the public on the projects' potential effects on historic properties.[5] The environmental document for these projects will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; and other interested parties. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the projects and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the planned projects.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to *GasProjectAddressChange@ferc.gov* stating your request. You must include the docket number PF22–03–000 for Virginia Reliability Project or PF22–04–000 for Commonwealth Energy Connector Project in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing

[5] The Advisory Council on Historic Preservation regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

OR

(2) Return the attached ''Mailing List Update Form'' (appendix 2).

Becoming an Intervenor

Once Columbia and Transco file their applications with the Commission, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Only intervenors have the right to seek rehearing of the Commission's decision and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214). Motions to intervene are more fully described at *https://www.ferc.gov/resources/guides/how-to.asp.* Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives formal applications for the projects, after which the Commission will issue a public notice that establishes an intervention deadline.

Additional Information

Additional information about the projects is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number in the ''Docket Number'' field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission's calendar located at *https://www.ferc.gov/news-events/events* along with other related information.

Dated: February 22, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–04130 Filed 2–25–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–1085–000]

Panorama Wind, 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 Panorama Wind, 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 March 14, 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: February 22, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–04131 Filed 2–25–22; 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: RP22–568–000.
Applicants: Columbia Gas Transmission, LLC.
Description: Compliance filing: Annual Report on Operational Transactions 2022 to be effective N/A.
Filed Date: 2/18/22.
Accession Number: 20220218–5191.
Comment Date: 5 p.m. ET 3/2/22.

Docket Numbers: RP22–569–000.
Applicants: Hardy Storage Company, LLC.
Description: Compliance filing: Annual Report on Operational Transactions 2022 to be effective N/A.
Filed Date: 2/18/22.
Accession Number: 20220218–5192.
Comment Date: 5 p.m. ET 3/2/22.

Docket Numbers: RP22–570–000.
Applicants: Crossroads Pipeline Company.
Description: Compliance filing: Annual Report on Operational Transactions 2022 to be effective N/A.
Filed Date: 2/18/22.
Accession Number: 20220218–5196.
Comment Date: 5 p.m. ET 3/2/22.

Docket Numbers: RP22–571–000.
Applicants: Columbia Gulf Transmission, LLC.
Description: Compliance filing: Annual Report on Operational Transactions 2022 to be effective N/A.
Filed Date: 2/18/22.
Accession Number: 20220218–5212.
Comment Date: 5 p.m. ET 3/2/22.

Docket Numbers: RP22–572–000.

Applicants: Perryville Gas Storage LLC.

Description: § 4(d) Rate Filing: Perryville Gas Storage SubmitsTariff Modifications to be effective 3/21/2022.

Filed Date: 2/18/22.

Accession Number: 20220218–5218.

Comment Date: 5 p.m. ET 3/2/22.

Docket Numbers: RP22–573–000.

Applicants: Golden Pass Pipeline LLC.

Description: Compliance filing: Golden Pass Pipeline LLC 2021 Operational Purchases and Sales Report to be effective N/A.

Filed Date: 2/22/22.

Accession Number: 20220222–5094.

Comment Date: 5 p.m. ET 3/7/22.

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.

Filings in Existing Proceedings

Docket Numbers: RP22–574–000.

Applicants: Golden Pass Pipeline LLC.

Description: § 4(d) Rate Filing: 2022 GPPL FERC Gas Tariff Clean Up to be effective 4/1/2022.

Filed Date: 2/22/22.

Accession Number: 20220222–5135.

Comment Date: 5 p.m. ET 3/7/22.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

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: February 22, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–04128 Filed 2–25–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9448–01–OAR]

Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990–2020

Correction

In notice document 2022–02694, appearing on page 8583 in the issue of Tuesday, February 15, 2022, make the following correction:

On page 8583, in the second column, in the **DATES** section, in the fourth line, ''March 11, 2022'' is corrected to read ''March 17, 2022''.

[FR Doc. C1–2022–02694 Filed 2–25–22; 8:45 am]

BILLING CODE 0099–10–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2014–0350; FRL–9616–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; EPA's National Fish Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), EPA's National Fish Program (EPA ICR Number 1959.07, OMB Control Number 2040–0226) 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 April 30, 2022. Public comments were previously requested via the **Federal Register** on August 3, 2021 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 March 30, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OW–2014–0350, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *OW-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

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

FOR FURTHER INFORMATION CONTACT: CDR Samantha Fontenelle, Office of Water, Office of Science and Technology, Standards and Health Protection Division (4305T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–2083; fax number: (202) 566–0409; email address: *fontenelle.samantha@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 *https://www.epa.gov/dockets.*

Abstract: This ICR is for voluntary information collections under the National Fish Program. These information collections would help EPA advance equitable and effective fish advisory programs that protect recreational and subsistence fishers and other underserved populations from consumption of contaminated fish. This information is collected under the authority of section 104 of the Clean Water Act, which provides for the collection of information to be used to protect human health and the environment. The information to be collected on a voluntary basis would include the following: Fish advisory information and fish tissue data collected to assist in making advisory decisions; state or tribal fish program information for the National Fish Advisory Program Evaluation; and, technical program information from

time to time. EPA would analyze the information to determine what science, guidance, technical assistance, and nationwide information are needed to help state and tribes have equitable and effective fish advisory programs. In addition, EPA would also use the information provided to facilitate information sharing and to ensure guidance documents are useful and technically accurate.

Form Numbers: None.

Respondents/affected entities: The 50 states, the District of Columbia, the five territories, authorized tribes with EPA-approved water quality standards (WQS), and the Great Lakes Indian Fish and Wildlife Commission.

Respondent's obligation to respond: Voluntary (Clean Water Act, Section 104)

Estimated number of respondents: Up to 103 (total).

Frequency of response: Once in 3-year period for some collections; periodically for one collection.

Total estimated burden: 1,185 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $65,268.77 (per year), includes $6,000 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an increase of 607 hours in the total estimated annual respondent burden compared with the ICR currently approved by OMB. This increase is due to EPA's efforts to advance equity and environmental justice in fish advisory programs. EPA is adding information collections to help EPA determine what science, guidance, technical assistance, and nationwide information are needed to help state and tribes have equitable and effective fish advisory programs that protect recreational and subsistence fishers and other underserved populations from consumption of contaminated fish. In addition, EPA will also use the information provided to facilitate information sharing and to ensure guidance documents are useful and technically accurate. The increase pertains to the addition of three voluntary information collections as part of implementing the EPA national advisory program: Information on state and tribal fish advisories; state and tribal program information for the National Fish Advisory Program Evaluation; and, technical program information from time to time.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–04124 Filed 2–25–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2021–0084; FRL–9617–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Mercury (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Mercury (EPA ICR Number 0113.14, OMB Control Number 2060–0097), 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 April 30, 2022. Public comments were previously requested, via the **Federal Register**, on April 13, 2021, 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 March 30, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2021–0084, to EPA online using *https://www.regulations.gov/* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be confidential business information 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 Emission Standards for Hazardous Air Pollutants (NESHAP) for Mercury (40 CFR part 61, subpart E) regulations apply to existing facilities and new facilities which process mercury ore to recover mercury, use mercury chlor-alkali cells to produce chlorine gas and alkali metal hydroxide, and incinerate or dry wastewater treatment plant sludge. 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: Owners and operators of facilities which process mercury ore to recover mercury, use mercury chlor-alkali cells to produce chlorine gas and alkali metal hydroxide, and incinerate and/or dry wastewater treatment plant sludge.

Respondent's obligation to respond: Mandatory (40 CFR part 61, subpart E).

Estimated number of respondents: 101 (total).

Frequency of response: Annually and semiannually.

Total estimated burden: 17,200 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $2,030,000 (per year), which includes $0 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment decrease in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. This decrease is not due to any program changes. The adjustment decrease in burden from the most recently-approved ICR is due to a decrease in the number of sources. Consultations with the Agency's internal industry experts have shown that a number of cell chlor-alkali plants have shut down since the previous ICR renewal, leading to a decrease in respondent labor hours and the number of responses. There are no capital or operation and maintenance costs associated with this ICR. The overall result is a decrease in burden.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–04133 Filed 2–25–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2014–0359; FRL–9615–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Underground Injection Control Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), Underground Injection Control (UIC) Program (EPA ICR Number 0370.27, OMB Control Number 2040–0042) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). This is a proposed extension of the ICR, which is currently approved through April 30, 2022. Public comments were previously requested via the **Federal Register** on August 25, 2021, 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 March 30, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OW–2014–0359, to EPA online using *https://www.regulations.gov* (our preferred method), by email to *OW-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be confidential business information 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: Kyle Carey, Drinking Water Protection Division, Office of Ground Water and Drinking Water, 4606M, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2322; fax number: (202) 564–3756; email address: *carey.kyle@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, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20004. 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: EPA developed the Underground Injection Control (UIC) Program under the authority of the Safe Drinking Water Act to establish a federal-state regulatory system to protect underground sources of drinking water (USDWs) from injection fluids and injection-related activities. These rules are designed to ensure that Americans receive safe drinking water, and ensure fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income. Injected fluids include hazardous waste, oil field brines or produced water, mineral processing fluids, various types of industrial fluids, automotive, sanitary, and other wastes, and carbon dioxide injected for geologic sequestration. Owners or operators of injection wells must obtain permits, conduct environmental monitoring, maintain records, and report results to EPA or the state agency (if the state has UIC primary enforcement responsibility (primacy)). States must report to EPA on permittee compliance and related information. This mandatory information is reported using standardized forms and annual reports. Reporting data are used by UIC authorities to ensure the protection of USDWs.

Form Numbers: 7520–1, 7520–2A, 7520–2B, 7520–3, 7520–4, 7520–6, 7520–7, 7520–8, 7520–11, 7520–16, 7520–17, 7520–18, and 7520–19.

Respondents/affected entities: Owners or operators of underground injection wells and State UIC primacy agencies.

Respondent's obligation to respond: Mandatory (40 CFR parts 144 through 148).

Estimated number of respondents: 37,677 (total).

Frequency of response: Annual, semi-annual, quarterly.

Total estimated burden: 1,631,360 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $363,309,464 (per year), includes $276,069,465 annualized capital or operation and maintenance costs.

Changes in the estimates: There is an increase of 339,100 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to adjustments that include an increase in the number of Class I, Class II, Class III, and Class VI permit applications expected to be prepared and reviewed by UIC permitting authorities during the upcoming ICR period. The overall increase is partially offset by an inventory adjustment that results in a decrease in the number of current operators that will perform monitoring, reporting, and recordkeeping activities over the life of an injection project (due to decreases in the injection well inventory). Programmatic changes that result in minor changes to the burden estimate include revisions to the reporting forms and changes in reporting of primacy state program information, including implementing electronic reporting options (which will reduce the burden to primacy agencies) and anticipated approval of Class VI UIC Program primacy for several states, which will increase state burden (by

shifting burden from EPA to the approved states).

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–04106 Filed 2–25–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2022–0132; FRL–9411–01–OCSPP]

Certain New Chemicals; Receipt and Status Information for January 2022

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA) to make certain information publicly available and to publish information in the **Federal Register** pertaining to submissions, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 01/01/2022 to 01/31/2022.

DATES: Comments identified by the specific case number provided in this document must be received on or before March 30, 2022.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2022–0132, and the specific case number for the chemical substance related to your comment, through the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Jim Rahai, Project Management and Operations Division (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8593; email address: *rahai.jim@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. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 01/01/2022 to 01/31/2022. The Agency is providing notice of receipt of PMNs, SNUNs, and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its website about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

B. What is the Agency's authority for taking this action?

Under TSCA, 15 U.S.C. 2601 *et seq.,* a chemical substance may be either an ''existing'' chemical substance or a ''new'' chemical substance. Any chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a ''new chemical substance,'' while a chemical substance that is listed on the TSCA Inventory is classified as an ''existing chemical substance.'' (See TSCA section 3(11).) For more information about the TSCA Inventory please go to: *https://www.epa.gov/tsca-inventory.*

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN, or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for ''test marketing'' purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to: *https://www.epa.gov/oppt/newchems.*

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the **Federal Register** certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting confidential business information (CBI).* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that

you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/comments.html.*

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the **Federal Register** after providing notice of such changes to the public and an opportunity to comment (See the **Federal Register** of May 12, 1995, (60 FR 25798) (FRL–4942–7). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its website about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs that have passed an initial screening by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices screened by EPA during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (*i.e.,* domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter ''A'' (*e.g.* P–18–1234A). The version column designates submissions in sequence as ''1'', ''2'', ''3'', etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions. Note also that future versions of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

TABLE I—PMN/SNUN/MCANS APPROVED* FROM 01/01/2022 TO 01/31/2022

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
J–22–0008A	2	12/21/2021	CBI	(G) Manufacture of an alcohol	(G) Modified Yeast.
J–22–0011	1	01/24/2022	CBI	(G) Ethanol productions	(G) Biofuel producing Saccharomyces cerevisiae modified, genetically stable.
P–18–0281A ...	4	01/14/2022	CBI	(G) Electrolyte additive	(G) Cyclic sulfate.
P–18–0350A ...	4	12/31/2021	Evonik Corporation	(S) Additive in water-borne UV-curable coatings, Filler & pigment treatment, Glass fiber treatment.	(G) Aqueous methacrylamido modified polysiloxane.
P–18–0374A ...	5	12/31/2021	Evonik Corporation	(S) Additive in a water-borne coating formulation, Glass fiber sizing, Fillers, pigments and glass bead treatment.	(G) Cationic aminomodified alkylpolysiloxane.
P–20–0092A ...	8	01/25/2022	CBI	(G) Coloration of fabric	(G) Napthalenesulfonic acid, amino-hydroxy-bis [sulfo-[(sulfooxy)ethyl]sulfonyl]phenyl]diazinyl]-,potassium sodium salt.
P–20–0175A ...	6	01/10/2022	CBI	(G) Proprietary Additive for WB&P Formulation, Proprietary Additive for Slats & CR Formulations, Proprietary Additive for PI Formulation.	(G) acid N-[4-(4-diarylalkyl]-, carbopolycyclic alkenyl, methyl ester.
P–20–0176A ...	6	01/10/2022	CBI	(G) Proprietary Additive for WB&P Formulation, Proprietary Additive for Slats & CR Formulations, Proprietary Additive for PI Formulation.	(G) acid N-(diarylalkyl)-, carbopolycyclic alkenyl, methyl ester.
P–20–0177A ...	6	01/10/2022	CBI	(G) Proprietary Additive for WB&P Formulation, Proprietary Additive for Slats & CR Formulations, Proprietary Additive for PI Formulation.	(G) carbopolycyclic alkenyl, 2-carboxylic acid, 2-[[[4-(4-diarylalkyl)]carbonyl]oxy]ethyl ester.
P–20–0178A ...	6	01/10/2022	CBI	(G) Proprietary Additive for WB&P Formulation, Proprietary Additive for Slats & CR Formulations, Proprietary Additive for PI Formulation.	(G) carbopolycyclic alkenyl, 2-carboxylic acid, 2-[[[(diarylalkyl)]carbonyl]oxy]ethyl ester.
P–21–0012A ...	5	01/06/2022	CBI	(G) The notified substance will be used as a fragrance ingredient.	(G) Multialkylbicycloalkenyl substituted propanenitrile.
P–21–0032	3	01/19/2022	Crison, LLC	(S) Mining collector, Asphalt emulsifier	(S) Poly[oxy(methyl-1,2-ethanediyl)], alpha-(3-aminopropyl)-omega-(1-methylethoxy)-.
P–21–0033	3	01/19/2022	Crison, LLC	(S) Mining collector, Asphalt emulsifier	(S) Poly[oxy(methyl-1,2-ethanediyl)], alpha-(3-aminopropyl)-omega-butoxy-.
P–21–0181A ...	5	01/10/2022	CBI	(G) Color developer	(G) 1,3-Benzenedicarboxamide, N1,N3-bis(carbomonocyclic)-5-[[(carbomonocyclic)amino]sulfonyl]-.
P–22–0021A ...	2	01/21/2022	CBI	(G) Nucleating Agent for Polyolefins	(G) Alkylphosphonic acid, calcium salt.

TABLE I—PMN/SNUN/MCANS APPROVED* FROM 01/01/2022 TO 01/31/2022—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–22–0022	2	01/04/2022	CBI	(G) dispersing additive	(G) Aryl-substituted-heterocyclic-polyamine, reaction products with polyethylene glycol alkyl-ether, and nitrogen and alkyl-substituted benzene.
P–22–0024	2	01/07/2022	CBI	(G) Ingredient in Industrial Coating	(G) Amino salt, polymer with 1,6-diisocyanatohexane, oxime- and glycol ether-blocked.
P–22–0025	2	01/03/2022	CBI	(S) Chemical intermediate	(G) Oxirane, 2-(chloromethyl)-, homopolymer, ether with dialkyl-alkanediol (2:1).
P–22–0027	3	01/18/2022	Takasago	(S) Fragrance in fine fragrance, deodorants, cosmetics, household products such as laundry detergents, air fresheners, shampoos and body washes.	(S) 2-Pentanone, 3-methyl-5-(2,2,3-trimethylcyclopentyl)-.
P–22–0028	2	01/12/2022	H.B. Fuller Company	(S) Industrial Adhesive	(G) Polyester with 1,4-benzenedicarboxylic acid, 1,4- dimethyl 1,4-benzebedicarboxylate, 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, 1,2-ethanediol, aliphatic polyester, 3-hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropanoate, 1,3-isobenzofurandione and 1,1'-methylenebis[4-isocyanatobenzene].
P–22–0028A	3	01/28/2022	H.B. Fuller Company	(S) Industrial Adhesive	(G) polyester with 1,4-benzenedicarboxylic acid, 1,4- dimethyl 1,4-benzebedicarboxylate, 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, 1,2-ethanediol, aliphatic polyester, 3-hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropanoate, 1,3-isobenzofurandione and 1,1'-methylenebis[4-isocyanatobenzene].
P–22–0029A	2	01/12/2022	H.B. Fuller Company	(S) Industrial Adhesive	(G) polyester with 1,4-benzenedicarboxylic acid, 1,4- dimethyl 1,4-benzebedicarboxylate, 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, 1,2-ethanediol, aliphatic polyester, 3-hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropanoate, 1,3-isobenzofurandione and 1,1'-methylenebis[isocyanatobenzene].
P–22–0029A	3	01/28/2022	H.B. Fuller Company	(S) Industrial Adhesive	(G) polyester with 1,4-benzenedicarboxylic acid, 1,4- dimethyl 1,4-benzebedicarboxylate, 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, 1,2-ethanediol, aliphatic polyester, 3-hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropanoate, 1,3-isobenzofurandione and 1,1'-methylenebis[isocyanatobenzene].
P–22–0030	2	01/12/2022	H.B. Fuller Company	(S) Industrial Adhesive	(G) Polyester with 1,4-benzenedicarboxylic acid, 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, 1,2-ethanediol, aliphatic polyester, 3-hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropanoate, 1,3-isobenzofurandione and 1,1'-methylenebis[4-isocyanatobenzene].
P–22–0030A	3	01/28/2022	H.B. Fuller Company	(S) Industrial Adhesive	(G) Polyester with 1,4-benzenedicarboxylic acid, 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, 1,2-ethanediol, aliphatic polyester, 3-hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropanoate, 1,3-isobenzofurandione and 1,1'-methylenebis[4-isocyanatobenzene].
P–22–0031	2	01/12/2022	H.B. Fuller Company	(S) Industrial Adhesive	(G) polyester with 1,4-benzenedicarboxylic acid, 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, 1,2-ethanediol, aliphatic polyester, 3-hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropanoate, 1,3-isobenzofurandione and 1,1'-methylenebis[isocyanatobenzene].
P–22–0031A	3	01/28/2022	H.B. Fuller Company	(S) Industrial Adhesive	(G) polyester with 1,4-benzenedicarboxylic acid, 2,2-dimethyl-1,3-propanediol, dodecanedioic acid, 1,2-ethanediol, aliphatic polyester, 3-hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropanoate, 1,3-isobenzofurandione and 1,1'-methylenebis[isocyanatobenzene].
P–22–0032	1	01/13/2022	CBI	(S) Reactive polymer for use in adhesives and sealants.	(G) Isocyanic acid, polymethylenepolyphenylene ester, polymer with a-hydro-w-hydroxypoly[oxy(alkanediyl)], diisocyanatobenzene] and a-alkane[w-hydroxypoly[oxy(alkanediyl)]].
P–22–0033	1	01/13/2022	CBI	(S) Adhesion promoter for use in industrial manufacturing operations.	(G) Alkylamine, alkoxysilyl-, hydrolyzed.

TABLE I—PMN/SNUN/MCANS APPROVED* FROM 01/01/2022 TO 01/31/2022—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–22–0034	2	01/26/2022	CBI	(G) Precursor to a Nucleating Agent for Polyolefins.	(G) Alkylphosphonic acid, disodium salt.
P–22–0035	1	01/25/2022	Allnex USA, Inc.	(S) To improve the reactivity of flexographic ink formulations when cured under LED UV light.	(G) Alkenoic acid, alkanediyl ester, polymer with bis(substituted alkyl)-alkanediol polymer with alkylene oxides alkenoate, and alkanamine.

*The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission prior to the start of the 90 day review period, and in no way reflects the final status of a complete submission review.

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs that have passed an initial screening by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (*e.g.,* amendment to generic name, specific name, technical contact information, etc.) and chemical substance identity.

TABLE II—NOCS APPROVED* FROM 01/01/2022 TO 01/31/2022

Case No.	Received date	Commencement date	If amendment, type of amendment	Chemical substance
P–18–0301	01/05/2022	12/18/2021	N	(G) Alkanedioic acid, polymer with cycloalkyl dimethanol, alkyl and cycloalkyl diisocyanates, dimethyl-alkanediol, dihydroxyalkanoic acid methylenebis[isocyanatocyclohexane, hydroxyethyl acrylate- and polyalkyl glycol monoalkyl ether blocked.
P–19–0065	01/05/2022	12/30/2021	N	(S) 2.lambda.5,4.lambda.5,6.lambda.5-1,3,5,2,4,6-triazatriphosphorine, 2,2,4,4,6,6-hexaphenoxy-.
P–20–0005	12/29/2021	11/30/2021	N	(G) Modified graphene.
P–20–0018	01/25/2022	01/08/2022	N	(G) Fatty acid dimers, polymers with glycerol and triglycerides.
P–20–0113	01/06/2022	11/29/2021	N	(G) Ashes (residues), reactions products with tricarboxylic acid, silicic acid ((H4SiO4) tetra-Et ester and 2-[[3-(trialkoxysilyl)alkoxy]methyl]oxirane.
P–21–0120	01/10/2022	01/08/2022	N	(G) Substituted alkanoic acid, substituted alkyll ester, homopolymer, ester with substituted carbomonocycle esters, and substituted hetermonocycle polymer with substituted heteromonocylcle carbamate, substituted alkylperoxoate—initiated.
P–21–0141	01/19/2022	01/13/2022	N	(S) Alkanes, C4-8—branched and linear.
P–95–0162	01/19/2022	01/07/2022	N	(G) 2-propenoic acid, 2-methyl-, ethylalkyl ester, polymer with alkenylcarbomocycle, 2-ethylhexyl 2-propenoate and substituted alkyl 2-methyl-2-propenoate, substituted non-metallate, tert-bu 2-ethylalkaneperoxoate-initiated.

*The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission.

In Table III of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information that has been received during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

TABLE III—TEST INFORMATION RECEIVED FROM 01/01/2022 TO 01/31/2022

Case No.	Received date	Type of test information	Chemical substance
P–16–0462	01/21/2022	Metals Analysis for Quarter 3 and Quarter 4 2021.	(G) Silane-treated aluminosilicate.
P–16–0543	12/29/2021	Exposure Monitoring Report (November 2021).	(G) Halogenophosphoric acid metal salt.
P–21–0204	01/13/2022	Acute Oral Toxicity Study in Rats (OECD Test Guideline 420) and Bacterial Reverse Mutation Test (Ames Assay, Test Guideline OECD 471).	(G) Sulfonium, bis(3,4-polyhalocarbocyclic)aryl-, alpha, alpha, beta, beta-polyhalopolyhydro-2,2-diaryl-4,7-methano-1,3-heteropolycyclic-5-alkanesulfonate (1:1).

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

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

Dated: February 15, 2022.

Pamela Myrick,

Director, Project Management and Operations Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2022–04125 Filed 2–25–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0975; FR ID 72983]

Information Collection 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 (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 collections. 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 comments should be submitted on or before April 29, 2022. If you anticipate that you will be submitting comments but find it difficult to do so within the time period allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *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:* 3060–0975.

Title: Sections 68.105 and 1.4000, Promotion of Competitive Networks in Local Telecommunications Markets Multiple Tenant Environments (MTEs).

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and State, local, or Tribal governments.

Number of Respondents and Responses: 5,022 respondents; 217,658 responses.

Estimated Time per Response: 0.5 hour—10 hours.

Frequency of Response: On occasion reporting requirement and third-party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151 and the Telecommunications Act of 1996, Public Law 104–104.

Total Annual Burden: 144,217 hours.

Total Annual Cost: No cost.

Needs and Uses: This information facilitates efficient interaction between premises owners and local exchange carriers (LECs) regarding the placement of the demarcation point, which marks the end of wiring under control of the LEC and the beginning of wiring under the control of the premises owner or subscriber. The demarcation point is a critical point of interconnection where competitive LECs can gain access to the inside wiring of the building to provide service to customers in the building. This collection also helps ensure that fixed wireless antennas covered by the OTARD rule comply with the Commission's limits on radiofrequency exposure and provides the Commission with information on the state of the market. In short, this collection helps foster competition in local telecommunications markets by ensuring that competing telecommunications providers can provide services to customers in multiple tenant environments.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–04115 Filed 2–25–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID 73457]

Deletion of Item From February 18, 2022 Open Meeting

February 17, 2022.

The following item has been adopted by the Commission and deleted from the list of items scheduled for consideration at the Friday, February 18, 2022, Open Meeting. This item was previously listed in the Commission's Sunshine Notice on Friday, February 11, 2022.

3	MEDIA	*Title:* Updating Technical Rules for Radio Broadcasters (MB Docket No. 21–263). *Summary:* The Commission will consider a Report and Order to eliminate or amend outmoded or unnecessary broadcast technical rules.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2022–04150 Filed 2–25–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS22–03]

Appraisal Subcommittee Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of meeting.

Description: In accordance with Section 1104(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for its regular meeting:

Location: This will be a virtual meeting via Zoom. Please visit the agency's homepage (*www.asc.gov*) and access the provided registration link in the What's New box. You MUST register in advance to attend this Meeting.

Date: March 9, 2022.

Time: 10:00 a.m. ET.

Status: Open.

Reports

Chairman

Executive Director

Grants Director

Financial Manager

Action and Discussion Items

Approval of Minutes

December 8, 2021 Special Meeting Minutes

Amendment to FY22 ASC Budget

7-Hour National USPAP Update Course

Selection of ASC Vice Chair

How to Attend and Observe an ASC Meeting: The meeting will be open to the public via live webcast only. Visit the agency's homepage (*www.asc.gov*) and access the provided registration link in the What's New box. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC Meetings.

James R. Park,

Executive Director.

[FR Doc. 2022–04166 Filed 2–25–22; 8:45 am]

BILLING CODE 6700–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS22–02]

Appraisal Subcommittee; Notice of Meeting; Cancellation

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of meeting; cancellation.

The Special Meeting, which was published in accordance with Section 1104 (b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, at 87 FR 8840, February 16, 2022 and scheduled for Wednesday, February 23, 2022 at 10:00 a.m. ET, was cancelled.

James R. Park,

Executive Director.

[FR Doc. 2022–04075 Filed 2–25–22; 8:45 am]

BILLING CODE 6700–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm*. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than March 28, 2022.

A. *Federal Reserve Bank of San Francisco* (Sebastian Astrada, Director, Applications) 101 Market Street, San Francisco, California 94105–1579:

1. *Seattle Bancshares, Inc., Seattle, Washington*; to become a bank holding company by acquiring Seattle Bank, Seattle, Washington.

Board of Governors of the Federal Reserve System, February 22, 2022.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–04069 Filed 2–25–22; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project ''AHRQ's National Nursing Home COVID–19 Coordinating Center.'' This proposed information collection was previously published in the **Federal Register** on December 8th, 2021 and allowed 60 days for public comment. AHRQ did not receive comments from members of the public. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by March 30, 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: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

AHRQ's National Nursing Home COVID–19 Coordinating Center

As of February 3, 2022, nursing homes have reported 902,964 confirmed cases of severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) infection and coronavirus disease since 2019 (COVID–19), resulting in over 147,000 COVID–19-related deaths The U.S. Department of Health and Human Services (HHS) has distributed funds to nursing homes and launched several initiatives to improve nursing home safety and infection control. AHRQ's National Nursing Home COVID–19 Action Network (*https://www.ahrq.gov/nursing-home/about/index.html*) (the Network) is a cornerstone of HHS's response, intended to provide training and assistance to nursing homes on best practices to minimize transmission of SARS–CoV–2. The Network expands AHRQ's programmatic efforts to address quality and safety in long-term care, and aligns with other agency efforts to provide COVID–19 guidance to nursing homes. As the pandemic continues, nursing homes require easy access and implementation support for up-to-date best practices on SARS–CoV–2 infection control, COVID–19 care and management, and safety measures to protect residents and staff.

AHRQ's National Nursing Home COVID–19 Coordinating Center plays a complementary role to the Network, serving as a bridge between AHRQ's Network initiatives and the nursing home quality improvement (QI) community. The Coordinating Center is tasked with (1) coordinating engagement with scientific and policy stakeholders to identify safety needs and best practices, (2) ensuring coordinated development and dissemination of QI tools and other resources, and (3) assessing the effectiveness of the Network in providing training and mentorship to support nursing homes in responding to the COVID–19 pandemic.

As part of the Coordinating Center activities, AHRQ seeks to conduct an assessment of whether and how the Network activities aided the nursing homes' efforts to mitigate the challenges posed by the COVID–19 pandemic. The goals of the performance assessment are to:

1. Assess the reach, retention, and engagement of the Network;

2. study the implementation approach, gaps and barriers;

3. study the long-term impact, sustainability, and replicability of the training program and Network activities.

This study is being conducted by AHRQ through its Coordinating Center contractor, NORC at the University of Chicago (NORC), pursuant to AHRQ's statutory authority to conduct and support training and technical assistance on health care and on systems for the delivery of such care. 42 U.S.C. 299a.

Method of Collection

To further achieve the goals of this performance assessment, AHRQ is requesting OMB approval for new data collection. More specifically, the new data collection activities intend to collect systematic information from nursing homes on the following:

- Motivations for participation and non-participation in the Network
- Context of participation (including state and local context, and participation in other COVID–19 related-initiatives)
- Perceptions on recruitment, engagement, and retention, including facilitators and barriers of engagement and retention
- Perceptions on the Network training and mentorship resources, including access to and utility of the Network training and resources
- Gaps in knowledge, skills, and resources required for identifying residents and staff infected with COVID–19
- Impacts on the prevention and spread of SARS-CoV–2, implementation of best practice safety measures; improvement of quality of care for residents with mild and asymptomatic cases; and reduction of social isolation for residents, families, and staff

The primary data collection includes the following activities:

- Survey of all participating nursing homes (approximately 8,308) and a 50% representative sample of nonparticipating nursing homes (approximately 2,782) eligible for the Provider Relief Fund. Separate survey instruments will be used for network participants (''Participant Survey'') and non-participants (''Non-Participant Survey''). The Participant Survey will be conducted primarily via a secure web-based platform. The Non-Participant Survey will be conducted via web and telephone.
- Key informant interviews with up to 96 individuals from 32 nursing homes participating in the Network across all assessment domains, conducted virtually on a secure platform.

Information collected will inform whether and how the Network activities aided the nursing homes' efforts to mitigate the challenges posed by the COVID–19 pandemic. This data collection effort will also provide information on why nursing homes may not have been able to participate in the Network (Non-Participant Survey). Findings from the assessment will allow AHRQ to:

- Assess the Network's reach and the effectiveness of the retention and engagement strategies;
- Study implementation of the Network's training sessions, mentorship and technical assistance activities, and dissemination of the safety and quality improvement tools;
- Study the Network's impact on ensuring availability of protective equipment, rapid identification of nursing home residents and staff infected with SARS–CoV–2, entry and transmission of COVID–19, and improving health outcomes; and
- Study the long-term impact, sustainability, and replicability of the training program and Network activities to address other patient safety and quality improvement priorities.

Estimated Annual Respondent Burden

Survey. The nursing home survey will have two survey instruments:

—Participant Survey for nursing home facilities that participated in the Network

—Non-Participant Survey for nursing homes that did not participate in the Network

For the Participant Survey we expect that 1,662 participants (20% response rate) will agree to participate on behalf of their facilities and that the survey will take about 20 minutes to complete. For the Non-Participant Survey, we expect that 556 participants will agree to participate (20% response rate) on behalf of their facilities and that the survey will take about 5 minutes to complete. This estimate is based on prior provider survey experience and the response rate for the Customer Satisfaction survey which was approximately 20%.

Key Informant Interviews. Key informant interviews will be conducted with up to 32 nursing homes (up to 3 staff from each nursing home in each interview, for a total of 96 staff) involved in the Network. All interviews are expected to last 60 minutes, including time for respondents to provide verbal consent for participation and ask any questions at the start.

The total annual burden hours for the survey and key informant interviews are estimated to be 688 hours, as shown in Exhibit 1.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Hours per response	Total burden hours
Survey instrument—participant	1,662	.33	548
Survey instrument—nonparticipant	556	.08	44
Nursing Home Key Informant Interview	96	1	96
Total	2,314		688

Exhibit 2 shows the estimated annual cost burden associated with the respondents' time to participate in this information collection, which comes to $41,837.28

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate **	Total cost burden
Survey instrument—participant	1,662	548	[1] $60.81	$33,323.88
Survey instrument—nonparticipant	556	44	[1] 60.81	2,675.64
Nursing Home Key Informant Interview (Management)	96	96	[1] 60.81	5,837.76
Total	2,314	688		41,837.28

** Wage rates were calculated using the mean hourly wage from the U.S. Department of Labor, Bureau of Labor Statistics, May 2020 National Occupational Employment and Wage Estimates for the United States, *https://www.bls.gov/oes/current/oes_nat.htm*.
[1] Average rate for Nursing Care Facilities: Management Occupations.

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: February 22, 2022.

Marquita Cullom,

Associate Director.

[FR Doc. 2022–04102 Filed 2–25–22; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970—0060]

Submission for OMB Review; Annual Report on Households Assisted by the Low Income Home Energy Assistance Program (LIHEAP)

AGENCY: Office of Community Services, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Community Services (OCS), Division of Energy Assistance, is requesting a 3-year extension of the Household Report Form (OMB #0970–0060, expiration 02/28/2022). Submission of the completed report is one requirement for LIHEAP grant recipients applying for federal LIHEAP block grant funds. OCS proposes minor changes related to reporting of supplemental funding and to update reporting dates and number of respondents.

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.* One can 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: States, the District of Columbia, and the Commonwealth of Puerto Rico are required by the Low-Income Energy Assistance Act of 1981 (42 U.S.C. 8624, Sec 2610) to report statistics for the previous federal fiscal year (FFY) on the following:

- Assisted and applicant households, by type of LIHEAP assistance and funding source;
- Assisted households receiving nominal payments of $50 or less, by funding source;
- Assisted households receiving only utility payment assistance, by funding source; this information will

automatically be transferred to the grant recipient's Performance Data Form;

- Assisted households, regardless of the type(s) of LIHEAP assistance or funding source, excluding households that only receive nominal payments of $50 or less;
- Assisted households, by type of LIHEAP assistance and funding source, having at least one vulnerable member who is at least 60 years or older, disabled, or 5 years old or younger;
- Assisted households, by type of LIHEAP assistance and funding source, with at least one member age 2 years or under;
- Assisted households, by type of LIHEAP assistance and funding source, with at least one member ages 3 years through 5 years; and
- Assisted households, regardless of the type(s) of LIHEAP assistance or funding source, having at least one member 60 years or older, disabled, or 5 years old or younger.

Indian tribal grant recipients are required to submit data only on the number of households, by funding source, receiving heating, cooling, energy crisis, and/or weatherization benefits.

In FFY 2020, OCS updated the form to allow for the reporting of households served by separate LIHEAP funding types and benefits provided by the following: (1) Funds from regular LIHEAP FFY appropriations acts, including any Continuing Resolutions and final appropriations acts, reallotted prior year funds, and federal LIHEAP funds carried-over to or expended in the current year; (2) supplemental funds from the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) (Pub. L. 116–136); and (3) funds from any subsequent supplemental LIHEAP appropriations acts. ACF proposes similar changes to the report for FFY 2022, including the addition of lines that allow for the reporting of households served by LIHEAP funds from the American Rescue Plan Act of 2021 (Pub. L. 117–2). OCS has also updated the request to reflect the current number of expected respondents and appropriate reporting dates.

The information is being collected for the Department's annual LIHEAP Report to Congress. The data also provides information about the need for LIHEAP funds. Finally, the data are used in the calculation of LIHEAP performance measures under the Government Performance and Results Act of 1993. The data elements will allow the accuracy of measuring LIHEAP targeting performance and LIHEAP cost efficiency.

Respondents: State governments, tribal governments, U.S. territories, and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Assisted Household Report—Long Form	56	1	43	2,408
Assisted Household Report—Short Form	151	1	2	302

Estimated Total Annual Burden Hours: 2,710.

Authority: U.S.C. 8629 and 45 CFR.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–04085 Filed 2–25–22; 8:45 am]

BILLING CODE 4184–80–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4247]

Patient-Focused Drug Development: Methods To Identify What Is Important to Patients; Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry, FDA staff, and other stakeholders entitled ''Patient-Focused Drug Development: Methods To Identify What Is Important to Patients.'' This guidance (Guidance 2) is the second in a series of four methodological guidance documents that FDA committed to develop to describe how to collect and submit information from patients and caregivers to be used for medical product development and regulatory decision making. This guidance finalizes the draft guidance of the same title issued on October 1, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on February 28, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–4247 for ''Patient-Focused Drug Development: Methods To Identify What Is Important to Patients.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Shannon Cole, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993–0002, 301–796–9208, *Shannon.Cole@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry, FDA staff, and other stakeholders entitled ''Patient-Focused Drug Development: Methods To Identify What Is Important to Patients.'' This guidance (Guidance 2) is the second in a series of four methodological patient-focused drug development guidance documents that FDA committed to develop to describe how stakeholders (patients, researchers, medical product developers, and others) can collect and submit information from patients and caregivers to be used for medical product development and regulatory decision making. This series of guidance documents is intended to facilitate the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can more consistently inform medical product development and regulatory decision making. The purpose of Guidance 2 is to present a range of methods and established best research practices to identify what is important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient's disease. In particular, the methods and best practices presented can help elicit relevant information from patients and other stakeholders, such as how their disease affects their daily lives; what they find most troublesome; and the challenges, problems, and burdens of the treatment for the disease.

This guidance finalizes the draft guidance entitled ''Patient-Focused Drug Development: Methods To Identify What Is Important to Patients'' issued on October 1, 2019 (84 FR 52114). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include incorporating the definitions of relevant terms within the body of the document instead of as part of a glossary. In addition, editorial changes and methodological clarifications were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Patient-Focused Drug Development: Methods To Identify What Is Important to Patients.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to collections of information from individuals under treatment or clinical examination in connection with research, which are not subject to review by the Office of Management and Budget (OMB) under 5 CFR 1320.3(h)(5). Therefore, clearance by the OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. This guidance also refers to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the PRA. The information collections described in this guidance are submitted to FDA to support the medical product's effectiveness and to support claims in approved medical product labeling (see 21 CFR 314.50, 314.126, and 601.2). The information collections have been approved under OMB control numbers 0910–0001 and 0910–0338. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130.

III. Additional Information

Section 3002 of Title III, Subtitle A, of the 21st Century Cures Act (Pub. L. 114–255) directs FDA to develop patient-focused drug development guidance to address a number of areas including under section 3002(c)(2): Methodological approaches that may be used to develop and identify what is important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the

management of the patient's disease. In addition, FDA committed to meet certain performance goals under the sixth authorization of the Prescription Drug User Fee Act. These goal commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders, as part of negotiations with regulated industry. Section J.1 of the commitment letter, ''Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making'' (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf*), outlines work, including the development of a series of guidance documents and associated public workshops to facilitate the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can more consistently inform drug development, and, as appropriate, regulatory decision making.

IV. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: February 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04152 Filed 2–25–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0002]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) at the sponsor's request because the product is no longer manufactured or marketed.

DATES: The approval is withdrawn as of February 28, 2022.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, *sujaya.dessai@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 093–329 for use of a prolonged-release bolus containing sulfamethazine in cattle because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 093–329, and all supplements and amendments thereto, is hereby withdrawn February 28, 2022.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of this application.

Dated: February 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03539 Filed 2–25–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0030]

Fresenius Kabi USA, LLC, et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of five abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of March 30, 2022

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 065408	Epirubicin Hydrochloride (HCl) Injection, 150 milligrams (mg)/75 milliliters (mL) (2 mg/mL), 10 mg/5 mL (2 mg/mL), 50 mg/25 mL (2 mg/mL), and 200 mg/100 mL (2 mg/mL).	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 065411	Epirubicin HCl Injection, 200 mg/100 mL (2 mg/mL) and 50 mg/25 mL (2 mg/mL).	Do.
ANDA 065440	Idarubicin HCl Injection, 1 mg/mL	Do.
ANDA 077790	Fludarabine Phosphate for Injection, 50 mg/vial	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045.
ANDA 091008	Gabapentin Capsules, 100 mg, 300 mg, and 400 mg	Jiangsu Hengrui Pharmaceuticals Co., Ltd., U.S. Agent, Venus Pharmaceutical Laboratories Inc., 506 Carnegie Center, Suite 100, Princeton, NJ 08540.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 30, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on March 30, 2022 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: February 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04153 Filed 2–25–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines Meeting Cancellation

AGENCY: Health Resources and Services Administration; Department of Health and Human Services.

ACTION: Notice of meeting cancellation.

SUMMARY: This is to notify the public that the March 3, 2022, meeting of the Advisory Commission on Childhood Vaccines (ACCV) is canceled and will be rescheduled. This meeting was announced in the **Federal Register**, Vol. 87, No. 20 on Monday, January 31, 2022 (FR Doc. 2022–01848 Filed 1–28–22). Future meetings will occur in June, September, and December of calendar year 2022 and were announced through the same **Federal Register** notice.

FOR FURTHER INFORMATION CONTACT: CDR Reed Grimes, Designated Federal Official, ACCV, 5600 Fishers Lane, Rockville, Maryland 20857, telephone: (301) 443–6634 or email: *ACCV@HRSA.gov*.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–04105 Filed 2–25–22; 8:45 am]

BILLING CODE 4165–15–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 PAR20–300: Maternal and Pediatric Pharmacology and Therapeutics.

Date: March 24, 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: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, *dianne.hardy@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Fellowships: Population Sciences and Epidemiology.

Date: March 24–25, 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: Annie Laurie McRee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 100, Bethesda, MD 20892, (301) 827–7396, *mcreeal@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Genes, Genomes and Genetics.

Date: March 29, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Guoqin Yu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1276, *guoqin.yu@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel NIH Research Enhancement Award (R15) in Oncological Sciences.

Date: March 30, 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: 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.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 22, 2022.

David W Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–04127 Filed 2–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Special Emphasis Panel; Pathway to Independence Awards (K99/R00, K22).

Date: March 24, 2022.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health,

Neuroscience Center, 6001 Executive BLVD, Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov*,

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Effectiveness and Implementation Research for Post-Acute Interventions to Optimize Long-Term Mental Health Outcomes in Low- and Middle-Income Countries.

Date: March 24, 2022.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Regina Dolan-Sewell, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive BLVD, Room 4154, MSC 9606, Bethesda, MD 20852, *regina.dolan-sewell@nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; BRAIN Initiative: Resources for Brain Cell Type Review Meeting (U01 & U24).

Date: March 29, 2022.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Evon S. Ereifej, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Rockville, MD 20852, *ereifejes@mail.nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; BRAIN Initiative: Research on the Ethical Implications of Advancements in Neurotechnology and Brain Science (R01).

Date: March 29, 2022.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive BLVD, Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: February 23, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–04158 Filed 2–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Immune Responses to Blood Transfusion.

Date: March 22, 2022.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Michael P. Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–Z, Bethesda, MD 20892, (301) 827–7975, *reillymp@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: February 22, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–04126 Filed 2–25–22; 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 Panel: Understanding Alzheimer's Disease—3.

Date: March 16, 2022.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–RM–22–003: Cellular Senescence Network: Murine Tissue Mapping Centers (U54).

Date: March 29–30, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lystranne Alysia Maynard Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–4809, *lystranne.maynard-smith@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA: SPARC Human Open Research Neural Engineering Technologies (HORNET) Initiative.

Date: March 29, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joseph D. Mosca, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7808, Bethesda, MD 20892, (301) 435–2344, *moscajos@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA, RM–22–004 and RM–22–005: Cellular Senescence Network: Technology Development and Application (UG3/UH3).

Date: April 1, 2022.

Time: 9:30 a.m. to 4:00 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: Tami Jo Kingsbury, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 710Q, Bethesda, MD 20892, (410) 274–1352, *tami.kingsbury@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Immunology.

Date: April 1, 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: Kenneth A. Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7852, Bethesda, MD 20892, (301) 435–1166, *roebuckk@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: February 22, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–04065 Filed 2–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Resource Related Research Projects (R24 Clinical Trial Not Allowed).

Date: March 22, 2022.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G33B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: John C. Pugh, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G33B, Rockville, MD 20852, (301) 435–2398, *pughjohn@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: February 23, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–04161 Filed 2–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities.

Date: March 28, 2022.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Santanu Banerjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2106, Bethesda, MD 20892, (301) 496–0000, *banerjees5@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: February 23, 2022.

Melanie Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–04162 Filed 2–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0023]

Request for Information (CBP Form 28)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than March 30, 2022 to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice 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 PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, telephone number 202–325–0056, or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer

Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (Volume 86 FR Page 72612) on December 22, 2021, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) 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) 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; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Request for Information.
OMB Number: 1651–0023.
Form Number: CBP Form 28.
Current Actions: Extension with a decrease in burden previously reported, no change to the information being collected.
Type of Review: Extension (with change).
Affected Public: Businesses.
Abstract: Under 19 U.S.C. 1500 and 1401a, Customs and Border Protection (CBP) is responsible for appraising merchandise by ascertaining or estimating its value; fixing the final classification of such merchandise under the tariff schedule; and fixing a rate of duty and final amount of duty to be paid on such merchandise. On occasions when the invoice or other documentation does not provide sufficient information for appraisement or classification, including for import compliance with trade agreements, preference treatment, or special provisions, CBP may request additional information using CBP Form 28, *Request for Information.* This form is sent by CBP personnel to importers, exporters, producers, or their agents, as applicable, requesting additional information. U.S. Customs and Border Protection (CBP) is authorized to collect the information requested on this form pursuant to U.S.C. 1509, 19 CFR 142.3, 19 CFR 151.11, and 19 CFR 181.72. CBP Form 28 is provided for by 19 CFR 151.11.
Type of Information Collection: Request for Information (CBP Form 28).
Estimated Number of Respondents: 13,415.
Estimated Number of Annual Responses per Respondent: 1.
Estimated Number of Total Annual Responses: 13,415.
Estimated Time per Response: 2 hours.
Estimated Total Annual Burden Hours: 26,830.

Dated: February 23, 2022.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2022–04156 Filed 2–25–22; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7050–N–09]

30-Day Notice of Proposed Information Collection: Housing Counseling Notice of Funding Opportunity (NOFO); OMB Control No.: 2502–0621

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* March 30, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_submission@omb.eop.gov* or *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: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on November 18, 2021 at 86 FR 64514.

A. Overview of Information Collection

Title of Information Collection: Housing Counseling Notice of Funding Opportunity (NOFO).
OMB Approval Number: 2502–0621.
OMB Expiration Date: 02/28/2022.
Type of Request: Revision of a currently approved collection.
Form Numbers: HUD–9906–L; HUD–9906–P; NOFO 9906 Charts (A2, B, E).
Description of the need for the information and proposed use: This information is collected in connection with HUD's Housing Counseling Program and will be used by HUD to determine that the Housing Counseling grant applicant meets the requirements of the Notice of Funding Opportunity (NOFO). Information collected is also used to assign points for awarding grant funds on a competitive and equitable basis. HUD's Office of Housing Counseling will also use the information to provide housing counseling services through private or public organizations with special competence and knowledge in counseling low and moderate-income families. The information is collected from housing counseling agencies that participate in HUD's Housing Counseling Program. The information is collected via the Form 9906 (grant application chart).
Respondents: Not-for-profit institutions; State, Local or Tribal Government.
Estimated Number of Respondents: 300.
Estimated Number of Responses: 300.
Frequency of Response: 1.

Average Hours per Response: 40.

Total Estimated Burden: 12,000 hours.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) 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) The accuracy of the agency'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 those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(5) ways to minimize the burden of the collection of information on those who are respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2022–04164 Filed 2–25–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[223A2100DD/AAKC001030/ A0A501010.999900]

Resumption of Preparation of an Environmental Impact Statement for the Proposed Coquille Indian Tribe Fee-to-Trust and Gaming Facility Project, Medford, Oregon; Correction

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice; correction.

SUMMARY: The Bureau of Indian Affairs (BIA) published a notice in the **Federal Register** of December 27, 2021, that listed incorrect dates.

DATES: On December 22, 2021, the Assistant Secretary—Indian Affairs remanded the Tribe's application to the BIA to complete the environmental review process.

FOR FURTHER INFORMATION CONTACT: Mr. Bryan Mercier, Northwest Regional Director, Bureau of Indian Affairs, Northwest Region, by mail: 911 Northeast 11th Avenue, Portland, Oregon 97232–4165; or by telephone: (503) 231–6702. 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.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of December 27, 2021, in 86 FR 73313, on page 73313, in the second column, in the **DATES** section, on the first line, ''November 19, 2021'' should read, ''December 22, 2021''.

In the same edition of the **Federal Register**, on page 73313, in the second column, in the **SUPPLEMENTARY INFORMATION** section, on line twelve, BIA included the sentence: ''On November 19, 2021, the Assistant Secretary—Indian Affairs withdrew the 2020 Denial and remanded the Tribe's application to the BIA to complete the environmental review process under the National Environmental Policy Act (NEPA).''

BIA is replacing that language with this corrected sentence: ''On December 22, 2021, the Assistant Secretary—Indian Affairs withdrew the 2020 Denial and remanded the Tribe's application to the BIA to complete the environmental review process under the National Environmental Policy Act (NEPA).''

Authority: This notice is published in accordance with sections 1501.7 and 1506.6 of the Council on Environmental Quality Regulations (40 CFR parts 1500 through 1508) implementing the procedural requirements of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321–4345 *et seq.*), and the Department of the Interior National Environmental Policy Act Regulations (43 CFR part 46), and is in the exercise of authority delegated to the Assistant Secretary—Indian Affairs by 209 DM 8.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2022–04086 Filed 2–25–22; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[223A2100DD/AAKC001030/ A0A501010.999900]

HEARTH Act Approval of Santa Rosa Band of Cahuilla Indians, California Leasing Ordinance

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) approved the Santa Rosa Band of Cahuilla Indians, California Leasing Ordinance under the Helping Expedite and Advance Responsible Tribal Homeownership Act of 2012 (HEARTH Act). With this approval, the Tribe is authorized to enter into business, agriculture, residential, and wind and solar leases without further BIA approval.

DATES: BIA issued the approval on February 7, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Sharlene Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1001 Indian School Road NW, Albuquerque, NM 87104, *sharlene.roundface@bia.gov,* (505) 563–3132. 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.

SUPPLEMENTARY INFORMATION:

I. Summary of the HEARTH Act

The HEARTH Act makes a voluntary, alternative land leasing process available to Tribes, by amending the Indian Long-Term Leasing Act of 1955, 25 U.S.C. 415. The HEARTH Act authorizes Tribes to negotiate and enter into business leases of Tribal trust lands with a primary term of 25 years, and up to two renewal terms of 25 years each, without the approval of the Secretary of the Interior (Secretary). The HEARTH Act also authorizes Tribes to enter into leases for residential, recreational, religious, or educational purposes for a primary term of up to 75 years without the approval of the Secretary. Participating Tribes develop Tribal leasing regulations, including an environmental review process, and then must obtain the Secretary's approval of those regulations prior to entering into leases. The HEARTH Act requires the Secretary to approve Tribal regulations if the Tribal regulations are consistent with the Department of the Interior's (Department) leasing regulations at 25 CFR part 162 and provide for an

environmental review process that meets requirements set forth in the HEARTH Act. This notice announces that the Secretary, through the Assistant Secretary—Indian Affairs, has approved the Tribal regulations for the Santa Rosa Band of Cahuilla Indians, California.

II. Federal Preemption of State and Local Taxes

The Department's regulations governing the surface leasing of trust and restricted Indian lands specify that, subject to applicable Federal law, permanent improvements on leased land, leasehold or possessory interests, and activities under the lease are not subject to State and local taxation and may be subject to taxation by the Indian Tribe with jurisdiction. See 25 CFR 162.017. As explained further in the preamble to the final regulations, the Federal government has a strong interest in promoting economic development, self-determination, and Tribal sovereignty. 77 FR 72440, 72447–48 (December 5, 2012). The principles supporting the Federal preemption of State law in the field of Indian leasing and the taxation of lease-related interests and activities applies with equal force to leases entered into under Tribal leasing regulations approved by the Federal government pursuant to the HEARTH Act.

Section 5 of the Indian Reorganization Act, 25 U.S.C. 5108, preempts State and local taxation of permanent improvements on trust land. *Confederated Tribes of the Chehalis Reservation* v. *Thurston County,* 724 F.3d 1153, 1157 (9th Cir. 2013) (citing *Mescalero Apache Tribe* v. *Jones,* 411 U.S. 145 (1973)). Similarly, section 5108 preempts State taxation of rent payments by a lessee for leased trust lands, because ''tax on the payment of rent is indistinguishable from an impermissible tax on the land.'' *See Seminole Tribe of Florida* v. *Stranburg,* 799 F.3d 1324, 1331, n.8 (11th Cir. 2015). In addition, as explained in the preamble to the revised leasing regulations at 25 CFR part 162, Federal courts have applied a balancing test to determine whether State and local taxation of non-Indians on the reservation is preempted. *White Mountain Apache Tribe* v. *Bracker,* 448 U.S. 136, 143 (1980). The *Bracker* balancing test, which is conducted against a backdrop of ''traditional notions of Indian self-government,'' requires a particularized examination of the relevant State, Federal, and Tribal interests. We hereby adopt the *Bracker* analysis from the preamble to the surface leasing regulations, 77 FR at 72447–48, as supplemented by the analysis below.

The strong Federal and Tribal interests against State and local taxation of improvements, leaseholds, and activities on land leased under the Department's leasing regulations apply equally to improvements, leaseholds, and activities on land leased pursuant to Tribal leasing regulations approved under the HEARTH Act. Congress's overarching intent was to ''allow Tribes to exercise greater control over their own land, support self-determination, and eliminate bureaucratic delays that stand in the way of homeownership and economic development in Tribal communities.'' 158 Cong. Rec. H. 2682 (May 15, 2012). The HEARTH Act was intended to afford Tribes ''flexibility to adapt lease terms to suit [their] business and cultural needs'' and to ''enable [Tribes] to approve leases quickly and efficiently.'' H. Rep. 112–427 at 6 (2012).

Assessment of State and local taxes would obstruct these express Federal policies supporting Tribal economic development and self-determination, and also threaten substantial Tribal interests in effective Tribal government, economic self-sufficiency, and territorial autonomy. *See Michigan* v. *Bay Mills Indian Community,* 572 U.S. 782, 810 (2014) (Sotomayor, J., concurring) (determining that ''[a] key goal of the Federal Government is to render Tribes more self-sufficient, and better positioned to fund their own sovereign functions, rather than relying on Federal funding''). The additional costs of State and local taxation have a chilling effect on potential lessees, as well as on a Tribe that, as a result, might refrain from exercising its own sovereign right to impose a Tribal tax to support its infrastructure needs. *See id.* at 810–11 (finding that State and local taxes greatly discourage Tribes from raising tax revenue from the same sources because the imposition of double taxation would impede Tribal economic growth).

Similar to BIA's surface leasing regulations, Tribal regulations under the HEARTH Act pervasively cover all aspects of leasing. *See* 25 U.S.C. 415(h)(3)(B)(i) (requiring Tribal regulations be consistent with BIA surface leasing regulations). Furthermore, the Federal government remains involved in the Tribal land leasing process by approving the Tribal leasing regulations in the first instance and providing technical assistance, upon request by a Tribe, for the development of an environmental review process. The Secretary also retains authority to take any necessary actions to remedy violations of a lease or of the Tribal regulations, including terminating the lease or rescinding approval of the Tribal regulations and reassuming lease approval responsibilities. Moreover, the Secretary continues to review, approve, and monitor individual Indian land leases and other types of leases not covered under the Tribal regulations according to the Part 162 regulations.

Accordingly, the Federal and Tribal interests weigh heavily in favor of preemption of State and local taxes on lease-related activities and interests, regardless of whether the lease is governed by Tribal leasing regulations or Part 162. Improvements, activities, and leasehold or possessory interests may be subject to taxation by the Santa Rosa Band of Cahuilla Indians, California.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2022–04094 Filed 2–25–22; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[223A2100DD/AAKC001030/A0A501010.999900]

HEARTH Act Approval of Table Mountain Rancheria Business Leasing Ordinance

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) approved the Table Mountain Rancheria Business Leasing Ordinance under the Helping Expedite and Advance Responsible Tribal Homeownership Act of 2012 (HEARTH Act). With this approval, the Tribe is authorized to enter into business leases without further BIA approval.

DATES: BIA issued the approval on February 11, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Sharlene Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1001 Indian School Road NW, Albuquerque, NM 87104, *sharlene.roundface@bia.gov,* (505) 563–3132.

SUPPLEMENTARY INFORMATION:

I. Summary of the HEARTH Act

The HEARTH Act makes a voluntary, alternative land leasing process available to Tribes, by amending the Indian Long-Term Leasing Act of 1955, 25 U.S.C. 415. The HEARTH Act

authorizes Tribes to negotiate and enter into business leases of Tribal trust lands with a primary term of 25 years, and up to two renewal terms of 25 years each, without the approval of the Secretary of the Interior (Secretary). The HEARTH Act also authorizes Tribes to enter into leases for residential, recreational, religious, or educational purposes for a primary term of up to 75 years without the approval of the Secretary. Participating Tribes develop Tribal leasing regulations, including an environmental review process, and then must obtain the Secretary's approval of those regulations prior to entering into leases. The HEARTH Act requires the Secretary to approve Tribal regulations if the Tribal regulations are consistent with the Department of the Interior's (Department) leasing regulations at 25 CFR part 162 and provide for an environmental review process that meets requirements set forth in the HEARTH Act. This notice announces that the Secretary, through the Assistant Secretary—Indian Affairs, has approved the Tribal regulations for the Table Mountain Rancheria.

II. Federal Preemption of State and Local Taxes

The Department's regulations governing the surface leasing of trust and restricted Indian lands specify that, subject to applicable Federal law, permanent improvements on leased land, leasehold or possessory interests, and activities under the lease are not subject to State and local taxation and may be subject to taxation by the Indian Tribe with jurisdiction. See 25 CF 162.017. As explained further in the preamble to the final regulations, the Federal government has a strong interest in promoting economic development, self-determination, and Tribal sovereignty. 77 FR 72440, 72447–48 (December 5, 2012). The principles supporting the Federal preemption of State law in the field of Indian leasing and the taxation of lease-related interests and activities applies with equal force to leases entered into under Tribal leasing regulations approved by the Federal government pursuant to the HEARTH Act.

Section 5 of the Indian Reorganization Act, 25 U.S.C. 5108, preempts State and local taxation of permanent improvements on trust land. *Confederated Tribes of the Chehalis Reservation* v. *Thurston County,* 724 F.3d 1153, 1157 (9th Cir. 2013) (citing *Mescalero Apache Tribe* v. *Jones,* 411 U.S. 145 (1973)). Similarly, section 5108 preempts State taxation of rent payments by a lessee for leased trust lands, because ''tax on the payment of rent is indistinguishable from an impermissible tax on the land.'' *See Seminole Tribe of Florida* v. *Stranburg,* 799 F.3d 1324, 1331, n.8 (11th Cir. 2015). In addition, as explained in the preamble to the revised leasing regulations at 25 CFR part 162, Federal courts have applied a balancing test to determine whether State and local taxation of non-Indians on the reservation is preempted. *White Mountain Apache Tribe* v. *Bracker,* 448 U.S. 136, 143 (1980). The *Bracker* balancing test, which is conducted against a backdrop of ''traditional notions of Indian self-government,'' requires a particularized examination of the relevant State, Federal, and Tribal interests. We hereby adopt the *Bracker* analysis from the preamble to the surface leasing regulations, 77 FR at 72447–48, as supplemented by the analysis below.

The strong Federal and Tribal interests against State and local taxation of improvements, leaseholds, and activities on land leased under the Department's leasing regulations apply equally to improvements, leaseholds, and activities on land leased pursuant to Tribal leasing regulations approved under the HEARTH Act. Congress's overarching intent was to ''allow Tribes to exercise greater control over their own land, support self-determination, and eliminate bureaucratic delays that stand in the way of homeownership and economic development in Tribal communities.'' 158 Cong. Rec. H. 2682 (May 15, 2012). The HEARTH Act was intended to afford Tribes ''flexibility to adapt lease terms to suit [their] business and cultural needs'' and to ''enable [Tribes] to approve leases quickly and efficiently.'' H. Rep. 112–427 at 6 (2012).

Assessment of State and local taxes would obstruct these express Federal policies supporting Tribal economic development and self-determination, and also threaten substantial Tribal interests in effective Tribal government, economic self-sufficiency, and territorial autonomy. *See Michigan* v. *Bay Mills Indian Community,* 572 U.S. 782, 810 (2014) (Sotomayor, J., concurring) (determining that ''[a] key goal of the Federal Government is to render Tribes more self-sufficient, and better positioned to fund their own sovereign functions, rather than relying on Federal funding''). The additional costs of State and local taxation have a chilling effect on potential lessees, as well as on a Tribe that, as a result, might refrain from exercising its own sovereign right to impose a Tribal tax to support its infrastructure needs. *See id.* at 810–11 (Finding that State and local taxes greatly discourage Tribes from raising tax revenue from the same sources because the imposition of double taxation would impede Tribal economic growth).

Similar to BIA's surface leasing regulations, Tribal regulations under the HEARTH Act pervasively cover all aspects of leasing. *See* 25 U.S.C. 415(h)(3)(B)(i) (requiring Tribal regulations be consistent with BIA surface leasing regulations). Furthermore, the Federal government remains involved in the Tribal land leasing process by approving the Tribal leasing regulations in the first instance and providing technical assistance, upon request by a Tribe, for the development of an environmental review process. The Secretary also retains authority to take any necessary actions to remedy violations of a lease or of the Tribal regulations, including terminating the lease or rescinding approval of the Tribal regulations and reassuming lease approval responsibilities. Moreover, the Secretary continues to review, approve, and monitor individual Indian land leases and other types of leases not covered under the Tribal regulations according to the Part 162 regulations.

Accordingly, the Federal and Tribal interests weigh heavily in favor of preemption of State and local taxes on lease-related activities and interests, regardless of whether the lease is governed by Tribal leasing regulations or Part 162. Improvements, activities, and leasehold or possessory interests may be subject to taxation by the Table Mountain Rancheria.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2022–04093 Filed 2–25–22; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[223A2100DD/AAKC001030/A0A501010.999900]

HEARTH Act Approval of Kootenai Tribe of Idaho Business Leasing Ordinance

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) approved the Kootenai Tribe of Idaho Business Leasing Ordinance under the Helping Expedite and Advance Responsible Tribal Homeownership Act of 2012 (HEARTH

Act). With this approval, the Tribe is authorized to enter into business leases without further BIA approval.

DATES: BIA issued the approval on February 1, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Sharlene Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1001 Indian School Road NW, Albuquerque, NM 87104, *sharlene.roundface@bia.gov,* (505) 563–3132.

SUPPLEMENTARY INFORMATION:

I. Summary of the HEARTH Act

The HEARTH Act makes a voluntary, alternative land leasing process available to Tribes, by amending the Indian Long-Term Leasing Act of 1955, 25 U.S.C. 415. The HEARTH Act authorizes Tribes to negotiate and enter into business leases of Tribal trust lands with a primary term of 25 years, and up to two renewal terms of 25 years each, without the approval of the Secretary of the Interior (Secretary). The HEARTH Act also authorizes Tribes to enter into leases for residential, recreational, religious, or educational purposes for a primary term of up to 75 years without the approval of the Secretary. Participating Tribes develop Tribal leasing regulations, including an environmental review process, and then must obtain the Secretary's approval of those regulations prior to entering into leases. The HEARTH Act requires the Secretary to approve Tribal regulations if the Tribal regulations are consistent with the Department of the Interior's (Department) leasing regulations at 25 CFR part 162 and provide for an environmental review process that meets requirements set forth in the HEARTH Act. This notice announces that the Secretary, through the Assistant Secretary—Indian Affairs, has approved the Tribal regulations for the Kootenai Tribe of Idaho.

II. Federal Preemption of State and Local Taxes

The Department's regulations governing the surface leasing of trust and restricted Indian lands specify that, subject to applicable Federal law, permanent improvements on leased land, leasehold or possessory interests, and activities under the lease are not subject to State and local taxation and may be subject to taxation by the Indian Tribe with jurisdiction. See 25 CFR 162.017. As explained further in the preamble to the final regulations, the Federal government has a strong interest in promoting economic development, self-determination, and Tribal sovereignty. 77 FR 72440, 72447–48 (December 5, 2012). The principles supporting the Federal preemption of State law in the field of Indian leasing and the taxation of lease-related interests and activities applies with equal force to leases entered into under Tribal leasing regulations approved by the Federal government pursuant to the HEARTH Act.

Section 5 of the Indian Reorganization Act, 25 U.S.C. 5108, preempts State and local taxation of permanent improvements on trust land. *Confederated Tribes of the Chehalis Reservation* v. *Thurston County,* 724 F.3d 1153, 1157 (9th Cir. 2013) (citing *Mescalero Apache Tribe* v. *Jones,* 411 U.S. 145 (1973)). Similarly, section 5108 preempts State taxation of rent payments by a lessee for leased trust lands, because ''tax on the payment of rent is indistinguishable from an impermissible tax on the land.'' *See Seminole Tribe of Florida* v. *Stranburg,* 799 F.3d 1324, 1331, n.8 (11th Cir. 2015). In addition, as explained in the preamble to the revised leasing regulations at 25 CFR part 162, Federal courts have applied a balancing test to determine whether State and local taxation of non-Indians on the reservation is preempted. *White Mountain Apache Tribe* v. *Bracker,* 448 U.S. 136, 143 (1980). The *Bracker* balancing test, which is conducted against a backdrop of ''traditional notions of Indian self- government,'' requires a particularized examination of the relevant State, Federal, and Tribal interests. We hereby adopt the *Bracker* analysis from the preamble to the surface leasing regulations, 77 FR at 72447–48, as supplemented by the analysis below.

The strong Federal and Tribal interests against State and local taxation of improvements, leaseholds, and activities on land leased under the Department's leasing regulations apply equally to improvements, leaseholds, and activities on land leased pursuant to Tribal leasing regulations approved under the HEARTH Act. Congress's overarching intent was to ''allow Tribes to exercise greater control over their own land, support self-determination, and eliminate bureaucratic delays that stand in the way of homeownership and economic development in Tribal communities.'' 158 Cong. Rec. H. 2682 (May 15, 2012). The HEARTH Act was intended to afford Tribes ''flexibility to adapt lease terms to suit [their] business and cultural needs'' and to ''enable [Tribes] to approve leases quickly and efficiently.'' H. Rep. 112–427 at 6 (2012).

Assessment of State and local taxes would obstruct these express Federal policies supporting Tribal economic development and self-determination, and also threaten substantial Tribal interests in effective Tribal government, economic self-sufficiency, and territorial autonomy. *See Michigan* v. *Bay Mills Indian Community,* 572 U.S. 782, 810 (2014) (Sotomayor, J., concurring) (determining that ''[a] key goal of the Federal Government is to render Tribes more self-sufficient, and better positioned to fund their own sovereign functions, rather than relying on Federal funding''). The additional costs of State and local taxation have a chilling effect on potential lessees, as well as on a Tribe that, as a result, might refrain from exercising its own sovereign right to impose a Tribal tax to support its infrastructure needs. *See id.* at 810–11 (finding that State and local taxes greatly discourage Tribes from raising tax revenue from the same sources because the imposition of double taxation would impede Tribal economic growth).

Similar to BIA's surface leasing regulations, Tribal regulations under the HEARTH Act pervasively cover all aspects of leasing. *See* 25 U.S.C. 415(h)(3)(B)(i) (requiring Tribal regulations be consistent with BIA surface leasing regulations). Furthermore, the Federal government remains involved in the Tribal land leasing process by approving the Tribal leasing regulations in the first instance and providing technical assistance, upon request by a Tribe, for the development of an environmental review process. The Secretary also retains authority to take any necessary actions to remedy violations of a lease or of the Tribal regulations, including terminating the lease or rescinding approval of the Tribal regulations and reassuming lease approval responsibilities. Moreover, the Secretary continues to review, approve, and monitor individual Indian land leases and other types of leases not covered under the Tribal regulations according to the Part 162 regulations.

Accordingly, the Federal and Tribal interests weigh heavily in favor of preemption of State and local taxes on lease-related activities and interests, regardless of whether the lease is governed by Tribal leasing regulations or Part 162. Improvements, activities, and leasehold or possessory interests

may be subject to taxation by the Kootenai Tribe of Idaho.

Wizipan Garriott,

Principal Deputy Assistant Secretary—Indian Affairs, Exercising by delegation the authority of the Assistant Secretary—Indian Affairs.

[FR Doc. 2022–04090 Filed 2–25–22; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0033436; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC, and Pueblo Grande Museum, City of Phoenix, AZ

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of the Interior, Bureau of Indian Affairs (BIA), Washington, DC, assisted by the Pueblo Grande Museum (PGM), in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, have determined that the cultural items listed in this notice meet the definition of either unassociated funerary objects or sacred objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the BIA through PGM. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the BIA through PGM at the address in this notice by March 30, 2022.

FOR FURTHER INFORMATION CONTACT: Lindsey Vogel-Teeter, Pueblo Grande Museum, 4619 E Washington Street, Phoenix, AZ 85034, telephone (602) 534–1572, email *lindsey.vogel-teeter@phoenix.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC, and in the physical custody of the Pueblo Grande Museum, City of Phoenix, AZ, that meet the definition of either unassociated funerary objects or sacred objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

In December of 1939, 184 cultural items were removed from site AZ T:12:3(PGM)/AZ T:12:9(ASM)/SRVSS Site 6/Villa Buena, located within the boundaries of the Gila River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the Salt River Valley Stratigraphic Survey (SRVSS), who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items, comprising 12 unassociated funerary objects and 172 sacred objects, have been housed at PGM since they were excavated. The 12 unassociated funerary items are one ceramic bowl, one ceramic disk, two ceramic jars, one lot of ceramic sherds, one grinding stone, three lots of shell beads, two shells, and one stone projectile point/drill. The 172 sacred objects are two ceramic censer fragments, three ceramic figurine fragments, one ceramic thick-walled vessel fragment, three crystal/quartz objects, seven worked faunal bones, 39 lots of shell beads, three shell bracelets, 37 lots of shell fragments, 48 shell ornaments, three shell tinklers, two stone mortars/stones with depression, two stone ornaments, one stone plummet, six stone rings, and 15 stone projectile points.

Site AZ T:12:3(PGM)/AZ T:12:9(ASM)/SRVSS Site 6/Villa Buena contained ballcourts, house mounds, and a compound. Based on ceramic types and architectural forms, the site was likely occupied during the Sweetwater through Civano phases of the Hohokam cultural sequence (A.D. 550–1450).

In October of 1939, 14 cultural items were removed from site AZ U:9:13(ASM)/AZ U:9:15(PGM)/SRVSS Site 23, located within the exterior boundaries of the Salt River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The 14 sacred objects are one ceramic figurine fragment, two shell bracelets, four shell ornaments, one stone canopas or medicine stone, three stone palettes, one stone ornament, one stone projectile point, and one worked stone.

Site AZ U:9:13(ASM)/AZ U:9:15(PGM)/SRVSS Site 23 contained nine trash mounds, multiple burials, and a canal. The material culture spanned the Estrella through Civano phases of the Hohokam cultural sequence (A.D. 450–1450).

In October of 1939, 24 cultural items were removed from site AZ U:9:16(PGM)/SRVSS Site 24, located within the exterior boundaries of the Salt River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The 24 sacred objects are 10 ceramic figurine fragments, eight ceramic bracelets, one shell ornament, four stone palettes, and one dog burial.

Site AZ U:9:16(PGM)/SRVSS Site 24 contained a compound, a house mound, 21 trash mounds, and a burial area. Based on architectural morphology and ceramic types, occupation spanned the Estrella through Civano phases of the Hohokam cultural sequence (A.D. 450–1450).

In 1939, one cultural item was removed from site AZ U:9:18(PGM)/SRVSS Site 26, located within the exterior boundaries of the Salt River Indian Reservation, Maricopa County, AZ. This item was excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural item has been housed at PGM since it was excavated. The one sacred object is a dog burial.

Site AZ U:9:18(PGM)/SRVSS Site 26 contained a compound, two trash mounds, a sherd area, and a burial area. Based on the material culture, occupation spanned the Sacaton through Civano phases of the Hohokam cultural sequence (A.D. 900–1450).

In June through August of 1939, 28 cultural items were removed from site AZ U:9:28(PGM)/SRVSS Site 62, located within the exterior boundaries of the Salt River Indian Reservation, Maricopa County, AZ. The items were excavated by personnel from the SRVSS, who were working out of PGM under a permit

issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The 28 sacred objects are one ceramic censer fragment, one ceramic effigy vessel fragment, three ceramic figurine fragments, three worked faunal bones, one lot of shell beads, one shell bracelet, two lots of shell fragments, 12 shell ornaments, one stone mortar/stone with depression, one stone ring, and two dog burials.

Site AZ U:9:28(PGM)/SRVSS Site 62 contained house mounds, trash mounds, and possibly a ballcourt. Based on ceramic types, the site was likely occupied from the Santa Cruz through Sacaton phases of the Hohokam cultural sequence (A.D. 850–1150).

In May of 1939, one cultural item was removed from site AZ U:9:29(PGM)/SRVSS Site 63, located within the exterior boundaries of the Salt River Indian Reservation, Maricopa County, AZ. This item was excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural item has been housed at PGM since it was excavated. The sacred object is one lot of shell fragments.

Site AZ U:9:29(PGM)/SRVSS Site 63 contained a sherd area and a round house. Based on architectural morphology and ceramic types, occupation was likely associated with the Soho through Civano phases of the Hohokam cultural sequence (A.D. 1150–1450) and historic O'odham culture (A.D. 1800–1939).

In 1939, two cultural items were removed from site AZ Z:2:1(PGM)/SRVSS Site 69, located within the exterior boundaries of the Gila Bend Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The two sacred objects are one lot of shell tinklers and one worked stone.

Site AZ Z:2:1(PGM)/SRVSS Site 69 contained a large sherd area. Based on ceramic types, occupation likely spanned the Gila Butte through Sacaton and Civano phases of the Hohokam cultural sequence (A.D. 750–1450).

In 1939, four cultural items were removed from site AZ T:16:1(PGM)/SRVSS Site 85, located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The four sacred objects are one shell bracelet, one lot of shell fragments, one worked faunal bone, and one worked stone.

Site AZ T:16:1(PGM)/SRVSS Site 85 contained round houses and ceramics associated with historic O'odham culture, and it was likely occupied during the years (A.D. 1700–1939).

In 1939, six cultural items were removed from site AZ T:16:8(ASM)/AZ T:16:2(PGM)/SRVSS Site 86, located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The six sacred objects are one shell bracelet, two shell ornaments, one stone mortar/stone with depression, and two stone palettes.

Site AZ T:16:8(ASM)/AZ T:16:2(PGM)/SRVSS Site 86 contained ballcourts, trash mounds, and a cremation area associated with the Gila Butte through Sacaton phases of the Hohokam cultural sequence (A.D. 750–1150).

In October of 1939, 25 cultural items were removed from site AZ U:9:33(PGM)/SRVSS Site 90, located within the exterior boundaries of the Salt River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items, comprising three unassociated funerary objects and 22 sacred objects, have been housed at PGM since they were excavated. The three unassociated funerary objects are one axe/grinding stone, one hammerstone, and one polishing stone. The 22 sacred objects are two ceramic effigy vessel fragments, one ceramic figurine fragment, one ceramic spindle whorl fragment, three crystal/quartz objects, two worked faunal bones, two lots of shell beads, two shell bracelets, five lots of shell fragments, two shell ornaments, one stone projectile point, and one worked stone.

Site AZ U:9:33(PGM)/SRVSS Site 90 contained seven trash mounds, a house area, canals, and a cremation area. Based on architectural forms and ceramic types, occupation likely spanned the Gila Butte through Civano phases of the Hohokam cultural sequence (A.D. 750–1450).

In 1939, three cultural items were removed from site AZ U:13:2(PGM)SRVSS Site 92, located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The three sacred objects are one shell bracelet, one lot of shell fragments, and one stone projectile point.

Site AZ U:13:2(PGM)SRVSS Site 92 contained a house mound and trash mound. Based on ceramic types and architectural forms, occupation likely spanned the Snaketown through Civano phases of the Hohokam cultural sequence (A.D. 600–1450).

In 1939, five cultural items were removed from site AZU:13:3(PGM)SRVSS Site 93, located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The five sacred objects are two crystal/quartz objects, one shell bracelet, one lot of shell fragments, and one stone ring.

Site AZ U:13:3(PGM)SRVSS Site 93 contained house mounds and ramada areas. It has been described as an early historic Pima village. Based on the material culture and historic documents, the site was likely occupied during the years (A.D. 1700–1939).

In 1939, three cultural items were removed from site AZ U:14:2(PGM)/SRVSS Site 94, located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The three sacred objects are one shell bracelet, one lot of shell fragments, and one worked stone.

Site AZ U:14:2(PGM)/SRVSS Site 94 contained a house mound associated with the Sacaton to Civano phases of the Hohokam cultural sequence (A.D. 900–1450).

In 1940, 33 cultural items were removed from site AZ U:9:35(PGM)/SRVSS Site 95, located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. These items were excavated by

personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The 33 sacred objects are seven ceramic figurine fragments, two ceramic thick-walled vessel fragments, two worked faunal bones, one shell bracelet, two lots of shell fragments, six shell ornaments, three stone mortars/stones with depression, two stone palettes, one stone plummet, six stone projectile points, and one worked stone.

Site AZ U:9:35(PGM)/SRVSS Site 95 contained eight trash mounds and cremation areas. Based on ceramic types, occupation likely spanned the Estrella through Civano phases of the Hohokam cultural sequence (A.D. 450–1450).

In 1940, one cultural item was removed from SRVSS Site 98, located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. This item was excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural item has been housed at PGM since it was excavated. The one sacred object is a shell bracelet.

SRVSS Site 98 contained a trash mound. Based on the material culture, occupation likely spanned the Gila Butte through Sacaton phases of the Hohokam cultural sequence (A.D. 750–1150).

In 1940, two cultural items were removed from SRVSS Site 99, located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The sacred objects are two stone mortars/stones with depression in each of them.

SRVSS Site 99 contained a trash mound. Based on the material culture, occupation likely spanned the Santa Cruz to Sacaton phases of the Hohokam cultural sequence (A.D. 800–1150).

In 1940, three cultural items were removed from SRVSS Site 102, located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The three sacred objects are two lots of shell fragments and one shell tinkler.

SRVSS Site 102 contained three trash mounds. Based on the material culture, occupation likely spanned the Snaketown through Civano phases of the Hohokam cultural sequence (A.D. 600–1450).

In 1940, one cultural item was removed from SRVSS Site 103, located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. This item was excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural item has been housed at PGM since it was excavated. The sacred object is a shell bracelet.

SRVSS Site 103 contained a trash mound. Based on the material culture, occupation likely spanned the Snaketown through Sacaton phases of the Hohokam cultural sequence (A.D. 600–1150).

In 1940, two cultural items were removed from SRVSS Site 104, located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The two sacred objects are one ceramic effigy vessel fragment and one worked stone.

SRVSS Site 104 contained a trash mound. Based on the material culture, occupation likely spanned the Santa Cruz through Soho phases of the Hohokam cultural sequence (A.D. 800–1300).

In 1940, two cultural items were removed from SRVSS Site 105, located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. These items were excavated by personnel from the SRVSS, who were working out of PGM under a permit issued by the U.S. Department of the Interior. The cultural items have been housed at PGM since they were excavated. The two sacred objects are one shell ornament and one stone projectile point.

SRVSS Site 105 contained a trash mound. Based on the material culture, occupation likely spanned the Santa Cruz through Civano phases of the Hohokam cultural sequence (A.D. 800–1450).

In 1963, one cultural item was removed by an unidentified person from the ''Snaketown area,'' most likely site AZ U:13:1(ASM), located within the exterior boundaries of the Gila River Indian Reservation, Maricopa County, AZ. The item was transferred to PGM sometime prior to 1995. The one unassociated funerary object is a ceramic bowl.

Site AZ U:13:1(ASM) was a large village containing canals, plazas, ballcourts, house groups, and a caliche-capped mound. Based on ceramic types, architectural forms, and other material culture attributes, the site was likely occupied from the Snaketown through Sacaton phases of the Hohokam cultural sequence (A.D. 600–1150).

The Ak-Chin Indian Community [previously listed as Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona]; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; and the Tohono O'odham Nation of Arizona comprise a single cultural group known as the O'odham. Cultural continuity between the prehistoric Hohokam archeological culture and present-day O'odham people is supported by continuities in settlement pattern, architectural technologies, basketry, textiles, ceramic technology, and ritual practices. Oral traditions that are documented for the Ak-Chin Indian Community [previously listed as Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona]; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; and the Tohono O'odham Nation of Arizona—hereafter referred to as ''The Tribes''—also support the cultural affiliation of these present-day Indian Tribes with Hohokam archeological sites and historical O'odham villages in central and southern Arizona.

A review of archeological field notes and reports shows that the cultural items listed in this notice as unassociated funerary objects were placed with individual human remains at the time of burial. During consultations, representatives of the Gila River Indian Community of the Gila River Indian Reservation, Arizona, and the Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona shared the information that intentionally buried canid remains are considered sacred because they are imbued with human spirit. Traditional knowledge relates that these animals communicate with humans during curing ceremonies and in other ways, and reinforces the belief that this role makes them sacred objects. The tribal consultants also affirmed that the other cultural items listed in this notice as sacred objects are specific

ceremonial objects utilized in traditional religious practices.

Determinations Made by the U.S. Department of the Interior, Bureau of Indian Affairs, Joined by the Pueblo Grande Museum

Officials of the U.S. Department of the Interior, Bureau of Indian Affairs, joined by the Pueblo Grande Museum have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), 16 of the cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from the specific burial sites of Native American individuals.
- Pursuant to 25 U.S.C. 3001(3)(C), 329 of the cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and sacred objects and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Lindsey Vogel-Teeter, Pueblo Grande Museum, 4619 E Washington Street, Phoenix, AZ 85034, telephone (602) 534–1572, email *lindsey.vogel-teeter@phoenix.gov,* by March 30, 2022. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects and sacred objects to The Tribes may proceed.

The U.S. Department of the Interior, Bureau of Indian Affairs, assisted by the Pueblo Grande Museum, is responsible for notifying The Tribes that this notice has been published.

Dated: February 16, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–04109 Filed 2–25–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0033437; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Haffenreffer Museum of Anthropology, Brown University, Bristol, RI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Haffenreffer Museum of Anthropology, Brown University, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of objects of cultural patrimony. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the Haffenreffer Museum of Anthropology, Brown University. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the Haffenreffer Museum of Anthropology, Brown University at the address in this notice by March 30, 2022.

FOR FURTHER INFORMATION CONTACT: Thierry Gentis, Curator, NAGPRA Coordinator, Haffenreffer Museum of Anthropology, Brown University, 300 Tower Street, Bristol, RI 02889, telephone (401) 863–5702, email *thierry_gentis@brown.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the Haffenreffer Museum of Anthropology, Brown University, Bristol, RI, that meet the definition of objects of cultural patrimony under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

In 1928, Rudolf F. Haffenreffer purchased a catlinite pipe bowl and wood pipe stem (78–45a, b) from William Everett Lincoln. The museum's catalog card states that they had been ''collected by William Everett Lincoln from the Stockbridge Indians in Massachusetts prior to 1928.'' Likewise, the museum's catalog cards state that two additional catlinite pipe bowls (1/396 and 1/397) purchased by Haffenreffer around the same time are to be attributed to the ''Stockbridge Indians, Stockbridge Massachusetts.''

In consultation with the Historic Preservation Manager of the Stockbridge-Munsee Band of Mohican Indians, the above items were determined to be culturally affiliated with the Stockbridge Munsee Community, Wisconsin. During consultation, the museum also determined that these pipes are still used in traditional ceremonies for medicinal and spiritual purposes. Additionally, the museum determined that the use of such pipes in diplomatic ceremonies denotes their symbolic value and continued historical and cultural importance for the Stockbridge-Munsee Community, Wisconsin, and as such, that they are communally owned, *i.e.,* they cannot be legally separated from the community by an individual.

Determinations Made by the Haffenreffer Museum of Anthropology, Brown University

Officials of the Haffenreffer Museum of Anthropology, Brown University have determined that:

- Pursuant to 25 U.S.C. 3001(3)(D), the four cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the objects of cultural patrimony and the Stockbridge Munsee Community, Wisconsin.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to

Thierry Gentis, Curator, Haffenreffer Museum of Anthropology, Brown University, 300 Tower Street, Bristol, RI 02889, telephone (401) 863–5702, email *thierry_gentis@brown.edu,* by March 30, 2022. After that date, if no additional claimants have come forward, transfer of control of these objects of cultural patrimony to the Stockbridge Munsee Community, Wisconsin may proceed.

The Haffenreffer Museum of Anthropology, Brown University is responsible for notifying the Stockbridge Munsee Community, Wisconsin that this notice has been published.

Dated: February 16, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–04110 Filed 2–25–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0033435; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Bryn Mawr College, Bryn Mawr, PA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Bryn Mawr College, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to Bryn Mawr College. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Bryn Mawr College at the address in this notice by March 30, 2022.

FOR FURTHER INFORMATION CONTACT: Marianne Weldon, Bryn Mawr College, 101 N Merion Ave, Bryn Mawr, PA 19010, telephone (610) 526–5022, email *mweldon@brynmawr.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of Bryn Mawr College, Bryn Mawr, PA, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

On an unknown date, two cultural items were removed from the Yazoo River region of Mississippi. William Sansom Vaux bequeathed a collection to the Academy of Natural Sciences (ANS) upon his death in 1882. That collection included the two cultural items. ANS accessioned them on June 27, 1912. In 1961, ANS loaned approximately 3,000 items to Bryn Mawr College, including the cultural items. In 1997, the ANS board voted to transfer control of the items to Bryn Mawr College and in 1998, ANS executed the transfer. The two unassociated funerary objects are one effigy pipe and one bowl.

Based on geographical and historical information provided by The Choctaw Nation of Oklahoma, the effigy pipe and bowl are culturally affiliated with The Choctaw Nation of Oklahoma. The geographical and historical evidence includes the 1820 Treaty of Doak's Stand, whereby The Choctaw Nation of Oklahoma ceded lands in the Yazoo River region to the United States.

Determinations Made by Bryn Mawr College

Officials of Bryn Mawr College have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the two cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and The Choctaw Nation of Oklahoma.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Marianne Weldon, Bryn Mawr College, 101 N Merion Avenue, Bryn Mawr, PA 19010, telephone (610) 526–5022, email *mweldon@brynmawr.edu,* by March 30, 2022. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to The Choctaw Nation of Oklahoma may proceed.

Bryn Mawr College is responsible for notifying the Cherokee Nation; Chitimacha Tribe of Louisiana; Eastern Band of Cherokee Indians; Jena Band of Choctaw Indians; Mississippi Band of Choctaw Indians; The Chickasaw Nation; The Choctaw Nation of Oklahoma; The Muscogee (Creek) Nation; and the United Keetoowah Band of Cherokee Indians in Oklahoma that this notice has been published.

Dated: February 16, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–04108 Filed 2–25–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0033438; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Fowler Museum at the University of California Los Angeles, Los Angeles, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Fowler Museum at the University of California Los Angeles (Fowler Museum at UCLA), in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of sacred objects and objects of cultural patrimony. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the Fowler Museum at UCLA. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the Fowler Museum at UCLA at the address in this notice by March 30, 2022.

FOR FURTHER INFORMATION CONTACT: Wendy G. Teeter, Ph.D., Fowler Museum at UCLA, Box 951549, Los Angeles, CA 90095–1549, telephone (310) 825–1864, email *wteeter@arts.ucla.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the Fowler Museum at the University of California Los Angeles, Los Angeles, CA, that meet both the definition of sacred objects and the definition of objects of cultural patrimony under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

In 1981, Steven and Susan Nelson gifted two Navajo medicine bundles (X81.197 and X81.196) to the Fowler Museum at UCLA, and in 1984, they gifted a suitcase of Navajo Yei ceremony dance regalia (X84.224) to the Museum. The two medicine bundles and one set of dance regalia are both sacred objects and objects of cultural patrimony.

The Navajo medicine bundles and dance regalia are used in current traditional religious ceremonial practice. These items are significant to the Navajo people, and they are considered both ''sacred objects'' and ''objects of cultural patrimony'' due to their having ongoing historical, traditional, and cultural importance central to Navajo (Diné) culture, spirituality, and religion.

Determinations Made by the Fowler Museum at the University of California Los Angeles

Officials of the Fowler Museum at the University of California Los Angeles have determined that:

- Pursuant to 25 U.S.C. 3001(3)(C), the three cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- Pursuant to 25 U.S.C. 3001(3)(D), the three cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the sacred objects and objects of cultural patrimony and the Navajo Nation, Arizona, New Mexico, & Utah.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Wendy G. Teeter, Ph.D., Fowler Museum at UCLA, Box 951549, Los Angeles, CA 90095–1549, telephone (310) 825–1864, email *wteeter@arts.ucla.edu,* by March 30, 2022. After that date, if no additional claimants have come forward, transfer of control of the sacred objects and objects of cultural patrimony to the Navajo Nation, Arizona, New Mexico, & Utah may proceed.

The Fowler Museum at the University of California Los Angeles is responsible for notifying the Navajo Nation, Arizona, New Mexico, & Utah that this notice has been published.

Dated: February 16, 2022.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2022–04107 Filed 2–25–22; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR02800000, 22XR0680A1, RX.17868949.0000000]

Notice of Intent To Prepare an Environmental Impact Statement and Hold Public Scoping Meetings on the 2021 Endangered Species Act Reinitiation of Section 7 Consultation on the Long-Term Operation of the Central Valley Project and State Water Project

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of intent; request for comments.

SUMMARY: The Bureau of Reclamation intends to prepare an Environmental Impact Statement (EIS) for analyzing potential modifications to the Long-Term Operation of the Central Valley Project (CVP) and the State Water Project (SWP). The authorized purposes of the CVP include, first, river regulation, improvement of navigation and flood control; second, irrigation and domestic uses and fish and wildlife mitigation, protection and restoration; and third, power and fish and wildlife enhancement. Reclamation is seeking suggestions and information on the alternatives and topics to be addressed and other important issues related to multi-year operations of the CVP and SWP.

DATES: Submit written comments on the scope of the EIS on or before March 30, 2022.

Reclamation will hold virtual public scoping meetings at the following dates and times. The virtual public scoping meetings are identified geographically; however, virtual attendance is open at all meetings. Comments during the scoping meetings will be recorded. If you do not wish to be recorded, you may submit written comments to the mailing address or email address below

1. Tuesday, March 8, 2022, 2 p.m. to 4 p.m., Sacramento, CA, virtual meeting.

2. Wednesday, March 9, 2022, 5:30 p.m. to 7:30 p.m., Red Bluff, CA, virtual meeting.

3. Thursday, March 10, 2022, 2 p.m. to 4 p.m., Fresno, CA, virtual meeting.

4. Tuesday, March 15, 2022, 5:306 p.m. to 7:30 p.m., Los Banos, CA, virtual meeting.

5. Wednesday, March 16, 2022, 2 p.m. to 4 p.m., Tracy, CA, virtual meeting.

6. Thursday, March 17, 2022, 2 p.m. to 4 p.m., Chico, CA, virtual meeting.

Information on participation will be posted at *www.usbr.gov/mp/bdo* by the day prior to the meeting.

ADDRESSES: Send written scoping comments, requests to be added to the mailing list, or requests for other special assistance needs to Cindy Meyer, Bureau of Reclamation, Bay-Delta Office, 801 I Street, Suite 140, Sacramento, CA 95814–2536; or by email to *sha-MPR-BDO@usbr.gov.*

To attend the virtual meetings, please go to *www.usbr.gov/mp/bdo* to find the web links to specific meetings dates.

FOR FURTHER INFORMATION CONTACT: Cindy Meyer, Bureau of Reclamation, Bay-Delta Office, 801 I Street, Suite 140, Sacramento, CA 95814–2536; telephone (916) 414–2425; email *sha-MPR-BDO@usbr.gov.* Persons who use a telecommunications device for the deaf may call the Federal Relay Service (FedRelay) at 1–800–877–8339 TTY/ASCII to contact the above individual during normal business hours or to leave a message or question after hours. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

Purpose and Need for the Proposed Action

Reclamation operates the CVP and the California Department of Water Resources (DWR) operates the SWP, under the 1986 Coordinated Operation Agreement, as amended in 2018, between the federal government and the State of California, as authorized by Public Law 99–546. A February 18, 2020, Record of Decision (2020 ROD) implements the Proposed Action consulted upon for 2019 Biological Opinions from the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS). On September 30, 2021, Reclamation requested to reinitiate consultation on the Long-Term Operation of the CVP and SWP under section 7 of the Endangered Species Act (ESA) due to anticipated modifications to the previous Proposed Action that may cause effects to ESA-listed species or designated critical habitat not analyzed in the current 2019 Biological Opinions. Modifications would address the review of the 2019 Biological Opinions required by Executive Order 13990 *Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,* and voluntarily reconcile CVP operating criteria with requirements of the SWP under the California Endangered Species Act.

The purpose of the proposed action considered in this EIS is to continue the operation of the CVP and the SWP, for authorized purposes, in a manner that:

- Meets requirements under Federal Reclamation law; other Federal laws and regulations; Federal permits and licenses; and State of California water rights, permits, and licenses pursuant to section 8 of the Reclamation Act;
- Satisfies Reclamation contractual obligations and agreements; and
- Implements authorized CVP fish and wildlife project purposes.

Operation of the CVP and SWP is needed to provide flood control and navigation; water supply; fish and wildlife mitigation, protection, and restoration and enhancement; and power generation. Operation of the CVP and SWP also provides recreation and water quality benefits.

Project Area (Area of Analysis)

The project area includes CVP service areas and CVP dams, power plants, diversions, canals, gates, and related Federal facilities located on Clear Creek; the Trinity, Sacramento, American, Stanislaus, and San Joaquin rivers; and in the Sacramento-San Joaquin Delta (Delta).

- A portion of the water from the Trinity River Basin is stored in Trinity Lake behind Trinity Dam, re-regulated in Lewiston Lake, and diverted through a system of tunnels and powerplants into Whiskeytown Reservoir on Clear Creek and then into the Sacramento River through Spring Creek upstream of Keswick Dam. Water is also released from Lewiston Dam to the Trinity River where it flows to the Klamath River.
- A portion of the water from the upper Sacramento River is stored in Shasta Reservoir and re-regulated in Keswick Reservoir. Water in Shasta may be diverted at Shasta Dam or released into the Sacramento River. Water from the upper Sacramento, imports from the Trinity River Basin, releases from other reservoirs owned or operated by local agencies, and other inflows enter the Sacramento River and may be diverted into the Tehama-Colusa and Corning canals at the Red Bluff Pumping Plant.
- A portion of the water from the American River is stored in Folsom Reservoir and re-regulated in Lake Natoma. Water in Folsom Reservoir may be diverted at Folsom Dam, be diverted into the Folsom South Canal, or be released into the American River.
- A portion of the water from the Stanislaus River is stored in New Melones Reservoir. Water in New Melones may be released into the Stanislaus River.
- A portion of the water from the upper San Joaquin River is stored in Millerton Reservoir behind Friant Dam. Water is diverted into the Madera and Friant-Kern canals or released into the San Joaquin River.
- The Sacramento River and San Joaquin River carry water to the Delta. As water moves down the mainstem of the Sacramento River, gates at the Delta Cross Channel are operated for water quality and flood management.
- Water in the Delta may be pumped into the Contra Costa Canal at Rock Slough and delivered to Contra Costa Water District. The C.W. Bill Jones Pumping Plant is at the southern end of the Delta, lifting water into the Delta Mendota Canal (DMC). CVP water is conveyed in the DMC for direct diversion or for delivery to San Luis Reservoir. Water from the San Luis Reservoir is also conveyed through the San Luis Canal and Pacheco Tunnel. The DMC–California Aqueduct Intertie connects the CVP and SWP conveyance facilities after export from the Delta. Prior to the Jones Pumping Plant, the Tracy Fish Collection Facility salvages salmonids and other species.

The project area includes SWP service areas downstream of the Feather River and SWP facilities in the Sacramento-San Joaquin Delta, Cache Slough Complex, and Suisun Marsh. Feather River operations of Lake Oroville and Oroville Dam are not addressed as part of this consultation.

- In the Cache Slough Complex the Barker Slough Pumping Plant lifts water into the North Bay Aqueduct.
- In Montezuma Slough, the Suisun Marsh Salinity Control Gates are tidally operated to maintain fresh water in Montezuma Slough and the Suisun Marsh.
- The Harvey O. Banks Pumping Plant at the southern end of the Delta, behind Clifton Court Forebay, lifts water into the California Aqueduct, which conveys water to the San Luis Reservoir for storage and to the South Bay Aqueduct for deliveries to the SWP contractors. The DMC–California Aqueduct Intertie connects the CVP and SWP conveyance facilities after export from the Delta. Prior to the Banks Pumping Plant, the Skinner Delta Fish Protection Facility salvages salmonids and other species.
- The SWP also pumps water through the Harvey O. Banks Pumping Plant and conveys it through the California Aqueduct to the Cross-Valley Canal, when the systems have capacity, for CVP water service contractors.

Proposed Action and Preliminary Alternatives To Be Considered

The EIS will consider a range of reasonable alternatives, consistent with 40 CFR 1502.14, including a No Action Alternative that would continue implementation of the 2020 ROD. Reasonable alternatives may include combinations of operation of CVP and SWP facilities and diversions, construction actions, habitat restoration, conservation hatchery practices, and monitoring and special studies. Reasonable alternatives may support consultation for actions by Sacramento River Settlement Contractors. Reasonable alternatives may include DWR operations for new storage projects. Reclamation is considering operation of the CVP and SWP under conditions of:

- Potential hydrologic and meteorologic climate change through 2040 including changes in precipitation, air temperatures, and sea level;

• Potential new storage, conveyance, and other water supply infrastructure;

• Potential implementation of voluntary agreements for the update of the Bay-Delta Water Quality Control Plan;

• Potential responses to drier years and drought conditions such as water transfers and temporary urgency change petitions; and

• Potential needs for new and adapted monitoring programs to address current and future information needs.

Each action alternative will fulfill the requirements of the need for the project as described in the ''Purpose and Need for Action'' section. Certain components of alternatives may be described programmatically and be subject to further compliance. The Final EIS will identify an agency-preferred alternative. Reclamation will consider reasonable alternatives identified through the National Environmental Policy Act (NEPA) scoping process and through the input required by Section 4004 of the Water Infrastructure Improvements for the Nation Act, Public Law 114–322.

Summary of Potential Impacts

The EIS will identify and describe reasonably foreseeable potential effects on the human environment from a reasonably close causal relationship. Effects include those occurring at the same time and place and those occurring later in time or at a different place (whether beneficial or adverse). Potential impacts areas include surface water supply, water quality, groundwater resources, air quality, greenhouse gas emissions, visual resources, aquatic resources, terrestrial biological resources, regional economics, land use and agricultural resources, recreation, hazards and hazardous materials, cultural resources, geology and soils, and climate change.

Reclamation expects to analyze flow management, temperature management, habitat, interactions with CVP and SWP facilities, conservation hatchery practices, and monitoring needs. Reclamation expects these actions to result in incidental take that requires consultation due to the potential to affect ESA-listed species. Reclamation intends to pursue the conference process for Longfin Smelt. Reclamation also anticipates analyzing differences in water supply deliveries and surplus power generation. The EIS will analyze measures that would avoid, minimize, or mitigate adverse environmental effects.

Statutory Authority and Anticipated Permits

NEPA [42 U.S.C. 4321 *et seq.*] requires that Federal agencies conduct an environmental analysis of their proposed actions to determine if the actions may significantly affect the human environment. The EIS will analyze the environmental effects that may result from the implementation of the proposed action and alternatives. In addition to NEPA, various other Federal, state, and local authorizations may be required for the Proposed Action. Applicable Federal laws include, but are not limited to, ESA, Magnuson-Stevens Fishery Conservation and Management Act, National Historic Preservation Act, and Clean Water Act.

Schedule for the Decision-Making Process

Reclamation will review and consider comments received during scoping and will prepare a scoping report. After the draft EIS is completed, anticipated in 2023, Reclamation will publish a notice of availability (NOA) and request public comments on the draft EIS. After the public comment period ends, Reclamation will then develop the final EIS and anticipates making the final EIS available to the public in 2024. In accordance with 40 CFR 1506.11, Reclamation will not make a decision or issue a Record of Decision (ROD) sooner than 30 days after the final EIS is released. Reclamation anticipates the issuance of a ROD by October 2024.

NEPA Cooperating Agencies

Reclamation will request the following Federal agencies to participate as cooperating agencies in accordance with the NEPA:

• USFWS,
• NMFS,
• Western Area Power Administration,
• U.S. Army Corps of Engineers; and
• U.S. Environmental Protection Agency.

Reclamation may invite additional Federal, state, and local agencies (*e.g.,* DWR, California Department of Fish and Wildlife, State Water Resources Control Board, Public Water Agencies) as potential cooperating agencies.

Indian Trust Assets and Environmental Justice

Reclamation will consult with federally recognized Indian tribes in the project area to request their input regarding the identification of any properties to which they might attach religious and cultural significance to within the area of potential effect. Once these areas are determined, Reclamation will enter government-to-government consultations with potentially affected tribes to identify and address concerns for Indian Trust Assets. There are Indian Trust Assets affected by the Trinity River Division and the potential impacts of CVP operation on those assets will be examined in the EIS. The EIS will examine the potential impacts to environmental justice issues throughout the project area.

Public Disclosure

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. Speakers during scoping meetings are recorded.

How To Request Reasonable Accommodation

For special assistance at one of the scoping meetings, please contact Cindy Meyer (above) or TDD 916–978–5608, at least five working days before the meetings. Information regarding this proposed action is available in alternative formats upon request.

Ernest Conant,

Regional Director, California Great Basin Region.

[FR Doc. 2022–04160 Filed 2–25–22; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1253]

Certain LTE-Compliant Cellular Communication Devices; Commission Determination Not To Review an Initial Determination Granting Complainant's Motion To Terminate the Investigation Based on Withdrawal of the Complaint Allegations; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 36) of the presiding Administrative Law Judge (''ALJ'') granting complainant's motion to

terminate the investigation in its entirety based on withdrawal of the complaint allegations.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On March 8, 2021, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by Evolved Wireless, LLC of Austin, Texas (''Evolved''). 86 FR 13399–400 (Mar. 8, 2021). The complaint alleged a violation of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain LTE-compliant cellular communication devices by reason of infringement of certain claims of U.S. Patent Nos. RE46,679; RE48,326 (''the '326 patent''); and 10,517,120 (''the '120 patent''). The complaint also alleged the existence of a domestic industry. The notice of investigation named Samsung Electronics Co., Ltd. of Gyeonngi-Do, Republic of Korea; Samsung Electronics America, Inc. of Ridgefield Park, New Jersey; and Motorola Mobility LLC of Chicago, Illinois as respondents. *Id.* at 13400. The Commission's Office of Unfair Import Investigations was also named as a party in this investigation. *Id.* Subsequently, the Commission terminated all asserted claims of the '120 patent and claims 19 and 20 of the '326 patent from the investigation by reason of withdrawal of the complaint allegations. Order No. 15 (Aug. 26, 2021), *unreviewed* by Notice (Sep. 24, 2021); Order No. 26 (Dec. 3, 2021), *unreviewed by* Notice (Dec. 20, 2021).

On January 13, 2022, complainant Evolved filed an unopposed motion to terminate this investigation by reason of withdrawal of complaint allegations under Commission Rule 210.21(a), 19 CFR 210.21(a). On January 19, 2022, the Commission investigative attorney filed a contingent statement of support of the motion.

On January 31, 2022, the ALJ issued the subject ID (Order No. 36) granting complainant's motion. The ID finds that there are no extraordinary circumstances that would prevent the requested termination of this investigation. The ID also finds Evolved has complied with the requirements of Commission Rule 210.21(a). No party petitioned for review of the ID.

The Commission has determined not to review the subject ID. The investigation is terminated in its entirety.

The Commission vote for this determination took place on February 22, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: February 22, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–04097 Filed 2–25–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1239]

Certain Gabapentin Immunoassay Kits and Test Strips, Components Thereof, and Methods Therefor; Commission Determination Not To Review an Initial Determination Terminating a Final Respondent Based on Settlement; Request for Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 29) terminating the final, non-defaulting respondent, Shanghai Chemtron Biotech Co. Ltd., in the above-captioned investigation based on settlement. The Commission has further determined to find that the complainants' declaration seeking immediate relief against a respondent previously found to be in default is moot. The Commission also requests written submissions from the parties, interested government agencies, and interested persons on remedy, the public interest, and bonding concerning the defaulted respondent.

FOR FURTHER INFORMATION CONTACT: Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3228. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On January 25, 2021, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by ARK Diagnostics, Inc. of Fremont, California (''ARK''). *See* 86 FR 6918–19. The complaint, as supplemented, alleges a violation of section 337 based upon the importation into the United States, sale for importation, or sale after importation into the United States of certain gabapentin immunoassay kits and test strips, components thereof, and methods therefor by reason of infringement of certain claims of U.S. Patent Nos. 8,828,665 and 10,203,345. *Id.* The complaint further alleges that a domestic industry exists. *Id.* The notice of investigation names fourteen respondents, including Shanghai Chemtron Biotech Co., Ltd. of Shanghai, China (''Shanghai Chemtron'') and Kappa City Biotech, SAS of Montlucon, France (''Kappa City''). *See id.* The complaint and notice of investigation were later amended to add two respondents. Order No. 8 (March 9, 2021), *unreviewed by* 86 FR 16640–41 (March 30, 2021).

The Commission previously terminated six respondents based on consent orders. Order Nos. 11 and 12 (Mar. 31, 2021), *unreviewed by* Comm'n Notice (Apr. 15, 2021); Order No. 14 (April 9, 2021), *unreviewed by* Comm'n Notice (Apr. 22, 2021); Order No. 15 (April 12, 2021), *unreviewed by* Comm'n Notice (May 12, 2021). The Commission also previously terminated three respondents based on settlement agreements. Order No. 13 (Apr. 5, 2021), *unreviewed by* Comm'n Notice (Apr. 19, 2021); Order No. 17 (May 5, 2021),

unreviewed by Comm'n Notice (May 18, 2021); Order No. 18 (May 20, 2021), *unreviewed by* Comm'n Notice (June 21, 2021). The Commission also terminated five respondents based on partial withdrawal of the complaint. Order No. 20 (June 4, 2021), *unreviewed by* Comm'n Notice (June 28, 2021); Order No. 21 (June 14, 2021), *unreviewed by* Comm'n Notice (July 1, 2021).

On May 18, 2021, the Commission determined not to review an initial determination (Order No. 16) finding Kappa City in default. Order No. 16 (Apr. 30, 2021), *unreviewed by* Comm'n Notice (May 18, 2021).

On December 7, 2021, ARK filed a declaration seeking immediate entry of a limited exclusion order and cease and desist order against Kappa City.

On January 20, 2022, ARK filed a motion to terminate this investigation with respect to Shanghai Chemtron based on a settlement.

On January 31, 2022, the presiding administrative law judge issued the subject ID granting the motion to terminate Shanghai Chemtron based on settlement. *See* Order No. 29 (Jan. 31, 2022). The subject ID finds that the motion complies with Commission Rule 210.21(b)(1) (19 CFR 210.21(b)) and that no extraordinary circumstances prevent denying the motion. The subject ID further finds that termination of Shanghai Chemtron based on settlement would not be contrary to the public interest.

No party petitioned for review of the subject ID.

The Commission has determined not to review the subject ID (Order No. 29). Shanghai Chemtron is terminated from the investigation.

The Commission has further determined that ARK's declaration is now moot given the termination of the final remaining non-defaulting respondent in this investigation. The Commission has also determined to request briefing on the issues of remedy, bonding, and the public interest.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) a cease and desist order that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist order would have on: (1) The public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding.

ARK is requested to submit proposed remedial orders for the Commission's consideration. ARK is further requested to state the dates that the Asserted Patents expire, to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on March 8, 2022. Reply submissions must be filed no later than the close of business on March 15, 2022. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337–TA–1239) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on February 22, 2022.

While temporary remote operating procedures are in place in response to COVID–19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission orders that the complainant complete service for any party/parties without a

method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: February 22, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–04080 Filed 2–25–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0009]

Agency Information Collection Activities; Proposed eCollection; eComments Requested: Law Enforcement Officers Killed and Assaulted Program, Analysis of Officers Feloniously Killed and Assaulted; and Law Enforcement Officers Killed and Assaulted Program; Analysis of Officers Accidentally Killed

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: Department of Justice, Federal Bureau of Investigation, Criminal Justice Information Services Division will be submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional 30 day until March 30, 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.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Law Enforcement Officers Killed and Assaulted Program, Analysis of Officers Feloniously Killed and Assaulted; and Law Enforcement Officers Killed and Assaulted Program, Analysis of Officers Accidentally Killed.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* Agency form number: 1–701 and 1–701a. Sponsoring component: Department of Justice, Federal Bureau of Investigation, Criminal Justice Information Services Division.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: City, county, state, federal, and tribal law enforcement agencies. Abstract: Under Title 28, U.S. Code, Section 534, Acquisition, Preservation, and Exchange of Identification Records; Appointment of Officials, this collection requests the number of officers killed or assaulted from law enforcement agencies in order for the FBI Uniform Crime Reporting Program to serve as the national clearinghouse for the collection and dissemination of law enforcement officer death/assault data and to publish these statistics in Law Enforcement Officers Killed and Assaulted.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* There are approximately 128 law enforcement agency respondents. This included 51 minutes for form 701 and 25 minutes for form 701–a.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 384.5 hours, annual burden, associated with this information collection. This is made up of 84.5 hours for form completion, and 300 hours for agency outreach and administrative burden.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: February 22, 2022.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2022–04089 Filed 2–25–22; 8:45 am]

BILLING CODE 4410–02–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–22–0005; NARA–2022–031]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on *regulations.gov* for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: We must receive responses on the schedules listed in this notice by April 15, 2022.

ADDRESSES: To view a records schedule in this notice, or submit a comment on one, use the following address: *https://www.regulations.gov/docket/NARA-22-0005/document.* This is a direct link to the schedules posted in the docket for this notice on *regulations.gov.* You may submit comments by the following method:

• *Federal eRulemaking Portal: https://www.regulations.gov.* On the website, enter either of the numbers cited at the top of this notice into the search field. This will bring you to the docket for this notice, in which we have

posted the records schedules open for comment. Each schedule has a 'comment' button so you can comment on that specific schedule. For more information on *regulations.gov* and on submitting comments, see their FAQs at *https://www.regulations.gov/faq.*

Due to COVID–19 building closures, we are currently temporarily not accepting comments by mail. However, if you are unable to comment via *regulations.gov*, you may email us at *request.schedule@nara.gov* for instructions on submitting your comment. You must cite the control number of the schedule you wish to comment on. You can find the control number for each schedule in parentheses at the end of each schedule's entry in the list at the end of this notice.

Due to COVID–19 building closures, we are currently temporarily not accepting comments by mail. However, if you are unable to comment via *regulations.gov*, you may contact *request.schedule@nara.gov* for instructions on submitting your comment. You must cite the control number of the schedule you wish to comment on. You can find the control number for each schedule in parentheses at the end of each schedule's entry in the list at the end of this notice.

FOR FURTHER INFORMATION CONTACT: Kimberly Keravuori, Regulatory and External Policy Program Manager, by email at *regulation_comments@nara.gov.* For information about records schedules, contact Records Management Operations by email at *request.schedule@nara.gov* or by phone at 301–837–1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule. We have uploaded the records schedules and accompanying appraisal memoranda to the *regulations.gov* docket for this notice as ''other'' documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the *regulations.gov* portal, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we will post on *regulations.gov* a ''Consolidated Reply'' summarizing the comments, responding to them, and noting any changes we have made to the proposed records schedule. We will then send the schedule for final approval by the Archivist of the United States. You may elect at *regulations.gov* to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. If you have a question, you can submit it as a comment, and can also submit any concerns or comments you would have to a possible response to the question. We will address these items in consolidated replies along with any other comments submitted on that schedule.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of Defense, Defense Threat Reduction Agency, Radiation Material Licensing Records (DAA–0374–2021–0001).
2. Department of State, Bureau of Energy Resources, Consolidated Schedule (DAA–0059–2018–0004).
3. Department of State, Bureau of Legislative Affairs, Consolidated Schedule (DAA–0059–2020–0011).
4. Department of Transportation, Federal Aviation Administration, Real Estate Management System (DAA–0237–2021–0008).
5. Consumer Financial Protection Bureau, Agency-wide, Home Mortgage Disclosure Act Data and Related Records (DAA–0587–2019–0002).
6. Consumer Product Safety Commission, Office of the Inspector General, Office of the Inspector General Records (DAA–0424–2020–0001).

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2022–04169 Filed 2–25–22; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Polar Programs; 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 Polar Programs (1130).

Date and Time: March 24–25, 2022; 11:00 a.m.–4:00 p.m.

Place:

National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314 | Virtual.

Registration for the virtual meeting will be available two weeks prior to the meeting date. Final agenda and registration link will be located on the AC's website at: *https://www.nsf.gov/geo/opp/advisory.jsp.*

Type of Meeting: Open.

Contact Person: Beverly Walker, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314; Telephone: (703) 292–2614.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To provide advice and recommendations to the National Science Foundation concerning support for polar research, education, infrastructure and logistics, and related activities.

Agenda

March 24, 2022; 11:00 a.m.–4:00 p.m. (Virtual)

- Upcoming field seasons and COVID–19
- Advisory Committee Liaison Updates
- Subcommittee on Diversity, Equity, and Inclusion
- Antarctic Research Vessel Updates
- NSF Geoscience Directorate Activities Updates

March 25, 2022; 11:00 a.m.–4:00 p.m. (Virtual)

- Polar Partnerships
- Meeting with the NSF Director & Chief Operating Officer
- NASEM Mid-Term Report
- South Pole Station
- Russian Science Collaborations

Dated: February 22, 2022.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2022–04100 Filed 2–25–22; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

National Artificial Intelligence Research Resource Task Force; 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: National Artificial Intelligence Research Resource Task Force (84629).

Date and Time: April 8, 2022, 11:00 a.m. to 5:00 p.m. EDT.

PLACE: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314. Virtual meeting attendance only.

To attend the virtual meeting, please send your request for the virtual meeting link to the following email: *cmessam@nsf.gov.*

Type of Meeting: Open.

Contact Person: Brenda Williams, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: 703–292–8900; email: *bwilliam@nsf.gov.*

Purpose of Meeting: The Task Force shall investigate the feasibility and advisability of establishing and sustaining a National Artificial Intelligence Research Resource; and propose a roadmap detailing how such resource should be established and sustained.

Agenda: In this meeting, the Task Force members will deliberate on the Task Force's interim report to the President and Congress. The Task Force members will also discuss their work plan for the remainder of 2022 and identify the key issues to study as they develop implementation-focused recommendations for inclusion in their final report.

Dated: February 22, 2022.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2022–04101 Filed 2–25–22; 8:45 am]

BILLING CODE 7555–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94298; File No. SR–NYSECHX–2022–02]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Article I, Rule 5 To Replace References to Employees and Officers of Intercontinental Exchange Group, Inc.

February 22, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on February 14, 2022, the NYSE Chicago, Inc. (''NYSE Chicago'' 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 self-regulatory organization. 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 Article I, Rule 5 (Designation of Authority) to replace references to employees and officers of Intercontinental Exchange Group, Inc., the Exchange's indirect parent company, with references to employees and officers of the Exchange. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Article I, Rule 5 (Designation of Authority) to replace references to employees and officers of Intercontinental Exchange Group, Inc. (''ICE''), the Exchange's indirect parent company, with references to employees and officers of the Exchange.

The Exchange adopted Rule 5 in 2019, stating that Rule 5 was substantially similar to the third paragraph of New York Stock Exchange Rule 1 (''NYSE Rule 1'').[4]

Like NYSE Rule 1, Rule 5 provides that, if the person named in a rule is not available, the chief executive officer (''CEO'') or chief regulatory officer (''CRO'') of the Exchange may designate one or more qualified employees of ICE to act in their place. Rule 5 goes on to

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 85190 (February 25, 2019), 84 FR 7154 (March 1, 2019) (SR–NYSECHX–2019–02) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Rules of the Exchange To Adopt Article 1, Rule 5).

state that, for purposes of a designation by the CEO, a qualified employee includes, among other things, any officer of ICE deemed by the CEO to possess the requisite knowledge and job qualifications.[5]

In practice, designations under Rule 5 are limited to Exchange employees and officers. To more accurately reflect actual practice, the Exchange proposes to replace the references to employees and officers of ICE in Rule 5 with references to employees and officers of the Exchange, as follows:

- In the first sentence, ''Intercontinental Exchange Group, Inc. ('ICE')'' would be replaced with ''the Exchange''; and
- In clause (1) of the second sentence, ''Exchange'' would be added before ''officer,'' and ''of ICE'' would be deleted.

The proposed changes would not result in any practical changes regarding which individuals would be eligible to perform the functions specified in Rule 5 and would not require the Exchange to change which individuals may currently performing these functions.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(5) of the Act,[7] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change would promote clarity and transparency in its rules. The Exchange believes that the change would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from the increased clarity and transparency that the change would introduce, thereby reducing potential confusion.

The Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest, because it would remove any potential confusion among market participants that may result if the Exchange retained references to ICE employees and ICE officers in Rule 5, adding clarity and transparency to Exchange rules. Moreover, the proposed change to the first prong of the definition of ''qualified employee'' for purposes of designation by the CEO would make it consistent with the first prong of the definition of ''qualified employee'' for purposes of designation by the CRO, reducing any potential confusion among market participants.

In practice, Exchange employees and officers, and not ICE employees and officers, are designated pursuant to Rule 5. The proposed changes would ensure that remained true, as under the changes only Exchange officers or Exchange employees could be qualified employees delegated authority by the CEO pursuant to Rule 5. For that reason, the Exchange believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[8] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather serve to promote clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection. The proposed changes would be administrative and would apply only to the Exchange, and therefore would not impose any unnecessary competitive burden on third parties.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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[9] and Rule 19b–4(f)(6)[10] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will 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–NYSECHX–2022–02 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–NYSECHX–2022–02. 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/*

[5] Article 1, Rule 5.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78f(b)(8).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 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.

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–NYSECHX–2022–02 and should be submitted on or before March 21, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–04084 Filed 2–25–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94292; File No. SR–CBOE–2022–005]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Permit P.M.-Settled S&P 500 Index Options That Expire on Tuesday or Thursday Under Its Nonstandard Expirations Pilot Program

February 22, 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 February 8, 2022, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to permit P.M.-settled S&P 500 Index (''SPX'') options that expire on Tuesday or Thursday under its Nonstandard Expirations Pilot Program. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, 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 Rule 4.13(e), which governs its Nonstandard Expirations Pilot Program (''Pilot Program''), to permit P.M.-settled SPX options that expire on Tuesday or Thursday. Under the existing Pilot Program, the Exchange is permitted to list P.M.-settled options on broad-based indexes that expire on: (1) Any Monday, Wednesday, or Friday (''Weekly Expirations'' or ''EOWs'') and (2) the last trading day of the month (''End of Month Expirations'' or ''EOMs'').[3]

Specifically, the proposed rule change amends Rule 4.13(e)(1) to add P.M.-settled SPX Weekly (''SPXW'') options that expire on Tuesday or Thursday as permissible Weekly Expirations under the Pilot Program (currently set to expire on May 2, 2022). The Exchange notes that permitting SPXW options with Tuesday and Thursday expirations, as proposed, is in addition to the SPXW options with Monday, Wednesday and Friday expirations that the Exchange may (and does) already list, as they are permissible Weekly Expirations for options on a broad-based index (*e.g.,* SPX) pursuant to Rule 4.13(e)(1). The Pilot Program for Weekly Expirations will apply to SPXW options with Tuesday and Thursday expirations in the same manner as it currently applies to P.M.-settled broad-based index options with Monday, Wednesday and Friday expirations. That is, as proposed, Rule 4.13(e)(1) provides that the Exchange may open for trading Weekly Expirations on any broad-based index eligible for standard options trading to expire on any Monday, Wednesday, or Friday (other than the third Friday-of-the-month or days that coincide with an EOM expiration). In addition, the Exchange may also open for trading Weekly Expirations on S&P 500 Index options to expire on any Tuesday or Thursday (other than days that coincide with an EOM expiration). Weekly Expirations shall be subject to all provisions of this Rule and treated the same as options on the same underlying index that expire on the third Friday of the expiration month; provided, however, that Weekly Expirations shall be P.M.-settled and new series in Weekly Expirations may be added up to and including on the expiration date for an expiring Weekly Expiration. The maximum number of expirations that may be listed for each Weekly Expiration (*i.e.,* a Monday expiration, Tuesday expiration, Wednesday expiration, Thursday expiration, or Friday expiration, as applicable) in a given class is the same as the maximum number of expirations permitted in Rule 4.13(a)(2) for standard options on the same broad-based index (which is 12 for SPX options). Weekly Expirations need not be for consecutive Monday, Tuesday, Wednesday, Thursday, or Friday expirations as applicable; however, the expiration date of a non-consecutive expiration may not be beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively. Weekly Expirations that are first listed in a given class may expire up to four weeks from the actual listing date. If the Exchange lists EOMs and Weekly Expirations as applicable in a given class, the Exchange will list an EOM instead of a Weekly Expiration that expires on the same day in the

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Rule 4.13(e).

given class.[4] Other expirations in the same class are not counted as part of the maximum number of Weekly Expirations for an applicable [5] broad-based index class. If the Exchange is not open for business on a respective Monday, the normally Monday expiring Weekly Expirations will expire on the following business day. If the Exchange is not open for business on a respective Tuesday, Wednesday, Thursday, or Friday, the normally Tuesday, Wednesday, Thursday, or Friday expiring Weekly Expirations will expire on the previous business day. The proposed rule change also adds that, if two different Weekly Expirations on S&P 500 Index options would expire on the same day because the Exchange is not open for business on a certain weekday, the Exchange will list only one of such Weekly Expirations. The Exchange believes it is appropriate to clarify in the rule text that the Exchange will list just one Weekly Expiration in such a case, as the two Weekly Expirations would essentially be the same options contract. For example, if the Exchange listed SPXW options with proposed Thursday expirations and Friday expirations and the Exchange was closed for business on a Friday then, pursuant to current Rule 4.13(e)(1), the normally expiring Friday expiration would expire on the previous business day—essentially making it an SPXW option with a Thursday expiration. Thus, expiring SPXW options in this case will always have the same weekday expiration (per the example, it is an SPXW option with a Thursday expiration, whether it was listed as an SPXW with a Thursday expiration or a Friday expiration). As such, for the sake of clarity in the rules and to mitigate any confusion regarding the listing of SPXW options when the Exchange is closed for business, the proposed rule change provides that the Exchange will list just one Weekly Expiration if two Weekly Expirations would expire on the same day due to the Exchange being closed for business. Also, like all Weekly Expirations listed pursuant to Rule 4.13(e)(4) of the Pilot Program, transactions in expiring SPXW options with Tuesday and Thursday expirations may be effected on the Exchange between the hours of 9:30 a.m. and 4:00 p.m. on their last trading day (Eastern Time). The Exchange makes a nonsubstantive clarifying change to Rule 4.13(e)(4) to provide that on the last trading day, Regular Trading Hours for expiring Weekly Expirations and EOMs are from 9:30 a.m. and 4:00 p.m. As SPXW options are also available for trading during Global Trading Hours, the proposed update merely clarifies that Rule 4.13(e)(4) refers to the close of Regular Trading Hours.[6] The proposed rule text is substantively identical to Rule 5.1, which governs trading hours on the Exchange generally, and provides that, on their last trading day, Regular Trading Hours for index options with nonstandard expirations are from 9:30 a.m. to 4:00 p.m.[7]

The Exchange believes that that [sic] the introduction of SPXW options with Tuesday and Thursday expirations will expand hedging tools available to market participants while also providing greater trading opportunities. By offering SPXW options with Tuesday and Thursday expirations along with the current Monday, Wednesday and Friday expirations, the proposed rule change will allow market participants to purchase SPXW options in a manner more aligned with specific timing needs and more effectively tailor their investment and hedging strategies and manage their portfolios. In particular, the proposed rule change will allow market participants to roll their positions on more trading days, thus with more precision, spread risk across more trading days and incorporate daily changes in the markets, which may reduce the premium cost of buying protection.

The Exchange proposes to abide by the same reporting requirements for the trading of SPXW options that expire on any Tuesday or Thursday that it does for the trading of P.M.-settled options on broad-based indexes that expire on any Monday, Wednesday, or Friday pursuant to the Pilot Program. The Exchange proposes to include data regarding SPXW options that expire on Tuesdays or Thursdays as it does for current Weekly Expirations on any broad-based index option in the Pilot Program annual report that it submits to the Securities and Exchange Commission (''Commission'') at least two months prior to the expiration date of the Pilot Program.[8] The Exchange is required to submit an annual report at least yearly. The annual report to the Commission addresses the following areas: Analysis of Volume & Open Interest, Monthly Analysis of Weekly Expirations & EOM Trading Patterns and Provisional Analysis of Index Price Volatility. Going forward, the Exchange will include the same areas of analysis for SPXW options with Tuesday and Thursday expirations in the annual reports. Additionally, the Exchange will provide the Commission with any additional data or analyses the Commission requests because it deems such data or analyses necessary to determine whether the Pilot Program, including SPXW options with Tuesday and Thursday expirations as proposed, is consistent with the Exchange Act. As it does for current Pilot Program products, the Exchange will make public on its website all data and analyses in connection with SPXW options with Tuesday and Thursday expirations it submits to the Commission under the Pilot Program.

The Exchange believes there is sufficient investor interest and demand in SPXW options with Tuesday and Thursday expirations to warrant inclusion in the Pilot Program and that the Pilot Program, as amended, will continue to provide investors with additional means of managing their risk exposures and carrying out their investment objectives.[9] The Exchange notes that during the Pilot Program's nearly 12-year tenure, the Exchange has not observed any significant adverse market effects or identified any regulatory concerns as a result of the Pilot Program, nor does it believe that additional expirations listed under the Pilot Program would result in any such impact or regulatory concerns. Based on a study conducted by Commission staff on the pilot data (including quarterly, weekly, EOM and third Friday expirations for P.M.-settled SPX options),[10] there is no evidence of any

[4] Given that each trading day of the week, as proposed, could be the last trading day of the month and the day in which a Weekly Expiration expires, the Exchange updates this rule text to streamline the language.

[5] The Exchange updates the rule text for additional clarity.

[6] The Exchange notes that the Exchange's GTH trading session was adopted after the Nonstandard Expirations Pilot Program. *See* Securities Exchange Release Nos. 62911 (September 14, 2010), 75 FR 57539 (September 21, 2010) (SR–CBOE–2009–075) (''Nonstandard Expirations Pilot Approval Order''); *and* 34–73704 (November 28, 2014), 79 FR 72044 (December 4, 2014) (SR–CBOE–2014–062) (order granting approval of proposed rule change to adopt Extended Trading Hours).

[7] *See* Rule 5.1.(b)(2)(C).

[8] *See* Nonstandard Expirations Pilot Approval Order.

[9] The Exchange additionally notes that it already allows SPXW options to expire on Tuesdays for normally Monday or Wednesday expiring SPXW options when the Exchange is not open for business on a respective Monday or Wednesday (as applicable), and already allows SPXW options to expire on Thursdays for normally Friday expiring SPXW options when the Exchange is not open for business on a respective Friday. Also, EOM options may currently be listed to expire on a Tuesday or Thursday.

[10] *See* Securities and Exchange Commission, Division of Economic Risk and Analysis, Memorandum, Cornerstone Analysis of PM Cash-Settled Index Option Pilots (February 2, 2021) (''SEC PM Pilot Memo'').at 13, available at: *https://*

Continued

significant adverse economic impact to the futures, index, or underlying index component securities markets as a result of the quantity of P.M.-settled SPX options that settle at the close or the amount of expiring open interest in P.M.-settled SPX options.[11]

With regard to the impact of this proposal on system capacity, the Exchange has analyzed its capacity and represents that it believes that the Exchange and OPRA have the necessary systems capacity to handle any potential additional traffic associated with trading of SPXW options with Tuesday and Thursday expirations. The Exchange does not believe that its Trading Permit Holders (''TPHs'') will experience any capacity issues as a result of this proposal and represents that it will monitor the trading volume associated with any possible additional options series listed as a result of this proposal and the effect (if any) of these additional series on market fragmentation and on the capacity of the Exchange's automated systems. Additionally, the Exchange notes that it recently implemented a strike mitigation initiative to reduce the number of strikes listed for SPXW options, effectively reducing the number of SPXW options series listed on the Exchange by approximately 10%; such that, upon adding SPXW options with Tuesday and Thursday expirations, the number of SPXW options series listed on the Exchange will be less than the number of such series that were listed prior to the implementation of the SPXW options strike reduction.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[12] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirements that the rules of an exchange be 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 facilitation 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)[14] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange does not believe that the addition of SPXW options with Tuesday and Thursday expirations to the Pilot Program will raise any prohibitive regulatory concerns, nor adversely impact fair and orderly markets on expiration days. The Exchange has not experienced any meaningful regulatory concerns, nor adverse impact on fair and orderly markets, in connection with the Pilot Program that has permitted the listing and trading of SPXW options with Monday, Wednesday and Friday expirations since 2010. Particularly, and as described above, the Exchange does not believe increases in the number P.M.-settled SPX options series will have any significant adverse economic impact on the futures, index, or underlying index component securities markets. The Exchange believes that the proposed rule change will provide investors with greater trading and hedging opportunities and flexibility, allowing them to transact in SPXW options in a manner more aligned with specific timing needs and more effectively tailor their investment and hedging objectives by listing SPXW options that expire each trading day of the week.

The Exchange notes also that it will include analysis in connection with SPXW options that expire on Tuesdays and Thursdays, in the same manner that it currently does for other Pilot Program products, in the annual reports it submits to the Commission, and will provide the Commission with any additional data or analyses the it may request if it deems such data or analyses necessary to determine whether the Pilot Program, including SPXW options with Tuesday and Thursday expirations as proposed, is consistent with the Exchange Act. The Exchange represents that it believes that it has the necessary systems capacity to support any additional traffic associated with trading of SPXW options with Tuesday and Thursday expirations and does not believe that its TPHs will experience any capacity issues as a result of this proposal. The Exchange will monitor the trading volume associated with any possible additional options series listed and the effect (if any) of these additional series on market fragmentation and on the capacity of the Exchange's automated systems. The Exchange again notes that, as a result of an SPXW options strike mitigation initiative recently implemented by the Exchange, the number of SPXW options series listed on the Exchange once Tuesday and Thursday expirations become available will be less than the number of such series that were listed prior to the implementation of the strike mitigation initiative.

The Exchange also notes that the nonsubstantive proposed rule change clarifying the trading session to which Rule 4.13(e)(4) refers will protect investors and the public interest by adding a clarification to rules governing the Pilot Program, as well as conforming such provision to Rule 5.1, which governs trading hours on the Exchange generally and has a substantively identical provision to that of the proposed rule change.[15]

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 Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because SPXW options with Tuesday and Thursday expirations will be available to all market participants. By listing SPXW options that expire Tuesdays and Thursdays, the proposed rule change will provide all investors that participate in the SPX options market greater trading and hedging opportunities and flexibility to meet their investment and hedging needs. Additionally, Tuesday and Thursday expiring SPXW options will trade in the same manner as Weekly Expirations currently trade.

The Exchange does not believe that the proposal to list SPXW options with

www.sec.gov/files/Analysis_of_PM_Cash_Settled_Index_Option_Pilots.pdf (''Option settlement quantity data for A.M.- and P.M.-settled options were obtained from the Cboe, including the number of contracts that settled in-the-money for each exchange-traded option series on the S&P 500 index . . . on expiration days from January 20, 2006 through December 31, 2018. Daily open interest and volume data for [SPX] option series were also obtained from Cboe, including open interest data from January 3, 2006 through December 31, 2018 and trading volume data from January 3, 2006 through December 31, 2018.'')

[11] *See id.* at 3. For example, the largest settlement event that occurred during the time period of the study (a settlement of $100.4 billion of notional on December 29, 2017) had an estimated impact on the futures price of only approximately 0.02% (a predicted impact of $0.54 relative to a closing futures price of $2,677).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] *Id.*

[15] *See supra* note 7.

Tuesday and Thursday expirations will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because SPX options (including SPXW options) are proprietary Exchange products. Other exchanges offer nonstandard expiration programs for index options and are welcome to similarly propose to list Tuesday and Thursday options on those indexes. To the extent that the addition of SPXW options that expire on Tuesdays and Thursdays available for trading on the Exchange makes the Exchange a more attractive marketplace to market participants at other exchanges, such market participants are free to elect to become market participants on the Exchange.

The proposed rule change to clarify the trading session referred to in Rule 4.13(e)(4) will not burden intramarket or intermarket competition because it is not intended to be a competitive rule change but instead is intended to add clarity to the Rules and conform the provision to the Rule that governs Exchange trading hours generally.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be 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–CBOE–2022–005 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–CBOE–2022–005. 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–CBOE–2022–005, and should be submitted on or before March 21, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–04082 Filed 2–25–22; 8:45 am]

BILLING CODE 8011–01–P

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–232, OMB Control No. 3235–0225]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 17f–4

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 350l–3520) (the ''Paperwork Reduction Act''), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Section 17(f) (15 U.S.C. 80a–17(f)) under the Investment Company Act of 1940 (the ''Act'')[1] permits registered management investment companies and their custodians to deposit the securities they own in a system for the central handling of securities (''securities depositories''), subject to rules adopted by the Commission.

Rule 17f–4 (17 CFR 270.17f–4) under the Act specifies the conditions for the use of securities depositories by funds[2] and their custodians.

The Commission staff estimates that 794 respondents (including an estimated 768 funds that may deal directly with a securities depository, an estimated 13 custodians, including 7 sub-custodians and 13 possible securities depositories)[3] are subject to

[1] 15 U.S.C. 80a.

[2] As amended in 2003, rule 17f–4 permits any registered investment company, including a unit investment trust or a face-amount certificate company, to use a security depository. *See,* Custody of Investment Company Assets With a Securities Depository, Investment Company Act Release No. 25934 (Feb. 13, 2003) (68 FR 8438 (Feb. 20, 2003)). The term ''fund'' or ''fund series'' is used in this Notice to mean a registered investment company.

[3] The Commission staff estimates that, as permitted by the rule, an estimated 4% of all active funds may deal directly with a securities depository instead of using an intermediary. The Commission estimates that, as permitted by the rule, an estimated 4% of all funds may deal directly with a securities depository. The number of custodians, including the number of sub-custodians is estimated from information collected from Form N–CENs filed with the Commission as of October 15, 2021. In addition, the Commission staff estimates the number of possible securities depositories by adding the 12 Federal Reserve Banks and one active registered clearing agency. The Commission staff recognizes that not all of these entities may currently be acting as a securities depository for fund securities.

the requirements in rule 17f–4. To the extent that Rule 17f–4(c)(4) provides that a sub-custodian can be qualified as a custodian for purposes of Rule 17f–4, sub-custodians are included as ''custodians'' in the estimates of burden hours and costs. While the rule is elective, but most, if not all, funds use depository custody arrangements.[4]

Rule 17f–4 contains two general conditions. First, a fund's custodian must be obligated, at a minimum, to exercise due care in accordance with reasonable commercial standards in discharging its duty as a securities intermediary to obtain and thereafter maintain financial assets. If the fund deals directly with a depository, the depository's contract or written rules for its participants must provide that the depository will meet similar obligations. All funds that deal directly with securities depositories in reliance on rule 17f–4 should have either modified their contracts with the relevant securities depository, or negotiated a modification in the securities depository's written rules when the rule was amended. Therefore, we estimate there is no ongoing burden associated with this collection of information.[5]

Second, the custodian must provide, promptly upon request by the fund, such reports as are available about the internal accounting controls and financial strength of the custodian. If a fund deals directly with a depository, the depository's contract with or written rules for its participants must provide that the depository will provide similar financial reports. Custodians and depositories usually transmit financial reports to funds twice each year.[6] The Commission staff estimates that 13 custodians, including 7 sub-custodians, spend approximately 2,330 hours (by support staff) annually in transmitting such reports to funds.[7] In addition, approximately 768 funds (*i.e.,* three percent of all funds) deal directly with a securities depository and may request periodic reports from their depository. Commission staff estimates that depositories spend approximately 179 hours (by support staff) annually transmitting reports to the 768 funds.[8] The total annual burden estimate for compliance with rule 17f–4's reporting requirement is therefore 2,509 hours.[9]

If a fund deals directly with a securities depository, rule 17f–4 requires that the fund implement internal control systems reasonably designed to prevent an unauthorized officer's instructions (by providing at least for the form, content, and means of giving, recording, and reviewing all officers' instructions). All funds that seek to rely on rule 17f–4 should have already implemented these internal control systems when the rule was amended. Therefore, there is no ongoing burden associated with this collection of information requirement.[10]

Based on the foregoing, the Commission staff estimates that the total annual hour burden of the rule's collection of information requirements is 2,509 hours.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act. This estimate is not derived from a comprehensive or even representative survey or study of the costs of Commission rules.

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 control number.

The public may view the background documentation for this information collection at the following website, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Lindsay.M.Abate@omb.eop.gov;* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John R. Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice March 30, 2022 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.

Dated: February 23, 2022.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2022–04171 Filed 2–25–22; 8:45 am]

BILLING CODE 8011–01–P

[4] Based on responses to Items C.12 of Form N–CEN (17 CFR 274.101), approximately 96 percent of funds' custodians maintain some or all fund securities in a securities depository pursuant to rule 17f–4.

[5] The Commission staff assumes that new funds relying on 17f–4 would choose to use a custodian instead of directly dealing with a securities depository because of the high costs associated with maintaining an account with a securities depository. Thus, new funds would not be subject to this condition.

[6] The estimated 13 custodians would handle requests for reports from 9,984 fund clients (approximately 768 fund clients per custodian) and the depositories from the remaining 768 funds that choose to deal directly with a depository. It is our understanding based on staff conversations with industry representatives that custodians and depositories transmit these reports to clients in the normal course of their activities as a good business practice regardless of whether they are requested. Therefore, for purposes of this PRA estimate, the Commission staff assumes that custodians transmit the reports to all fund clients.

[7] (9,984 fund clients × 2 reports) = 19,968 transmissions. The staff estimates that each transmission would take approximately 7 minutes for a total of approximately 2,330 hours (7 minutes × 19,968 transmissions).

[8] (768 fund clients who may deal directly with a securities depository × 2 reports) = 1,536 transmissions. The staff estimates that each transmission would take approximately 7 minutes for a total of approximately 179 hours (7 minutes × 1,536 transmissions).

[9] 2,230 hours for custodians and 179 hours for securities depositories.

[10] The Commission staff assumes that new funds relying on 17f–4 would choose to use a custodian instead of directly dealing with a securities depository because of the high costs associated with maintaining an account with a securities depository. Thus new funds would not be subject to this condition.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94297; File No. SR–NYSE–2022–09]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 1 To Replace References to Employees and Officers of Intercontinental Exchange Group, Inc.

February 22, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on February 14, 2022, New York Stock Exchange LLC (''NYSE'' 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 1 (''The Exchange'') to replace references to employees and officers of Intercontinental Exchange Group, Inc., the Exchange's indirect parent

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

company, with references to employees and officers of the Exchange. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 1 (''The Exchange'') to replace references to employees and officers of Intercontinental Exchange Group, Inc. (''ICE''), the Exchange's indirect parent company, with references to employees and officers of the Exchange.

Prior to 2013, NYSE Euronext was the ultimate parent company of the Exchange. At that time, Rule 1 referred to NYSE Euronext. In 2013, ICE (then called IntercontinentalExchange Group, Inc.) acquired NYSE Euronext and its subsidiaries, including the Exchange.[4] In connection with the acquisition, references to NYSE Euronext in Rule 1 were replaced wholesale with references to ICE.[5]

As a result of the changes, Rule 1 provides that, if the person named in a rule is not available, the chief executive officer (''CEO'') or chief regulatory officer (''CRO'') of the Exchange may designate one or more qualified employees of ICE to act in their place. Rule 1 goes on to state that, for purposes of a designation by the CEO, a qualified employee includes, among other things, any officer of ICE deemed by the CEO to possess the requisite knowledge and job qualifications.[6]

In practice, designations under Rule 1 are limited to Exchange employees and officers. To more accurately reflect actual practice, the Exchange proposes to replace the references to employees and officers of ICE in Rule 1 with references to employees and officers of the Exchange, as follows:

- In the first sentence of the third paragraph, ''Intercontinental Exchange Group, Inc. ('ICE')'' would be replaced with ''the Exchange''; and
- in clause (1) of the second sentence of the third paragraph, ''Exchange'' would be added before ''officer,'' and ''of ICE'' would be deleted.

The proposed changes would not result in any practical changes regarding which individuals would be eligible to perform the functions specified in Rule 1 and would not require the Exchange to change which individuals may currently performing these functions.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change would promote clarity and transparency in its rules. The Exchange believes that the change would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from the increased clarity and transparency that the change would introduce, thereby reducing potential confusion.

The Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest, because it would remove any potential confusion among market participants that may result if the Exchange retained references to ICE employees and ICE officers in Rule 1, adding clarity and transparency to Exchange rules. Moreover, the proposed change to the first prong of the definition of ''qualified employee'' for purposes of designation by the CEO would make it consistent with the first prong of the definition of ''qualified employee'' for purposes of designation by the CRO, reducing any potential confusion among market participants.

In practice, Exchange employees and officers, and not ICE employees and officers, are designated pursuant to Rule 1. The proposed changes would ensure that remained true, as under the changes only Exchange officers or Exchange employees could be qualified employees delegated authority by the CEO pursuant to Rule 1. For that reason, the Exchange believes that the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[9] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather serve to promote clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection. The proposed changes would be administrative and would apply only to the Exchange, and therefore would not impose any unnecessary competitive burden on third parties.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

[4] *See* Securities Exchange Act Release No. 70210 (August 15, 2013), 78 FR 51758 (August 21, 2013) (SR–NYSE–2013–42, SR–NYSEMKT–2013–50, and SR–NYSEArca–2013–62) (order granting approval of proposed rule change relating to a corporate transaction in which NYSE Euronext will become a wholly-owned subsidiary of IntercontinentalExchange Group, Inc.). *See also* Securities Exchange Act Release No. 72158 (May 13, 2014), 79 FR 28784 (May 19, 2014) (SR–NYSE–2014–23) (notice of filing and immediate effectiveness of proposed rule change relating to name changes of its ultimate parent, IntercontinentalExchange Group, Inc., and its indirect parents, IntercontinentalExchange, Inc. and NYSE Euronext Holdings LLC).

[5] *See* Exhibit 5K to SR–NYSE–2013–42 (June 14, 2013), at 276–278, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse/rule-filings/filings/2013/NYSE-2013-42.pdf.*

[6] Rule 1.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(8).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 [10] and Rule 19b–4(f)(6) [11] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will 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–NYSE–2022–09 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–NYSE–2022–09. 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–NYSE–2022–09 and should be submitted on or before March 21, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–04083 Filed 2–25–22; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 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.

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94293; File No. SR–Phlx–2022–07]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Strategy Caps for Reversal and Conversion and Jelly Roll Strategies

February 22, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on February 9, 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, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Phlx's Pricing Schedule at Options 7, Section 4, ''Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY).''

The Exchange originally filed the proposed pricing changes on February 1, 2022 (SR–PHLX–2022–06). On February 9, 2022, the Exchange withdrew that filing and submitted this filing.

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 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

Phlx proposes to amend its pricing within Options 7, Section 4, ''Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY).'' Specifically, Phlx proposes to amend the daily strategy

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

cap for reversal and conversion [4] and jelly roll [5] strategies.

Today, to qualify for a strategy cap, the buy and sell side of a transaction must originate either from the Exchange Trading Floor or as a Floor Qualified Contingent Cross Order.[6] Currently, the Exchange offers the following strategy caps:

Floor options transactions—multiply listed options	Strategy	Qualification	Daily/monthly cap
Lead Market Maker, Market Maker, Professional, Firm and Broker-Dealer.	dividend	executed on the same trading day in the same class of options when such members are trading: (1) In their own proprietary accounts; or (2) on an agency basis. If transacted on an agency basis, the daily cap will apply per beneficial account..	$1,100 (daily).
Lead Market Maker, Market Maker, Professional, Firm and Broker-Dealer.	reversal and conversion, merger, short stock interest, jelly roll, and box spread strategies.	executed on the same trading day for all classes of options in the aggregate when such members are trading (1) in their own proprietary accounts; or (2) on an agency basis. If transacted on an agency basis, the daily cap will apply per beneficial account..	$1,000 (daily) if more than one class of options, $700 (daily) if only in a single class of options.
Per member organization	dividend, merger, short stock interest, reversal and conversion, jelly roll and box spread strategies (''Monthly Strategy Cap'').	combined executions in a month when trading in its own proprietary accounts.	$65,000 (monthly).

The Exchange offers strategy caps for various types of strategies, including dividend,[7] merger,[8] short stock interest,[9] reversal and conversion, jelly roll, and box spread [10] strategies. Of note, NDX, NDXP, and XND Options Transactions are excluded from strategy cap pricing.

Specifically, today, the Exchange offers a reversal and conversion, merger, short stock interest, jelly roll and box spread strategy cap, which is applicable to Lead Market Makers,[11] Market Makers,[12] Professionals,[13] Firms [14] and Broker-Dealers,[15] of $1,000 (daily) if more than one class of options, and $700 (daily) if only in a single class of options.[16] The aforementioned strategy cap applies to reversal and conversion, merger, short stock interest, jelly roll and box spread strategies executed on the same trading day for all classes of options in the aggregate when such members are trading (1) in their own proprietary accounts; or (2) on an agency basis.[17]

The Exchange is proposing to lower the daily strategy cap for Lead Market Makers, Market Makers, Professionals, Firms and Broker-Dealers who execute reversal and conversion and jelly roll strategies on the same trading day. The Exchange proposes to cap reversal and conversion and jelly roll strategies for all classes of options in the aggregate when such members are trading (1) in their own proprietary accounts; or (2) on an agency basis at $200 daily. As is the case today, if transacted on an agency

[4] Reversal and conversion strategies are transactions that employ calls and puts of the same strike price and the underlying stock. Reversals are established by combining a short stock position with a short put and a long call position that shares the same strike and expiration. Conversions employ long positions in the underlying stock that accompany long puts and short calls sharing the same strike and expiration. *See* Options 7, Section 4.

[5] A jelly roll strategy is defined as transactions created by entering into two separate positions simultaneously. One position involves buying a put and selling a call with the same strike price and expiration. The second position involves selling a put and buying a call, with the same strike price, but with a different expiration from the first position. *See* Options 7, Section 4.

[6] *See* Phlx's Pricing Schedule at Options 7, Section 4. A Floor Qualified Contingent Cross Order is comprised of an originating order to buy or sell at least 1,000 contracts that is identified as being part of a qualified contingent trade coupled with a contra-side order or orders totaling an equal number of contracts. The term ''qualified contingent trade'' shall have the same meaning set forth in Options 3, Section 12(a)(3). *See* Options 8, Section 30(e).

[7] A dividend strategy is defined as transactions done to achieve a dividend arbitrage involving the purchase, sale and exercise of in-the-money options of the same class, executed the first business day prior to the date on which the underlying stock goes ex-dividend. *See* Options 7, Section 4.

[8] A merger strategy is defined as transactions done to achieve a merger arbitrage involving the purchase, sale and exercise of options of the same class and expiration date, executed the first business day prior to the date on which shareholders of record are required to elect their respective form of consideration, *i.e.,* cash or stock. *See* Options 7, Section 4.

[9] A short stock interest strategy is defined as transactions done to achieve a short stock interest arbitrage involving the purchase, sale and exercise of in-the-money options of the same class. *See* Options 7, Section 4.

[10] A box spread strategy is a strategy that synthesizes long and short stock positions to create a profit. Specifically, a long call and short put at one strike is combined with a short call and long put at a different strike to create synthetic long and synthetic short stock positions, respectively. *See* Options 7, Section 4.

[11] As provided in the Pricing Schedule within Options 7, Section 1(c), ''The term ''Lead Market Maker'' applies to transactions for the account of a Lead Market Maker (as defined in Options 2, Section 12(a)). A Lead Market Maker is an Exchange member who is registered as an options Lead Market Maker pursuant to Options 2, Section 12(a). An options Lead Market Maker includes a Remote Lead Market Maker which is defined as an options Lead Market Maker in one or more classes that does not have a physical presence on an Exchange floor and is approved by the Exchange pursuant to Options 2, Section 11.''

[12] As provided in the Pricing Schedule within Options 7, Section 1(c), ''The term ''Market Maker'' is defined in Options 1, Section 1(b)(28) as a member of the Exchange who is registered as an options Market Maker pursuant to Options 2, Section 12(a). A Market Maker includes SQTs and RSQTs as well as on and Floor Market Makers.''

[13] As provided in the Pricing Schedule within Options 7, Section 1(c), ''The term ''Professional'' applies to transactions for the accounts of Professionals, as defined in Options 1, Section 1(b)(45) means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s).''

[14] As provided in the Pricing Schedule within Options 7, Section 1(c), ''The term ''Firm'' applies to any transaction that is identified by a member or member organization for clearing in the Firm range at OCC.''

[15] As provided in the Pricing Schedule within Options 7, Section 1(c), ''The term ''Broker-Dealer'' applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category.''

[16] For example, if a Lead Market Maker executed reversal and conversion strategies only in AAPL options, and otherwise met the qualifications for a reversal and conversion cap, the proposed $700 daily cap would apply. If the Lead Market Maker executed reversal and conversion strategies in AAPL and SPY options, and otherwise met the qualifications for a reversal and conversion cap, the proposed $1,000 daily cap would apply.

[17] If transacted on an agency basis, the daily cap applies per beneficial account.

basis, the daily strategy cap would apply per beneficial account. The Exchange would not amend the current strategy caps for merger, short stock interest, and box spread strategies. The qualifications for the reversal and conversion and jelly roll strategy cap remains the same. Finally, the proposed daily strategy cap continues to apply to executions for all classes of options.

The Exchange believes that its proposal will incentivize members to transact a greater number of reversal and conversion and jelly roll strategies because the strategy cap would be lowered from $1,000/$700 daily (depending on the class of options) to $200 daily.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[18] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[19] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [20]

Likewise, in *NetCoalition* v. *Securities and Exchange Commission* [21] (''NetCoalition'') the D.C. Circuit upheld the Commission's use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.[22] As the court emphasized, the Commission ''intended in Regulation NMS that 'market forces, rather than regulatory requirements' play a role in determining the market data . . . to be made available to investors and at what cost.'' [23]

Further, ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . ..'' [24] Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

The Exchange's proposal to decrease the reversal and conversion and jelly roll strategy cap applicable to Lead Market Makers, Market Makers, Professionals, Firms and Broker-Dealers from $1,000/$700 daily (depending on the class of options) to $200 daily, with the same qualifications as today, is reasonable because it will incentivize Lead Market Makers, Market Makers, Professionals, Firms and Broker-Dealers to execute a greater number of reversal and conversion and jelly roll strategies for the opportunity to qualify for the lower daily strategy cap. Strategy fee caps defray brokerage costs associated with executing strategy transactions.

Today, NYSE Arca, Inc. (''NYSE Arca'') and NYSE American LLC (''NYSE American'') cap certain strategy fees as low as $200.[25] The Exchange believes that lowering the reversal and conversion and jelly roll strategy cap from $1,000/$700 daily (depending on the class of options) to $200 daily will allow the Exchange to more effectively compete with other options exchanges who offer lower strategy caps for these two particular strategies. The Exchange notes that reversal and conversion and jelly roll strategies are popular strategies that may be transacted by any Phlx member or member organization. To the extent that the proposed change attracts more reversal and conversion and jelly roll strategy executions to the Exchange, this increased (open outcry) order flow would continue to make the Exchange a more competitive venue for order execution. To the extent the proposed change continues to attract greater volume and liquidity, the Exchange believes the proposed change would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to effectively compete for strategy trades. Finally, the Exchange cannot predict with certainty whether any, or how many, Phlx members and member organizations would avail themselves of this proposed fee change. The Exchange believes that Phlx members and member organizations that execute reversal and conversion and jelly roll strategies on the Exchange can achieve the proposed daily cap of $200 and that this proposal may encourage Phlx members and member organizations to execute reversal and conversion and jelly roll strategies on the Exchange.

The Exchange's proposal to decrease the reversal and conversion and jelly roll strategy cap applicable to Lead Market Makers, Market Makers, Professionals, Firms and Broker-Dealers from $1,000/$700 daily (depending on the class of options) to $200 daily, with the same qualifications as today, is equitable and not unfairly discriminatory because all Lead Market Makers, Market Makers, Professionals, Firms and Broker-Dealers may qualify for the reversal and conversion and jelly roll strategy cap provided those strategies are executed on the same trading day for all classes of options in the aggregate when such members are trading either in their own proprietary accounts or on an agency basis. While Customers [26] are not offered strategy caps, Customers are not assessed Options Transaction Charges within Options 7, Section 4.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(4) and (5).

[20] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[21] *NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[22] *See NetCoalition,* at 534–535.

[23] *Id.* at 537.

[24] *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[25] NYSE Arca and NYSE American applies a strategy cap of $200 on transactions fees for qualifying strategies traded on the same trading day for those ATP Holders that trade at least 25,000 monthly billable contract sides in qualifying Strategy Executions. The strategies include: (a) Reversals and conversions, (b) box spreads, (c) short stock interest spreads, (d) merger spreads, and (e) jelly rolls.

[26] As provided in the Pricing Schedule within Options 7, Section 1(c), ''The term 'Customer' applies to any transaction that is identified by a member or member organization for clearing in the Customer range at The Options Clearing Corporation ('OCC') which is not for the account of a broker or dealer or for the account of a 'Professional' (as that term is defined in Options 1, Section 1(b)(45)).''

necessary or appropriate in furtherance of the purposes of the Act.

Inter-Market Competition

The proposal does not impose an undue burden on inter-market competition. The Exchange believes its proposal remains competitive with other options markets and will offer market participants with another choice of where to transact options. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Moreover, the proposal is designed to encourage Phlx members and member organizations to execute reversal and conversion and jelly roll strategies on the Exchange as a primary execution venue. To the extent that the proposed change attracts more reversal and conversion and jelly roll strategies to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution.

Intra-Market Competition

The proposed amendments do not impose an undue burden on intra-market competition.

The Exchange's proposal to decrease the reversal and conversion and jelly roll strategy cap applicable to Lead Market Makers, Market Makers, Professionals, Firms and Broker-Dealers from $1,000/$700 daily (depending on the class of options) to $200 daily, with the same qualifications as today, does not impose an undue burden on competition because all Lead Market Makers, Market Makers, Professionals, Firms and Broker-Dealers may qualify for the reversal and conversion and jelly roll strategy cap provided those strategies are executed on the same trading day for all classes of options in the aggregate when such members are trading either in their own proprietary accounts or on an agency basis. While Customers are not offered strategy caps, Customers are not assessed Options Transaction Charges within Options 7, Section 4.

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

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[27]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) 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–2022–07 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2022–07. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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–Phlx–2022–07, and should be submitted on or before March 21, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2022–04079 Filed 2–25–22; 8:45 am]

BILLING CODE 8011–01–P

[27] 15 U.S.C. 78s(b)(3)(A)(ii).

[28] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2022–0009]

Agency Information Collection Activities: New Emergency Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes a new, emergency information collection.

SSA is asking OMB for approval of this information collection fourteen days after the date of publication of this **Federal Register** Notice, independent of public comment, due to its emergency nature. However, we still welcome comment on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. We will consider any comments when

we ultimately extend this information collection beyond the standard six-month emergency approval. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA.

Comments: https://www.reginfo.gov/public/do/PRAMain. Submit your comments online referencing Docket ID Number [SSA–2022–0009].

(SSA) Social Security Administration, OLCA, Attn: Director, Office of Regulations and Reports Clearance, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov*.

Or you may submit your comments online through *https://www.reginfo.gov/public/do/PRAMain,* referencing Docket ID Number [SSA–2022–0009]. We recommend submitting comments via this link as the fastest way for them to reach us.

SSA is submitting the information collection below to OMB for clearance. If you wish to submit comments, we recommend you do so no later than March 30, 2022. However, please be aware that due to the emergency nature of this collection, SSA will be seeking OMB clearance in advance of this date. Individuals may obtain copies of this OMB clearance package by writing to *OR.Reports.Clearance@ssa.gov.*

Electronic Protective Filing Tool—20 CFR 404.630, and 20 CFR 416.340–416.345—0960–NEW.

The COVID–19 pandemic limited the public's access to Social Security Administration (SSA) Field Offices (FOs), requiring SSA to rapidly modernize and improve online services available to the public. Since the beginning of the pandemic, underserved populations who have historically relied on in-office appointments and service decreased their submissions of Supplemental Security Income (SSI) claims. SSA uses the term ''People facing barriers'' to refer to these vulnerable populations, which include low-income individuals (especially those over age 65), the homeless, people with limited English proficiency, and disabled children.

Background

Historically, individuals contact SSA by phone, in person, or by mail to express interest in filing for benefits. Because same-day service to file an application is not always possible or individuals prefer to have an appointment, SSA technicians use eLAS (OMB No. 0960–0822) to set up appointments and record the protective filing date for potential claimants. This process ensures that potential claimants do not miss out on possible benefits due to the lack of same-day service.

Protective filing is the precursor to filing an application for benefits. Protective filing refers to the date by which SSA receives an individual's intent to file for Social Security benefits, Medicare Part A (Health Insurance), or SSI payments, which SSA then uses as the application date provided the individual files an application within a specific amount of time after that date. For instance, if an individual files an application for SSI payments within 60 days of the protective filing date, or an application for Social Security benefits within 6 months of the protective filing date, SSA uses the protective filing date as the application filing date. Thus, it is as if the application was filed on the day the individual contacted SSA to express interest in filing, which often results in SSA processing the application faster for that individual.

SSA developed an online tool to allow internet users to request an appointment to file an application for benefits and to establish a protective filing date with SSA. The electronic protective filing tool will allow individuals to submit information for the appointment request using a computing device, such as a personal computer or handheld (mobile) device instead of calling SSA by phone or visiting an FO. The tool will be available to potential claimants, as well as those individuals assisting them.

Information the Electronic Protective Filing Tool Will Collect

After entering the tool from a landing page, individuals begin on a welcome screen with a link to the Terms of Service and a link to the Privacy Act statement. Following review of the information on the welcome screen, the system will ask the individual to tell us whether they are answering these questions about themselves, or about another person. To do so, the system will present several options for individual to select from the categories of individuals who, under current regulations, can establish a protective filing date. The next screens ask for basic information about the individual who will be claiming benefits, or requesting SSI payments. Additionally, the tool will collect the name, phone number, and email address (optional) of the person submitting the information, if that person is different than the person who will be claiming benefits or SSI payments.

Once the system collects the data, it gives the individual the opportunity to review the information provided and electronically sign and submit the form. The system then transmits the information into eLAS and establishes a protective filing date. In addition, if the individual provided an email address(es), the electronic protective filing tool generates an email confirmation and sends it to the individual who will be claiming benefits or requesting SSI payments, and, if applicable, to the individuals submitting the appointment request on the claimant's behalf.

Subsequently, eLAS will notify SSA of the pending request, and an SSA technician will use the information submitted to schedule an appointment and send a notification of the date, time, and type of appointment to the individual who will be claiming benefits.

Need for Information Collection; Collection Methodology; How Information Will Be Used

To bridge the gap in services available to people facing barriers, SSA created a new online electronic protective filing tool that will allow individuals to request an appointment to file their application thereby establishing a protective filing date.

SSA will inform the public of the availability of the tool through various public outreach campaigns. Individuals will access the tool online through SSA's website, *SSA.gov*. The tool will allow individuals to submit basic information for the appointment request using a computing device, such as a personal computer or handheld (mobile) device instead of calling SSA by phone or visiting an FO. The electronic protective filing tool will be available to potential claimants, as well as those individuals assisting them.

Once the individual submits the requested information, the system will transmit the information into eLAS to document the protective filing date, and an SSA technician will schedule an appointment for an application interview.

The respondents are individuals requesting an appointment with an intent to file for Social Security benefits, Medicare Part A (Health Insurance), or SSI payments, or other third-party individuals helping claimants with the filing process.

Alternatives to Completing the Information Collection

Members of the public who prefer not to use the online version of this IC, or who do not have access to the internet, may continue to visit an FO, call SSA's 800 Number (or an FO), or write to SSA to establish a protective filing date for an application for benefits.

Need for Emergency Paperwork Reduction Act Approval

Based on the unexpected decrease in SSI claim submissions, mostly from people facing barriers, SSA is concerned this population needs more options and flexibility to help them apply for SSI. Our goal in developing this new SSI claims tool is to offer that flexibility, and to make it as easy as possible to complete the process. We are seeking emergency PRA approval because it is important to us to start offering this new tool to everyone, particularly underserved populations, as soon as we can. An emergency PRA approval would facilitate rapid rollout of the tool, and would mitigate the delay inherent in the extensive time period of the standard OMB approval cycle.

Type of Request: New (emergency) information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Respondent Type 1 (ex: Potential Applicants)	17,000	1	6	1,700	* $27.07	** $46,019
Respondent Type 2 (ex: Professional Assistors)	2,125	10	7	2,479	* 25.09	** 62,198
Respondent Type 3 (ex: Attorney Representatives)	2,125	2	7	496	* 71.59	** 35,509
Totals	21,250			4,675		** 143,726

* We based this figure on the average U.S. worker's hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm#00-0000*), on average wages for Community and Social Service Organizations as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes210000.htm*), and on average lawyer's hourly salary as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes231011.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this online tool; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the tool. *There is no actual charge to respondents to complete the online tool.*

Dated: February 24, 2022.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2022–04301 Filed 2–25–22; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 11665]

Notice of Shipping Coordinating Committee Meeting in Preparation for International Maritime Organization LEG 109 Meeting

The Department of State will conduct a public meeting at 1:00 p.m. on Tuesday, March 15, 2022, by way of teleconference. The primary purpose of the meeting is to prepare for the 109th session of the International Maritime Organization's (IMO) Legal Committee (LEG 109) to be held remotely from March 21 to March 25, 2022.

Members of the public may participate up to the capacity of the teleconference phone line, which can handle 500 participants. To RSVP, participants should contact the meeting coordinator, Mr. Stephen Hubchen, by email at *Stephen.K.Hubchen@uscg.mil.* To access the teleconference line, participants should call (202) 475–4000 and use Participant Code: 877 239 87#.

The agenda items to be considered at this meeting mirror those to be considered at LEG 109, and include:

—Adoption of the agenda
—Report of the Secretary-General on credentials
—Facilitation of the entry into force and harmonized interpretation of the 2010 HNS Protocol
—Fair treatment of seafarers:
(a) Provision of financial security in case of abandonment of seafarers, and shipowners' responsibilities in respect of contractual claims for personal injury to, or death of, seafarers, in light of the progress of amendments to the ILO Maritime Labour Convention, 2006
(b) Fair treatment of seafarers in the event of a maritime accident
(c) Fair treatment of seafarers detained on suspicion of committing maritime crimes
(d) Guidelines for port State and flag State authorities on how to deal with seafarer abandonment cases
—Advice and guidance in connection with the implementation of IMO instruments
—Measures to prevent unlawful practices associated with the fraudulent registration and fraudulent registries of ships
—Measures to assess the need to amend liability limits
—Claims Manual for the International Convention on Civil Liability for Bunker Oil Pollution Damage, 2001
—Piracy and armed robbery against ships
—Work of other IMO bodies
—Technical cooperation activities related to maritime legislation
—Review of the status of conventions and other treaty instruments emanating from the Legal Committee
—Work programme
—Election of officers
—Any other business
—Consideration of the report of the Committee on its 109th session

Please note: The IMO may, on short notice, adjust the LEG 109 agenda to accommodate the constraints associated with the virtual meeting format. Any changes to the agenda will be reported to those who RSVP.

Those who plan to participate may contact the meeting coordinator, Mr. Stephen Hubchen, by email at *Stephen.K.Hubchen@uscg.mil,* by phone at (202) 372–1198, or in writing at United States Coast Guard (CG–LMI–P), ATTN: Mr. Stephen Hubchen, 2703 Martin Luther King Jr. Ave. SE, Stop 7509, Washington, DC 20593–7509. Members of the public needing reasonable accommodation should advise Mr. Hubchen not later than March 8, 2022. Requests made after that

date will be considered, but might not be possible to fulfill.

Additional information regarding this and other IMO public meetings may be found at: *https://www.dco.uscg.mil/IMO.*

(Authority: 22 U.S.C. 2656 and 5 U.S.C. 552)

Emily A. Rose,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2022–04177 Filed 2–25–22; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice: 11670]

International Seabed Authority

ACTION: Notice of public meeting

SUMMARY: The Department of State will hold a public meeting to prepare for the meeting of the International Seabed Authority (ISA) Council to be held at ISA Headquarters, Kingston, Jamaica, from March 21–April 1, 2022.

DATES: The public meeting will be held via WebEx on March 16, 2022, 3 p.m.–4 p.m. Eastern Standard Time

FOR FURTHER INFORMATION CONTACT: If you would like to participate in this meeting, please send your (1) name, (2) organization/affiliation, and (3) email address and phone number, to Greg O'Brien at *OBrienGJ@state.gov.*

SUPPLEMENTARY INFORMATION: The Department of State will hold a public meeting at 3 p.m. EST on Wednesday, March 16, 2022, to prepare for the first part of the twenty-seventh session of the ISA Council. This public meeting will be held by way of WebEx, with a capacity of up to 1000 members of the public to participate. To RSVP, participants should contact the meeting coordinator, Greg O'Brien, by email at *OBrienGJ@state.gov* for log on and dial-in information, and to request reasonable accommodation. Requests for reasonable accommodation received after March 11, 2022, will be considered but might not be possible to fulfill.

The ISA Council will convene the first part of its twenty-seventh session on March 21–April 1, 2022, at ISA Headquarters in Kingston, Jamaica. The agenda for this session includes the Draft regulations on exploitation of mineral resources in the Area. Additional information on the ISA is available at *www.isa.org.jm.*

We are inviting interested stakeholders to this virtual public meeting to share views about this session of the ISA Council, in particular to provide information to assist the U.S. Government in developing its positions. We will provide a brief overview of the upcoming session and listen to the viewpoints of U.S. stakeholders. Comments are particularly welcome on the Facilitator's text on Part IV and VI of the Draft regulations concerning protection and preservation of the marine environment and plans for closing a seabed mining area; the Facilitator's text draws on textual proposals from ISA delegations and various proposals of the Legal and Technical Commission. The Facilitator's text is document ISBA/27/C/IWG/ENV/CRP.1 and can be accessed at: *https://isa.org.jm/node/20859.* The information obtained from this session will help the U.S. observer delegation prepare for participation in the first part of the twenty-seventh session of the ISA Council.

Gregory J. O'Brien,

Acting Deputy Director, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2022–04295 Filed 2–25–22; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice 11663]

Clean Energy Resources Advisory Committee

ACTION: Announcement of meeting.

SUMMARY: The Department of State will host a virtual, open meeting of the Clean Energy Resources Advisory Committee (CERAC). There will not be an in-person option for this meeting.

DATES:

Date and Time: CERAC will meet virtually March 15, 2022 from 11:00 to 12:30 (EST).

Participation: Members of the public wishing to participate must RSVP by March 8, 2022 via email to *CERAC@state.gov* (subject line: RSVP). The Department will provide login information prior to the meeting. Requests for reasonable accommodation should be submitted no later than March 8, 2022. Reasonable accommodation requests received after that date will be considered, but may not be possible to fulfill.

FOR FURTHER INFORMATION CONTACT: Bureau of Energy Resources Senior Energy Officer Sara Ferchichi at *CERAC@state.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: This Committee will provide input and advice regarding energy minerals and metals, their supply chains, and end uses. The purpose of this inaugural meeting is to provide introductions and discuss priorities for the Committee moving forward.

Statements: Comments should be emailed to *CERAC@state.gov* with ''PUBLIC COMMENT'' as the subject line at least 48 hours before the start of the meeting. During this meeting, there will not be an option for members of the public to make oral statements.

Zachary A. Parker,

Director, Office of Directives Management, U.S. Department of State.

[FR Doc. 2022–04091 Filed 2–25–22; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF STATE

[Public Notice: 11647]

National Action Plan on Responsible Business Conduct: Notice of Opportunity To Submit Written Comments

SUMMARY: On June 16, 2021, Secretary of State Antony Blinken announced on behalf of the Biden-Harris Administration that the Department will soon begin updating and revitalizing the United States' National Action Plan on Responsible Business Conduct (NAP RBC) for U.S. businesses operating and investing abroad. This notice provides background and welcomes written comments concerning this initiative for U.S. Government agencies to take into account in developing the updated NAP RBC. Comments may concern issues addressed in the prior (2016) NAP RBC or other issues suggested as priorities.

DATES: Comments must be received May 31, 2022. Logistics for submitting comments are described below.

ADDRESSES: You may submit comments by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal eRulemaking Portal.

1. Go to *www.regulations.gov/#DOS–2022–0002*.

2. Click the ''Comment Now!'' icon and complete the required fields; and

3. Enter or attach your comments.

- *Mail:* Submit written comments to: ATTN: RBC–NAP, U.S. Department of State, Washington, DC 20520, 2201 C St. NW, Washington, DC 20520, Office of Investment Affairs (EB/IFD/OIA), Room 4669.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information

(*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. We will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

SUPPLEMENTARY INFORMATION: The Administration is updating the NAP RBC to show how the U.S. Government encourages businesses to achieve high standards of responsible business conduct and champions U.S. businesses that demonstrate best practices in that regard. It will also highlight what the U.S. Government is doing, including with partners, to encourage responsible business conduct by U.S. businesses operating and investing abroad.

The Department of State is leading the update of the NAP RBC in coordination with the White House and other federal agencies. The process will involve U.S. private sector, civil society, and workers' organizations, and will serve to promote RBC by U.S. businesses operating and investing abroad. The last National Action Plan—the U.S. Government's first—was published on December 16, 2016. (See 2016 National Action Plan on Responsible Business Conduct here: *https://2009-2017.state.gov/e/eb/eppd/csr/naprbc/265706.htm*).

RBC is a broad concept based on growing evidence that businesses can perform well while doing good, and that governments should create and facilitate the conditions for this to take place. The principles underlying this concept are encompassed in the UN Guiding Principles on Business and Human Rights and the OECD Guidelines for Multinational Enterprises. They place importance on three aspects of the business-society relationship:

- Emphasizing and accentuating the positive contributions businesses can make to economic, environmental, and social progress.
- Committing to robust due diligence efforts, including identifying and mitigating adverse impacts of business conduct, and remedying abuses where they occur.
- Ensuring businesses are aware of and complying with legal obligations within their supply chains both at home and overseas.

We are updating the NAP in light of the U.S. Government's commitment to promoting fair play, the rule of law, and high standards for global commerce in line with democratic values and responsible business conduct. This includes supporting a foreign policy that benefits the middle class by ensuring workers' rights and a level playing field for American workers; protecting the environment; combating the climate crisis; promoting rights-respecting technology deployment; and helping U.S. businesses to be global leaders in promoting respect for human rights and responsible business conduct in the communities where they operate.

The revitalized NAP will build upon the previous framework. We are committed to coordinating and advancing policies that promote responsible business conduct by U.S. businesses operating and investing abroad, and work with all stakeholders to reach our joint goals.

Further information, including Frequently Asked Questions, is available on the following website: *https://www.state.gov/responsible-business-conduct-national-action-plan/.*

For questions concerning this notice, contact the State Department's NAP RBC team at *RBCNAP@state.gov.*

(Authority: 22 U.S.C. 2656)

Zachary A. Parker,

Director, Office of Directives Management, U.S. Department of State.

[FR Doc. 2022–04178 Filed 2–25–22; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2020–0144]

[Hours of Service of Drivers: Mountain Blade Runner Helicopters, LLC (MBR Helicopters); Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition; denial of application for exemption.

SUMMARY: FMCSA announces its decision to deny the exemption request from Mountain Blade Runner Helicopters, LLC (MBR Helicopters) for an exemption from the hours-of-service (HOS) regulations for operators of its ground support equipment. MBR Helicopters requested relief from the 14-hour ''driving window'' rule and the requirement that drivers have 10 consecutive hours off duty at the end of the work shift. The exemption would allow drivers of MBR Helicopters' ground support equipment a 16-hour window to complete all driving and enable them to use an 8-consecutive hour off-duty break, combined with at least 2 additional off-duty hours during the 16-hour driving window. FMCSA analyzed the exemption application and public comments, and determined that the application lacked evidence that the exemption would ensure a level of safety equivalent to or greater than that which would be achieved absent such exemption.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Clemente, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; (202) 366–2722; *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *www.regulations.gov* and insert the docket number, FMCSA–2020–0144 in the ''Keyword'' box and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or

class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Current Regulations

Under 49 CFR 395.3(a)(1), a driver may not drive without first taking 10 consecutive hours off duty, and 49 CFR 395.3(a)(2) permits a driver to drive only during a period of 14 consecutive hours after coming on duty following 10 consecutive hours off duty. The driver may not drive after the end of the 14-consecutive-hour period, without first taking 10 consecutive hours off duty.

IV. Request for Exemption

MBR Helicopters requested relief from the 14-hour ''driving window'' rule and the requirement that drivers have 10 consecutive hours off duty at the end of the work shift. The requested exemption would allow drivers of MBR Helicopters' ground support equipment a 16-hour window within which to complete all driving and enable them to use an 8-consecutive hour off-duty break, combined with at least 2 additional off-duty hours during the 16-hour driving window.

MBR Helicopters has been serving the utility helicopter industry and its customers since 2008 in the State of Colorado and across the United States. MBR Helicopters requested this exemption for approximately 10 of its drivers of ground support commercial motor vehicles (CMVs), all of whom possess commercial driver licenses (CDLs) with applicable endorsements. MBR Helicopters currently operates a fleet of Class 5 straight trucks and pickup trucks that pull trailers. Drivers of ground support equipment are specially trained to refuel, rig, reload, and maintain helicopters. They also operate CMVs transporting helicopter fuel that requires a CDL with a hazardous materials and tank endorsement.

The driver of an MBR Helicopters ground-support CMV typically drives an average of 60 miles one way to a remote landing zone, arrives at dawn, performs duties during the day, drives back to an airport to refill the tank with helicopter fuel, then drives back to the place of lodging near dusk. During the day, ground crew members have relatively few duties, allowing 2 or more hours off duty between tasks. This schedule varies greatly depending on customer needs. In general, however, when not responding to or returning from incidents, work days usually last about 8 to 10 hours, including all on-duty and driving time.

MBR Helicopters' contracts with government agencies specify that its maintenance personnel must be available for a maximum of 14 hours, and that maintenance personnel may extend their duty day to 16 hours. The ground crews travel between the helicopter base and the place of lodging, thus making it difficult to stay within the 14-hour limit because of travel before and after the work day.

V. Method To Ensure an Equivalent or Greater Level of Safety

To ensure an equivalent level of safety, MBR Helicopters proposed the following conditions and alternative HOS provisions:

- MBR Helicopters' drivers would, on average, use the exemption once every 2 weeks during the months of April through October;
- MBR Helicopters' drivers would not drive after the 16th hour after coming on duty;
- MBR Helicopters' drivers would take 8 hours consecutively off duty before coming on duty again;
- MBR Helicopters' drivers must have at least 2 hours off duty during the16-hour period; and
- MBR Helicopters' drivers must be responding to or returning from an active incident as requested by an officer of a public agency or public utility.

MBR Helicopters stated that these conditions and alternatives are designed to keep the drivers using the potential exemption from driving fatigued. MBR Helicopters added that these conditions would ensure that the drivers authorized to use this exemption have guidelines that would enable them to use it only when necessary.

VI. Public Comments

On December 18, 2020, FMCSA published notice of the MBR Helicopters application and requested public comment (85 FR 82574). The Agency received two comments, both opposing the exemption request. The Commercial Vehicle Safety Alliance stated the following:

> In MBR Helicopters' request they fail to adequately identify how their drivers will maintain an equivalent level of safety while operating under extended hours-of-service requirements, which is a key component to a credible exemption request. Granting this request would extend the amount of time drivers can operate, exposing them to higher risk for fatigue and negatively impacting safety. Under extenuating emergency circumstances, emergency declarations are issued that waive the hours-of-service requirements for drivers responding to the emergency. Emergency declarations exist for the exact reasons outlined in the exemption request, to allow for operation beyond the current hours-of-service framework when there is an emergency that requires an expedited response. Short of an emergency declaration, there isn't a reasonable need for relaxation of the hours-of-service requirements to the level requested in this application. FMCSA should deny the exemption request.

Mr. Michael Millard added:

> When working wildfires and other emergency activities MBR has the use of Part 390.23 as applicable to work the emergency based on its safety protocols. MBR doesn't specify whether or not the eight-hour break includes a commute time to and from work which makes the eight hours more like six hours or less. I hope the FMCSA denies MBR's request. If eight hours were suitable for drivers to get adequate rest, then the Federal Motor Carrier Safety Regulations should be revised to accommodate the trucking industry.

VII. FMCSA Safety Analysis and Decision

When the Agency established the HOS rules, it relied upon research indicating that the requirements improve CMV safety. The HOS regulations provide a 14-hour window within which all driving must be completed and, with the exception of the adverse driving clause dna the sleeper berth provision, all drivers subject to the HOS requirements must adhere to this restriction which helps to ensure that drivers remain alert during the work shift. In addition, the current regulations require that drivers of property-carrying vehicles have 10 consecutive hours off duty at the end of the work shift to ensure adequate opportunities for recuperative rest prior to the beginning of the next work shift.

The exemption application does not provide sufficient countermeasures to enable the Agency to conclude that the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with the current regulations. There is no basis to conclude that extending the 14-hour ''driving window'' for the applicant would ensure the requisite level of safety or that decreasing the mandatory off-duty period would provide drivers with a sufficient amount of rest.

FMCSA has reviewed MBR's application and the public comments and has concluded that the requisite level of safety cannot be ensured, for the reasons discussed above. Accordingly,

FMCSA denies the request for an exemption.

Robin Hutcheson,

Acting Administrator.

[FR Doc. 2022–04073 Filed 2–25–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Bond Guarantee Program, Fiscal Year 2022; Guarantee Availability

Funding Opportunites: Bond Guarantee Program, FY 2022; Notice of Guarantee Availability.

Funding Opportunity Title: Notice of Guarantee Availability (NOGA) inviting Qualified Issuer Applications and Guarantee Applications for the Community Development Financial Institutions (CDFI) Bond Guarantee Program.

Announcement Type: Announcement of opportunity to submit Qualified Issuer Applications and Guarantee Applications.

Catalog of Federal Domestic Assistance (CFDA) Number: 21.011.

Dates: Qualified Issuer Applications and Guarantee Applications may be submitted to the CDFI Fund starting on the date of publication of this NOGA. In order to be considered for the approval of a Guarantee in fiscal year (FY) 2022, Qualified Issuer Applications must be submitted by 11:59 p.m. Eastern Time (ET) on April 20, 2022 and Guarantee Applications must be submitted by 11:59 p.m. ET on April 26, 2022. If applicable, CDFI Certification Applications must be received by the CDFI Fund by 11:59 p.m. ET on March 28, 2022. Under FY 2022 authority, Bond Documents and Bond Loan documents must be executed, and Guarantees will be provided, in the order in which Guarantee Applications are approved or by such other criteria that the CDFI Fund may establish, in its sole discretion, and in any event by December 31, 2022.

Executive Summary: This NOGA is published in connection with the CDFI Bond Guarantee Program, administered by the Community Development Financial Institutions Fund (CDFI Fund), the U.S. Department of the Treasury (Treasury). Through this NOGA, the CDFI Fund announces the availability of up to $500 million of Guarantee Authority in FY 2022. This NOGA explains application submission and evaluation requirements and processes, and provides agency contacts and information on CDFI Bond Guarantee Program outreach. Parties interested in being approved for a Guarantee under the CDFI Bond Guarantee Program must submit Qualified Issuer Applications and Guarantee Applications for consideration in accordance with this NOGA. Capitalized terms used in this NOGA and not defined elsewhere are defined in the CDFI Bond Guarantee Program regulations (12 CFR 1808.102) and the CDFI Program regulations (12 CFR 1805.104).

I. Guarantee Opportunity Description

A. Authority. The CDFI Bond Guarantee Program was authorized by the Small Business Jobs Act of 2010 (Pub. L. 111–240; 12 U.S.C. 4713a) (the Act). Section 1134 of the Act amended the Riegle Community Development and Regulatory Improvement Act of 1994 (12 U.S.C. 4701, *et seq.*) to provide authority to the Secretary of the Treasury (Secretary) to establish and administer the CDFI Bond Guarantee Program.

B. Bond Issue size; Amount of Guarantee authority. In FY 2022, the Secretary may guarantee Bond Issues having a minimum Guarantee of $100 million each, and up to an aggregate total of $500 million, or other amounts authorized by FY 2022 Appropriations.

C. Program summary. The purpose of the CDFI Bond Guarantee Program is to support CDFI lending by providing Guarantees for Bonds issued for Eligible Community or Economic Development Purposes, as authorized by section 1134 and 1703 of the Act. The Secretary, as the Guarantor of the Bonds, will provide a 100% Guarantee for the repayment of the Verifiable Losses of Principal, Interest, and Call Premium of Bonds issued by Qualified Issuers. Qualified Issuers, approved by the CDFI Fund, will issue Bonds that will be purchased by the Federal Financing Bank. The Qualified Issuer will use 100% of Bond Proceeds to provide Bond Loans to Eligible CDFIs, which will use Bond Loan proceeds for Eligible Community and Economic Development Purposes, including providing Secondary Loans to Secondary Borrowers in accordance with the Secondary Loan Requirements. Secondary Loans may support lending in the following asset classes: CDFI-to-CDFI, CDFI to Financing Entity, Charter Schools, Commercial Real Estate, Daycare Centers, Healthcare Facilities, Rental Housing, Rural Infrastructure, Owner-Occupied Home Mortgages, Licensed Senior Living and Long-Term Care Facilities, Small Business, and Not-for-Profit Organizations, as these terms are defined in the Secondary Loan Requirements (Underwriting Review Checklist), which can be found on the CDFI Fund's website at *www.cdfifund.gov/bond.*

D. Review Guarantee Applications, in general.

1. Qualified Issuer Applications submitted with Guarantee Applications will have priority for review over Qualified Issuer Applications submitted without Guarantee Applications. With the exception of the aforementioned prioritized review, all Qualified Issuer Applications and Guarantee Applications will be reviewed by the CDFI Fund on an ongoing basis, in the order in which they are received, or by such other criteria that the CDFI Fund may establish in its sole discretion.

2. Guarantee Applications that are incomplete or require the CDFI Fund to request additional or clarifying information may delay the ability of the CDFI Fund to move the Guarantee Application to the next phase of review. Submitting an incomplete Guarantee Application earlier than other applicants does not ensure first approval.

3. Qualified Issuer Applications and Guarantee Applications that were received in FY 2021 and that were neither withdrawn nor declined in FY 2021 will be considered under FY 2022 authority.

4. Pursuant to the Regulations at 12 CFR 1808.504(c), the Guarantor may limit the number of Guarantees issued per year or the number of Guarantee Applications accepted to ensure that a sufficient examination of Guarantee Applications is conducted.

E. Additional reference documents. In addition to this NOGA, the CDFI Fund encourages interested parties to review the following documents, which have been posted on the CDFI Bond Guarantee Program page of the CDFI Fund's website at *http://www.cdfifund.gov/bond.*

1. Guarantee Program Regulations. The regulations that govern the CDFI Bond Guarantee Program were published on February 5, 2013 (78 FR 8296; 12 CFR part 1808) (the Regulations), and provide the regulatory requirements and parameters for CDFI Bond Guarantee Program implementation and administration including general provisions, eligibility, eligible activities, applications for Guarantee and Qualified Issuer, evaluation and selection, terms and conditions of the Guarantee, Bonds, Bond Loans, and Secondary Loans.

2. Application materials. Details regarding Qualified Issuer Application and Guarantee Application content requirements are found in this NOGA and the respective application materials.

Interested parties should review the template Bond Documents and Bond Loan documents that will be used in connection with each Guarantee. The template documents are posted on the CDFI Fund's website for review. Such documents include, among others:

a. The Secondary Loan Requirements, which contain the minimum required criteria (in addition to the Eligible CDFI's underwriting criteria) for a loan to be accepted as a Secondary Loan or Other Pledged Loan. The Secondary Loan Requirements include the General Requirements and the Underwriting Review Checklist;

b. The Agreement to Guarantee, which describes the roles and responsibilities of the Qualified Issuer, will be signed by the Qualified Issuer and the Guarantor, and will include term sheets as exhibits that will be signed by each individual Eligible CDFI;

c. The Term Sheet(s), which describe the material terms and conditions of the Bond Loan from the Qualified Issuer to the Eligible CDFI. The CDFI Fund website includes template term sheets for the General Recourse Structure (GRS), the Alternative Financial Structure (AFS), and for the CDFI to Financing Entity Asset Class utilizing pooled tertiary loans;

d. The Bond Trust Indenture, which describes the responsibilities of the Master Servicer/Trustee in overseeing the Trust Estate and the servicing of the Bonds, which will be entered into by the Qualified Issuer and the Master Servicer/Trustee;

e. The Bond Loan Agreement, which describes the terms and conditions of Bond Loans, and will be entered into by the Qualified Issuer and each Eligible CDFI that receives a Bond Loan;

f. The Bond Purchase Agreement, which describes the terms and conditions under which the Bond Purchaser will purchase the Bonds issued by the Qualified Issuer, and will be signed by the Bond Purchaser, the Qualified Issuer, the Guarantor and the CDFI Fund; and

g. The Future Advance Promissory Bond, which will be signed by the Qualified Issuer as its promise to repay the Bond Purchaser. The template documents may be updated periodically, as needed, and will be tailored, as appropriate, to the terms and conditions of a particular Bond, Bond Loan, and Guarantee. Additionally, the CDFI Fund may impose terms and conditions that address risks unique to the Eligible CDFI's business model and target market, which may include items such as concentration risk of a specific Eligible CDFI, geography or Secondary Borrower.

The Bond Documents and the Bond Loan documents reflect the terms and conditions of the CDFI Bond Guarantee Program and will not be substantially revised or negotiated prior to execution.

F. Frequently Asked Questions. The CDFI Fund may periodically post on its website responses to questions that are asked by parties interested in applying to the CDFI Bond Guarantee Program.

G. Designated Bonding Authority. The CDFI Fund has determined that, for purposes of this NOGA, it will not solicit applications from entities seeking to serve as a Qualified Issuer in the role of the Designated Bonding Authority, pursuant to 12 CFR 1808.201, in FY 2022.

H. Noncompetitive process. The CDFI Bond Guarantee Program is a non-competitive program through which Qualified Issuer Applications and Guarantee Applications will undergo a merit-based evaluation (meaning, applications will not be scored against each other in a competitive manner in which higher ranked applicants are favored over lower ranked applicants).

I. Relationship to other CDFI Fund programs.

1. Award funds received under any other CDFI Fund Program cannot be used by any participant, including Qualified Issuers, Eligible CDFIs, and Secondary Borrowers, to pay principal, interest, fees, administrative costs, or issuance costs (including Bond Issuance Fees) related to the CDFI Bond Guarantee Program, or to fund the Risk-Share Pool for a Bond Issue.

2. Bond Proceeds may not be used to refinance any projects financed and/or supported with proceeds from the Capital Magnet Fund (CMF).

3. Bond Proceeds may not be used to refinance a leveraged loan during the seven-year NMTC compliance period. However, Bond Proceeds may be used to refinance a QLICI after the seven-year NMTC compliance period has ended, so long as all other programmatic requirements are met.

4. The terms Qualified Equity Investment, Community Development Entity, and QLICI are defined in the NMTC Program's authorizing statute, 26 U.S.C. 45D.

J. Relationship and interplay with other Federal programs and Federal funding. Eligible CDFIs may not use Bond Loans to refinance existing Federal debt or to service debt from other Federal credit programs.

1. The CDFI Bond Guarantee Program underwriting process will include a comprehensive review of the Eligible CDFI's concentration of sources of funds available for debt service, including the concentration of sources from other Federal programs and level of reliance on said sources, to determine the Eligible CDFI's ability to service the additional debt.

2. In the event that the Eligible CDFI proposes to use other Federal funds to service Bond Loan debt or as a Credit Enhancement for Secondary Loans, the CDFI Fund may require, in its sole discretion, that the Eligible CDFI provide written assurance from such other Federal program in a form that is acceptable to the CDFI Fund and that the CDFI Fund may rely upon, that said use is permissible.

K. Contemporaneous application submission. Qualified Issuer Applications may be submitted contemporaneously with Guarantee Applications; however, the CDFI Fund will review an entity's Qualified Issuer Application and make its Qualified Issuer determination prior to approving a Guarantee Application. As noted above in D(1), review priority will be given to any Qualified Issuer Application that is accompanied by a Guarantee Application.

L. Other restrictions on use of funds. Bond Proceeds may not be used to finance or refinance any trade or business consisting of the operation of any private or commercial golf course, country club, massage parlor, hot tub facility, suntan facility, racetrack or other facility used for gambling, or any store the principal business of which is the sale of alcoholic beverages for consumption off-premises. Bond Proceeds may not be used to finance or refinance tax-exempt obligations or to finance or refinance projects that are also financed by tax-exempt obligations if: (a) Such financing or refinancing results in the direct or indirect subordination of the Bond Loan or Bond Issue to the tax-exempt obligations, or (b) such financing or refinancing results in a corresponding guarantee of the tax-exempt obligation. Qualified Issuers and Eligible CDFIs must ensure that any financing made in conjunction with tax-exempt obligations complies with CDFI Bond Guarantee Program Regulations.

II. General Application Information

The following requirements apply to all Qualified Issuer Applications and Guarantee Applications submitted under this NOGA, as well as any Qualified Issuer Applications and Guarantee Applications submitted under the FY 2021 NOGA that were neither withdrawn nor declined in FY 2021.

A. CDFI Certification Requirements.

1. In general. By statute and regulation, the Qualified Issuer applicant must be either a Certified

CDFI (an entity that the CDFI Fund has officially notified that it meets all CDFI certification requirements as set forth in 12 CFR 1805.201) or an entity designated by a Certified CDFI to issue Bonds on its behalf. An Eligible CDFI must be a Certified CDFI as of the Bond Issue Date and must maintain its CDFI certification throughout the term of the corresponding Bond.

2. CDFI Certification requirements. Pursuant to the regulations that govern CDFI certification (12 CFR 1805.201), an entity may be certified if it is a legal entity (meaning, that it has properly filed articles of incorporation or other organizing documents with the State or other appropriate body in the jurisdiction in which it was legally established, as of the date the CDFI Certification Application is submitted) and meets the following requirements:

a. *Primary Mission requirement (12 CFR 1805.201(b)(1)):* To be a Certified CDFI, an entity must have a primary mission of promoting community development, which mission must be consistent with its Target Market. In general, the entity will be found to meet the primary mission requirement if its incorporating documents or board-approved narrative statement (*i.e.,* mission statement or resolution) clearly indicate that it has a mission of purposefully addressing the social and/or economic needs of Low-Income individuals, individuals who lack adequate access to capital and/or financial services, distressed communities, and other underserved markets. An Affiliate of a Controlling CDFI, seeking to be certified as a CDFI (and therefore, approved to be an Eligible CDFI to participate in the CDFI Bond Guarantee Program), must demonstrate that it meets the primary mission requirement on its own merit, pursuant to the regulations and the CDFI Certification Application and related guidance materials posted on the CDFI Fund's website.

b. *Financing Entity requirement (12 CFR 1805.201(b)(2)):* To be a Certified CDFI, an entity must demonstrate that its predominant business activity is the provision of Financial Products and Financial Services, Development Services, and/or other similar financing.

On April 10, 2015, the CDFI Fund published a revision of 12 CFR 1805.201(b)(2), the section of the CDFI certification regulation that governs the ''financing entity'' requirement. The regulatory change creates a means for the CDFI Fund, in its discretion, to deem an Affiliate (meaning, in this case, an entity that is Controlled by a certified CDFI; see 12 CFR 1805.104) to have met the financing entity requirement based on the financing activity or track record of the Controlling CDFI (Control is defined in 12 CFR 1805.104), solely for the purpose of participating in the CDFI Bond Guarantee Program as an Eligible CDFI. This change is key to the creation of an AFS for the Bond Guarantee Program (see Section II(B)(2) of this NOGA for more information on the AFS). In order for the Affiliate to rely on the Controlling CDFI's financing track record, (A) the Controlling CDFI must be a Certified CDFI; (B) there must be an operating agreement that includes management and ownership provisions in effect between the two entities (prior to the submission of a CDFI Certification Application and in form and substance that is acceptable to the CDFI Fund); and (C) the Affiliate must submit a complete CDFI Certification Application to the CDFI Fund no later than 11:59 p.m. ET on March 28, 2022 in order for it to be considered for CDFI certification and participation in the FY 2022 application round of the CDFI Bond Guarantee Program. This regulatory revision affects only the Affiliate's ability to meet the financing entity requirement for purposes of CDFI certification: Said Affiliate must meet the other certification criteria in accordance with the existing regulations governing CDFI certification.

i. The revised regulation also states that, solely for the purpose of participating in the CDFI Bond Guarantee Program, the Affiliate's provision of Financial Products and Financial Services, Development Services, and/or other similar financing transactions does not need to be arms-length in nature if such transaction is by and between the Affiliate and Controlling CDFI, pursuant to an operating agreement that (a) includes management and ownership provisions, (b) is effective prior to the submission of a CDFI Certification Application, and (c) is in form and substance that is acceptable to the CDFI Fund.

ii. An Affiliate whose CDFI certification is based on the financing activity or track record of a Controlling CDFI is not eligible to receive financial or technical assistance awards or tax credit allocations under any other CDFI Fund program until such time that the Affiliate meets the financing entity requirement based on its own activity or track record.

iii. If an Affiliate elects to satisfy the financing entity requirement based on the financing activity or track record of a Controlling CDFI, and if the CDFI Fund approves such Affiliate as an Eligible CDFI for the sole purpose of participation in the CDFI Bond Guarantee Program, said Affiliate's CDFI certification will terminate if: (A) It does not enter into Bond Loan documents with its Qualified Issuer within one (1) year of the date that it signs the term sheet (which is an exhibit to the Agreement to Guarantee); (B) it ceases to be an Affiliate of the Controlling CDFI; or (C) it ceases to adhere to CDFI certification requirements.

iv. An Affiliate electing to satisfy the financing entity requirement based on the financing activity or track record of a Controlling CDFI does not need to have completed any financing activities prior to the date the CDFI Certification Application is submitted or approved. However, the Affiliate and the Controlling CDFI must have entered into the operating agreement described in (b)(i)(B) above, prior to such date, in form and substance that is acceptable to the CDFI Fund.

c. *Target Market requirement (12 CFR 1805.201(b)(3)):* To be a Certified CDFI, an entity must serve at least one eligible Target Market (either an Investment Area or a Targeted Population) by directing at least 60% of all of its Financial Product activities to one or more eligible Target Markets.

i. Solely for the purpose of participation as an Eligible CDFI in the FY 2022 application round of the CDFI Bond Guarantee Program, an Affiliate of a Controlling CDFI may be deemed to meet the Target Market requirement by virtue of serving either:

(A) An Investment Area through ''borrowers or investees'' that serve the Investment Area or provide significant benefits to its residents (pursuant to 12 CFR 1805.201(b)(3)(ii)(F)). For purposes of this NOGA, the term ''borrower'' or ''investee'' includes a borrower of a loan originated by the Controlling CDFI that has been transferred to the Affiliate as lender (which loan must meet Secondary Loan Requirements), pursuant to an operating agreement with the Affiliate that includes ownership/investment and management provisions, which agreement must be in effect prior to the submission of a CDFI Certification Application and in form and substance that is acceptable to the CDFI Fund. Loans originated by the Controlling CDFI do not need to be transferred prior to application submission; however, such loans must be transferred before certification of the Affiliate is effective. If an Affiliate has more than one Controlling CDFI, it may meet this Investment Area requirement through one or more of such Controlling CDFIs' Investment Areas; or

(B) a Targeted Population, which shall mean the individuals, who are Low Income persons or lack adequate access to Financial Products or Financial

Services in the entity's Target Market meeting the requirements of 12 CFR 1805.201(b)(3)(iii) of the CDFI Program Regulations as designated in the Recipient's most recently approved CDFI certification documentation. Pursuant to 12 CFR 1805.201(b)(3)(iii)(B) if a loan originated by the Controlling CDFI has been transferred to the Affiliate as lender (which loan must meet Secondary Loan Requirements) and the Controlling CDFI's financing entity activities serve the Affiliate's Targeted Population pursuant to an operating agreement that includes ownership/investment and management provisions by and between the Affiliate and the Controlling CDFI, which agreement must be in effect prior to the submission of a CDFI Certification Application and in form and substance that is acceptable to the CDFI Fund. Loans originated by the Controlling CDFI do not need to be transferred prior to application submission; however, such loans must be transferred before certification of the Affiliate is effective. If an Affiliate has more than one Controlling CDFI, it may meet this Targeted Population requirement through one or more of such Controlling CDFIs' Targeted Populations.

An Affiliate that meets the Target Market requirement through paragraphs (ii) (A) or (B) above, is not eligible to receive financial or technical assistance awards or tax credit allocations under any other CDFI Fund program until such time that the Affiliate meets the Target Market requirements based on its own activity or track record.

ii. If an Affiliate elects to satisfy the target market requirement based on paragraphs (c)(ii)(A) or (B) above, the Affiliate and the Controlling CDFI must have entered into the operating agreement as described above, prior to the date that the CDFI Certification Application is submitted, in form and substance that is acceptable to the CDFI Fund.

d. *Development Services requirement (12 CFR 1805.201(b)(4)):* To be a Certified CDFI, an entity must provide Development Services in conjunction with its Financial Products. Solely for the purpose of participation as an Eligible CDFI in the FY 2022 application round of the CDFI Bond Guarantee Program, an Affiliate of a Controlling CDFI may be deemed to meet this requirement if: (i) Its Development Services are provided by the Controlling CDFI pursuant to an operating agreement that includes management and ownership provisions with the Controlling CDFI that is effective prior to the submission of a CDFI Certification Application and in form and substance that is acceptable to the CDFI Fund and (ii) the Controlling CDFI must have provided Development Services in conjunction with the transactions that the Affiliate is likely to purchase, prior to the date of submission of the CDFI Certification Application.

e. *Accountability requirement (12 CFR 1805.201(b)(5)):* To be a Certified CDFI, an entity must maintain accountability to residents of its Investment Area or Targeted Population through representation on its governing board and/or advisory board(s), or through focus groups, community meetings, and/or customer surveys. Solely for the purpose of participation as an Eligible CDFI in the FY 2022 application round of the CDFI Bond Guarantee Program, an Affiliate of a Controlling CDFI may be deemed to meet this requirement only if it has a governing board and/or advisory board that has the same composition as the Controlling CDFI and such governing board or advisory board has convened and/or conducted Affiliate business prior to the date of submission of the CDFI Certification Application. If an Affiliate has multiple Controlling CDFIs, the governing board and/or advisory board may have a mixture of representatives from each Controlling CDFI so long as there is at least one representative from each Controlling CDFI.

f. *Non-government Entity requirement (12 CFR 1805.201(b)(6)):* To be a Certified CDFI, an entity can neither be a government entity nor be Controlled by one or more governmental entities.

g. for the FY 2022 application round of the CDFI Bond Guarantee Program, only one Affiliate per Controlling CDFI may participate as an Eligible CDFI. However, there may be more than one Affiliate participating as an Eligible CDFI in any given Bond Issue.

3. Operating agreement. An operating agreement between an Affiliate and its Controlling CDFI, as described above, must provide, in addition to the elements set forth above, among other items: (i) Conclusory evidence that the Controlling CDFI Controls the Affiliate, through investment and/or ownership; (ii) explanation of all roles, responsibilities and activities to be performed by the Controlling CDFI including, but not limited to, governance, financial management, loan underwriting and origination, record-keeping, insurance, treasury services, human resources and staffing, legal counsel, dispositions, marketing, general administration, and financial reporting; (iii) compensation arrangements; (iv) the term and termination provisions; (v) indemnification provisions, if applicable; (vi) management and ownership provisions; and (vii) default and recourse provisions.

4. For more detailed information on CDFI certification requirements, please review the CDFI certification regulation (12 CFR 1805.201) and CDFI Certification Application materials/guidance posted on the CDFI Fund's website. Interested parties should note that there are specific regulations and requirements that apply to Depository Institution Holding Companies, Insured Depository Institutions, Insured Credit Unions, and State-Insured Credit Unions.

5. Uncertified entities, including an Affiliate of a Controlling CDFI, that wish to apply to be certified and designated as an Eligible CDFI in the FY 2022 application round of the CDFI Bond Guarantee Program must submit a CDFI Certification Application to the CDFI Fund by 11:59 p.m. ET on March 28, 2022. Any CDFI Certification Application received after such date and time, as well as incomplete applications, will not be considered for the FY 2022 application round of the CDFI Bond Guarantee Program.

6. In no event will the Secretary approve a Guarantee for a Bond from which a Bond Loan will be made to an entity that is not an Eligible CDFI. The Secretary must make FY 2022 Guarantee Application decisions, and the CDFI Fund must close the corresponding Bonds and Bond Loans, prior to the end of FY 2022 (September 30, 2022). Accordingly, it is essential that CDFI Certification Applications are submitted timely and in complete form, with all materials and information needed for the CDFI Fund to make a certification decision. Information on CDFI certification, the CDFI Certification Application, and application submission instructions may be found on the CDFI Fund's website at *www.cdfifund.gov.*

B. Recourse and Collateral Requirements.

1. General Recourse Structure (GRS). Under the GRS, the Bond is a nonrecourse obligation to the Qualified Issuer, and the Bond Loan is a full general recourse obligation to the Eligible CDFI.

2. Alternative Financial Structure (AFS). An AFS can be used as a limited recourse option to a Controlling CDFI or group of Controlling CDFIs. The AFS is an Affiliate of a Controlling CDFI(s) that is created for the sole purpose of participation as an Eligible CDFI in the CDFI Bond Guarantee Program. The AFS must be an Affiliate of a Controlling CDFI(s) and must be certified as a CDFI in accordance with

the requirements set forth in Section II(A) of this NOGA. The AFS, as the Eligible CDFI, provides a general full recourse obligation to repay the Bond Loan, and the Bond Loan is on the balance sheet of the AFS. The requirements for the AFS are delineated in the template term sheet located on the CDFI Fund website at *https://www.cdfifund.gov/programs-training/Programs/cdfi-bond/Pages/apply-step.aspx#step2.*

C. Application Submission.

1. Electronic submission. All Qualified Issuer Applications and Guarantee Applications must be submitted through the CDFI Fund's Awards Management Information System (AMIS). Applications sent by mail, fax, or other form will not be permitted, except in circumstances that the CDFI Fund, in its sole discretion, deems acceptable. Please note that Applications will not be accepted through *Grants.gov.* For more information on AMIS, please visit the AMIS Landing Page at *https://amis.cdfifund.gov.*

2. Applicant identifier numbers. Please note that, pursuant to Office of Management and Budget (OMB) guidance (68 FR 38402), each Qualified Issuer applicant and Guarantee applicant must provide, as part of its Application, its Dun and Bradstreet Data Universal Numbering System (DUNS) number, if applicable, as well as DUNS numbers for its proposed Program Administrator, its proposed Servicer, and each Certified CDFI that is included in the Qualified Issuer Application and Guarantee Application. In addition, each Application must include a valid and current Employer Identification Number (EIN), with a letter or other documentation from the IRS confirming the Qualified Issuer applicant's EIN, as well as EINs for its proposed Program Administrator, its proposed Servicer, and each Certified CDFI that is included in any Application. An Application that does not include such DUNS numbers, EINs, and documentation is incomplete and will be rejected by the CDFI Fund. Applicants should allow sufficient time for the IRS and/or Dun and Bradstreet to respond to inquiries and/or requests for the required identification numbers.

3. System for Award Management (SAM). Registration with SAM is required for each Qualified Issuer applicant, its proposed Program Administrator, its proposed Servicer, and each Certified CDFI that is included in any Application. The CDFI Fund will not consider any Applications that do not meet the requirement that each entity must be properly registered before the date of Application submission. The SAM registration process may take one month or longer to complete. A signed notarized letter identifying the SAM authorized entity administrator for the entity associated with the DUNS number is required. This requirement is applicable to new entities registering in SAM, as well as to existing entities with registrations being updated or renewed in SAM. Applicants without DUNS and/or EIN numbers should allow for additional time as an applicant cannot register in SAM without those required numbers. Applicants that have previously completed the SAM registration process must verify that their SAM accounts are current and active. Each applicant must continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an Application under consideration by a Federal awarding agency. The CDFI Fund will not consider any applicant that fails to properly register or activate its SAM account and these restrictions also apply to organizations that have not yet received a DUNS or EIN number. Applicants must contact SAM directly with questions related to registration or SAM account changes as the CDFI Fund does not maintain this system and has no ability to make changes or correct errors of any kind. For more information about SAM, visit *https://www.sam.gov.*

4. AMIS accounts. Each Qualified Issuer applicant, its proposed Program Administrator, its proposed Servicer, and each Certified CDFI that is included in the Qualified Issuer Application or Guarantee Application must register User and Organization accounts in AMIS. Each such entity must be registered as an Organization and register at least one User Account in AMIS. As AMIS is the CDFI Fund's primary means of communication with applicants with regard to its programs, each such entity must make sure that it updates the contact information in its AMIS account before any Application is submitted. For more information on AMIS, please visit the AMIS Landing Page at *https://amis.cdfifund.gov.*

D. Form of Application.

1. As of the date of this NOGA, the Qualified Issuer Application, the Guarantee Application, and related application instructions for this round may be found on the CDFI Bond Guarantee Program's page on the CDFI Fund's website at *http://www.cdfifund.gov/bond.*

2. Paperwork Reduction Act. Under the Paperwork Reduction Act (44 U.S.C. chapter 35), an agency may not conduct or sponsor a collection of information, and an individual is not required to respond to a collection of information, unless it displays a valid OMB control number. Pursuant to the Paperwork Reduction Act, the Qualified Issuer Application, the Guarantee Application, and the Secondary Loan Requirements have been assigned the following control number: 1559–0044.

3. Application deadlines. In order to be considered for the issuance of a Guarantee under FY 2022 program authority, Qualified Issuer Applications must be submitted by 11:59 p.m. ET on April 20, 2022, and Guarantee Applications must be submitted by 11:59 p.m. ET on April 26, 2022. Qualified Issuer Applications and Guarantee Applications received in FY 2021 that were neither withdrawn nor declined will be considered under FY 2022 authority. If applicable, CDFI Certification Applications must be received by the CDFI Fund by 11:59 p.m. ET on March 28, 2022.

4. Format. Detailed Qualified Issuer Application and Guarantee Application content requirements are found in the Applications and application guidance. The CDFI Fund will read only information requested in the Application and reserves the right not to read attachments or supplemental materials that have not been specifically requested in this NOGA, the Qualified Issuer, or the Guarantee Application. Supplemental materials or attachments such as letters of public support or other statements that are meant to bias or influence the Application review process will not be read.

5. Application revisions. After submitting a Qualified Issuer Application or a Guarantee Application, the applicant will not be permitted to revise or modify the Application in any way unless authorized or requested by the CDFI Fund.

6. Material changes.

a. In the event that there are material changes after the submission of a Qualified Issuer Application prior to the designation as a Qualified Issuer, the applicant must notify the CDFI Fund of such material changes information in a timely and complete manner. The CDFI Fund will evaluate such material changes, along with the Qualified Issuer Application, to approve or deny the designation of the Qualified Issuer.

b. In the event that there are material changes after the submission of a Guarantee Application (including, but not limited to, a revision of the Capital Distribution Plan or a change in the Eligible CDFIs that are included in the Application) prior to or after the designation as a Qualified Issuer or approval of a Guarantee Application or Guarantee, the applicant must notify the

CDFI Fund of such material changes information in a timely and complete manner. The Guarantor will evaluate such material changes, along with the Guarantee Application, to approve or deny the Guarantee Application and/or determine whether to modify the terms and conditions of the Agreement to Guarantee. This evaluation may result in a delay of the approval or denial of a Guarantee Application.

E. Eligibility and completeness review. The CDFI Fund will review each Qualified Issuer and Guarantee Application to determine whether it is complete and the applicant meets eligibility requirements described in the Regulations, this NOGA, and the Applications. An incomplete Qualified Issuer Application or Guarantee Application, or one that does not meet eligibility requirements, will be rejected. If the CDFI Fund determines that additional information is needed to assess the Qualified Issuer's and/or the Certified CDFIs' ability to participate in and comply with the requirements of the CDFI Bond Guarantee Program, the CDFI Fund may require that the Qualified Issuer furnish additional, clarifying, confirming or supplemental information. If the CDFI Fund requests such additional, clarifying, confirming or supplemental information, the Qualified Issuer must provide it within the timeframes requested by the CDFI Fund. Until such information is provided to the CDFI Fund, the Qualified Issuer Application and/or Guarantee Application will not be moved forward for the substantive review process.

F. Regulated entities. In the case of Qualified Issuer applicants, proposed Program Administrators, proposed Servicers, and Certified CDFIs that are included in the Qualified Issuer Application or Guarantee Application that are Insured Depository Institutions and Insured Credit Unions, the CDFI Fund will consider information provided by, and views of, the Appropriate Federal and State Banking Agencies. If any such entity is a CDFI bank holding company, the CDFI Fund will consider information provided by the Appropriate Federal Banking Agencies of the CDFI bank holding company and its CDFI bank(s). Throughout the Application review process, the CDFI Fund will consider financial safety and soundness information from the Appropriate Federal Banking Agency. Each regulated applicant must have a composite CAMELS/CAMEL rating of at least ''3'' and/or no material concerns from its regulator. The CDFI Fund also reserves the right to require a regulated applicant to improve safety and soundness conditions prior to being approved as a Qualified Issuer or Eligible CDFI. In addition, the CDFI Fund will take into consideration Community Reinvestment Act assessments of Insured Depository Institutions and/or their Affiliates.

G. Prior CDFI Fund recipients. All applicants must be aware that success under any of the CDFI Fund's other programs is not indicative of success under this NOGA. Prior CDFI Fund recipients should note the following:

1. Pending resolution of noncompliance. If a Qualified Issuer applicant, its proposed Program Administrator, its proposed Servicer, or any of the Certified CDFIs included in the Qualified Issuer Application or Guarantee Application is a prior recipient or allocatee under any CDFI Fund program and (i) it has submitted reports to the CDFI Fund that demonstrate noncompliance with a previously executed agreement with the CDFI Fund, and (ii) the CDFI Fund has yet to make a final determination as to whether the entity is noncompliant with its previously executed agreement, the CDFI Fund will consider the Qualified Issuer Application or Guarantee Application pending full resolution, in the sole determination of the CDFI Fund, of the noncompliance.

2. Previous findings of noncompliance. If a Qualified Issuer applicant, its proposed Program Administrator, its proposed Servicer, or any of the Certified CDFIs included in the Qualified Issuer Application or Guarantee Application is a prior recipient or allocatee under any CDFI Fund program and the CDFI Fund has made a final determination that the entity is noncompliant with a previously executed agreement with the CDFI Fund, but has not notified the entity that it is ineligible to apply for future CDFI Fund program awards or allocations, the CDFI Fund will consider the Qualified Issuer Application or Guarantee Application. However, it is strongly advised that the entity take action to address such noncompliance finding, as repeat findings of noncompliance may result in the CDFI Fund determining the entity ineligible to participate in future CDFI Fund program rounds, which could result in any pending applications being deemed ineligible for further review. The CDFI Bond Guarantee Program staff cannot resolve compliance matters; instead, please contact the CDFI Fund's Office of Compliance Monitoring and Evaluation Unit (OCME) if your organization has questions about its current compliance status or has been found not in compliance with a previously executed agreement with the CDFI Fund.

3. Ineligibility due to noncompliance. The CDFI Fund will not consider a Qualified Issuer Application or Guarantee Application if the applicant, its proposed Program Administrator, its proposed Servicer, or any of the Certified CDFIs included in the Qualified Issuer Application or Guarantee Application, is a prior recipient or allocatee under any CDFI Fund program and if, as of the date of Qualified Issuer Application or Guarantee Application submission, (i) the CDFI Fund has made a determination that such entity is noncompliant with a previously executed agreement and (ii) the CDFI Fund has provided written notification that such entity is ineligible to apply for any future CDFI Fund program awards or allocations. Such entities will be ineligible to submit a Qualified Issuer or Guarantee Application, or be included in such submission, as the case may be, for such time period as specified by the CDFI Fund in writing.

H. Review of Bond and Bond Loan documents. Each Qualified Issuer and proposed Eligible CDFI will be required to certify that its appropriate senior management, and its respective legal counsel, has read the Regulations (set forth at 12 CFR part 1808, as well as the CDFI certification regulations set forth at 12 CFR 1805.201, as amended, and the environmental quality regulations set forth at 12 CFR part 1815) and the template Bond Documents and Bond Loan documents posted on the CDFI Fund's website including, but not limited to, the following: Bond Trust Indenture, Supplemental Indenture, Bond Loan Agreement, Promissory Note, Bond Purchase Agreement, Designation Notice, Secretary's Guarantee, Collateral Assignment, Reimbursement Note, Opinion of Bond Counsel, Opinion of Counsel to the Borrower, Escrow Agreement, and Closing Checklist.

I. Contact the CDFI Fund. A Qualified Issuer applicant, its proposed Program Administrator, its proposed Servicer, or any Certified CDFIs included in the Qualified Issuer Application or Guarantee Application that are prior CDFI Fund recipients are advised to: (i) Comply with requirements specified in CDFI Fund assistance, allocation, and/or award agreement(s), and (ii) contact the CDFI Fund to ensure that all necessary actions are underway for the disbursement or deobligation of any outstanding balance of said prior award(s). Any such parties that are unsure about the disbursement status of any prior award should submit a Service

Request through that organization's AMIS Account.

All outstanding reporting and compliance questions should be directed to the Office of Compliance Monitoring and Evaluation help desk by AMIS Service Requests. The CDFI Fund will respond to applicants' reporting, compliance, or disbursement questions between the hours of 9:00 a.m. and 5:00 p.m. ET, starting on the date of the publication of this NOGA.

J. Evaluating prior award performance. In the case of a Qualified Issuer, a proposed Program Administrator, a proposed Servicer, or Certified CDFI that has received awards from other Federal programs, the CDFI Fund reserves the right to contact officials from the appropriate Federal agency or agencies to determine whether the entity is in compliance with current or prior award agreements, and to take such information into consideration before issuing a Guarantee. In the case of such an entity that has previously received funding through any CDFI Fund program, the CDFI Fund will review the entity's compliance history with the CDFI Fund, including any history of providing late reports, and consider such history in the context of organizational capacity and the ability to meet future reporting requirements.

The CDFI Fund may also bar from consideration any such entity that has, in any proceeding instituted against it in, by, or before any court, governmental, or administrative body or agency, received a final determination within the three years prior to the date of publication of this NOGA indicating that the entity has discriminated on the basis of race, color, national origin, disability, age, marital status, receipt of income from public assistance, religion, or sex, including, but not limited, to discrimination under (i) Title VI of the Civil Rights Act of 1964 (Pub. L. 88–352) which prohibits discrimination on the basis of race, color or national origin; (ii) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. 1681–1683, 1685–1686), which prohibits discrimination on the basis of sex; (iii) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), which prohibits discrimination on the basis of handicaps; (iv) the Age Discrimination Act of 1975, as amended (42 U.S.C. 6101–6107), which prohibits discrimination on the basis of age; (v) the Drug Abuse Office and Treatment Act of 1972 (Pub. L. 92–255), as amended, relating to nondiscrimination on the basis of drug abuse; (vi) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (Pub. L. 91–616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (vii) Sections 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290 dd–3 and 290 ee–3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (viii) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. 3601 *et seq.*), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (ix) any other nondiscrimination provisions in the specific statute(s) under which Federal assistance is being made; and (x) the requirements of any other nondiscrimination statutes which may apply to the CDFI Bond Guarantee Program.

K. Civil Rights and Diversity. Any person who is eligible to receive benefits or services from the CDFI Fund or Recipients under any of its programs is entitled to those benefits or services without being subject to prohibited discrimination. The Department of the Treasury's Office of Civil Rights and Diversity enforces various Federal statutes and regulations that prohibit discrimination in financially assisted and conducted programs and activities of the CDFI Fund. If a person believes that s/he has been subjected to discrimination and/or reprisal because of membership in a protected group, s/he may file a complaint with: Director, Office of Civil Rights, and Diversity, 1500 Pennsylvania Ave. NW, Washington, DC 20220 or (202) 622–1160 (not a toll-free number).

L. Statutory and national policy requirements. The CDFI Fund will manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with the U.S. Constitution, Federal Law, and public policy requirements: Including, but not limited to, those protecting free speech, religious liberty, public welfare, the environment, and prohibiting discrimination.

M. Changes to review procedures. The CDFI Fund reserves the right to change its completeness, eligibility and evaluation criteria, and procedures if the CDFI Fund deems it appropriate. If such changes materially affect the CDFI Fund's decision to approve or deny a Qualified Issuer Application, the CDFI Fund will provide information regarding the changes through the CDFI Fund's website.

N. Decisions are final. The CDFI Fund's Qualified Issuer Application decisions are final. The Guarantor's Guarantee Application decisions are final. There is no right to appeal the decisions. Any applicant that is not approved by the CDFI Fund or the Guarantor may submit a new Application and will be considered based on the newly submitted Application. Such newly submitted Applications will be reviewed along with all other pending Applications in the order in which they are received, or by such other criteria that the CDFI Fund may establish, in its sole discretion.

III. Qualified Issuer Application

A. General. This NOGA invites interested parties to submit a Qualified Issuer Application to be approved as a Qualified Issuer under the CDFI Bond Guarantee Program.

1. Qualified Issuer. The Qualified Issuer is a Certified CDFI, or an entity designated by a Certified CDFI to issue Bonds on its behalf, that meets the requirements of the Regulations and this NOGA, and that has been approved by the CDFI Fund pursuant to review and evaluation of its Qualified Issuer Application. The Qualified Issuer will, among other duties: (i) Organize the Eligible CDFIs that have designated it to serve as their Qualified Issuer; (ii) prepare and submit a complete and timely Qualified Issuer and Guarantee Application to the CDFI Fund; (iii) if the Qualified Issuer Application is approved by the CDFI Fund and the Guarantee Application is approved by the Guarantor, prepare the Bond Issue; (iv) manage all Bond Issue servicing, administration, and reporting functions; (v) make Bond Loans; (vi) oversee the financing or refinancing of Secondary Loans; (vii) ensure compliance throughout the duration of the Bond with all provisions of the Regulations, and Bond Documents and Bond Loan Documents entered into between the Guarantor, the Qualified Issuer, and the Eligible CDFI; and (viii) ensure that the Master Servicer/Trustee complies with the Bond Trust Indenture and all other applicable regulations. Further, the role of the Qualified Issuer also is to ensure that its proposed Eligible CDFI applicants possess adequate and well performing assets to support the debt service of the proposed Bond Loan.

2. Qualified Issuer Application. The Qualified Issuer Application is the document that an entity seeking to serve as a Qualified Issuer submits to the CDFI Fund to apply to be approved as a Qualified Issuer prior to consideration of a Guarantee Application.

3. Qualified Issuer Application evaluation, general. Each Qualified Issuer Application will be evaluated by

the CDFI Fund and, if acceptable, the applicant will be approved as a Qualified Issuer, in the sole discretion of the CDFI Fund. The CDFI Fund's Qualified Issuer Application review and evaluation process is based on established procedures, which may include interviews of applicants and/or site visits to applicants conducted by the CDFI Fund. Through the Application review process, the CDFI Fund will evaluate Qualified Issuer applicants on a merit basis and in a fair and consistent manner. Each Qualified Issuer applicant will be reviewed on its ability to successfully carry out the responsibilities of a Qualified Issuer throughout the life of the Bond. The Applicant must currently meet the criteria established in the Regulations to be deemed a Qualified Issuer. Qualified Issuer Applications that are forward-looking or speculate as to the eventual acquisition of the required capabilities and criteria are unlikely to be approved. Qualified Issuer Application processing will be initiated in chronological order by date of receipt; however, Qualified Issuer Applications that are incomplete or require the CDFI Fund to request additional or clarifying information may delay the ability of the CDFI Fund to deem the Qualified Issuer Application complete and move it to the next phase of review. Submitting a substantially incomplete application earlier than other applicants does not ensure first approval.

B. Qualified Issuer Application: Eligibility.

1. CDFI certification requirements. The Qualified Issuer applicant must be a Certified CDFI or an entity designated by a Certified CDFI to issue Bonds on its behalf.

2. Designation and attestation by Certified CDFIs. An entity seeking to be approved by the CDFI Fund as a Qualified Issuer must be designated as a Qualified Issuer by at least one Certified CDFI. A Qualified Issuer may not designate itself. The Qualified Issuer applicant will prepare and submit a complete and timely Qualified Issuer Application to the CDFI Fund in accordance with the requirements of the Regulations, this NOGA, and the Application. A Certified CDFI must attest in the Qualified Issuer Application that it has designated the Qualified Issuer to act on its behalf and that the information in the Qualified Issuer Application regarding it is true, accurate, and complete.

C. Substantive review and approval process.

1. Substantive review.

a. If the CDFI Fund determines that the Qualified Issuer Application is complete and eligible, the CDFI Fund will undertake a substantive review in accordance with the criteria and procedures described in the Regulations, this NOGA, the Qualified Issuer Application, and CDFI Bond Guarantee Program policies.

b. As part of the substantive evaluation process, the CDFI Fund reserves the right to contact the Qualified Issuer applicant (as well as its proposed Program Administrator, its proposed Servicer, and each designating Certified CDFI in the Qualified Issuer Application) by telephone, email, mail, or through on-site visits for the purpose of obtaining additional, clarifying, confirming, or supplemental application information. The CDFI Fund reserves the right to collect such additional, clarifying, confirming, or supplemental information from said entities as it deems appropriate. If contacted for additional, clarifying, confirming, or supplemental information, said entities must respond within the time parameters set by the CDFI Fund or the Qualified Issuer Application will be rejected.

2. Qualified Issuer criteria. In total, there are more than 60 individual criteria or sub-criteria used to evaluate a Qualified Issuer applicant, and all materials provided in the Qualified Issuer Application will be used to evaluate the applicant. Qualified Issuer determinations will be made based on Qualified Issuer applicants' experience and expertise, in accordance with the following criteria:

a. Organizational capability.

i. The Qualified Issuer applicant must demonstrate that it has the appropriate expertise, capacity, experience, and qualifications to issue Bonds for Eligible Purposes, or is otherwise qualified to serve as Qualified Issuer, as well as manage the Bond Issue on the terms and conditions set forth in the Regulations, this NOGA, and the Bond Documents, satisfactory to the CDFI Fund.

ii. The Qualified Issuer applicant must demonstrate that it has the appropriate expertise, capacity, experience, and qualifications to originate, underwrite, service and monitor Bond Loans for Eligible Purposes, targeted to Low-Income Areas and Underserved Rural Areas.

iii. The Qualified Issuer applicant must demonstrate that it has the appropriate expertise, capacity, experience, and qualifications to manage the disbursement process set forth in the Regulations at 12 CFR 1808.302 and 1808.307.

b. Servicer. The Qualified Issuer applicant must demonstrate that it has (either directly or contractually through another designated entity) the appropriate expertise, capacity, experience, and qualifications, or is otherwise qualified to serve as Servicer. The Qualified Issuer Application must provide information that demonstrates that the Qualified Issuer's Servicer has the expertise, capacity, experience, and qualifications necessary to perform certain required administrative duties (including, but not limited to, Bond Loan servicing functions).

c. Program Administrator. The Qualified Issuer applicant must demonstrate that it has (either directly or contractually through another designated entity) the appropriate expertise, capacity, experience, and qualifications, or is otherwise qualified to serve as Program Administrator. The Qualified Issuer Application must provide information that demonstrates that the Qualified Issuer's Program Administrator has the expertise, capacity, experience, and qualifications necessary to perform certain required administrative duties (including, but not limited to, compliance monitoring and reporting functions).

d. Strategic alignment. The Qualified Issuer applicant will be evaluated on its strategic alignment with the CDFI Bond Guarantee Program on factors that include, but are not limited to: (i) Its mission's strategic alignment with community and economic development objectives set forth in the Riegle Act at 12 U.S.C. 4701; (ii) its strategy for deploying the entirety of funds that may become available to the Qualified Issuer through the proposed Bond Issue; (iii) its experience providing up to 30-year capital to CDFIs or other borrowers in Low-Income Areas or Underserved Rural Areas as such terms are defined in the Regulations at 12 CFR 1808.102; (iv) its track record of activities relevant to its stated strategy; and (v) other factors relevant to the Qualified Issuer's strategic alignment with the program.

e. Experience. The Qualified Issuer applicant will be evaluated on factors that demonstrate that it has previous experience: (i) Performing the duties of a Qualified Issuer including issuing bonds, loan servicing, program administration, underwriting, financial reporting, and loan administration; (ii) lending in Low-Income Areas and Underserved Rural Areas; and (iii) indicating that the Qualified Issuer's current principals and team members have successfully performed the required duties, and that previous experience is applicable to the current principals and team members.

f. Management and staffing. The Qualified Issuer applicant must demonstrate that it has sufficiently

strong management and staffing capacity to undertake the duties of Qualified Issuer. The applicant must also demonstrate that its proposed Program Administrator and its proposed Servicer have sufficiently strong management and staffing capacity to undertake their respective requirements under the CDFI Bond Guarantee Program. Strong management and staffing capacity is evidenced by factors that include, but are not limited to: (i) A sound track record of delivering on past performance; (ii) a documented succession plan; (iii) organizational stability including staff retention; and (iv) a clearly articulated, reasonable, and well-documented staffing plan.

g. Financial strength. The Qualified Issuer applicant must demonstrate the strength of its financial capacity and activities including, among other items, financially sound business practices relative to the industry norm for bond issuers, as evidenced by reports of Appropriate Federal Banking Agencies, Appropriate State Agencies, or auditors. Such financially sound business practices will demonstrate: (i) The financial wherewithal to perform activities related to the Bond Issue such as administration and servicing; (ii) the ability to originate, underwrite, close, and disburse loans in a prudent manner; (iii) whether the applicant is depending on external funding sources and the reliability of long-term access to such funding; (iv) whether there are foreseeable counterparty issues or credit concerns that are likely to affect the applicant's financial stability; and (v) a budget that reflects reasonable assumptions about upfront costs as well as ongoing expenses and revenues.

h. Systems and information technology. The Qualified Issuer applicant must demonstrate that it (as well as its proposed Program Administrator and its proposed Servicer) has, among other things: (i) A strong information technology capacity and the ability to manage loan servicing, administration, management, and document retention; (ii) appropriate office infrastructure and related technology to carry out the CDFI Bond Guarantee Program activities; and (iii) sufficient backup and disaster recovery systems to maintain uninterrupted business operations.

i. Pricing structure. The Qualified Issuer applicant must provide its proposed pricing structure for performing the duties of Qualified Issuer, including the pricing for the roles of Program Administrator and Servicer. Although the pricing structure and fees shall be decided by negotiation between market participants without interference or approval by the CDFI Fund, the CDFI Fund will evaluate whether the Qualified Issuer applicant's proposed pricing structure is feasible to carry out the responsibilities of a Qualified Issuer over the life of the Bond to help ensure sound implementation of the program.

j. Other criteria. The Qualified Issuer applicant must meet such other criteria as may be required by the CDFI Fund, as set forth in the Qualified Issuer Application or required by the CDFI Fund in its sole discretion, for the purposes of evaluating the merits of a Qualified Issuer Application. The CDFI Fund may request an on-site review of Qualified Issuer applicant to confirm materials provided in the written application, as well as to gather additional due diligence information. The on-site reviews are a critical component of the application review process and will generally be conducted for all applicants not regulated by an Appropriate Federal Banking Agency or Appropriate State Agency. The CDFI Fund reserves the right to conduct a site visit of regulated entities, in its sole discretion.

k. Third-party data sources. The CDFI Fund, in its sole discretion, may consider information from third-party sources including, but not limited to, periodicals or publications, publicly available data sources, or subscriptions services for additional information about the Qualified Issuer applicant, the proposed Program Administrator, the proposed Servicer, and each Certified CDFI that is included in the Qualified Issuer Application. Any additional information received from such third-party sources will be reviewed and evaluated through a systematic and formalized process.

D. Notification of Qualified Issuer determination. Each Qualified Issuer applicant will be informed of the CDFI Fund's decision in writing, by email using the addresses maintained in the entity's AMIS account. The CDFI Fund will not notify the proposed Program Administrator, the proposed Servicer, or the Certified CDFIs included in the Qualified Issuer Application of its decision regarding the Qualified Issuer Application; such contacts are the responsibility of the Qualified Issuer applicant.

E. Qualified Issuer Application rejection. In addition to substantive reasons based on the merits of its review, the CDFI Fund reserves the right to reject a Qualified Issuer Application if information (including administrative errors) comes to the attention of the CDFI Fund that adversely affects an applicant's eligibility, adversely affects the CDFI Fund's evaluation of a Qualified Issuer Application, or indicates fraud or mismanagement on the part of a Qualified Issuer applicant or its proposed Program Administrator, its proposed Servicer, and any Certified CDFI included in the Qualified Issuer Application. If the CDFI Fund determines that any portion of the Qualified Issuer Application is incorrect in any material respect, the CDFI Fund reserves the right, in its sole discretion, to reject the Application.

IV. Guarantee Applications

A. This NOGA invites Qualified Issuers to submit a Guarantee Application to be approved for a Guarantee under the CDFI Bond Guarantee Program.

1. Guarantee Application.

a. The Guarantee Application is the application document that a Qualified Issuer (in collaboration with the Eligible CDFI(s) that seek to be included in the proposed Bond Issue) must submit to the CDFI Fund in order to apply for a Guarantee. The Qualified Issuer shall provide all required information in its Guarantee Application to establish that it meets all criteria set forth in the Regulations at 12 CFR 1808.501 and this NOGA and can carry out all CDFI Bond Guarantee Program requirements including, but not limited to, information that demonstrates that the Qualified Issuer has the appropriate expertise, capacity, and experience and is qualified to make, administer and service Bond Loans for Eligible Purposes. An Eligible CDFI may be an existing certified or certifiable CDFI (the GRS), or the Eligible CDFI may be an Affiliate of a Controlling CDFI(s) that is created for the sole purpose of participation as an Eligible CDFI in the CDFI Fund Bond Guarantee Program (the AFS; see Section II(B) of this NOGA for Recourse and Collateral Requirements and Section II(A) of this NOGA for certification requirements for certifiable CDFIs and Affiliates of Controlling CDFIs).

b. The Guarantee Application comprises a Capital Distribution Plan and at least one Secondary Capital Distribution Plan, as well as all other requirements set forth in this NOGA or as may be required by the Guarantor and the CDFI Fund in their sole discretion, for the evaluation and selection of Guarantee applicants.

2. Guarantee Application evaluation, general. The Guarantee Application review and evaluation process will be based on established standard procedures, which may include interviews of applicants and/or site visits to applicants conducted by the

CDFI Fund. Through the Application review process, the CDFI Fund will evaluate Guarantee applicants on a merit basis and in a fair and consistent manner. Each Guarantee applicant will be reviewed on its ability to successfully implement and carry out the activities proposed in its Guarantee Application throughout the life of the Bond. Eligible CDFIs must currently meet the criteria established in the Regulations to participate in the CDFI Bond Guarantee Program. Guarantee Applications that are forward-looking or speculate as to the eventual acquisition of the required capabilities and criteria by the Eligible CDFI(s) are unlikely to be approved. Guarantee Application processing will be initiated in chronological order by date of receipt; however, Guarantee Applications that are incomplete or require the CDFI Fund to request additional or clarifying information may delay the ability of the CDFI Fund to deem the Guarantee Application complete and move it to the next phase of review. Submitting a substantially incomplete application earlier than other applicants does not ensure first approval.

B. Guarantee Application: Eligibility.

1. Eligibility; CDFI certification requirements. If approved for a Guarantee, each Eligible CDFI must be a Certified CDFI as of the Bond Issue Date and must maintain its respective CDFI certification throughout the term of the corresponding Bond. For more information on CDFI Certification and the certification of affiliated entities, including the deadlines for submission of certification applications, see part II of this NOGA.

2. Qualified Issuer as Eligible CDFI. A Qualified Issuer may not participate as an Eligible CDFI within its own Bond Issue, but may participate as an Eligible CDFI in a Bond Issue managed by another Qualified Issuer.

3. Attestation by proposed Eligible CDFIs. Each proposed Eligible CDFI must attest in the Guarantee Application that it has designated the Qualified Issuer to act on its behalf and that the information pertaining to the Eligible CDFI in the Guarantee Application is true, accurate and complete. Each proposed Eligible CDFI must also attest in the Guarantee Application that it will use Bond Loan proceeds for Eligible Purposes and that Secondary Loans will be financed or refinanced in accordance with the applicable Secondary Loan Requirements.

C. Guarantee Application: Preparation. When preparing the Guarantee Application, the Eligible CDFIs and Qualified Issuer must collaborate to determine the composition and characteristics of the Bond Issue, ensuring compliance with the Act, the Regulations, and this NOGA. The Qualified Issuer is responsible for the collection, preparation, verification, and submission of the Eligible CDFI information that is presented in the Guarantee Application. The Qualified Issuer will submit the Guarantee Application for the proposed Bond Issue, including any information provided by the proposed Eligible CDFIs. In addition, the Qualified Issuer will serve as the primary point of contact with the CDFI Fund during the Guarantee Application review and evaluation process.

D. Review and approval process.

1. Substantive review.

a. If the CDFI Fund determines that the Guarantee Application is complete and eligible, the CDFI Fund will undertake a substantive review in accordance with the criteria and procedures described in the Regulations at 12 CFR 1808.501, this NOGA, and the Guarantee Application. The substantive review of the Guarantee Application will include due diligence, underwriting, credit risk review, and Federal credit subsidy calculation, in order to determine the feasibility and risk of the proposed Bond Issue, as well as the strength and capacity of the Qualified Issuer and each proposed Eligible CDFI. Each proposed Eligible CDFI will be evaluated independently of the other proposed Eligible CDFIs within the proposed Bond Issue; however, the Bond Issue must then cumulatively meet all requirements for Guarantee approval. In general, applicants are advised that proposed Bond Issues that include a large number of proposed Eligible CDFIs are likely to substantially increase the review period.

b. As part of the substantive review process, the CDFI Fund may contact the Qualified Issuer (as well as the proposed Eligible CDFIs included in the Guarantee Application) by telephone, email, mail, or through an on-site visit for the sole purpose of obtaining additional, clarifying, confirming, or supplemental application information. The CDFI Fund reserves the right to collect such additional, clarifying, confirming or supplemental information as it deems appropriate. If contacted for additional, clarifying, confirming, or supplemental information, said entities must respond within the time parameters set by the CDFI Fund or the Guarantee Application will be rejected.

2. Guarantee Application criteria.

a. In general, a Guarantee Application will be evaluated based on the strength and feasibility of the proposed Bond Issue, as well as the creditworthiness and performance of the Qualified Issuer and the proposed Eligible CDFIs. Guarantee Applications must demonstrate that each proposed Eligible CDFI has the capacity for its respective Bond Loan to be a secured, general recourse obligation of the proposed Eligible CDFI and to deploy the Bond Loan proceeds within the required disbursement timeframe as described in the Regulations. Unless receiving significant support from a Controlling CDFI, or Credit Enhancements, Eligible CDFIs should not request Bond Loans greater than their current total asset size or which would otherwise significantly impair their net asset or net equity position. In general, an applicant requesting a Bond Loan more than 50% of its total asset size should be prepared to clearly demonstrate that it has a reasonable plan to scale its operations prudently and in a manner that does not impair its net asset or net equity position. Further, an entity with a limited operating history or a history of operating losses is unlikely to meet the strength and feasibility requirements of the CDFI Bond Guarantee Program, unless it receives significant support from a Controlling CDFI, or Credit Enhancements.

b. The Capital Distribution Plan must demonstrate the Qualified Issuer's comprehensive plan for lending, disbursing, servicing and monitoring each Bond Loan in the Bond Issue. It includes, among other information, the following components:

i. Statement of Proposed Sources and Uses of Funds: Pursuant to the requirements set forth in the Regulations at 12 CFR1808.102(bb) and 1808.301, the Qualified Issuer must provide: (A) A description of the overall plan for the Bond Issue; (B) a description of the proposed uses of Bond Proceeds and proposed sources of funds to repay principal and interest on the proposed Bond and Bond Loans; (C) a certification that 100% of the principal amount of the proposed Bond will be used to make Bond Loans for Eligible Purposes on the Bond Issue Date; and (D) description of the extent to which the proposed Bond Loans will serve Low-Income Areas or Underserved Rural Areas;

ii. Bond Issue Qualified Issuer cash flow model: The Qualified Issuer must provide a cash flow model displaying the orderly repayment of the Bond and the Bond Loans according to their respective terms. The cash flow model shall include disbursement and repayment of Bonds, Bond Loans, and Secondary Loans. The cash flow model shall match the aggregated cash flows

from the Secondary Capital Distribution Plans of each of the underlying Eligible CDFIs in the Bond Issue pool. Such information must describe the expected distribution of asset classes to which each Eligible CDFI expects to disburse funds, the proposed disbursement schedule, quarterly or semi-annual amortization schedules, interest-only periods, maturity date of each advance of funds, and assumed net interest margin on Secondary Loans above the assumed Bond Loan rate;

iii. Organizational capacity: If not submitted concurrently, the Qualified Issuer must attest that no material changes have occurred since the time that it submitted the Qualified Issuer Application;

iv. Credit Enhancement (if applicable): The Qualified Issuer must provide information about the adequacy of proposed risk mitigation provisions designed to protect the financial interests of the Federal Government, either directly or indirectly through supporting the financial strength of the Bond Issue. This includes, but is not limited to, the amount and quality of any Credit Enhancements, terms and specific conditions such as renewal options, and any limiting conditions or revocability by the provider of the Credit Enhancement. For any third-party providing a Credit Enhancement, the Qualified Issuer must provide the following information on the third-party: Most recent three years of audited financial statements, a brief analysis of the such entity's creditworthiness, and an executed letter of intent from such entity that indicates the terms and conditions of the Credit Enhancement. Any Credit Enhancement must be pledged, as part of the Trust Estate, to the Master Servicer/Trustee for the benefit of the Federal Financing Bank;

v. Proposed Term Sheets: The CDFI Fund website includes template term sheets for the GRS, the AFS, and the asset class CDFI to Financing Entity utilizing pooled tertiary loans. For each Eligible CDFI that is part of the proposed Bond Issue, the Qualified Issuer must submit a proposed Term Sheet using the applicable template provided on the CDFI Fund's website. The proposed Term Sheet must clearly state all relevant and critical terms of the proposed Bond Loan including, but not limited to: The Bond Loan Collateral Requirements described in Section II(B) of this NOGA, any requested prepayment provisions, unique conditions precedent, proposed covenants and exact amounts/percentages for determining the Eligible CDFI's ability to meet program requirements, and terms and exact language describing any Credit Enhancements. Terms may be either altered and/or negotiated by the CDFI Fund in its sole discretion, based on the proposed structure in the application, to ensure that adequate protection is in place for the Guarantor;

vi. Secondary Capital Distribution Plan(s): Each proposed Eligible CDFI must provide a comprehensive plan for financing, disbursing, servicing and monitoring Secondary Loans, address how each proposed Secondary Loan will meet Eligible Purposes, and address such other requirements listed below that may be required by the Guarantor and the CDFI Fund. For each proposed Eligible CDFI relying, for CDFI certification purposes, on the financing entity activity of a Controlling CDFI, the Controlling CDFI must describe how the Eligible CDFI and the Controlling CDFI, together, will meet the requirements listed below:

(A) *Narrative and Statement of Proposed Sources and Uses of Funds: Each Eligible CDFI will:* (1) Provide a description of proposed uses of funds, including the extent to which Bond Loans will serve Low-Income Areas or Underserved Rural Areas, and the extent to which Bond Loan proceeds will be used (i) to make the first monthly installment of a Bond Loan payment, (ii) pay Issuance Fees up to 1% of the Bond Loan, and (iii) finance Loan Loss Reserves related to Secondary Loans; (2) attest that 100% of Bond Loan proceeds designated for Secondary Loans will be used to finance or refinance Secondary Loans that meet Secondary Loan Requirements; (3) describe a plan for financing, disbursing, servicing, and monitoring Secondary Loans; (4) indicate the expected asset classes to which it will lend under the Secondary Loan Requirements; (5) indicate examples of previous lending and years of experience lending to a specific asset class, especially with regards to the number and dollar volume of loans made in the five years prior to application submission to the specific asset classes to which an Eligible CDFI is proposing to lend Bond Loan proceeds; (6) provide a table detailing specific uses and timing of disbursements, including terms and relending plans if applicable; and (7) a community impact analysis, including how the proposed Secondary Loans will address financing needs that the private market is not adequately serving and specific community benefit metrics;

(B) *Eligible CDFI cash flow model:* Each Eligible CDFI must provide a cash flow model of the proposed Bond Loan which: (1) Matches each Eligible CDFI's portion of the Qualified Issuer's cash flow model; and (2) tracks the flow of funds through the term of the Bond Issue and demonstrates disbursement and repayment of the Bond Loan, Secondary Loans, and any utilization of the Relending Fund, if applicable. Such information must describe: The expected distribution of asset classes to which each Eligible CDFI expects to disburse funds, the proposed disbursement schedule, quarterly or semi-annual amortization schedules, interest-only periods, maturity date of each advance of funds, and the assumed net interest margin on Secondary Loans above the assumed Bond Loan rate;

(C) *Organizational capacity:* Each Eligible CDFI must provide documentation indicating the ability of the Eligible CDFI to manage its Bond Loan including, but not limited to: (1) Organizational ownership and a chart of affiliates; (2) organizational documents, including policies and procedures related to loan underwriting and asset management; (3) management or operating agreement, if applicable; (4) an analysis by management of its ability to manage the funding, monitoring, and collection of loans being contemplated with the proceeds of the Bond Loan; (5) information about its board of directors; (6) a governance narrative; (7) description of senior management and employee base; (8) independent reports, if available; (9) strategic plan or related progress reports; and (10) a discussion of the management and information systems used by the Eligible CDFI;

(D) *Policies and procedures:* Each Eligible CDFI must provide relevant policies and procedures including, but not limited to: A copy of the asset-liability matching policy, if applicable; and loan policies and procedures which address topics including, but not limited to: Origination, underwriting, credit approval, interest rates, closing, documentation, asset management, and portfolio monitoring, risk-rating definitions, charge-offs, and loan loss reserve methodology;

(E) *Financial statements:* Each Eligible CDFI must provide information about the Eligible CDFI's current and future financial position, including but not limited to: (1) Audited financial statements for the prior three (3) most recent Fiscal Years; (2) current year-to-date or interim financial statement for the immediately prior quarter end of the Fiscal Year; (3) a copy of the current year's approved budget or projected budget if the entity's Board has not yet approved such budget; and (4) a three (3) year pro forma projection of the statement of financial position or balance sheet, statement of activities or income statement, and statement of cash

flows in the standardized template provided by the CDFI Fund;

(F) *Loan portfolio information:* Each Eligible CDFI must provide information including, but not limited to: (1) Loan portfolio quality report; (2) pipeline report; (3) portfolio listing; (4) a description of other loan assets under management; (5) loan products; (6) independent loan review report; (7) impact report case studies; and (8) a loan portfolio by risk rating and loan loss reserves; and

(G) *Funding sources and financial activity information:* Each Eligible CDFI must provide information including, but not limited to: (1) Current grant information; (2) funding projections; (3) credit enhancements; (4) historical investor renewal rates; (5) covenant compliance; (6) off-balance sheet contingencies; (7) earned revenues; and (8) debt capital statistics.

vii. Assurances and certifications that not less than 100% of the principal amount of Bonds will be used to make Bond Loans for Eligible Purposes beginning on the Bond Issue Date, and that Secondary Loans shall be made as set forth in subsection 1808.307(b); and

viii. Such other information that the Guarantor, the CDFI Fund and/or the Bond Purchaser may deem necessary and appropriate.

c. The CDFI Fund will use the information described in the Capital Distribution Plan and Secondary Capital Distribution Plan(s) to evaluate the feasibility of the proposed Bond Issue, with specific attention paid to each Eligible CDFI's financial strength and organizational capacity. For each proposed Eligible CDFI relying, for CDFI certification purposes, on the financing entity activity of a Controlling CDFI, the CDFI Fund will pay specific attention to the Controlling CDFI's financial strength and organizational capacity as well as the operating agreement between the proposed Eligible CDFI and the Controlling CDFI. All materials provided in the Guarantee Application will be used to evaluate the proposed Bond Issue. In total, there are more than 100 individual criteria or sub-criteria used to evaluate each Eligible CDFI. Specific criteria used to evaluate each Eligible CDFI shall include, but not be limited to, the following criteria below. For each proposed Eligible CDFI relying, for CDFI certification purposes, on the financing entity activity of a Controlling CDFI, the following specific criteria will also be used to evaluate both the proposed Eligible CDFI and the Controlling CDFI:

i. Historical financial ratios: Ratios which together have been shown to be predictive of possible future default will be used as an initial screening tool, including total asset size, net asset or Tier 1 Core Capital ratio, self-sufficiency ratio, non-performing asset ratio, liquidity ratio, reserve over nonperforming assets, and yield cost spread;

ii. Quantitative and qualitative attributes under the ''CAMELS'' framework: After initial screening, the CDFI Fund will utilize a more detailed analysis under the ''CAMELS'' framework, including but not limited to the following. If a Guarantee Application receives a summary rating of materially deficient during the CAMELS review the application will be recommended for denial.

(A) *Capital Adequacy:* Attributes such as the debt-to-equity ratio, status, and significance of off-balance sheet liabilities or contingencies, magnitude, and consistency of cash flow performance, exposure to affiliates for financial and operating support, trends in changes to capitalization, and other relevant attributes;

(B) *Asset Quality:* Attributes such as the charge-off ratio, adequacy of loan loss reserves, sector concentration, borrower concentration, asset composition, security and collateralization of the loan portfolio, trends in changes to asset quality, and other relevant attributes;

(C) *Management:* Attributes such as documented best practices in governance, strategic planning and board involvement, robust policies and procedures, tenured and experienced management team, organizational stability, infrastructure and information technology systems, and other relevant attributes;

(D) *Earnings and Performance:* Attributes such as net operating margins, deployment of funds, self-sufficiency, trends in earnings, and other relevant attributes;

(E) *Liquidity:* Attributes such as unrestricted cash and cash equivalents, ability to access credit facilities, access to grant funding, covenant compliance, affiliate relationships, concentration of funding sources, trends in liquidity, and other relevant attributes;

(F) *Sensitivity:* The CDFI Fund will stress test each Eligible CDFI's projected financial performance under scenarios that are specific to the unique circumstance and attributes of the organization. Additionally, the CDFI Fund will consider other relevant criteria that have not been adequately captured in the preceding steps as part of the due diligence process. Such criteria may include, but not be limited to, the size and quality of any third-party Credit Enhancements or other forms of credit support.

iii. Other criteria: (A) *Overcollateralization:* The commitment by an Eligible CDFI to over-collateralize a proposed Bond Loan with excess Secondary Loans is a criterion that may affect the viability of a Guarantee Application by decreasing the estimated net present value of the long-term cost of the Guarantee to the Federal Government, by decreasing the probability of default, and/or increasing the recovery rate in the event of default. An Eligible CDFI committing to overcollateralization may not be required to deposit funds in the Relending Account, subject to the maintenance of certain unique requirements that are detailed in the template Agreement to Guarantee and Bond Loan Agreement.

(B) *Credit Enhancements:* The provision of third-party Credit Enhancements, including any Credit Enhancement from a Controlling CDFI or any other affiliated entity, is a criterion that may affect the viability of a Guarantee Application by decreasing the estimated net present value of the long-term cost of the Guarantee to the Federal Government. Credit Enhancements are considered in the context of the structure and circumstances of each Guarantee Application.

(C) *On-Site Review:* The CDFI Fund may request an on-site review of an Eligible CDFI to confirm materials provided in the written application, as well as to gather additional due diligence information. The on-site reviews are a critical component of the application review process and will generally be conducted for all applicants not regulated by an Appropriate Federal Banking Agency or Appropriate State Agency. The CDFI Fund reserves the right to conduct a site visit of regulated entities, in its sole discretion.

(D) *Secondary Loan Asset Classes:* Eligible CDFIs that propose to use funds for new products or lines of business must demonstrate that they have the organizational capacity to manage such activities in a prudent manner. Failure to demonstrate such organizational capacity may be factored into the consideration of Asset Quality or Management criteria as listed above in this section.

3. Credit subsidy cost. The credit subsidy cost is the net present value of the estimated long-term cost of the Guarantee to the Federal Government as determined under the applicable provisions of the Federal Credit Reform Act of 1990, as amended (FCRA).

Treasury has not received appropriated amounts from Congress to cover the credit subsidy costs associated with Guarantees issued pursuant to this NOGA. In accordance with FCRA, Treasury must consult with, and obtain the approval of, OMB for Treasury's calculation of the credit subsidy cost of each Guarantee prior to entering into any Agreement to Guarantee.

E. Guarantee approval; Execution of documents.

1. The Guarantor, in the Guarantor's sole discretion, may approve a Guarantee, after consideration of the recommendation from the CDFI Bond Guarantee Program's Credit Review Board and/or based on the merits of the Guarantee Application.

2. The Guarantor reserves the right to approve Guarantees, in whole or in part, in response to any, all, or none of the Guarantee Applications submitted in response to this NOGA. The Guarantor also reserves the right to approve any Guarantees in an amount that is less than requested in the corresponding Guarantee Application. Pursuant to the Regulations at 12 CFR 1808.504(c), the Guarantor may limit the number of Guarantees made per year to ensure that a sufficient examination of Guarantee Applications is conducted.

3. The CDFI Fund will notify the Qualified Issuer in writing of the Guarantor's approval or disapproval of a Guarantee Application. Bond Documents and Bond Loan documents must be executed, and Guarantees will be provided, in the order in which Guarantee Applications are approved or by such other criteria that the CDFI Fund may establish, in its sole discretion, and in any event by September 30, 2022.

4. Please note that the most recently dated templates of Bond Documents and Bond Loan documents that are posted on the CDFI Fund's website will not be substantially revised or negotiated prior to closing of the Bond and Bond Loan and issuance of the corresponding Guarantee. If a Qualified Issuer or a proposed Eligible CDFI does not understand the terms and conditions of the Bond Documents or Bond Loan documents (including those listed in Section II.H., above), it should ask questions or seek technical assistance from the CDFI Fund. However, if a Qualified Issuer or a proposed Eligible CDFI disagrees or is uncomfortable with any term/condition, or if legal counsel cannot provide a legal opinion in substantially the same form and content of the required legal opinion, it should not apply for a Guarantee.

5. The Guarantee shall not be effective until the Guarantor signs and delivers the Guarantee.

F. Guarantee denial. The Guarantor, in the Guarantor's sole discretion, may deny a Guarantee, after consideration of the recommendation from the Credit Review Board and/or based on the merits of the Guarantee Application. If any Guarantee Application receives a summary rating of materially deficient during the CAMELS underwriting review, the application will be recommended for denial. In addition, the Guarantor reserves the right to deny a Guarantee Application if information (including any administrative error) comes to the Guarantor's attention that adversely affects the Qualified Issuer's eligibility, adversely affects the evaluation or scoring of an Application, or indicates fraud or mismanagement on the part of the Qualified Issuer, Program Administrator, Servicer, and/or Eligible CDFIs.

Further, if the Guarantor determines that any portion of the Guarantee Application is incorrect in any material respect, the Guarantor reserves the right, in the Guarantor's sole discretion, to deny the Application.

V. Guarantee Administration

A. Pricing information. Bond Loans will be priced based upon the underlying Bond issued by the Qualified Issuer and purchased by the Federal Financing Bank (FFB or Bond Purchaser). As informed by CDFI Fund underwriting according to the criteria laid out in Section II ''General Application Information'' and Section IV ''Guarantee Applications'' of this NOGA, the FFB will set the liquidity premium at the time of the Bond Issue Date, based on the duration and maturity of the Bonds according to the FFB's lending policies (*www.treasury.gov/ffb*). Liquidity premiums will be charged in increments of 1/8th of a percent (*i.e.,* 12.5 basis points).

B. Fees and other payments. The following table includes some of the fees that may be applicable to Qualified Issuers and Eligible CDFIs after approval of a Guarantee of a Bond Issue, as well as Risk-Share Pool funding, prepayment penalties or discounts, and Credit Enhancements. The table is not exhaustive; additional fees payable to the CDFI Fund or other parties may apply.

Fee	Description
Agency Administrative Fee	Payable monthly to the CDFI Fund by the Eligible CDFI Equal to 10 basis points (annualized) on the amount of the unpaid principal of the Bond Issue.
Bond Issuance Fees	Amounts paid by an Eligible CDFI for reasonable and appropriate expenses, administrative costs, and fees for services in connection with the issuance of the Bond (but not including the Agency Administrative Fee) and the making of the Bond Loan. Fees negotiated between the Qualified Issuer, the Master Servicer/Trustee, and the Eligible CDFI. Up of 1% of Bond Loan Proceeds may be used to finance Bond Issuance Fees.
Servicer Fee	The fees paid by the Eligible CDFI to the Qualified Issuer's Servicer. Servicer fees are negotiated between the Qualified Issuer and the Eligible CDFI.
Program Administrator Fee	The fees paid by the Eligible CDFI to the Qualified Issuer's Program Administrator. Program Administrator fees are negotiated between the Qualified Issuer and the Eligible CDFI.
Master Servicer/Trustee Fee	The fees paid by the Qualified Issuer and the Eligible CDFI to the Master Servicer/Trustee to carry out the responsibilities of the Bond Trust Indenture. In general, the Master Servicer/Trustee fee for a Bond Issue with a single Eligible CDFI is the greater of 16 basis points per annum or $6,000 per month once the Bond Loans are fully disbursed. Fees for Bond Issues with more than one Eligible CDFI are negotiated between the Master Servicer/Trustee, Qualified Issuer, and Eligible CDFI. Any special servicing costs and resolution or liquidation fees due to a Bond Loan default are the responsibility of the Eligible CDFI. Please see the template legal documents at *https://www.cdfifund.gov/programs-training/Programs/cdfi-bond/Pages/closing-disbursement-step.aspx#step4* for more specific information.
Risk-Share Pool Funding	The funds paid by the Eligible CDFIs to cover Risk-Share Pool requirements; capitalized by pro rata payments equal to 3% of the amount disbursed on the Bond Loan from all Eligible CDFIs within the Bond Issue.
Prepayment Premiums or Discounts	Prepayment premiums or discounts are determined by the FFB at the time of prepayment.

Fee	Description
Credit Enhancements	Pledges made to enhance the quality of a Bond and/or Bond Loan. Credit Enhancements include, but are not limited to, the Principal Loss Collateral Provision and letters of credit. Credit Enhancements must be pledged, as part of the Trust Estate, to the Master Servicer/Trustee for the benefit of the Federal Financing Bank.

C. Terms for Bond Issuance and disbursement of Bond Proceeds. In accordance with 12 CFR 1808.302(f), each year, beginning on the one year anniversary of the Bond Issue Date (and every year thereafter for the term of the Bond Issue), each Qualified Issuer must demonstrate that no less than 100% of the principal amount of the Guaranteed Bonds currently disbursed and outstanding has been used to make loans to Eligible CDFIs for Eligible Purposes. If a Qualified Issuer fails to demonstrate this requirement within the 90 days after the anniversary of the Bond Issue Date, the Qualified Issuer must repay on that portion of Bonds necessary to bring the Bonds that remain outstanding after such repayment is in compliance with the 100% requirement above.

D. Secondary Loan Requirements. In accordance with the Regulations, Eligible CDFIs must finance or refinance Secondary Loans for Eligible Purposes (not including loan loss reserves) that comply with Secondary Loan Requirements. The Secondary Loan Requirements are found on the CDFI Fund's website at *https://www.cdfifund.gov/programs-training/Programs/cdfi-bond/Pages/compliance-step.aspx#step5.* Applicants should become familiar with the published Secondary Loan Requirements (both the General Requirements and the Underwriting Review Checklist). Secondary Loan Requirements are subject to a Secondary Loan commitment process managed by the Qualified Issuer. Eligible CDFIs must execute Secondary Loan documents (in the form of promissory notes) with Secondary Borrowers as follows: (i) No later than 12 months after the Bond Issue Date, Secondary Loan documents representing at least 50% of the Bond Loan proceeds allocated for Secondary Loans, and (ii) no later than 24 months after the Bond Issue Date, Secondary Loan documents representing 100% of the Bond Loan proceeds allocated for Secondary Loans. In the event that the Eligible CDFI does not comply with the foregoing requirements of clauses (i) or (ii) of this paragraph, the available Bond Loan proceeds at the end of the applicable period shall be reduced by an amount equal to the difference between the amount required by clauses (i) or (ii) for the applicable period minus the amount previously committed to the Secondary Loans in the applicable period. Secondary Loans shall carry loan maturities suitable to the loan purpose and be consistent with loan-to-value requirements set forth in the Secondary Loan Requirements. Secondary Loan maturities shall not exceed the corresponding Bond or Bond Loan maturity date. It is the expectation of the CDFI Fund that interest rates for the Secondary Loans will be reasonable based on the borrower and loan characteristics.

E. Secondary Loan Collateral Requirements.

1. The Regulations state that Secondary Loans must be secured by a first lien of the Eligible CDFI on pledged collateral, in accordance with the Regulations (at 12 CFR 1808.307(f)) and within certain parameters. Examples of acceptable forms of collateral may include, but are not limited to: Real property (including land and structures), leasehold interests, machinery, equipment and movables, cash and cash equivalents, accounts receivable, letters of credit, inventory, fixtures, contracted revenue streams from non-Federal counterparties, provided the Secondary Borrower pledges all assets, rights and interests necessary to generate such revenue stream, and a Principal Loss Collateral Provision. Intangible assets, such as customer relationships and intellectual property rights, are not acceptable forms of collateral. Loans secured by real property that are still in a construction phase will only be permitted when backed by a letter of credit issued by a bank deemed acceptable by the CDFI Bond Guarantee Program, in a format deemed acceptable to the CDFI Bond Guarantee Program, that guarantees the full value of the pledged collateral until at minimum completion of the construction and stabilization phases.

2. The Regulations require that Bond Loans must be secured by a first lien on a collateral assignment of Secondary Loans, and further that the Secondary Loans must be secured by a first lien or parity lien on acceptable collateral.

3. Valuation of the collateral pledged by the Secondary Borrower must be based on the Eligible CDFI's credit policy guidelines and must conform to the standards set forth in the Uniform Standards of Professional Appraisal Practice (USPAP) and the Secondary Loan Requirements.

4. Independent third-party appraisals are required for the following collateral: Real estate, leasehold interests, fixtures, machinery and equipment, movables stock valued in excess of $250,000, and contracted revenue stream from non-Federal creditworthy counterparties. Secondary Loan collateral shall be valued using the cost approach, net of depreciation and shall be required for the following: Accounts receivable, machinery, equipment and movables, and fixtures.

F. Qualified Issuer approval of Bond Loans to Eligible CDFIs. The Qualified Issuer shall not approve any Bond Loans to an Eligible CDFI where the Qualified Issuer has actual knowledge, based upon reasonable inquiry, that within the past five (5) years the Eligible CDFI: (i) Has been delinquent on any payment obligation (except upon a demonstration by the Qualified Issuer satisfactory to the CDFI Fund that the delinquency does not affect the Eligible CDFI's creditworthiness), or has defaulted and failed to cure any other obligation, on a loan or loan agreement previously made under the Act; (ii) has been found by the Qualified Issuer to be in default of any repayment obligation under any Federal program; (iii) is financially insolvent in either the legal or equitable sense; or (iv) is not able to demonstrate that it has the capacity to comply fully with the payment schedule established by the Qualified Issuer.

G. Credit Enhancements; Principal Loss Collateral Provision.

1. In order to achieve the statutory zero-credit subsidy constraint of the CDFI Bond Guarantee Program and to avoid a call on the Guarantee, Eligible CDFIs are encouraged to include Credit Enhancements and Principal Loss Collateral Provisions structured to protect the financial interests of the Federal Government. Any Credit Enhancement or Principal Loss Collateral Provision must be pledged, as part of the Trust Estate, to the Master Servicer/Trustee for the benefit of the Federal Financing Bank.

2. Credit Enhancements may include, but are not limited to, payment guarantees from third parties or Affiliate(s), non-Federal capital, lines or letters of credit, or other pledges of

financial resources that enhance the Eligible CDFI's ability to make timely interest and principal payments under the Bond Loan.

3. As distinct from Credit Enhancements, Principal Loss Collateral Provisions may be provided in lieu of pledged collateral and/or in addition to pledged collateral. A Principal Loss Collateral Provision shall be in the form of cash or cash equivalent guarantees from non-Federal capital in amounts necessary to secure the Eligible CDFI's obligations under the Bond Loan after exercising other remedies for default. For example, a Principal Loss Collateral Provision may include a deficiency guarantee whereby another entity assumes liability after other default remedies have been exercised, and covers the deficiency incurred by the creditor. The Principal Loss Collateral Provision shall, at a minimum, provide for the provision of cash or cash equivalents in an amount that is not less than the difference between the value of the collateral and the amount of the accelerated Bond Loan outstanding.

4. In all cases, acceptable Credit Enhancements or Principal Loss Collateral Provisions shall be proffered by creditworthy providers and shall provide information about the adequacy of the facility in protecting the financial interests of the Federal Government, either directly or indirectly through supporting the financial strength of the Bond Issue. The information provided must include the amount and quality of any Credit Enhancements, the financial strength of the provider of the Credit Enhancement, the terms, specific conditions such as renewal options, and any limiting conditions or revocability by the provider of the Credit Enhancement.

5. For Secondary Loans benefitting from a Principal Loss Collateral Provision (*e.g.,* a deficiency guarantee), the entity providing the Principal Loss Collateral Provision must be underwritten based on the same criteria as if the Secondary Loan were being made directly to that entity with the exception that the guarantee need not be collateralized.

6. If the Principal Loss Collateral Provision is provided by a financial institution that is regulated by an Appropriate Federal Banking Agency or an Appropriate State Agency, the guaranteeing institution must demonstrate performance of financially sound business practices relative to the industry norm for providers of collateral enhancements as evidenced by reports of Appropriate Federal Banking Agencies, Appropriate State Agencies, and auditors, as appropriate.

7. In the event that the Eligible CDFI proposes to use other Federal funds to service Bond Loan debt or as a Credit Enhancement, the CDFI Fund may require, in its sole discretion, that the Eligible CDFI provide written assurance from such other Federal program, in a form that is acceptable to the CDFI Fund and that the CDFI Fund may rely upon, that said use is permissible.

H. Reporting Requirements.

1. Reports.

a. General. As required pursuant to the Regulations at 12 CFR 1808.619, and as set forth in the Bond Documents and the Bond Loan documents, the CDFI Fund will collect information from each Qualified Issuer which may include, but will not be limited to:

(i) Quarterly and annual financial reports and data (including an OMB single audit per 2 CFR 200 Subpart F, as applicable) for the purpose of monitoring the financial health, ratios and covenants of Eligible CDFIs that include asset quality (nonperforming assets, loan loss reserves, and net charge-off ratios), liquidity (current ratio, working capital, and operating liquidity ratio), solvency (capital ratio, self-sufficiency, fixed charge, leverage, and debt service coverage ratios); (ii) annual reports as to the compliance of the Qualified Issuer and Eligible CDFIs with the Regulations and specific requirements of the Bond Documents and Bond Loan documents; (iii) Master Servicer/Trustee summary of program accounts and transactions for each Bond Issue; (iv) Secondary Loan Certifications describing Eligible CDFI lending, collateral valuation, and eligibility; (v) financial data on Secondary Loans to monitor underlying collateral, gauge overall risk exposure across asset classes, and assess loan performance, quality, and payment history; (vi) annual certifications of compliance with program requirements; (vii) material event disclosures including any reports of Eligible CDFI management and/or organizational changes; (viii) annual updates to the Capital Distribution Plan (as described below); (ix) supplements and/or clarifications to correct reporting errors (as applicable); (x) project level reports to understand overall program impact and the manner in which Bond Proceeds are deployed for Eligible Community or Economic Development Purposes; and (xi) such other information that the CDFI Fund and/or the Bond Purchaser may require, including but not limited to racial and ethnic data showing the extent to which members of minority groups are beneficiaries of the CDFI Bond Guarantee Program, to the extent permissible by law.

b. Additional reporting by Qualified Issuers. A Qualified Issuer receiving a Guarantee shall submit annual updates to the approved Capital Distribution Plan, including an updated Proposed Sources and Uses of Funds for each Eligible CDFI, noting any deviation from the original baseline with regards to both timing and allocation of funding among Secondary Loan asset classes. The Qualified Issuer shall also submit a narrative, no more than five (5) pages in length for each Eligible CDFI, describing the Eligible CDFI's capacity to manage its Bond Loan. The narrative shall address any Notification of Material Events and relevant information concerning the Eligible CDFI's management information systems, personnel, executive leadership or board members, as well as financial capacity. The narrative shall also describe how such changes affect the Eligible CDFI's ability to generate impacts in Low-Income or Underserved Rural Areas.

c. Change of Secondary Loan asset classes. Any Eligible CDFI seeking to expand the allowable Secondary Loan asset classes beyond what was approved by the CDFI Bond Guarantee Program's Credit Review Board or make other deviations that could potentially result in a modification, as that term is defined in OMB Circulars A–11 and A–129, must receive approval from the CDFI Fund before the Eligible CDFI can begin to enact the proposed changes. The CDFI Fund will consider whether the Eligible CDFI possesses or has acquired the appropriate systems, personnel, leadership, and financial capacity to implement the revised Capital Distribution Plan. The CDFI Fund will also consider whether these changes assist the Eligible CDFI in generating impacts in Low-Income or Underserved Rural Areas. Such changes will be reviewed by the CDFI Bond Guarantee Program and presented to the Credit Review Board for approval, and, if required, appropriate consultation will be made with OMB to ensure compliance with OMB Circulars A–11 and A–129, prior to notifying the Eligible CDFI if such changes are acceptable under the terms of the Bond Loan Agreement.

d. Reporting by Affiliates and Controlling CDFIs. In the case of an Eligible CDFI relying, for CDFI certification purposes, on the financing entity activity of a Controlling CDFI, the CDFI Fund will require that the Affiliate and Controlling CDFI provide certain joint reports, including but not limited to those listed in subparagraph 1(a) above.

e. Detailed information on specific reporting requirements and the format, frequency, and methods by which this information will be transmitted to the CDFI Fund will be provided to Qualified Issuers, Program Administrators, Servicers, and Eligible CDFIs through the Bond Loan Agreement, correspondence, and webinar trainings, and/or scheduled outreach sessions.

f. Reporting requirements will be enforced through the Agreement to Guarantee and the Bond Loan Agreement, and will contain a valid OMB control number pursuant to the Paperwork Reduction Act, as applicable.

g. Each Qualified Issuer will be responsible for the timely and complete submission of the annual reporting documents, including such information that must be provided by other entities such as Eligible CDFIs, Secondary Borrowers or Credit Enhancement providers. If such other entities are required to provide annual report information or documentation, or other documentation that the CDFI Fund may require, the Qualified Issuer will be responsible for ensuring that the information is submitted timely and complete. Notwithstanding the foregoing, the CDFI Fund reserves the right to contact such entities and require that additional information and documentation be provided directly to the CDFI Fund.

h. Annual Assessments. Each Qualified Issuer and Eligible CDFI will be required to have an independent third-party conduct an Annual Assessment of its Bond Loan portfolio. The Annual Assessment is intended to support the CDFI Fund's annual monitoring of the Bond Loan portfolio and to collect financial health, internal control, investment impact measurement methodology information related to the Eligible CDFIs. This assessment is consistent with the program's requirements for Compliance Management and Monitoring (CMM) and Portfolio Management and Loan Monitoring (PMLM), and will be required pursuant to the Bond Documents and the Bond Loan documents. The assessment will also add to the Department of the Treasury's review and impact analysis on the use of Bond Loan proceeds in underserved communities and support the CDFI Fund in proactively managing portfolio risks and performance. The Annual Assessment criteria for Qualified Issuers and Eligible CDFIs is available on the CDFI Fund's website.

i. The CDFI Fund reserves the right, in its sole discretion, to modify its reporting requirements if it determines it to be appropriate and necessary; however, such reporting requirements will be modified only after notice to Qualified Issuers. Additional information about reporting requirements pursuant to this NOGA, the Bond Documents and the Bond Loan documents will be subject to the Paperwork Reduction Act, as applicable.

2. Accounting.

a. In general, the CDFI Fund will require each Qualified Issuer and Eligible CDFI to account for and track the use of Bond Proceeds and Bond Loan proceeds. This means that for every dollar of Bond Proceeds received from the Bond Purchaser, the Qualified Issuer is required to inform the CDFI Fund of its uses, including Bond Loan proceeds. This will require Qualified Issuers and Eligible CDFIs to establish separate administrative and accounting controls, subject to the applicable OMB Circulars.

b. The CDFI Fund will provide guidance to Qualified Issuers outlining the format and content of the information that is to be provided on an annual basis, outlining and describing how the Bond Proceeds and Bond Loan proceeds were used.

VI. Agency Contacts

A. General information on questions and CDFI Fund support. The CDFI Fund will respond to questions and provide support concerning this NOGA, the Qualified Issuer Application and the Guarantee Application between the hours of 9:00 a.m. and 5:00 p.m. ET, starting with the date of the publication of this NOGA. The final date to submit questions is April 13, 2022. Applications and other information regarding the CDFI Fund and its programs may be obtained from the CDFI Fund's website at *http://www.cdfifund.gov.* The CDFI Fund will post on its website responses to questions of general applicability regarding the CDFI Bond Guarantee Program.

B. The CDFI Fund's contact information is as follows:

TABLE 2—CONTACT INFORMATION

Type of question	Telephone No. (not toll free)	Email addresses
CDFI Bond Guarantee Program	(202) 653–0421, Option 5.	*bgp@cdfi.treas.gov.*
CDFI Certification	(202) 653–0423	*ccme@cdfi.treas.gov.*
Compliance Monitoring and Evaluation	(202) 653–0423	*ccme@cdfi.treas.gov.*
Information Technology Support	(202) 653–0422	*AMIS@cdfi.treas.gov.*

C. Communication with the CDFI Fund. The CDFI Fund will communicate with applicants, Qualified Issuers, Program Administrators, Servicers, Certified CDFIs and Eligible CDFIs, using the contact information maintained in their respective AMIS accounts. Therefore, each such entity must maintain accurate contact information (including contact person and authorized representative, email addresses, fax numbers, phone numbers, and office addresses) in its respective AMIS account. For more information about AMIS, please see the AMIS Landing Page at *https://amis.cdfifund.gov.*

VII. Information Sessions and Outreach

The CDFI Fund may conduct webcasts, webinars, or information sessions for organizations that are considering applying to, or are interested in learning about, the CDFI Bond Guarantee Program. The CDFI Fund intends to provide targeted outreach to both Qualified Issuer and Eligible CDFI participants to clarify the roles and requirements under the CDFI Bond Guarantee Program. For further information, or to sign up for alerts, please visit the CDFI Fund's website at *http://www.cdfifund.gov.*

Authority: Pub. L. 111–240; 12 U.S.C. 4701, *et seq.*; 12 CFR part 1808; 12 CFR part 1805;12 CFR part 1815.

Jodie L. Harris,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2022–04007 Filed 2–25–22; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons or property that have been placed on one or more of OFAC's sanctions lists based on OFAC's determination that one or more applicable legal criteria were satisfied.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

A. Blocking of Property and Interests in Property Pursuant to E.O. 14024

On February 22, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below. U.S. persons are generally prohibited from engaging in transactions with them. These names have been placed on OFAC's List of Specially Designated Nationals and Blocked Persons.

BILLING CODE 4810–AL–P

Individuals

1. BORTNIKOV, Alexander Vasilievich (Cyrillic: БОРТНИКОВ, Александр Васильевич) (a.k.a. BORTNIKOV, Alexander), Moscow, Russia; DOB 15 Nov 1951; POB Perm, Russia; nationality Russia; Gender Male (individual) [NPWMD] [UKRAINE-EO13661] [RUSSIA-EO14024] (Linked To: FEDERAL SECURITY SERVICE).

   Designated pursuant to section 1(a)(iii) of Executive Order 14024 of April 15, 2021, "Blocking Property With Respect To Specified Harmful Foreign Activities of the Government of the Russian Federation," (E.O. 14024) for being or having been a leader, official, senior executive officer, or member of the board of directors of the Government of the Russian Federation.

2. KIRIYENKO, Sergei Vladilenovich (Cyrillic: КИРИЕНКО, Сергей Владиленович) (a.k.a. KIRIYENKO, Sergei), Moscow, Russia; DOB 26 Jul 1962; POB Sukhumi, Georgia; nationality Russia; Gender Male (individual) [UKRAINE-EO13661] [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(iii) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of the Government of the Russian Federation.

3. FRADKOV, Petr Mikhailovich (Cyrillic: ФРАДКОВ, Пётр Михайлович) (a.k.a. FRADKOV, Petr; a.k.a. FRADKOV, Petr Mihaylovich; a.k.a. FRADKOV, Pyotr Mikhailovich; a.k.a. FRADKOV, Pyotr Mikhaylovich; a.k.a. FRAKOV, Pyetr Mikhaylovich), 33-1 Prospekt Mira, Apt. 34, Moscow, Russia; DOB 07 Feb 1978; POB Moscow, Russia; nationality Russia; Gender Male; Passport 530285387 (Russia) issued 31 Oct 2012 expires 12 Jul 2022; National ID No. 45033399117 (Russia) (individual) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector and the financial services sector of the Russian Federation economy.

4. BORTNIKOV, Denis Aleksandrovich (Cyrillic: БОРТНИКОВ, Денис Александрович), Moscow, Russia; DOB 19 Nov 1974; POB Leningrad region, Russia; nationality Russia; Gender Male (individual) [RUSSIA-EO14024] (Linked To: BORTNIKOV, Alexander Vasilievich).

Designated pursuant to sections 1(a)(iii) and 1(a)(v) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of the Government of the Russian Federation and for being the spouse or adult child of Alexander Vasilievich Bortnikov, a person whose property and interests in property are blocked pursuant to section 1(a)(ii) or (iii) of E.O. 14024.

5. KIRIYENKO, Vladimir Sergeevich (Cyrillic: КИРИЕНКО, Владимир Сергеевич) (a.k.a. KIRIYENKO, Vladimir), Nesivizhsky Pereulok 12 Bld 1 Flat 16, Moscow 119021, Russia; DOB 27 May 1983; POB Nizhny Novgorod, Russia; nationality Russia; Gender Male; Passport 731167796 (Russia) issued 06 Sep 2013 expires 17 Feb 2022 (individual) [RUSSIA-EO14024] (Linked To: KIRIYENKO, Sergei Vladilenovich).

   Designated pursuant to sections 1(a)(iii) and 1(a)(v) of E.O. 14024 for being or having been a leader, official, senior executive officer, or member of the board of directors of the Government of the Russian Federation and for being the spouse or adult child of Sergei Vladilenovich Kiriyenko, a person whose property and interests in property are blocked pursuant to section 1(a)(ii) or (iii) of E.O. 14024.

Entities

1. ALKES TREID OOO (Cyrillic: ООО АЛЬКЕС ТРЕЙД) (a.k.a. ALKES TREID LLC), Ul. Smirnovskaya d. 10, Str. 3. Pom VIII, Moscow, 109052, Russia (Cyrillic: Улица Смирновская, Дом 10, Строение 3, Помещение VIII, Москва 109052, Russia); Organization Established Date 08 Feb 2018; Tax ID No. 7722437025 (Russia); Registration Number 1187746135862 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

   Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

2. ANTARES OOO (Cyrillic: ООО АНТАРЕС) (a.k.a. ANTARES LLC; a.k.a. LIMITED LIABILITY COMPANY ANTARES (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ АНТАРЕС)), Ul. Smirnovskaya d. 10, Str. 8. kabinet 10, Moscow 109052, Russia (Cyrillic: Ул. Смирновская, д. 10, стр. 8, каб. 10, Москва 109052, Russia); Organization Established Date 02 Jun 2017; Tax ID No. 7722399997 (Russia); Registration Number 7722399997 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

   Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

3. ELITNYE DOMA OOO (Cyrillic: ООО ЭЛИТНЫЕ ДОМА) (f.k.a. ELITNYE DOMA AO; a.k.a. ELITNYE DOMA LLC; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU ELITNYE DOMA), Ul.

Smirnovskaya d. 10, Str. 8, Kabinet 8, Moscow 109052, Russia (Cyrillic: Ул. Смирновская, д. 10, Стр. 8, Каб. 8, Москва 109052, Russia); Organization Established Date 26 Feb 2004; Tax ID No. 7706415641 (Russia); Registration Number 1147748157061 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

4. ERA FUND LIMITED LIABILITY COMPANY (a.k.a. ERA FUND LLC (Cyrillic: ООО ФОНД ЭРА); a.k.a. OOO PSB-FINTEKH (Cyrillic: ООО ПСБ-ФИНТЕХ)), Ul. Novo-Sadovaya D. 3 Komnata 163 Floor 3, Samara 443100, Russia (Cyrillic: Улица Ново-садовая, дом 3, комната 163 этаж 3, Самара 443100, Russia); Organization Established Date 04 Sep 2017; Tax ID No. 6316237712 (Russia); Registration Number 1176313076433 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

   Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

5. KHOLTSVUD OOO (Cyrillic: ООО ХОЛЬЦВУД) (a.k.a. HOLZVUD; a.k.a. KHOLTSVUD LLC; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU KHOLTSVUD (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ ХОЛЬЦВУД)), Ul. Smirnovskaya D. 10, Str. 8, Kabinet 8, Moscow 109052, Russia (Cyrillic: Ул. Смирновская, Д. 10, Стр. 8, Каб. 8, Москва 109052, Russia); Organization Established Date 08 Sep 2014; Registration ID 5147746070368 (Russia); Tax ID No. 7722854607 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

   Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

6. KOURF OOO (Cyrillic: ООО КОУРФ) (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU KOURF (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ КОУРФ)), Pr-Kt Oktyabrskii D. 111/119, Pom. 1, Komnata 6, Floor 2, Lyubertsy 140002, Russia (Cyrillic: Проспект Октябрьский, Дом 111/119, Помещение 1, Комната 6, Этаж 2, Люберцы 140002, Russia); Organization Established Date 05 Apr 2010; Tax ID No. 5027160402 (Russia); Registration Number 1105027004213 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

7. MANAGEMENT COMPANY PROMSVYAZ LLC (Cyrillic: УПРАВЛЯЮЩАЯ КОМПАНИЯ ПРОМСВЯЗЬ) (a.k.a. UK PROMSVYAZ OOO), d.13 str. 1 etazh 5 kom. 1-31, ul. Nikoloyamskaya, Moscow 109240, Russia; Organization Established Date 10 Jul 2002; Tax ID No. 7718218817 (Russia); Registration Number 1027718000067 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

   Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

8. PASKAL OOO (Cyrillic: ООО ПАСКАЛЬ) (a.k.a. PASKAL LLC), Ul. Smirnovskaya D. 10, Str. 8 Kabinet 12, Moscow 109052, Russia (Cyrillic: Ул. Смирновская д. 10, стр. 8 каб. 12, Москва 109052, Russia); Organization Established Date 09 Apr 2015; Tax ID No. 7725269347 (Russia); Registration Number 1157746322370 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

   Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

9. PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY (Cyrillic: ПУБЛИЧНОЕ АКЦИОНЕРНОЕ ОБЩЕСТВО ПРОМСВЯЗЬБАНК) (f.k.a. OJSC PROMSVYAZBANK; a.k.a. PROMSVYAZBANK PAO (Cyrillic: ПАО ПРОМСВЯЗЬБАНК); a.k.a. PROMSVYAZBANK PJSC; a.k.a. PUBLICHNOE AKTSIONERNOE OBSHCHESTVO PROMSVYAZBANK), Smirnovskaya Street 10/22, Moscow 109052, Russia; SWIFT/BIC PRMSRUMM; Website www.psbank.ru; BIK (RU) 044525555; Organization Established Date 2001; Target Type Financial Institution; Tax ID No. 7744000912 (Russia); Government Gazette Number 40148343 (Russia); Registration Number 1027739019142 (Russia) [RUSSIA-EO14024].

   Designated pursuant to section 1(a)(i) of E.O. 14024 for operating or having operated in the defense and related materiel sector and the financial services sector of the Russian Federation economy.

10. PSB AVIALIZING OOO (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU PSB AVIALIZING), d. 65A etazh 2, pom. 17-30, bulvar Gagarina Perm, Permski Kr. 614077, Russia; Organization Established Date 20 Jul 2020; Tax ID No. 5906167110 (Russia); Government Gazette Number 44885614 (Russia); Registration Number 1205900018532 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

11. PSB BIZNES OOO (Cyrillic: ООО ПСБ БИЗНЕС) (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU PSB BIZNES; a.k.a. OOO PSB BIZNES; a.k.a. OOO VENTURE FUND SME; a.k.a. SME VENTURE LLC; a.k.a. VENCHURNY FOND MSB OOO), d. 23 Str. 3 pom. II kom. 1K, 1L, 1M, 1N, 1O, 1P, ul. Lva Tolstogo, Moscow 119021, Russia; Organization Established Date 23 Sep 2013; Tax ID No. 5042129460 (Russia); Government Gazette Number 18098784 (Russia); Registration Number 1135042007539 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

12. PSB INNOVATIONS AND INVESTMENTS LIMITED LIABILITY COMPANY (a.k.a. "ITSBT LLC"; a.k.a. "ITSBT OOO"; a.k.a. "PSB I AND I LLC"; a.k.a. "PSB I&I LLC"; a.k.a. "PSB II OOO" (Cyrillic: "ООО ПСБ ИИ")), vn.ter.g. munitsipalny okrug Sokolniki, ul Strommnyka d. 18 str. 27, kom., Moscow 107076, Russia; Organization Established Date 19 Aug 2015; Tax ID No. 7731290146 (Russia); Registration Number 115774762381 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

13. PSB-FOREKS OOO (a.k.a. FUND FOR NON-BANKING TECHNOLOGIES LIMITED LIABILITY COMPANY; a.k.a. LIMITED LIABILITY COMPANY PSB-FOREKS (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ ПСБ-ФОРЕКС); a.k.a. PSB-FOREKS LLC; a.k.a. "FNBT LLC" (Cyrillic: "ООО ФНБТ")), D. 7, Str. 8, Pom. III Kom. N1 Etazh 2, Naberezhnaya Derbenevskaya, Moscow 115114, Russia; Organization Established Date 11 Jul 2016; Tax ID No. 7725323192 (Russia); Registration Number 1167746652193 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

14. SAINT-PETERSBURG INTERNATIONAL BANKING CONFERENCE LLC (a.k.a. LIMITED LIABILITY COMPANY SAINT-PETERSBURG INTERNATIONAL BANKING CONFERENCE (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ САНКТ-ПЕТЕРБУРГСКАЯ МЕЖДУНАРОДНАЯ БАНКОВСКАЯ КОНФЕРЕНЦИЯ); a.k.a. PSB AVTOFAKTORING), Ul. Smirnovskaya D. 10, Str. 8, Komnata 7, Moscow 109052, Russia; d. 42, Moskovskoe Shosse, Sergiev Posad, Moscow Oblast 141300, Russia (Cyrillic: д. 42, Московское Шоссе, Сергиев Посад, Московская Область 141300, Russia); Organization Established Date 30 Dec 2010; Tax ID No. 5042116461 (Russia); Registration Number 1105042007806 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

15. SERGIEVO-POSAD LEND OOO (Cyrillic: ООО СЕРГИЕВО-ПОСАД ЛЭНД) (a.k.a. SERGIEVO-POSAD LAND; a.k.a. SERGIEVO-POSAD LEND; a.k.a. SERGIEVO-POSAD LEND LLC), Ul. Tsentralnaya D. 36, Shemetovo, Sergiev Posad 141335, Russia (Cyrillic: Ул. Центральная д. 36, Шеметово, Сергиев Посад 141335, Russia); Organization Established Date 19 Apr 2011; Tax ID No. 5042118606 (Russia); Registration Number 115042002371 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

16. TEKHNOSOFT OOO (Cyrillic: ООО ТЕХНОСОФТ) (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU TEKHNOSOFT (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ ТЕХНОСОФТ)), UL. Nobelya D. 5, ET 2 POM.29 Ter. Skolkovo Innovatsionnogo Tsentra, 121205, Russia; Organization Established Date 11 Jul 2014; Tax ID No. 7703813813 (Russia); Registration Number 1147746784866 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

17. TRINITEX OOO (Cyrillic: ООО ТРИНИТЕКС) (a.k.a. TRINITEX LLC), d. 10 Str. 8 kom. 8, ul. Smirnovskaya, Moscow 109052, Russia; Organization Established Date 19 Apr 2018; Tax ID No. 7751142717 (Russia); Government Gazette Number 28329368 (Russia); Registration Number 1187746421576

(Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

18. PSB LIZING OOO (Cyrillic: ПСБ ЛИЗИНГ ООО) (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTSVENNOSTYU PSB LIZING (Cyrillic: ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ ПСБ ЛИЗИНГ); a.k.a. PSB LEASING LLC), Room 8, Building 22, ul Smirnovkaya 10, Moscow 109052, Russia (Cyrillic: Улица Смирновская, Дом 10, Комната 8, Строение 22, Город Москва 109052, Russia); Organization Established Date 05 Jul 2006; Tax ID No. 7722581759 (Russia); Government Gazette Number 96441526 (Russia); Registration Number 1067746771784 (Russia) [RUSSIA-EO14024] (Linked To: PROMSVYAZBANK PUBLIC JOINT STOCK COMPANY).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, Promsvyazbank Public Joint Stock Company, a person whose property and interests in property are blocked pursuant to E.O. 14024.

19. STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK (f.k.a. BANK FOR FOREIGN TRADE OF THE U.S.S.R.; a.k.a. GK VEB.RF; a.k.a. GOSUDARSTVENNAYA KORPORATSIYA RAZVITIYA VEB.RF; a.k.a. STATE DEVELOPMENT CORPORATION VEB.RF (Cyrillic: ГОСУДАРСТВЕННАЯ КОРПОРАЦИЯ РАЗВИТИЯ ВЭБ.РФ); a.k.a. VEB.RF (Cyrillic: ВЭБ.РФ); f.k.a. VNESHECONOMBANK; f.k.a. VNESHEKONOMBANK GK; f.k.a. VNESHEKONOMBANK SSSR; a.k.a. "BANK FOR DEVELOPMENT"; a.k.a. "VEB"), Akademik Sakharov Ave 9, Moscow 107996, Russia; Pr-kt, Akademika Sakharova, D. 9, Moscow 107078, Russia (Cyrillic: Пр-Кт Академика Сахарова, Д. 9, Город Москва 107078, Russia); SWIFT/BIC BFEARUMM; Website www.veb.ru; BIK (RU) 044525060; Executive Order 13662 Directive Determination - Subject to Directive 1; Organization Established Date 18 Aug 1922; Target Type State-Owned Enterprise; alt. Target Type Financial Institution; Tax ID No. 7750004150 (Russia); Government Gazette Number 00005061 (Russia); Registration Number 1077711000102 (Russia); For more information on directives, please visit the following link: http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives. [UKRAINE-EO13662] [RUSSIA-EO14024].

Designated pursuant to section 1(a)(i) and 1(a)(vii) of E.O. 14024 for operating or having operated in the financial services sector of the Russian Federation economy and for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, the Government of the Russian Federation.

20. EXIMBANK OF RUSSIA JSC (a.k.a. AO ROSEKSIMBANK (Cyrillic: АО РОСЭКСИМБАНК); a.k.a. EXIMBANK OF RUSSIA; a.k.a. EXIMBANK OF

RUSSIA ZAO; a.k.a. GOSUDARSTVENNY SPETSIALIZIROVANNY ROSSISKI EKSPORTNO-IMPORTNY BANK (ZAKRYTOE AKTSIONERNOE OBSHCHESTVO); a.k.a. ROSEKSIMBANK, ZAO; a.k.a. RUSSIAN EXPORT-IMPORT BANK; a.k.a. STATE SPECIALIZED RUSSIAN EXPORT-IMPORT BANK JOINT-STOCK COMPANY (Cyrillic: ГОСУДАРСТВЕННЫЙ СПЕЦИАЛИЗИРОВАННЫЙ РОССИЙСКИЙ ЭКСПОРТНО-ИМПОРТНЫЙ БАНК АКЦИОНЕРНОЕ ОБЩЕСТВО)), 12 Krasnopresnenskaya Embankments, Moscow 123610, Russia; SWIFT/BIC EXIRRUMM; Website eximbank.ru; Executive Order 13662 Directive Determination - Subject to Directive 1; Organization Established Date 24 May 1994; Target Type Financial Institution; Tax ID No. 7704001959 (Russia); Legal Entity Number 253400HA6URWT39X2982; Registration Number 1027739109133 (Russia); All offices worldwide; for more information on directives, please visit the following link: http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives. [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

21. RUSSIAN AGENCY FOR EXPORT CREDIT AND INVESTMENT INSURANCE OJSC (a.k.a. EKSAR OAO; a.k.a. EXIAR; a.k.a. EXIAR JSC; a.k.a. EXIAR OJSC; a.k.a. ROSSISKOE AGENTSTVO PO STRAKHOVANIYU EKSPORTNYKH KREDITOV I INVESTITSI OTKRYTOE AKTSIONERNOE OBSHCHESTVO; a.k.a. RUSSIAN AGENCY FOR EXPORT CREDIT AND INVESTMENT INSURANCE JSC), nab. Krasnopresnenskaya d. 12, Moscow 123610, Russia; Website exiar.ru; Executive Order 13662 Directive Determination - Subject to Directive 1; Organization Established Date 13 Oct 2011; Target Type Government Entity; Tax ID No. 7704792651 (Russia); Registration Number 1117746811566 (Russia); For more information on directives, please visit the following link: http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives. [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

22. JSC SLAVA (a.k.a. AO SLAVA; a.k.a. MOSCOW JOINT STOCK COMPANY SLAVA SECOND WATCH FACTORY), Ul. Verkhnaya d. 34, Str. 1, 2 Et, Pom. 8, Komn. 50, Moscow 125040, Russia; Website www.slava-watch.com; Tax ID

No. 7714046028 (Russia); Registration Number 1027700324530 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

23. LLC VEB.RF ASSET MANAGEMENT (a.k.a. VEB.RF UPRAVLENIE AKTIVAMI), B-R 31 Novinskii D., Floor 7, Pomeshch. I. Kom 16, Moscow 123242, Russia; Tax ID No. 9704032929 (Russia); Registration Number 1207700367930 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

24. LLC TORGOVY KVARTAL-NOVOSIBIRSK, Ul. Frunze d. 238, Novosibirsk 630112, Russia; Website www.sibmoll.ru; Tax ID No. 5405230467 (Russia); Registration Number 1025401906639 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

25. JSC INFRAVEB (a.k.a. AKTSIONERNOE OBSHCHESTVO VEB INFRASTRUKTURA; a.k.a. AO INFRAVEB), ul. Mashi Poryvaevoi D. 7 str. V, Moscow 107078, Russia; ul. Vozdvizhenka D. 7/6, str. 1, et/pom/kom 3/II/7, Moscow 119019, Russia; Website vebinfra.ru; Tax ID No. 7704133578 (Russia); Registration Number 1027739088410 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

26. LLC RESORT ZOLOTOE KOLTSO (a.k.a. KURORT ZOLOTOE KOLTSO (Cyrillic: КУРОРТ ЗОЛОТОЕ КОЛЬЦО); a.k.a. LLC KURORT ZOLOTOE KOLTSO), ul. Svobody D. 8, office 6, g. Pereslavl-Zalesskii, 152020, Russia; Shosse Varshavskoe D 47, korp 4, Moscow 114230, Russia; Tax ID No. 7724331673 (Russia); Registration Number 1157746795733 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

27. JSC RUSSIAN EXPORT CENTER (a.k.a. AKTSIONERNOE OBSHCHESTVO ROSSIISKII EKSPORTNYI TSENTR; f.k.a. AO NATSIONALNY EKSPORTNY TSENTR; a.k.a. AO ROSSIISKII EKSPORTNYI TSENTR; a.k.a. AO ROSSISKI EKSPORTNY TSENTR), D. 12 etazh 13 pom. 1301, naberezhnaya Krasnopresnenskaya, Moscow 123610, Russia; Website exportcenter.ru; Tax ID No. 7703376553 (Russia); Registration Number 1157746363994 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

28. LLC VEB VENTURES (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU VEB VENCHURS; f.k.a. OOO VEB INNOVATSIYA; a.k.a. OOO VEB VENCHURS; f.k.a. VEB INNOVATIONS; a.k.a. VEB VENCHURS), D. 2 etazh 7, Ul. Bleza Paskalya Ter. Skolkovo Innovatsionnogo, Moscow 121205, Russia; Website vebinnovations.ru; Tax ID No. 7731373995 (Russia); Registration Number 1177746639036 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

29. LLC VEB SERVICE (a.k.a. VEB SERVICE; a.k.a. VEB SERVIS), PR-KT Akademika Sakharova D. 9, Komnata 205 K, Moscow 107078, Russia; Tax ID No. 7708325680 (Russia); Registration Number 1177746934023 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR

DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

30. LLC SPECIAL ORGANIZATION FOR PROJECT FINANCE FACTORY OF PROJECT FINANCE (a.k.a. SPETSIALIZIROVANNOE OBSHCHESTVO PROEKTNOGO FINANSIROVANIYA FABRIKA PROEKTNOGO FINANSIROVANIYA; a.k.a. "PROJECT FINANCE FACTORY"), pr-kt Akademika Sakharova d. 9, komnata 220, Moscow 107078, Russia; Tax ID No. 7708330489 (Russia); Registration Number 1187746103885 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

31. LLC SIBUGLEMET GROUP (a.k.a. GRUPPA SIBUGLEMET), ul. Mashi Poryvaevoi d. 34, kom. 3, Moscow 107078, Russia; Tax ID No. 7708320240 (Russia); Registration Number 1177746596268 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

32. JSC ANGSTREM-T (a.k.a. AKTSIONERNOE OBSHCHESTVO ANGSTREM-T), pr-kt Georgievskii d. 7, Zelenograd 124498, Russia; Registration ID 1057735022377 (Russia); Tax ID No. 7735128151 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

33. LLC NM-TEKH (a.k.a. NM-TEKH), pr-kt Georgievskii d. 7, Zelenograd 124498, Russia; al. Solnechnaya d. 6, floor 1 pom. xii office 4, 4a, Zelenograd 124527, Russia; Tax ID No. 7735183410 (Russia); Registration Number 1197746306790

(Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

34. JSC PFC CSKA (a.k.a. AO PFK TSSKA; a.k.a. JOINT STOCK COMPANY PROFESSIONAL FOOTBALL CLUB CSKA), Ul. 3-ya Peschanaya, d, 2a, severo-zapadnoe administrativnoe zdanie, 10-I et, Moscow 125252, Russia; Website www.pfc-cska.com; Tax ID No. 7734046851 (Russia); Registration Number 1027739880893 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

35. LLC BAIKAL CENTER (a.k.a. BAIKAL.TSENTR; a.k.a. TSENTR RAZVITIYA BAIKALSKOGO REGIONA), Vozdvizhenka d. 7/6, str. 1, pomeshch. 10, Moscow 119019, Russia; Tax ID No. 7704732846 (Russia); Registration Number 1097746515240 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

36. LLC PROGOROD (a.k.a. NOVYE GORODSKIE PROEKTY; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU NOVYE GORODSKIE PROEKTY; a.k.a. OOO PROGOROD), d. 10 etazh 7 pom. XIII kom. 2,ul. Vozdvizhenka, Moscow 125009, Russia; Tax ID No. 9704013161 (Russia); Registration Number 1207700089101 (Russia) [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

37. BANK BELVEB OJSC (a.k.a. BANK BELVEB OPEN JOINT STOCK COMPANY; a.k.a. BELVESHECONOMBANK OAO; a.k.a. BELVNESHECONOMBANK OPEN JOINT STOCK COMPANY), 29 Pobeditelei ave., Minsk 220004, Belarus; Myasnikova, 32, Minsk 220050, Belarus; SWIFT/BIC BELBBY2X; Website bveb.by; Executive Order 13662 Directive Determination - Subject to Directive 1; Organization Established Date 23 Dec 1991; Target Type Financial Institution; Tax ID No. 7750004150 (Russia); Legal Entity Number 25340038P8SYW80B9W34 (Russia); All offices worldwide; for more information on directives, please visit the following link: http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives. [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

38. VEB LEASING OJSC (a.k.a. OAO VEB LIZING; a.k.a. OJSC VEB LEASING; a.k.a. OPEN JOINT STOCK COMPANY VEB LEASING; a.k.a. OTKRYTOE AKTSIONERNOE OBSHCHESTVO VEB LIZING), d. 10 ul. Vozdvizhenka, Moscow 125009, Russia; Str. Dolgorukovskaya, 7, Novoslobodskaya, Moscow 127006, Russia; Website veb-leasing.ru; Executive Order 13662 Directive Determination - Subject to Directive 1; Organization Established Date 2003; Tax ID No. 7709413138 (Russia); Registration Number 1037709024781 (Russia); For more information on directives, please visit the following link: http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives. [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

39. PROMINVESTBANK (a.k.a. COMMERCIAL INDUSTRIAL AND INVESTMENT BANK PUBLIC JOINT STOCK COMPANY; a.k.a. JOINT STOCK COMMERCIAL INDUSTRIAL AND INVESTMENT BANK PUBLIC JOINT STOCK COMPANY; a.k.a. PSC PROMINVESTBANK; a.k.a. PUBLIC STOCK COMPANY JOINT STOCK COMMERCIAL INDUSTRIAL AND INVESTMENT BANK), 12, Shevchenko lane, Kyiv 01001, Ukraine; SWIFT/BIC UPIBUAUX; Website pib.ua; Executive Order 13662 Directive Determination - Subject to Directive 1; Organization Established Date 26 Aug 1992; Target Type Financial Institution; Registration Number 00039002 (Ukraine); All offices worldwide; for more information on directives, please visit

the following link: http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives. [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

40. VEB CAPITAL (a.k.a. LLC VEB CAPITAL; a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU INVESTITSIONNA YA KOMPANIYA VNESHEKONOMBANKA; a.k.a. OOO VEB KAPITAL), d. 7 str. A ul. Mashi Poryvaevoi, Moscow 107078, Russia; Website vebcapital.ru; Executive Order 13662 Directive Determination - Subject to Directive 1; Organization Established Date 24 Dec 2009; Tax ID No. 7708710924 (Russia); Registration Number 1097746831709 (Russia); For more information on directives, please visit the following link: http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives. [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

41. VEB ENGINEERING LLC (a.k.a. OBSHCHESTVO S OGRANICHENNOI OTVETSTVENNOSTYU VEB INZHINIRING; a.k.a. OOO VEB ENGINEERING; a.k.a. OOO VEB INZHINIRING; a.k.a. VEB ENGINEERING LIMITED LIABILITY COMPANY), d. 9 prospekt Akademika Sakharova, Moscow 107996, Russia; Per. Lyalin D. 19, Korpus 1, Pom. XXIV, Kom 11, Moscow 101000, Russia; Website vebeng.ru; Executive Order 13662 Directive Determination - Subject to Directive 1; Organization Established Date 11 Mar 2010; Tax ID No. 7708715560 (Russia); Registration Number 1107746181674 (Russia); For more information on directives, please visit the following link: http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives. [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

42. JSC VEB.DV (a.k.a. AO VEB.DV; f.k.a. FAR EAST AND BAIKAL REGION DEVELOPMENT FUND OJSC; f.k.a. JSC FAR EAST AND ARCTIC REGION DEVELOPMENT FUND; f.k.a. OJSC THE FAR EAST AND BAIKAL REGION DEVELOPMENT FUND), Nab. Presnenskaya D. 10, pom II komn 8-59, Moscow 123112, Russia; Website fondvostok.ru; Executive Order 13662 Directive Determination - Subject to Directive 1; Tax ID No. 2721188289 (Russia); Registration Number 1112721010995 (Russia); For more information on directives, please visit the following link: http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives. [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

43. VEB ASIA LIMITED, Suite 5808, 58/F, Two International Finance Center, 8 Finance Street Central, Hong Kong, China; Executive Order 13662 Directive Determination - Subject to Directive 1; Organization Established Date 08 Apr 2013; Registration Number 1886537 (Hong Kong); For more information on directives, please visit the following link: http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives. [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

44. LLC INFRASTRUCTURE MOLZHANINOVO (Cyrillic: ООО ИНФРАСТРУКТУРА МОЛЖАНИНОВО) (a.k.a. INFRASTRUKTURA MOLZHANINOVO; f.k.a. LLC RESAD (Cyrillic: ООО РЕСАД); f.k.a. RESAD LLC), ul. Bryanskaya D. 5, et 4 pom. I kom 25, Moscow 121059, Russia; Executive Order 13662 Directive Determination - Subject to Directive 1; Tax ID No. 7733109347 (Russia); Registration Number 1027739071337 (Russia); For more information on directives, please visit the following link: http://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives. [UKRAINE-EO13662] [RUSSIA-EO14024] (Linked To: STATE CORPORATION BANK FOR DEVELOPMENT AND FOREIGN ECONOMIC AFFAIRS VNESHECONOMBANK).

    Designated pursuant to section 1(a)(vii) of E.O. 14024 for being owned or controlled by, or for having acted or purported to act for or on behalf of, directly

or indirectly, State Corporation Bank for Development and Foreign Economic Affairs Vnesheconombank, a person whose property and interests in property are blocked pursuant to E.O. 14024.

Vessels

1. BALTIC LEADER (Cyrillic: БАЛТИК ЛИДЕР) Roll-on Roll-off 8,831GRT Russia flag; Vessel Registration Identification IMO 9220639 (vessel) [RUSSIA-EO14024] (Linked To: PSB LIZING OOO).

   Identified as property in which PSB Lizing OOO, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

2. FESCO MAGADAN (Cyrillic: ФЕСКО МАГАДАН) Container Ship 7,519GRT Russia flag; Vessel Registration Identification IMO 9287699 (vessel) [RUSSIA-EO14024] (Linked To: PSB LIZING OOO).

   Identified as property in which PSB Lizing OOO, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

3. FESCO MONERON (Cyrillic: ФЕСКО МОНЕРОН) Container Ship 7,519GRT Russia flag; Vessel Registration Identification IMO 9277412 (vessel) [RUSSIA-EO14024] (Linked To: PSB LIZING OOO).

   Identified as property in which PSB Lizing OOO, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

4. LINDA (Cyrillic: ЛИНДА) (f.k.a. "LADY D" (Cyrillic: "ЛЕДИ Д")) Crude Oil Tanker 61,991GRT Russia flag; Vessel Registration Identification IMO 9256858 (vessel) [RUSSIA-EO14024] (Linked To: PSB LIZING OOO).

   Identified as property in which PSB Lizing OOO, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.
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5. PEGAS (Cyrillic: ПЕГАС) (f.k.a. "PERUN" (Cyrillic: "ПЕРУН")) Crude Oil Tanker 61,991GRT Russia flag; Vessel Registration Identification IMO 9256860 (Russia) (vessel) [RUSSIA-EO14024] (Linked To: PSB LIZING OOO).

   Identified as property in which PSB Lizing OOO, a person whose property and interests in property are blocked pursuant to E.O. 14024, has an interest.

B. Persons Determined To Be Subject to Directive 1A Under E.O. 14024

On February 22, 2022, OFAC determined that the following entities (a) are political subdivisions, agencies, or instrumentalities of the Government of the Russian Federation; and (b) shall be subject to the prohibitions of Directive 1A under E.O. 14024, ''Prohibitions Related to Certain Sovereign Debt of the Russian Federation,'' which replaces and supersedes Directive 1 of April 15, 2021 under E.O. 14024. These names have been placed on OFAC's Non-SDN Menu-Based Sanctions List.

1. MINISTRY OF FINANCE OF THE RUSSIAN FEDERATION (Cyrillic: МИНИСТЕРСТВО ФИНАНСОВ РОССИЙСКОЙ ФЕДЕРАЦИИ), 9 Ilyinka Street, Moscow 109097, Russia (Cyrillic: ул. Ильинка, 9, Москва 109097, Russia); Target Type Government Entity; Executive Order 14024 Directive Information - For more information on directives, please visit the following link: https://home.treasury.gov/policy-issues/financial-sanctions/sanctions-programs-and-country-information/russian-harmful-foreign-activities-sanctions#directives; Executive Order 14024 Directive Information Subject to Directive 1a - As of the effective date, participation in the secondary market for ruble or non-ruble denominated bonds issued on or after the effective date by the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation is prohibited.; Listing Date (EO 14024 Directive 1a): 22 Feb 2022; Effective Date (EO 14024 Directive 1a): 01 Mar 2022 [RUSSIA-EO14024].

2. NATIONAL WEALTH FUND OF THE RUSSIAN FEDERATION (Cyrillic: ФОНД НАЦИОНАЛЬНОГО БЛАГОСОСТОЯНИЯ), 9 Ilyinka Street, Moscow 109097, Russia (Cyrillic: ул. Ильинка, 9, Москва 109097, Russia); Target Type Government Entity; Executive Order 14024 Directive Information - For more information on directives, please visit the following link: https://home.treasury.gov/policy-issues/financial-sanctions/sanctions-programs-and-country-information/russian-harmful-foreign-activities-sanctions#directives; Executive Order 14024 Directive Information Subject to Directive 1a - As of the effective date, participation in the secondary market for ruble or non-ruble denominated bonds issued on or after the effective date by the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation is prohibited.; Listing Date (EO 14024 Directive 1a): 22 Feb 2022; Effective Date (EO 14024 Directive 1a): 01 Mar 2022 [RUSSIA-EO14024].

3. CENTRAL BANK OF THE RUSSIAN FEDERATION (Cyrillic: ЦЕНТРАЛЬНЫЙ БАНК РОССИЙСКОЙ ФЕДЕРАЦИИ) (a.k.a. BANK OF RUSSIA; a.k.a. BANK OF RUSSIA, CENTRAL BANK; a.k.a. BANK ROSSI, FEDERAL STATE BUDGETARY INSTITUTION; a.k.a. CENTRAL BANK OF RUSSIA; a.k.a. TSENTRALNY BANK ROSSISKOI FEDERATSII), Neglinnaya St 12, Moscow 107016, Russia; Moscow, Russia; SWIFT/BIC CBRFRUMM; Website www.cbr.ru; Organization Established Date 13 Jul 1990; Organization Type: Central banking; Target Type Government Entity; Executive Order 14024 Directive Information - For more information on directives, please visit the following link: https://home.treasury.gov/policy-issues/financial-sanctions/sanctions-programs-and-country-information/russian-harmful-foreign-activities-sanctions#directives; Executive Order 14024 Directive Information Subject to Directive 1a - As of the effective date, participation in the secondary market for ruble or non-ruble denominated bonds issued on or after the effective date by the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation is prohibited.; Listing Date (EO 14024 Directive 1a): 22 Feb 2022; Effective Date

(EO 14024 Directive 1a): 01 Mar 2022; Tax ID No. 7702235133 (Russia); Government Gazette Number 00032253 (Russia); Registration Number 1037700013020 (Russia) [RUSSIA-EO14024].

Dated: February 22, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–04092 Filed 2–25–22; 8:45 am]

BILLING CODE 4810–AL–C

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act; Meeting

TIME AND DATE: March 3, 2022, from 1:30 p.m. to 4:30 p.m., Eastern time.

PLACE: This meeting will be accessible via conference call and screensharing. Any interested person may call 877–853–5247 (US toll free), 888–788–0099 (US toll free), +1 929–205–6099 (US toll), or +1 669–900–6833 (US toll), Conference ID 920 2493 9329, to participate in the meeting. The website to participate via Zoom meeting and screenshare is *https://kellen.zoom.us/meeting/register/tJYtde2hrTIpGN1UxVfSCrLBaqt3I-sDBwzt.*

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Board of Directors (the ''Board'') will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of the meeting will include:

Agenda

I. Welcome and Call to Order—UCR Board Chair

The UCR Board Chair will welcome attendees, call the meeting to order, call roll for the Board, confirm the presence of a quorum, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Board Agenda—UCR Board Chair

For Discussion and Possible Action

The proposed Agenda will be reviewed, and the Board will consider adoption.

Ground Rules

➢ Board actions taken only in designated areas on agenda.

IV. Approval of Board Minutes of the January 27, 2022 UCR Board Meeting—UCR Board Chair

For Discussion and Possible Action

Draft Minutes from the January 27, 2022 UCR Board meeting will be reviewed. The Board will consider action to approve.

V. Report of the Federal Motor Carrier Safety Administration (FMCSA)—FMCSA Representative

The FMCSA will provide a report on any relevant activity.

VI. Chief Legal Officer Report—UCR Chief Legal Officer

The UCR Chief Legal Officer will report on matters of interest to the UCR Plan.

VII. Engagement Letter Between the UCR Plan and the Bradley Law Firm—UCR Executive Director and UCR Board Chair

For Discussion and Possible Board Action

A general engagement letter between the UCR Plan and the Bradley Law Firm, covering the broad scope of legal issues directed to Alex Leath by the UCR Plan in calendar year 2022, will be presented to the UCR Board for its consideration and approval.

VIII. Subcommittee Reports

Audit Subcommittee—UCR Audit Subcommittee Chair

A. UCR Compliance Snapshot—UCR Audit Subcommittee Chair

The UCR Audit Subcommittee Chair will review audit compliance rates for the states for registration years 2020, 2021, and 2022 and will include compliance percentages for Focused Anomaly Reviews (FARs), retreat audits, and registration compliance percentages as mandated by the UCR Board. A new element has been added that focuses on the states' enforcement and citations actually issued versus the ''Should Have Been'' (''SHB'') road-stops that were not cited. The new feature ranks the states based on citation percentages.

B. Discuss the New IRP and IFTA Reports Available on the NRS—UCR Audit Subcommittee Chair and DSL Transportation Services, Inc. (DSL)

The UCR Audit Subcommittee Chair and DSL will discuss the value of following up on the Title 49 CFR 392.2 violations. The discussion will highlight the financial value to the states by vetting these companies for UCR compliance, commercial registration, IFTA, intrastate, interstate operating authority and safety compliance. Title 49 CFR 392.2 requires commercial motor vehicles to operate in accordance with the laws, ordinances, and regulations of the jurisdiction in which they are operating within.

C. Review 2022 Kansas SHB Report—Audit Subcommittee Chair, Verna Jackson, and DSL

The UCR Audit Subcommittee Chair, supported by Verna Jackson and DSL, will explain the Kansas review process. The discussion will focus on the value of following up on 49 CFR 392.2 violators to ensure both UCR and safety compliance, and the correlation between various NRS tools available to the states.

Finance Subcommittee—UCR Finance Subcommittee Chair

A. Redemption of Certificates of Deposit (CDs)—UCR Finance Subcommittee Chair and UCR Depository Manager

For Discussion and Possible Board Action

The UCR Finance Subcommittee Chair and UCR Depository Manager will discuss the opportunity to redeem up to two separate CDs prior to maturity and use the proceeds to purchase U.S. Treasury Bills which have higher income earning potential than CDs do. The Board may take action to redeem the CDs and use the proceeds to purchase U.S. Treasury Bills.

B. Fee Recommendation for 2023 Registration Year—UCR Comment—UCR Finance Subcommittee Chair and UCR Depository Manager

The UCR Finance Subcommittee Chair and the UCR Depository Manager will provide an update on the issuance of a comment to the FMCSA by UCR resulting from the Notice of Preliminary Rulemaking published on January 24, 2022. The comment updated the fee calculations by using more current data

than was used in the original recommendation submitted to the Secretary of The U.S. Department of Transportation and the FMCSA in August 2021.

Education and Training Subcommittee—UCR Education and Training Subcommittee Chair

A. Update on Current and Future Training Initiatives—UCR Education and Training Subcommittee Chair

The UCR Education and Training Subcommittee Chair and the UCR Operations Manager will provide an update on the current and planned future training initiatives for the UCR Plan.

IX. Contractor Reports—UCR Executive Director

- *UCR Executive Director's Report*

The UCR Executive Director will provide a report covering recent activity for the UCR Plan.

- *DSL Transportation Services, Inc.*

DSL Transportation Services, Inc. will report on the latest data from the FARs program, discuss motor carrier inspection results, pilot projects and other matters.

- *Seikosoft*

Seikosoft will provide an update on recent/new activity related to the National Registration System.

- *UCR Administrator Report (Kellen)*

The UCR staff will provide a management report covering recent activity for the Depository, Operations, and Communications.

X. Other Business—UCR Board Chair

The UCR Board Chair will call for any other items Board members would like to discuss.

XI. Adjournment—UCR Board Chair

The UCR Board Chair will adjourn the meeting.

This agenda will be available no later than 5:00 p.m. Eastern time, February 23, 2022 at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2022–04317 Filed 2–24–22; 4:15 pm]

BILLING CODE 4910–YL–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0679]

Agency Information Collection Activity Under OMB Review: Certification of Change or Correction of Name Government Life Insurance

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection are due no later than March 30, 2022.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0679'' in any correspondence.

SUPPLEMENTARY INFORMATION: Written comments and recommendations for the proposed information collection should be sent 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. Refer to ''OMB Control No. 2900–0679.

Authority: 44 U.S.C. 3501–21.

Title: Certification of Change or Correction of Name Government Life Insurance (VA Form 29–586).

OMB Control Number: 2900–0679.

Type of Review: Extension of a currently approved collection.

Abstract: The form is used by the insured as a certification of change or correction of name. The information on the form is required by law, U.S.C. 1904 and 1942.

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 **Federal Register** notice with a 60-day comment period soliciting comments on this collection of information was published at 86 FR 244 on December 23, 2021, pages 73102 and 73103.

Affected Public: Individuals or Households.

Estimated Annual Burden: 20 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 120.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–04059 Filed 2–25–22; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 87 Monday,
No. 39 February 28, 2022

Part II

Department of Transportation

49 CFR Part 40
Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Addition of Oral Fluid Specimen Testing for Drugs; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket DOT–OST–2021–0093]

RIN 2105–AE94

Procedures for Transportation Workplace Drug and Alcohol Testing Programs: Addition of Oral Fluid Specimen Testing for Drugs

AGENCY: Office of the Secretary, U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Department of Transportation is proposing to amend the transportation industry drug testing program procedures regulation to include oral fluid testing. This will give employers a choice that will help combat employee cheating on urine drug tests and provide a more economical, less intrusive means of achieving the safety goals of the program. The proposal includes other provisions to update the Department's regulation, and to harmonize, as needed, with the new Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid established by the U.S. Department of Health and Human Services.

DATES: Comments to the notice of proposed rulemaking should be submitted by March 30, 2022. Late-filed comments will be considered to the extent practicable.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor Room W12–140, Washington, DC 20590–0001.
- *Hand delivery:* West Building Ground Floor, Room W–12–140, 1200 New Jersey Ave. SE, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

Instructions: To ensure proper docketing of your comment, please include the agency name and docket number DOT–OST–2021–0093 or the Regulatory Identification Number (RIN), 2105–AE94 for the rulemaking at the beginning of your comments. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Patrice M. Kelly, JD, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone number 202–366–3784; *ODAPCwebmail@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Purpose

The Department of Transportation (DOT) is issuing this notice of proposed rulemaking (NPRM) to revise part 40 of title 49 of the Code of Federal Regulations (Part 40), ''Procedures for Transportation Workplace Drug and Alcohol Testing Programs'' to add the oral fluid testing procedures to the existing urine drug testing procedures for safety-sensitive transportation employees subject to drug testing under Part 40 (hereinafter referred to as ''employees''). This action is based on the Department of Health and Human Services' (HHS) establishment of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) for Federal workplace drug testing programs. HHS determined that oral fluid testing conducted in accordance with the OFMG provides ''the same scientific and forensic supportability of drug test results as the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine . . . .'' (84 FR 57554). The OFMG final rule was published on October 25, 2019, and became effective January 1, 2020.

In addition to adding oral fluid as a drug testing method and harmonizing with pertinent OFMG sections, we also propose to clarify certain Part 40 provisions that cover urine drug testing procedures; to remove provisions that no longer are necessary; to add clarifying language to other provisions such as updated definitions and web links, as appropriate; and to update provisions to reflect issues that have arisen in recent practice.

II. Authority for This Rulemaking

This rulemaking is promulgated under the authority originally enacted in the Omnibus Transportation Employee Testing Act (OTETA) of 1991, codified at 49 U.S.C. 45102 and 45104 (aviation industry testing), 49 U.S.C. 20140 (rail), 49 U.S.C. 31306 (motor carrier), and 49 U.S.C. 5331 (transit). OTETA requires that the Department incorporate the HHS Mandatory Guidelines, including amendments, into the Department's regulations for testing and laboratory requirements for aviation, rail, motor carrier, and transit testing. Additional authority at 5 U.S.C. 7301 note and Executive Order 12564, establish HHS as the agency that establishes scientific and technical guidelines for Federal workplace drug testing programs and standards for certification of laboratories engaged in such drug testing.

While DOT has discretion concerning many aspects of its regulations governing testing in the transportation industries' regulated programs, DOT follows the HHS Mandatory Guidelines for the laboratory and specimen testing procedures. Effective January 1, 2020, the OFMG allowed the option to use oral fluid specimens for Federal drug testing. As described in the OFMG rulemaking, the advantage of every oral fluid collection is that it will be directly observed, as opposed to most urine collections, which are unobserved. While directly observed urine specimen collections have long been the most effective method for preventing individuals from cheating on their drug tests by substituting or adulterating their specimens, directly observed urine collection may only be done in certain circumstances due to employee privacy concerns (see 49 CFR 40.67). Unlike directly observed urine collections, an oral fluid collection is much less intrusive on the tested employee's privacy. By providing the option of collecting an oral fluid specimen, DOT is broadening options for the testing of safety-sensitive employees in the transportation industries. As discussed below, oral fluid collection can also reduce costs of compliance with Part 40.

III. Background

On November 21, 1988, the Department first published its drug testing program procedures regulation, Part 40, as an interim final rule (53 FR 47002). The Department based the scientific requirements in that rule on the 1988 HHS Mandatory Guidelines for Federal Agency Employee Drug Testing Programs (53 FR 11970, Apr. 11, 1988), which set forth the scientific procedures for laboratories to analyze urine specimens for the presence of specified drugs at the HHS-required cutoff levels for the initial and confirmation tests for each specific drug in urine testing. These cutoff levels for urine were established at levels to show prohibited use of the specified drugs.

When the Department adopted its first drug testing final rule, we established a procedure for urine collections generally to take place with visual and aural privacy afforded to each employee, unless suspicious activity under 49 CFR 40.25(f)(14), (16) and (23) (53 FR 47002, Nov. 21, 1988) called for

a direct observed collection (*i.e.,* body-to-bottle observation). In December of 2000, the Department comprehensively rewrote Part 40 into plain language. The direct observation provisions for urine were placed in 49 CFR 40.67, with the body-to-bottle observation requirement remaining unchanged. (65 FR 79462, Dec. 19, 2000).

Urine collections are potentially invasive searches and seizures of private citizens, subject to scrutiny under the Fourth Amendment of the United States Constitution. Consequently, the Department has always approached the collection of urine from transportation safety-sensitive employees with a concern for employee privacy, which must be balanced carefully against the Department's need to protect transportation safety. The Department protects individual rights by ensuring visual and aural privacy for employees undergoing urine testing. Allowing directly observed collections only for ''cause'' (*i.e.,* suspicious activity at the collection site or as determined by the laboratory testing of a specimen) is another protection. Yet, because the vast majority of DOT-regulated urine drug collections are unobserved, the program remains vulnerable to cheating by employees at the collection site, which can result in adulteration or substitution.

In June 2008, the Department added provisions to strengthen directly observed collection requirements to include more effective observation procedures and expanded the circumstances that would warrant a direct observation procedure to address cheating on drug tests. (73 FR 35961, June 25, 2008). Although the 2008 final rule was challenged in court and initially stayed, the stay was lifted, and the final rule was reinstated. (74 FR 37949, July 30, 2019). This action was based on the unanimous decision of the United States Court of Appeals for the District of Columbia Circuit. The court's decision affirmed the Department's enhanced direct observation procedures to prevent the use of prosthetic devices used for cheating and to expand direct observation to tests of people who had already violated the rules (*e.g.,* return-to-duty and follow-up tests for persons who had tested positive or refused to test). See *BNSF Railway Company* v. *Department of Transportation,* 566 F.3d 200 (D.C. Cir. 2009).

Before the Department's move to expand the direct observation procedures, HHS was aware of the potential for cheating on urine tests and had begun its own rulemaking to explore alternative testing methods. In 2004, HHS solicited public comment upon the following alternative testing methods, all of which would be directly observed: oral fluid, hair, and sweat testing. (69 FR 19673, Apr. 13, 2004). HHS stated: ''Addition of these specimens to the Federal Workplace Drug Testing Program would complement urine drug testing and aid in combating the threat from industries devoted to subverting drug testing through adulteration, substitution, and dilution.'' (*Id.* at 19675). HHS noted that there were problems with all three of the proposed alternative matrices but asked for additional scientific information and sought information on appropriate levels for proficiency testing for these alternatives.

While the science supporting oral fluid testing did not meet the standards of HHS in 2004, science and research studies have now reached a point where HHS is able to determine that oral fluid testing is an appropriate alternative testing method for identifying illicit drug use in the Federal workplace. As such, HHS proposed adding oral fluid testing to the Federal employee workplace testing program (80 FR 28054, May 15, 2015) and finalized this proposal, which became effective for Federal employee workplace testing on January 1, 2020 (84 FR 57554, Oct. 25, 2019).

The Department is proposing to add oral fluid testing as an alternative testing method because, as noted above, it has been determined by HHS to be scientifically viable for Federal workplace programs and because it provides a directly observed collection for every test. The collection of oral fluid is less invasive than directly observed urine collection and, therefore, is consistent with the careful balancing of an individual's right to privacy with the Department's strong interest in preserving transportation safety by deterring illicit drug use.

The Department's testing statutes specifically require that the Department incorporate the HHS Mandatory Guidelines, which are scientific and technical guidelines that ''establish comprehensive standards for all aspects of laboratory-controlled substances testing'' to ensure full reliability and accuracy in testing. Because HHS has published its final OFMG, thereby approving oral fluid testing as a reliable means of detecting illicit drug use for Federal employees, the Department is proposing to allow, but not require, oral fluid specimen testing as an alternative method under Part 40, for use by DOT-regulated employers for required transportation industry workplace testing. Specifically, we are seeking comments as to whether there are circumstances where either urine or oral fluid should be mandatory. We are also proposing to amend some of our provisions that pertain to both urine and oral fluid testing to harmonize with pertinent sections of the urine and oral fluid HHS Mandatory Guidelines. We are proposing to clarify certain existing Part 40 provisions that cover the handling of urine specimens, remove provisions that are no longer necessary (such as erroneous compliance dates), add clarifying language to other provisions (such as updated definitions and web links where necessary), and modify a few substantive provisions to address issues that have arisen in practice (such as whether a test cancelled by a medical review officer (MRO) can ever be uncancelled, and whether a Substance Abuse Professional (SAP) should be allowed to conduct evaluations virtually).

IV. Principal Policy Considerations

Oral Fluid as an Alternative Drug Testing Method for Workplace Testing

Since 2004, when HHS previously considered oral fluid testing, the scientific viability of that testing has advanced. In its 2019 final rule, HHS stated that ''[t]he scientific basis for the use of oral fluid as an alternative specimen for drug testing has now been broadly established and the advances in the use of oral fluid in detecting drugs have made it possible for this alternative specimen to be used in Federal programs with the same level of confidence that has been applied to the use of urine.'' (84 FR 57554; Oct. 25, 2019). Importantly, HHS stated that its ''OFMG provide the same scientific and forensic supportability of drug test results as the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine . . . .'' *Id.*

In its 2019 OFMG, HHS recognized that products have emerged that can help people to adulterate a urine specimen. HHS emphasized that establishing oral fluid as a testing method would allow Federal agencies greater flexibility to address testing needs while minimizing the opportunity for specimen adulteration or substitution. (84 FR 57554, 57571; Oct. 25, 2019).

Adulterating and substituting unobserved urine specimens is not a new issue to drug testing. In upholding the Office of Drug and Alcohol Policy and Compliance's (ODAPC) 2008 final rule allowing additional direct observation procedures, the U.S. Court of Appeals for the District of Columbia Circuit recognized the ''cheating'' problem: ''especially in light of

evidence of a growing proliferation of products that facilitate cheating on drug tests, the Department solicited comment on additional procedures to strengthen testing integrity.'' *BNSF Railway* v. *US Department of Transportation,* 566 F.3d at 202.

In the *BNSF* court case, the D.C. Circuit upheld directly observed urine collections under the specific circumstances imposed by the Department because of the imminent threat of individuals cheating on drug tests. The court acknowledged that ''the Department determined that it was 'not practicable' to ignore the cheating problem.'' *Id.* at 204. The court also accepted that oral fluid testing was not an acceptable method because HHS had not yet approved any specimen testing except urine. *Id.* at 205. With all of this considered, the court upheld the Department's direct observation procedures. *Id.* at 208–209. If the proposal to allow oral fluid testing is adopted, we could allow the use of oral fluid testing in lieu of observed urine tests to assist in addressing the cheating problem acknowledged in the *BNSF* case.

While the Department does not have data on how much cheating is occurring, the problem exists and poses a direct threat to transportation safety. The court in *BNSF* noted: ''Acknowledging that it had no statistics on the rates of actual use of such devices, the Department inferred their use from the anecdotal evidence of their availability.'' Because the successful use of a cheating device would produce a negative drug test result, this would not show up in statistical reports as ''cheating.'' Thus, the court agreed with DOT that ''it was 'illogical' to require statistical evidence of cheating. Given that people presumably buy cheating devices to use them, we think this approach quite reasonable . . .'' Consequently, the court recognized that the DOT could not base the rulemaking on statistical data on cheating. The court concluded, '' 'It is one thing to set aside agency action under the Administrative Procedure Act because of failure to adduce empirical data that can readily be obtained. It is something else to insist upon obtaining the unobtainable. *BNSF,* 566 F.3d at 204 (internal citations omitted)).

The Department recognizes that the court upheld directly observed urine tests in specific circumstances covered in the regulation. In this rulemaking, the Department is proposing, as an option to employers, a specimen collection methodology that is inherently a directly observed collection and a much less invasive form of direct observation drug test collection.

In evaluating the progress of science of oral fluid testing and its scientific viability, HHS also looked at its forensic defensibility in workplace testing. Specifically, HHS addressed concerns about passive exposure as the result of someone else's drug use (*e.g.,* from second-hand smoke) in the context of cutoffs or metabolites used in oral fluid testing, particularly with regard to marijuana. (84 FR 57557, 57558; Oct. 25, 2019). HHS concluded that a 4 ng/mL screening test cutoff for THC would detect use of marijuana while eliminating possibilities of positive tests resulting from passive exposure, as directed by the SUPPORT for Patients and Communities Act, Public Law 115–271, 8107(b). (See 84 FR at 57558; Oct. 25, 2019).

HHS has verified the science, set the cutoffs for testing, and begun the laboratory certification process for oral fluid testing. Pursuant to the statutory directive to incorporate HHS's scientific and technical guidelines, the Department proposes to offer oral fluid testing to DOT-regulated employers as an alternative to urine testing.

Using Oral Fluid Testing as an Alternative Method Can Reduce Costs

We recognize that oral fluid testing is generally less expensive than urine testing. We understand that an oral fluid test can cost between $10 to $20 less than a urine testing (*e.g.,* about $50 for a typical urine testing process, vs. about $35 for an oral fluid testing process, with the largest part of the difference being attributable to the collection process). We are seeking public comment on the costs of oral fluid testing as compared to urine testing so that we can affirm or adjust that cost assumption.

We also seek public comment on whether DOT-regulated employers would continue to utilize the services of external qualified collectors for oral fluid, or whether employers would train their own company personnel to become qualified collectors for oral fluid testing purposes. If companies train internal personnel instead of contracting with external providers, would this be due to costs, convenience or other reasons, and what would be the cost implications of the two approaches?

In addition to flexibility for employers, there are potential cost savings in the ''shy bladder'' collection procedures and related medical examinations. Currently there are situations in which a urine specimen collection is attempted but not completed. For example, when an employee is unable to provide a sufficient quantity of urine, Part 40 provides an alternative process with multiple steps. The employee receives up to three hours of time to provide a sufficient specimen and is urged to consume up to 40 ounces of fluids. If after three hours these procedures do not result in a sufficient urine specimen, the employee must be medically evaluated to determine whether there is an adequate medical explanation why the employee could not provide sufficient urine. (49 CFR 40.193 and 40.195). This involves much time on the part of the collector, employee, employer, MRO, and physician. In addition, there are the costs of medical examinations for individuals who have short-term and long-term medical conditions that cause, or are claimed to cause, an inability to provide a sufficient urine specimen.

Since the Part 40 comprehensive rewrite in the late 1990s, groups representing individuals with ''Paruresis'' have raised concerns that a urine collection is problematic for individuals with this condition. Also, employees who are undergoing dialysis treatments or who have significant prostate issues could have difficulty providing a urine specimen and may require referrals to evaluating physicians to determine the legitimacy of their medical inability to provide a urine specimen. With the above in mind, collecting an oral fluid specimen may eliminate the need for a medical evaluation and result in a shorter employee visit to the collection site.

Allowing Alternative Specimens Provides Flexibility to Employers

In proposing oral fluid testing, the Department is not requiring employers to use oral fluid testing instead of urine testing, or for every test reason (*e.g.,* pre-employment, random, etc.). Instead, we are proposing to offer employers the flexibility in the type of specimen they collect. That flexibility will provide several benefits. For example, when an employer determines that a DOT post-accident or a reasonable cause/suspicion test is needed, oral fluid collections could be done at the scene of the accident or the incident. The collection could be done by any oral fluid collector qualified under Part 40–either an external contractor or a DOT-regulated company employee. There are fewer requirements for oral fluid collection sites, as discussed below. The ready availability of collectors and the reduced expectations for collection site requirements should facilitate prompt, less expensive collections for post-

accident and reasonable cause/suspicion testing. We would appreciate public comments on these matters.

Understanding Windows of Detection

In proposing oral fluid testing, the Department is offering an alternative specimen for drug testing; however, we are not proposing to eliminate urine drug testing. Each specimen type offers different benefits to assist employers in detecting and deterring illegal drug use, and no single specimen type is perfect for every situation. It is important to understand the benefits and limitations of each method.

There are different windows of detection that employers should consider when deciding whether to use a urine test or an oral fluid test as the preferred form of testing for any specific test reason. We have reviewed various scientific sources referenced below to compile the list of windows of detection, and we invite public comment, especially from oral fluid device manufacturers and laboratories, as to the accuracy of the information presented in the chart below. Any additional public comments pertaining to the accuracy and completeness of the table below would also be appreciated.

Category of drug [1]	Oral fluid testing window of detection	Urine testing window of detection
Amphetamines	1–3 days [2]	1–9 days [2].
Methamphetamines	1–4 days [2]	2–4 days [2].
Cocaine	1–4 days [2 3]	1–5 days [2 3].
Opioids	1–2 days [2]	2–4 days [2].
Marijuana	Up to 24 hours [2 4]	3–67 days [2 5].
Phencyclidine (PCP)	1–3 days [6]	Up to 5 days [6].

[1] Detection windows in the sources are dependent on amount of drug ingested, situations such as regular heavy use, and cutoff concentrations used.

[2] Cone E.J., Huestis MA. Ann N.Y. Acad Sci. 2007;1098:51–103, pp. 35–37, 42, 45–51, 54 *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2700061/pdf/nihms118888.pdf*.

[3] Jufer R., Walsh S.L., Cone E.J., et al. J Anal Toxicol. 2006;30(7):458–462, 460. *https://academic.oup.com/jat/article/30/7/458/711502*.

[4] Newmeyer M.N., Desrosiers N.A., Lee D., et al. Drug Test Anal. 2014;6(10):1002–1010 *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4169757/pdf/nihms578748.pdf*.

[5] Huestis M.A., Mitchell J.M., Cone EJ. J Anal Toxicol. 1996;20(6):441–452 *https://academic.oup.com/jat/article/20/6/441/777647*.

[6] Cook C.E., Brine D.S., Jeffcoat A.R., et al. Clinical Pharmacology and Therapeutics. 1982; 31(5)625–634—*While the authors did not report oral fluid concentrations, they did report correlation between plasma levels and oral fluid levels. As PCP was detectable in plasma for 72 h (last time point) it is reasonable to assume PCP can also be detected in oral fluid that long.*

If an employer is looking to detect recent drug use, (*i.e.,* reasonable cause/suspicion, post-accident), an employer may find that the more immediate window of detection associated with oral fluid is acceptable. However, if an employer is looking to detect a pattern of intermittent drug use through pre-employment, random, return-to-duty, follow-up testing, the delayed windows of detection in urine may be preferable. We seek comment on whether oral fluid or urine should be mandated, or prohibited, for certain test reasons, based on windows of detection. Should an employer and its service agent be allowed to opt for a different methodology if the first test cannot be completed because of an insufficient specimen or other reason? Because there is no drug testing that determines impairment, oral fluid is being introduced to detect use, as urine has done throughout the history of the DOT-regulated drug testing program.

Substance Abuse Professional Remote Evaluations

During the COVID–19 public health emergency, the Department recognized that it might not be possible or advisable for a SAP to meet face-to-face with a client. As a result, we issued a guidance document on April 4, 2020 to allow remote evaluations for a period of time, and we extended the guidance several times. The Department's COVID guidance was issued in 2020–2021 and can be viewed at: *www.transportation.gov/odapc/Statement_of_Enforcement_Discretion_SAPs_and_Service_Agents.* We said that, while a remote evaluation may not provide as much information as an in-person meeting, it is preferable to not having a SAP evaluation at all. To make a remote evaluation as effective as possible, the guidance document recommended certain technical parameters and added that SAPs should document the format of the assessment in the final SAP report. We also said that we would not view a remote evaluation as being an act of serious noncompliance meriting resort to the Public Interest Exclusion (PIE) process.

Based on informal contacts with the SAP community, we believe this guidance has been well received, with a considerable use of remote evaluations by SAPs since the inception of the guidance. Moreover, it is plausible that telehealth will become a regular part of medical practice in a wide variety of fields in the future.

To make remote evaluations or assessments a regular option for the SAP's practice under Part 40, we are proposing amendments to several sections of the regulation. Consistent with guidance issued in the context of the COVID–19 public health emergency, this proposal would give SAPs the option of choosing to conduct evaluations remotely in lieu of face-to-face meetings. Part 40 currently requires all SAP assessments to be done face-to-face. An in-person evaluation provides SAPs with the opportunity to objectively evaluate ''non-verbals''—physical cues to internal feelings, thoughts, and behaviors. It allows the SAP to be aware of the client's appearance, posture, carriage, ability to make eye contact, and ability to relate in person, as well as other physical characteristics that might be indicative of problems associated with alcohol abuse and/or drug use.

The most important proposed change regarding SAP evaluations is to § 40.291(a)(1). The amendment would replace the current requirement for a face-to-face meeting with an option: The SAP could do the evaluation either face-to-face or remotely. If the evaluation is to be done remotely, there would be three criteria that the process would need to meet, to ensure that the SAP can still objectively evaluate ''non-verbals'' and physical characteristics to a sufficient extent. These criteria are also based on the provisions of the Department's guidance document.

First, the technology used must permit real-time two-way audio and visual interaction between the SAP and the employee. A phone conversation not

including video would not meet this criterion.

Second, the quality of the technology (*e.g.,* speed of the internet connection, clarity of the display), would have to be sufficient to allow the SAP to gather all the visual and audible information the SAP would normally observe in a face-to-face interaction. In addition, the technology would have to have sufficiently robust security to protect the confidentiality of the conversation.

Third, a SAP could only use the technology in question if the SAP's State-issued license authorizes the SAP to do so. The SAP's use of the technology would have to stay within the parameters of that authority (*e.g.,* a State license may permit a practitioner to work only with clients in the State of licensure). We are also seeking public comment, especially from SAPs, regarding whether their respective State license would allow them to evaluate individuals who live in a different State from where the SAP is licensed. Is this already allowed? Now that virtual video evaluations are often done outside of the DOT-regulated context, would evaluation of individuals not in one's State of licensure be allowed? For a SAP remotely evaluating an individual outside of the SAP's locality, what steps could ensure a working knowledge of quality programs and qualified counselors available to the employee?

While we continue to believe that face-to-face interactions are the ''gold standard'' for the SAP evaluations, we also believe that the remote evaluation option may have considerable merit, and we seek comment on the proposed approach, as well as on the specific technical parameters under which SAPs would perform remote virtual evaluations. We welcome comments regarding the experience of both SAP and employees under the COVID–19 guidance. We also seek comment on whether remote virtual evaluations and assessments should be limited to certain circumstances, *e.g.,* natural disasters, pandemic situations, and where there are few or no SAPs available.

Other Matters of Interest

As noted above, the Department works closely with HHS on matters concerning workplace drug testing. On September 10, 2020, HHS published a notice of proposed Mandatory Guidelines proposing to add hair testing to the drug testing specimen types authorized for the Federal employee testing program. (85 FR 56108). Because HHS is still considering amendments to its Mandatory Guidelines to permit hair testing, comments to DOT concerning the use of hair testing are not relevant at this time.

In addition, we are proposing to amend § 40.67 to address situations where a same gender observer is not available for the collection of urine specimens. Specifically, we request public comment on allowing direct observations by any licensed or certified medical professional legally authorized to take part in a medical examination in the jurisdiction where the collection takes place.

Currently, per § 40.141(b), MROs must personally contact pharmacies to verify a prescription that an employee has cited as a potential legitimate medical explanation for a laboratory-confirmed positive test. We believe it would increase efficiency and assist MRO office workflow if MRO staff were able to make these inquiries. The Department seeks comment on whether this change is advisable and what the estimated cost savings would be.

In addition to the above, we request comments on whether there are situations in which a test, once cancelled, should be ''uncancelled'' if circumstances dictate (*e.g.,* a test is cancelled because paperwork is missing or delayed, but the paperwork is later found and provided to the MRO). Or, alternatively, should a test, once cancelled, remain cancelled to ensure finality? We specifically seek comment from MROs on the practicality of administering such a process, and from employers on the effect that an ''uncancelled'' test would have when administering their drug testing program. To be clear, this would not apply to those specimens ''rejected'' by the laboratory because of a fatal flaw and ultimately reported by the MRO as cancelled. We have proposed language in § 40.207(d) to address this circumstance. We have also included a requirement for a party seeking to reverse a cancellation to consult ODAPC if the decision is being made more than 60 days after the cancellation, which is the same consultation requirement we have in § 40.149(a)(4), where we allow an MRO to reopen a verified test after 60 days. Providing this information helps ODAPC to provide advice to MROs regarding what to consider and potential concerns.

V. Section-by-Section Analysis

In drafting the proposed oral fluid amendments to Part 40, the Department is not creating a separate subpart of Part 40 concerning oral fluid testing. Since many of the provisions of Part 40 can be applied to specimen types in addition to urine, we have sought to integrate provisions concerning oral fluid testing within the current Part 40 structure. However, since the provisions applicable to Alcohol Testing, SAPs, the PIE process, and some other provisions would not change based on which specimen types are authorized, we are not proposing changes to those provisions.

Consistent with changes made in the substantive provisions of the rule, we propose to modify some section titles as well as adding new sections. In many cases, the modifications revise current titles specifying urine testing so that they address oral fluid and potential future testing matrices.

40.3 What do the terms used in this part mean?

In addition to proposing to delete the definition of ''screening drug test'' because the term is not used in Part 40, the proposed rule would delete the definition of ''Invalid drug test'' because that is a term that HHS does not use, as such.

The term ''invalid result'' is an HHS term with a very specific meaning and HHS does not have a defined term of ''Invalid drug test.'' The term ''invalid'' is sometimes misunderstood in arbitrations, courtrooms, and other settings to incorrectly suggest a lack of certainty about the underlying testing event. A laboratory reporting an invalid result to the MRO does not mean that the underlying drug testing event was not valid. For example, when the laboratory reports that there was an ''invalid result,'' it is not a characterization of the employer's authority to conduct the testing, the collection process, etc. The ''invalid result'' refers only to the fact that the laboratory has not been able to complete testing or obtain a valid drug test result (*e.g.,* because of an unidentified adulterant, an interfering substance, or an abnormal physical characteristic). Also, for consistency with HHS terminology, we are removing the defined term ''invalid drug test'' in the definitions section, § 40.3, and are updating §§ 40.123(c), 40.129(a) and 40.129(d) to use the term ''invalid result''.

The proposal would add definitions of seven terms as part of our effort to harmonize Part 40 with the HHS Guidelines and to update Part 40 as needed. An ''alternative specimen'' is an authorized specimen of a type other than the one previously collected. For example, in a case where the initial collection was urine, oral fluid would be an alternative specimen. The ''cutoff'' is the quantitative point distinguishing a need for further testing or whether a laboratory result, for example, is

positive or negative (*e.g.,* 2 ng/ml is the confirmatory test cutoff for a positive vs. negative oral fluid result reported by the laboratory for THC). We are also proposing to add definitions for ''oral fluid specimen'' and ''urine specimen.'' ''Specimen'' is the generic term for any fluid, breath or material collected from someone for a drug or alcohol test. We are proposing to add ''Undiluted (neat) oral fluid'', using the same language HHS uses in Section 1.5 of its Oral Fluid Mandatory Guidelines. We have also added a definition for the FMCSA's Commercial Driver's License (CDL) Drug and Alcohol Clearinghouse (Clearinghouse).

We are also proposing to add a new definition for ''SSN or Employee ID No.'', and some minor changes to rule language in §§ 40.14, 40.45, 40.97, 40.163 and 40.311 for the following reasons. Since its inception in 1988, Part 40 has required program participants to use the donor's Social Security Number (SSN) or an employee identification (ID) number in various sections. For example, the employer must supply the collection site with the ''Donor SSN, Employee I.D., or CDL State and No.'' as referenced on the Federal Drug Testing Custody and Control Form (CCF). For the Alcohol Testing Form (ATF), the employer must supply the donor's ''SSN or Employee ID No.'' In addition to the unique specimen ID number on the CCF and the specimen seals, having the SSN or employee ID number on the form assists the MRO in matching the Copy 1 of the CCF from the laboratory with their copy, Copy 2 of the CCF. The SSN or the employee ID number may be used by the employer to, for example, run random selection lists and ensure that test results are associated with the correct employee. The SAP is required to utilize the SSN on the SAP initial and final reports to the employer.

In the Federal Motor Carrier Safety Administration's (FMCSA) Commercial Driver's License Clearinghouse final rule (81 FR 87686; Dec. 5, 2016), which required the creation of the Drug and Alcohol Clearinghouse database (Clearinghouse), the FMCSA amended 49 CFR 382.123(a) and (b) to require that, for FMCSA-regulated drivers undergoing DOT-regulated testing, the employer use a Commercial Driver's License (CDL) number and State of issuance, instead of the SSN or other employee ID number, on the CCF and Alcohol Testing Form (ATF) for all drug and alcohol tests conducted under part 382. It is important to note that the Clearinghouse final rule did not affect or otherwise allow use of the CDL number for a CDL driver operating under another DOT agency's regulation and subject to a test not under Part 382 (*e.g.,* employers of CDL drivers under PHMSA or FTA). Under this proposal, those employers could also use the CDL numbers, which could potentially increase efficiency and reduce confusion.

We are proposing to create a definition of ''SSN or Employee No.'' in § 40.3 that would conform to and explicitly acknowledge this existing requirement for CDL holders regulated by the FMCSA and to allow the use of the CDL number for the drivers being tested under the regulations of the other DOT agencies.

In addition, we are proposing the changes because some employers already consider an employee's ID number to be the individual's personal driver's license number, State-issued identification number, or other State-issued or federally issued identification number. We believe that it would be less confusing to explicitly state that it is allowable to use these forms of ID, which can be verified by viewing the actual ID.

With increasing concerns of identity theft, SAPs, employers and others have indicated that the use of one's SSN is becoming increasingly difficult and risky. Some corporations are only allowing the use of 4 or 6 digits of the SSN, and others prohibit the use of the SSN entirely. We are proposing the additional options of other official identifications issued by State or Federal authorities to also address these concerns.

Consequently, we are proposing to create a new definition ''SSN or Employee No.'' that will allow a collector, MRO, SAP, BAT, STT or other service agent or employer to utilize only the CDL number and State of issuance for FMCSA-regulated drivers tested under Part 382, and to allow the CDL number to be used as an option on tests conducted under the authority of the other DOT Agencies. The definition would also allow any other State-issued or federally- issued identification number to fulfill Part 40 requirement for a unique identification number.

We are proposing to modify seventeen definitions. For the most part, the changes are not substantive, and would simply conform Part 40's wording with that of the HHS guidelines. For example, ''collection container'' refers to vessels used in all collections, whether of urine or oral fluid. In the definition of ''specimen bottle,'' we propose noting that the term could include terms like ''tube'' or ''vial'' used in oral fluid testing.

§ 40.13 How do DOT drug and alcohol tests relate to non-DOT tests?

The Department is proposing minor changes to paragraphs (b), (c), and (d) of this section to clarify them in the context of oral fluid testing. For example, paragraph (d) is made applicable only to urine testing since oral fluid testing is not part of the normal medical examination procedure to which the paragraph applies.

We propose to redesignate paragraphs the current paragraphs (e) and (f), as new paragraphs (f) and (g), and would add a new paragraph (e) emphasizing that a drug or alcohol test administered as directed by a medical examiner, exclusively as part of a medical examination required for an employee to qualify for a certificate or license, is not a DOT drug or alcohol test under Part 40 and related DOT agency drug and alcohol testing rules. For example, if a certified medical examiner decided to give a motor carrier driver a drug test as part of an examination for medical card purposes, that would be a ''non-DOT test.'' An employer could request a required DOT pre-employment test be conducted when the medical examination is being conducted, as currently permitted under 49 U.S.C. 31306(d).

We added a new paragraph (h) to further emphasize that DOT drug and alcohol tests are authorized to be conducted only on safety-sensitive employees as designated in the agency drug and alcohol testing regulations and must not be conducted on non-regulated persons. (See Section II of this proposed rule for a discussion of DOT's testing authorities.) DOT testing is a legal warrantless search and seizure permitted by the Fourth Amendment of the Constitution. The DOT's strong interest in maintaining transportation safety, when weighed against an individual's right to privacy, allows DOT's regulated testing to pass Constitutional scrutiny. See *Bluestein* v. *Skinner,* 908 F.2d 451 (9th Cir. 1990); *Skinner* v. *Railway Labor Executives' Assn.,* 489 U.S. 682 (1989); *Treasury Employees* v. *Von Raab,* 489 U.S. 656 (1989). However, there is no Federal transportation safety interest in using this testing for individuals other than safety-sensitive employees. Consequently, DOT testing cannot be conducted on employees not regulated by the DOT agencies. DOT regulations also do not allow company-authorized non-DOT testing to satisfy an employer's obligation to meet its minimal annual testing rate for DOT testing.

§ 40.14 What information must employers provide to collectors?

Paragraph (b) in this section would be modified for clarity and to recognize that, in the motor carrier industry, FMCSA requires the CDL to be used for purposes of the Drug and Alcohol Clearinghouse (Clearinghouse) (see 49 CFR 382.705). A new paragraph (k) would be inserted for ''the specimen type to be collected'' and a new paragraph (l) is proposed to specify if a urine test is to be directly observed.

§ 40.21 May an employer stand down an employee before the MRO has completed the verification process?

Where there is a stand down waiver in place, the proposed rule would add a new paragraph (c)(2)(vii)(C) of this section to explain that an employer, after receiving a verified negative result, must not send an employee back in for another test using a different specimen type. We have clarified that the employer can send and employee in for an alternative specimen collection if the MRO cancelled the tested (*e.g.,* per the requirements of § 40.159). The authority to stand down an employee is very limited and requires an employer to obtain an actual waiver from the DOT agency before implementing a stand down policy. The waiver authorizes the employer to 'stand down' an employee from performing safety-sensitive functions based on a laboratory confirmed positive result until the MRO issues the employer a verified result, which may be negative. We are proposing that an employer cannot conduct another test on the employee after an MRO verifies the test as negative. We want to prevent harassment of employees who ultimately have an MRO-verified negative result and we do not want employers to attempt to conduct a second test to see if the window of detection could later impact the result.

§ 40.23 What actions do employers take after receiving verified test results?

The proposed rule would make minor conforming changes in the language of this section to account for the proposed use of oral fluid testing. In the introductory language of paragraph (f), the specification of urine testing would be deleted because the paragraph would apply to oral fluid as well as urine testing. In paragraphs (f)(1) and(5), language would be added emphasizing that oral fluid collection is always directly observed. In the event of an invalid specimen, the subsequent direct observation collection could either be an oral fluid collection or a urine collection under direct observation.

§ 40.25 Must an employer check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties?

In January 2020, FMCSA implemented its Clearinghouse regulation requiring FMCSA-regulated employers that employ drivers subject to the CDL testing requirements of 49 CFR part 382 to query the Clearinghouse drug and alcohol database for information about an employee's past violations of the drug and alcohol testing rules. Until January 2023, FMCSA-regulated employers have dual requirements: Query the Clearinghouse *and* continue to follow the procedure of § 40.25, as set forth in § 382.413.

Beginning January 6, 2023, FMCSA-regulated employers will rely solely on querying the Clearinghouse with respect to present or former FMCSA-regulated employers of an FMCSA-regulated applicant, in accordance with § 382.413(b). For example, after January 6, 2023, a motor carrier vetting a prospective employee would check the Clearinghouse to determine whether the driver's previous FMCSA-regulated employer(s) reported drug and alcohol testing program violations by that driver. To conform the requirements of § 40.25 with these existing FMCSA requirements, we are proposing to add a paragraph stating if an applicant's past employment was with an employer regulated by, for example, the Federal Transit Administration or the Federal Aviation Administration (FAA), the gaining motor carrier employer would continue to use § 40.25 to check on that individual's past compliance with the Department's rules, since drug or alcohol violations incurred while the driver was employed by a DOT modal administration other than FMCSA will not have been recorded in the Clearinghouse. We are proposing to add a new paragraph (a)(3) to this section to remind employers that when hiring an employee subject to both FMCSA and another DOT agency's drug and alcohol testing program, they must query the Clearinghouse and request the information about the employee listed in paragraphs (b) through (j) of this section from any other DOT agency for whom the employee previously worked.

§ 40.26 What form must an employer use to report Management Information System (MIS) data to a DOT agency?

The proposed rule would make a simple editorial change, substituting a reference to appendix J for a reference to appendix H. This conforms to a re-designation of the appendix letters but would make no substantive changes to the section or form.

§ 40.29 and similar sections

In the current Part 40, there are several sections (§§ 40.29, 40.37, 40.113, 40.169, 40.189, 40.217, and 40.313) that list, for readers' information, other sections of the regulation touching a given topic (*e.g.,* employer responsibilities in § 40.29). These lists of cross-references were intended to assist readers in finding other relevant information. However, in the 20 years since these sections were placed in Part 40, electronic search tools have become much more sophisticated and ubiquitous. Under these circumstances, the Department proposes removing them as no longer necessary. The Department seeks comment on whether users continue to find the cross-reference lists helpful enough to retain.

§ 40.31 Who may collect specimens for DOT drug testing?

The provisions of this section would be updated to separately specify the requirements for collectors of urine and oral fluid specimens, respectively. We proposed adding wording to require oral fluid collectors to be qualified. In addition, we added wording to make it clear that employees, relatives, and close friends of the employees cannot conduct collections, consistent with existing guidance in the Department's Specimen Collection Guidelines. The Department seeks comment on these proposed revisions.

§ 40.33 What training requirements must a collector meet for urine collection?

The proposed rule would change the title of § 40.33 to reflect its focus on urine collectors. We are also proposing a change to § 40.33(f) to clarify that damage to a specimen resulting in it being cancelled does not require retraining of the collector, unless the error actually occurred during the collection process. We understand that some MROs are requiring collector retraining when a specimen is cancelled because the damage occurred during the transportation process. When a specimen is damaged by a delivery truck, sort facility, or other part of the transportation process, or is lost in transit, it would not be the result of an error by the collector during the collection process. Consequently, we are proposing language to clarify a collector is not subject to the time and costs of retraining for errors outside the collection process.

§ 40.35 What training requirements must a collector meet for oral fluid collection?

The proposed rule would renumber existing § 40.35 to become § 40.36, and add a new section § 40.35 concerning training for oral fluid collectors. Our intent is to parallel, as closely as possible, our existing training requirements for urine specimen collectors. We seek comment on any differences that may exist between the training for collectors for each specimen type. We anticipate, in many cases, that collectors may be cross-trained in the two modes of collection.

In discussing who is authorized to monitor the mock collections exercise for oral fluid collectors, the proposed rule retains the provision applicable to urine collector training, which states that someone who has performed DOT collections for at least a year is qualified. However, since the oral fluid collection process is new to the DOT testing regime, there initially will not be anyone who has collected DOT oral fluid specimens for a year. The Department seeks comment on how best to address this transition issue. For example, would it be sufficient for a monitor, during the first year or two under the DOT oral fluid testing process, to have had experience in oral fluid collections in non-DOT oral fluid testing? Should only someone who has been through a ''train the trainer'' course be able to monitor the mock collections test until there are oral fluid collectors with a year of experience in DOT oral fluid collections? What role, if any, should oral fluid device manufacturers play in the process?

Redesignation Table

Beginning with subpart D (see below), the Department is proposing to redesignate (*i.e.,* renumber and reorder) numerous sections of Part 40 to provide a more easily followed flow for users of the regulation provisions specific to oral fluid drug testing. For the convenience of the reader, we are displaying these proposed redesignations in the preamble section of the NPRM.

The Department recognizes that practitioners have likely become accustomed to particular section numbers for drug testing procedures under the present regulation. While we believe that the reorganization will create a logical structure for the rule, we seek comment on whether the reorganization would cause any significant degree of confusion for practitioners, and if so, how confusion could be mitigated.

For the convenience of the reader, we are including this redesignation table to show what the renumbering would be, if the proposed changes are adopted:

PROPOSED REDESIGNATIONS THE FOLLOWING SECTIONS OF PART 40 AS FOLLOWS

Old section	New section
40.35	40.36.
40.41	40.42.
40.45	40.40.
40.47	40.41.
40.49	40.44.
40.51	40.45.
40.73	40.79.
40.85	40.82.
40.87	40.85.
40.89	40.86.
40.91	40.87.
40.93	40.88.
40.95	40.89.
40.96	40.90.
40.99	40.84.
Appendix B	Appendix D.
Appendix C	Appendix E.
Appendix D	Appendix F.
Appendix E	Appendix G.
Appendix F	Appendix H.
Appendix G	Appendix I.
Appendix H	Appendix J.

Subpart D—Collection Sites, Forms, Equipment and Supplies Used in DOT Collections

As a starting point, it is important to remember that oral fluid drug testing and saliva alcohol testing are completely distinct. The devices, procedures and outcomes are never interchangeable. In Part 40, we are only proposing the provisions applicable to oral fluid testing procedures in subpart D. The saliva alcohol testing provisions in subparts K–L remain unchanged.

To accommodate the addition of provisions pertaining to oral fluid drug testing, the Department is proposing to reorganize subpart D. Sections applying to the DOT drug testing process generally, regardless of specimen type, would come first. Renumbered §§ 40.40 and 40.41 would contain the content of present §§ 40.45 and 40.47, concerning the use of the Federal Drug Testing Custody and Control Form (CCF) in all DOT collections. We note that HHS revised the CCF in August 2020. The 2020 CCF and instructions for completing the CCF for both urine and oral fluid collections are available on the HHS website, *https://www.samhsa.gov.* The DOT has posted the 2020 CCF on our website, *https://www.transportation.gov/odapc,* and we will post instructions for oral fluid collections upon promulgation of any final rule to allow oral fluid for DOT-regulated drug testing.

The above sections would no longer contain the words ''urine'' and ''urination,'' because these sections now would apply to oral fluid collections and would include ''any other appropriate contact information'' to permit the inclusion of email addresses or other means of contacting the appropriate parties. The Department is considering removing requirements related to fax numbers on the CCF, allowing the fax number if the parties have one. We seek comment on whether specifying the use of fax numbers remains relevant. We are proposing to add a provision allowing the Designated Employer Representative's (DER) name and contact information to be preprinted on the CCF. We specifically seek comments from the laboratories on the availability of space on the CCF to pre-print the information, as well as the logistics and timeliness of sending out updated CCFs with the new DER information. To recognize the responsibility of collectors, as well as collection site operators, for proper collections, we would add ''collectors'' to the title of § 40.43.

In the proposed reorganization of the subpart, §§ 40.42–40.45 would cover urine testing (renumbered § 40.42 in the proposed rule contains the material now found in § 40.41, while renumbered §§ 40.44 and 40.45 contain the material now found in §§ 40.49 and 40.51). Then we would add new §§ 40.47–40.51, covering oral fluid testing. These provisions largely parallel their urine testing counterparts. We seek comment on the content of the new oral fluid provisions, including whether it would be useful to address any additional differences between the urine and oral fluid testing procedures.

We are proposing to modify renumbered § 40.40 to clarify what address and telephone number a collector must provide on the CCF. In January of 2002, ODAPC issued a Question and Answer (Q&A) explaining that the collection site address should not be a corporate or ''main office'' address. In addition, the Q&A stated that the collector's telephone number on the CCF should be the number to directly reach the individual collector and/or the collector's supervisor and not a corporate ''toll free'' number to a call center. Under the proposal, if an MRO, laboratory, employer or any DOT staff need to speak with the collector, the telephone number provided on the CCF must give access directly to that collector. This proposal would codify requirements for the collection site address and collector's telephone number, which would render the Q&A unnecessary.

In § 40.48(c)(1), we use the term ''dry mouth.'' This is shorthand, similar to the term ''shy bladder'' used for urine collections, for a situation in which an employee is unable to produce a sufficient specimen.

§ 40.49 What materials are used to collect oral fluid?

We are proposing to add this section to require that collection devices meet the requirements being set forth in a new appendix B. The devices meeting the requirements in appendix B would be allowed for DOT-regulated collections. It is important to note that not all of the devices that HHS would allow for the OFMG will be allowed for DOT-regulated collections under 49 CFR part 40. Each collection must include a split that is subdivided from the original specimen collection. *See* 49 U.S.C. 45104(5) (aviation industry testing), 49 U.S.C. 20140(c)(5) (rail), 49 U.S.C. 31306(c)(5) (motor carrier), and 49 U.S.C. 5331(d)(5) (transit). All the devices meeting the requirements in appendix B will allow a single specimen to be subdivided in the presence of the donor. For example, a device could allow two specimens to be collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes; or a device could collect a specimen with a single pad, which can be subdivided into two separate collection tubes. We are seeking public comment as to whether there are other device types we should mention that allow one single specimen to be collected and then subdivided in the donor's presence.

We are also seeking public comment as to whether the devices should be sufficiently transparent so the collector can observe whether there is anything unusual about the specimen collected and take action to perform a re-collection, if appropriate.

§ 40.61 What are the preliminary steps in the drug testing collection process?

In paragraphs (b)(1) and (3), the term ''drug testing'' or ''drug test'' would be used in place of ''urine,'' since the provision applies to the testing of either specimen type. We propose to split the existing (b)(3) into (b)(3) and a revised (b)(4). The proposed revision to (b)(3) prohibits collection of any kind of specimen from an unconscious donor. The proposed revision to (b)(4) includes the remaining sentences of the current (b)(3), with a change to the final sentence of proposed paragraph (b)(4). The final sentence in (b)(4), if adopted, would be changed to emphasize that an employer must decide whether a given circumstance constitutes a refusal. In paragraph (f)(5)(i), we would note that, when a directly observed test is needed, either a directly observed urine collection or oral fluid collection would suffice. In (f)(5)(i), we propose to remind the collector to note on the CCF whether a directly observed urine or oral fluid test will be conducted.

In addition, we are proposing changes to §§ 40.61(e) and § 40.73(a)(1) (proposed to be redesignated as § 40.79(a)(1) because HHS made changes to the CCF. The DOT requires its regulated entities to use HHS's OMB-approved CCF.

DOT worked closely with HHS on the revised CCF, which incorporates changes necessary as a result of HHS's establishment of scientific and technical guidelines for the inclusion of oral fluid specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The majority of changes to the CCF were made to allow the collection of oral fluid specimens, which are not currently authorized in the DOT drug testing. The revisions also include other changes to improve the clarity and presentation of the form.

However, because of the revisions to the CCF, it is necessary for DOT to amend two sections of Part 40. Specifically, the instructions for completing the old CCF were provided on the back of Copy 5 of that form. These instructions are not provided on the revised CCF, and instead, instructions for completing the form can be found on the HHS and DOT (Office of Drug and Alcohol Policy and Compliance) websites. Consequently, we are proposing to amend the rule text in 49 CFR 40.61(e) to reflect the repositioning of the instructions. Also, we are proposing to amend § 40.73(a)(1) (proposed to be redesignated as § 40.79(a)(1)) to note that the employee needs to provide all information required in Step 5 of the revised CCF. This information includes the donor's printed name and signature, date of the collection, date of birth, daytime and evening phone numbers, and email address.

§ 40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?

We are proposing to modify § 40.63(a) to remind collectors to ensure that all items in Step 1 of the CCF are completed. Specifically, we propose to add a parenthetical to remind collectors to check the box for the DOT agency in Step 1.D, and to write an address for the actual collection site in Step 1.G.

§ 40.65 What does the collector check for when the employee presents a urine specimen?

The proposed rule would make two changes to the current regulation to ensure that when an immediate re-collection under direct observation is needed (*e.g.,* because the temperature of a urine specimen is out of range or there were signs of tampering), regardless of whether the first specimen was urine or oral fluid, the required directly observed collection could be either urine or oral fluid. For example, if a directly observed collection is needed after a urine collection, the second could be either an oral fluid collection (inherently directly observed) or a urine collection carried out under the direct observation procedures set forth in § 40.67. After the second collection is done, each specimen collected must be sent to the appropriate laboratory (*i.e.,* a laboratory certified by HHS for that specimen type).

We are asking for public comment about how communication would take place between the employer and the collection site to ensure that an alternate methodology is or even should be available. Who should decide whether to collect an alternative specimen? Should the collector be the one to determine whether to collect an alternate specimen when a situation allows for it? Should the employer and the service agents communicate in advance to ensure that the alternate specimen type is authorized, if the employer wants one—with devices and laboratories designated? Could this be accomplished through the contract between the employer and the service agent? Are there other means of communication to facilitate the collection site process?

§ 40.67 When and how is a directly observed urine collection conducted?

In addition to altering the title of the section to refer only to urine collections, the proposed rule would make a substantive change to paragraph (g), regarding who may act as the observer in a directly observed urine collection. The paragraph would retain the general requirement that the observer have the same gender as the employee, but make an exception for licensed or certified medical professionals or those who are legally authorized to take part in a medical examination in the jurisdiction where the collection takes place. It is commonplace in medical settings for opposite-gender personnel to take part in examining a patient (*e.g.,* a female doctor, physician's assistant, nurse, Emergency Medical Technician, or an

individual who holds a ''Persons-In-Charge Medical Care'' U.S. Coast Guard designation who might be examining a male patient). To reduce the circumstances in which an observed urine collection might be delayed for lack of a same-gender observer, we propose that an opposite-gender medical professional, if available, could perform this task. The donor would not be permitted to decline the direct observed collection by an opposite gender medical professional and such a refusal would fall under § 40.191(a)(4), if the proposal is adopted. We seek comment on whether there should be any limitations on the types of medical professionals who could perform this function. In addition, we would appreciate comments on whether there are religious or other concerns that should be considered in the regulatory language proposed.

We want to clarify that the collector does not enter the reason for the direct observation in the ''Remarks'' section of the CCF if the employer is sending the employee in for a required directly observed collection (*e.g.,* a return-to-duty test, a follow-up test, a test where the MRO has instructed the employer to send an employee in for a directly observed collection). The ''Remarks'' section needs to be used only when the collector moves to a directly observed collection and the employer did not know about it in advance. Thus, we are proposing to amend § 40.67(e)(2) to change a cross-reference to ''§ 40.67(b)'' to become a cross-reference to ''§ 40.67(c)(2)-(4)''. This is because § 40.67(e)(2) is an instruction to collectors to follow through with an entry on the ''Remarks'' line on a CCF when an event under § 40.67(c) takes place. This has nothing to do with § 40.67(b), so this cross-reference is being corrected. We are proposing to make a technical amendment to § 40.67(c)(1) to strike the reference to paragraph (b) because it is an incorrect reference.

§ 40.69 How is a monitored urine collection conducted?

The proposed rule would add new introductory language emphasizing that a monitored collection would be conducted if a urine collection takes place in a multi-stall restroom and the collector cannot secure all sources of water and other substances that could be used for adulteration and substitution (49 CFR 40.42(f)(2)(ii)).

§ 40.71 How does the collector prepare the urine specimens?

The proposed rule would make a minor clarifying change, instructing the collector of a urine specimen to check both the boxes for ''urine'' and ''split specimen'' on the CCF.

§ 40.72–§ 40.74

These three new proposed sections would establish the collection procedures for oral fluid testing, consistent with the HHS OFMG and parallel, in many respects, to the administrative aspects of urine collections. For information on the parallel HHS provisions and the HHS rationale for putting them into effect, please see the OFMG, (84 FR 57554, Oct. 25, 2019).

At several points in these sections (*e.g.,* § 40.72(a)(2)), the proposed rule emphasizes the proper relationship between collection sites and employers in cases involving conduct that could be considered a refusal. In each case, the collector does not make a unilateral, final decision, but rather provides information on the circumstances to the employer, who per § 40.355(i), has the non-delegable duty to make decisions in these cases.

The oral fluid specimen collector is expected to follow both the Part 40 requirements for collections, as well as the manufacturer's instructions on how to collect the specimen. The collector must check the expiration date on each device. Each device will have its own instructions and, therefore, these are not specifically covered in the proposed regulatory text. When we refer to conducting the collection ''correctly'' in these sections, we mean using the oral fluid device in the manner described by its manufacturer.

Subpart F

The proposed rule would reorganize subpart F (49 CFR 40.81–40.97), which addresses drug testing laboratories, to create a logical progression of urine drug testing, oral fluid drug testing, and provisions common to both. This reorganization involves renumbering several provisions and, in some cases, adding language to specify where a provision applies only to urine drug testing. For example, the title of renumbered § 40.86 (§ 40.89 in the current regulation) would be changed to read ''§ 40.86 What is urine validity testing, and are laboratories required to conduct it?''

In several places in the text of § 40.97, several requirements are specified to apply only to urine testing, as they have no application to oral fluid testing. We restated § 40.97 in its entirety, given the number of individual changes made for this purpose.

These editorial changes are not intended to modify the substance of the provisions in question. However, we would call readers' attention to two proposed substantive changes. First, in renumbered § 40.84 (§ 40.99 in the current regulation), laboratories would be required to keep non-negative specimens for only 90 days, rather than the present one-year requirement. This change is intended to reduce storage burdens on laboratories. We are not aware of any reason a laboratory would need to keep the actual specimen beyond 90 days. This change would not affect the 2-year record retention requirement that HHS has set for documentation supporting the laboratory's analysis of a non-negative specimen. This would not change a litigation hold placed upon the specimen and the paperwork. We seek comment on this change, as well as the more general question of whether interested parties find the reorganization of the Subpart F useful.

The most notable new portion of this subpart, consisting of §§ 40.91–40.93, concerns cutoff concentrations and validity testing for oral fluid specimens. These three new sections are drawn from the HHS OFMG and are intended to be consistent with the HHS provisions. For information on the parallel HHS provisions and the HHS rationale for putting them into effect, see the OFMG (84 FR 57554).

In § 40.111, we propose to add language to paragraphs (a) and (d) to clarify that in their statistical reports to employers and DOT, laboratories need to submit reports to employers for the specimens for which the laboratory tests.

In addition, we added language in § 40.111 to clarify that a laboratory withdrawing from National Laboratory Certification Program (NLCP) program certification is required to file with both employers and the DOT an aggregate statistical summary for the last period in which it conducted DOT-regulated testing. This data is important to the Department because it helps DOT identify trends regarding non-negative results (*e.g.,* positives, adulterated, substituted and invalid) and cancelled tests.

Subpart G—Medical Review Officers

For the most part, MROs would continue to do their jobs as they have under the current regulation. However, the Department is proposing a few changes to the MRO provisions. Specifically, in § 40.121, we would delete the word ''urine'' from paragraph (c)(1)(i), because training for MROs should also include oral fluid testing. We seek comment on whether existing and/or new MROs should receive

additional training specifically with respect to their role in oral fluid testing and, if so, what subjects it should cover.

In § 40.127, concerning MRO reviews of negative results, we propose specifying that MROs need not review more than 500 negative results ''of all specimen types combined'' in any quarter. This is to clarify that, by adding oral fluid testing to the regulation, we do not intend to increase MROs' negative test result review requirements.

In § 40.129(d), we propose deleting ''drug test report'' and adding the word ''result'' following ''invalid test.'' In § 40.135(d), we propose deleting the word ''test'' and adding the word ''result.'' This would keep the language of that paragraph internally consistent and consistent with the definition of the term ''invalid result'' in § 40.3.

In § 40.139(b), we are proposing to add the cutoffs for oral fluid laboratory-confirmed results. This is important because there are different cutoffs for the MRO to consider when the specimen is oral fluid versus urine. These cutoffs trigger a clinical examination for the use of the naturally occurring opiates, codeine and morphine. In addition, in § 40.139(c), we propose to delete a reference to ''urine,'' since the provision would apply to all DOT drug tests.

The proposed rule would make two clarifying changes to § 40.145. In § 40.145(g)(3), we would delete the word ''urine'' and substitute ''drug,'' since in this context we would apply the requirement to test in an HHS-certified laboratory to any such test, whether urine or oral fluid. In paragraph (h) we would add the word ''urine'' after ''substituted''.

In § 40.151, we propose clarifying the language of paragraph (a) to direct MROs not to accept the result of any drug test not collected and tested under Part 40 procedures. In talking to employees who contact ODAPC following a positive drug test, we often hear, ''I went to my own doctor the next day and took another test and it was negative.'' This paragraph emphasizes that MROs cannot accept such a claim, which does not overturn the MRO's decision. We also deleted language referring to DNA tests since use of those tests is prohibited elsewhere in the regulation (see 49 CFR 40.153(e) and 40.331(f)). In paragraph (b), we would change ''urine'' container to ''collection'' container in recognition of the advent of oral fluid testing. In paragraph (g), we deleted reference to ''MDEA'', since it had been removed in a previous rulemaking (82 FR 52229 (Nov. 13, 2017)), in response to HHS deleting MDEA from the drug testing panel. MDEA is a Schedule I drug in the amphetamines class that was previously a required confirmatory test analyte under the HHS Guidelines, but which HHS removed.

In § 40.151, we also propose a technical amendment to paragraph (i), replacing the wording ''with no detectable creatinine'' with ''when the creatinine level is below the laboratory's limit of detection.'' This would ensure consistency with the requirement for laboratories to provide a numerical value for a substituted result (see 49 CFR 40.97(e)(2)). Also, it is our understanding that all HHS/NLCP-certified laboratories must have an established limit of detection for creatinine of 1mg/dL or less. Therefore, when a laboratory reports a creatinine concentration level at less than its limit of detection, MROs can be assured that it falls below the creatinine concentration of 2mg/dL for a substituted specimen and that an individual cannot physiologically produce such a urine specimen.

In § 40.159, in paragraph (a)(1) we propose to correct the reference to § 40.96(c) to become § 40.96(b) and we propose adding a new sentence to paragraph (a)(5)(ii), which would require re-collection when an invalid test is cancelled. The added sentence would direct that an alternative specimen be collected if practicable (*e.g.,* oral fluid, if the specimen was urine). This could result in a more efficient process and reduce the likelihood of multiple invalid specimens resulting from use of the same specimen type.

In § 40.163(c)(2), we propose a small change, substituting ''employee'' for ''donor.'' In § 40.163(e), we are also making minor wording changes to clarify what records the MRO needs to retain after having reported a result and to clarify that when completing Copy 2 of the CCF, either the MRO must sign and date it (for both negatives and non-negatives) or MRO staff must stamp and date it (for negatives only).

§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

In § 40.177, we propose adding a reference to the sections pertaining to oral fluid testing.

§ 40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

In § 40.179, the proposed rule would change referenced section numbers in accordance with renumbering and new oral fluid provisions elsewhere in the regulations.

§ 40.181 What does the second laboratory do with a urine split specimen when it is tested to reconfirm a substituted test result?

In § 40.181, the proposed rule would change referenced section numbers in accordance with renumbering and new oral fluid provisions elsewhere in the regulations. In addition, § 40.181 would be changed to refer only to urine testing, since the creatinine and specific gravity apply only to urine testing.

§ 40.187 What does the MRO do with split specimen laboratory results?

In § 40.187, the proposed rule would change references to appendix D to appendix F in accordance with the redesignations.

§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?

This proposed provision carries through the main points of Part 40's existing refusals provision, the main addition being a provision describing what can constitute a refusal in an oral fluid collection. The proposed section would make a variety of small wording changes to take oral fluid testing into account (*e.g.,* in paragraph (a)(8)), ''fail to permit an inspection of the employee's oral cavity or fail to remove objects from his or her mouth''), as well as specifying situations that are applicable only to urine testing (*e.g.,* in paragraph (a)(9)), ''fail to comply with an instruction to permit inspection to allow the observer to determine whether there is a prosthetic device in use'').

Like the pre-employment urine collection process, the oral fluid pre-employment collection process generally would not begin until the device is unwrapped. If an employee does not appear for a pre-employment drug test or leaves the collection site before receiving or unwrapping the device, this is not a refusal under § 40.191. However, as in urine testing, certain blatant conduct by the employee at the collection site could constitute a refusal before the collection device is unwrapped. For example, if an employee arriving for a pre-employment test, engages in disruptive or combative conduct at the collection site, a collector could report a refusal to the employer for determination.

In addition, it is important to note that when an employee is undergoing a pre-employment test and the collector switches to an alternate device, it is considered a continuation of the original collection and is not subject to

the pre-employment exception for leaving the collection site before the second device is opened. For example, if a collector begins with one specimen methodology (*e.g.,* urine) and switches to oral fluid (*e.g.,* because the employee was unable to provide a sufficient specimen), the employee must not leave the collection site without refusal consequences.

The proposed rule would revise § 40.191(d) and add a new paragraph (c)(1) to § 40.261 to clarify an often-misunderstood point about who has the authority to declare that conduct at the collection site constitutes a refusal to test. The Department has received many inquiries in which employers have automatically treated as a refusal any situation in which the collection site notes a refusal in the remarks section of the CCF. This is not correct.

Under the long-existing § 40.355(i), making collection site refusal decisions is a ''non-delegable'' duty of the actual employer. Service agents, such as collectors, BATs or STTs, are not authorized to make this decision. Their role is to provide information to the employer concerning the circumstances of the event. Then the employer, who as a matter of prudence would contact the employee and the collector or BAT to gather information, should make the decision, taking the entirety of the circumstances into account. The employer would have the discretion to consider circumstances that may satisfactorily excuse the employee's conduct. For FMCSA-regulated owner-operators, C/TPAs stand in the shoes of employers for the purposes of determining whether the individual refused a test (49 CFR 382.705(b)(6)).

For example, we have heard multiple times about situations in which an employee provides an insufficient quantity of urine, begins the ''shy bladder'' procedure, but the procedure is cut short because the collection site closes before the employee has had three hours to produce a sufficient urine specimen, as allowed by § 40.193(b)(2). If the collection site nevertheless reports the matter to the employer as a refusal, the employer has discretion to determine that there was no intent on the part of the employee to evade the process. If the employer determines that a refusal did not occur, the employer would treat the test as an administratively closed non-event. FMCSA-regulated employers would have the discretion not report such non-events to the Clearinghouse as refusals. The same thinking might apply in a situation in which a documented family medical emergency led the employee to leave the collection site.

For random tests administratively closed as a non-event by the employer, no further action is required. For those testing events that require a ''negative'' test result (*e.g.,* return-to-duty, follow-up), the employer would send the employee back for another collection. In all cases, the employer should document exactly what happened to explain why the employer concluded a refusal did not occur.

§ 40.193 What happens when an employee does not provide a sufficient amount of specimen for a drug test?

The most important change that this section would make is the addition of oral fluid testing to paragraph (a), adding insufficient specimen provisions for oral fluid testing, parallel to, but briefer than, the existing provisions of dealing with insufficient urine specimens. Because of the differences between the two types of specimen collections, the insufficient specimen collection procedure is shorter in duration than the insufficient urine specimen collection procedure (*e.g.,* in an oral fluid collection, there would not be a need for a three-hour wait period). In paragraph (e), the proposed rule would add examples of conditions that might succeed as medical explanations of providing an insufficient quantity of oral fluid (*e.g.,* autoimmune diseases), as well as examples that would not constitute a valid medical explanation (*e.g.,* unsupported assertions of dehydration). We seek comment on what sort of evidence is needed to avoid an assertion being viewed as ''unsupported'' for this purpose. We note that because alternative specimens will be available, using a different type of specimen in an insufficient quantity case may be an option. That is, if a urine specimen is insufficient, the collector could follow up with an oral fluid collection, or vice-versa. In such a case, following the insufficient urine specimen procedures would become unnecessary. The Department seeks comment on both this concept and whether specific language to this effect should be included in the regulatory text.

We also seek public comment, especially from device manufacturers, regarding whether allowing a donor to rinse with up to 8 ounces of water is an appropriate amount of fluid for rinsing for the purposes of both §§ 40.72(b) and 40.193(b)(2). Should we allow more or less? Would measuring less than 8 ounces be difficult for collectors?

We also seek comment on whether a qualified collector should be able to make a decision about what methodology to use after an insufficient specimen occurs, or whether this should be a decision left to the employer, depending, for example on the employer's contract with a C/TPA, laboratory, or collection site. In addition, when following an insufficient specimen collection, consistent with the HHS OFMG, the collector would complete a new CCF for the alternative specimen collection. Is this an appropriate way of handling such situations, or would it be better to continue the current practice and use the original CCF with relevant cross-outs and notations in the remarks section?

§ 40.195 What happens when an individual is unable to provide a sufficient amount of specimen for a pre-employment follow-up or return-to-duty test because of a permanent or long-term medical condition?

The only textual change in § 40.195 in the proposed rule is in the title, where the more general ''specimen'' is substituted for ''urine,'' in view of the addition of oral fluid testing to the program.

§ 40.197 What happens when an employer receives a report of a dilute urine specimen?

The only textual change in § 40.197 in the proposed rule is in the title, where the word urine would be inserted because this section concerns situations that arise only in urine testing.

§ 40.199 What problems always cause a drug test to be cancelled?

Section 40.199, the ''fatal flaws'' section of the rule, would be expanded by adding a new fatal flaw for use of an expired oral fluid collection device, in paragraph (b)(8). In paragraph (b)(7) of § 40.199, the term ''urine'' would be replaced with ''specimen,'' reflecting the addition of oral fluid testing to the program.

§ 40.201 What problems always cause a drug test to be cancelled and may result in a requirement for another collection?

In paragraph (b)(7) of § 40.199 and paragraph (f) of § 40.201, the term ''urine'' would be replaced with ''specimen,'' reflecting the addition of oral fluid testing to the program.

§ 40.207 What is the effect of a cancelled drug test?

Throughout the history of Part 40, there has not been a regulatory provision that allows an MRO to ''uncancel'' a test that the MRO has cancelled. New paragraph (d) is proposed so that an MRO can reverse

the cancellation of a test. Currently, §§ 40.203, 40.205, and 40.208 address situations that require a test to be cancelled by an MRO, if there is not corrective action. For example, if an MRO does not receive a timely memorandum for the record from a collector regarding required information that was omitted from the CCF, the MRO may cancel the test. Once an MRO cancels a test due to an uncorrected correctible error, there is currently no authority for the MRO to reverse that cancellation decision. So, if the memorandum for the record arrives, but the MRO staff misses it, the cancelled test cannot be reversed without this proposed rule change. That inability has created additional cost for the employer, inconvenience for the employee, and also confusion because some MROs think they already have this authority. Adding this provision will reduce costs and confusion. In addition, for those testing events for which an employer needs a negative result (*i.e.,* pre-employment, return-to-duty or follow-up), an employee must go in and re-take the test, if the MRO cannot un-cancel it after the error is corrected.

§ 40.210 What kinds of drug tests are permitted under the regulations?

This proposed revision notes that oral fluid and/or urine specimens can be collected, and must be tested at HHS-certified laboratories. No other specimen methodologies are currently permitted.

We are proposing that an employer can use one or the other, but not both urine and oral fluid methodologies at the beginning of the testing event. For example, if an employee is sent for a test, either a urine or oral fluid specimen can be collected, but not both simultaneously. However, if there is a problem in the collection that necessitates a second collection (*e.g.,* insufficient quantity of urine, temperature out of range, or insufficient oral fluid), we want to propose that a second methodology could be used to complete the collection process for the testing event. If we adopt this provision, would the employer and/or its service agent be the correct one(s) to make the decision as to which methodology to use in the second collection?

§ 40.225 What form is used for an alcohol test?

This proposed revision would make a conforming change to § 40.225 and redesignate appendix G to be appendix I.

§ 40.261 What is a refusal to take an alcohol test, and what are the consequences?

We are proposing to add a new paragraph (c)(1) to this section, parallel to the proposed § 40.191(b) for drug testing. It spells out the respective responsibilities of the service agent(s) and the DER in making decisions about whether a situation during an alcohol test constitutes a refusal to test. In a situation in which there is not an employee signature, at Step 2 of the ATF (see paragraph (a)(6) of this section), but a result is nonetheless forwarded to the employer, we recommend that the employer take a case-by-case approach, for example not treating as a refusal a situation in which there is no signature but there is an affidavit from an STT or BAT explaining the situation.

§ 40.283 How does a certification organization obtain recognition for its members as SAPs?

In § 40.283, there is a conforming change redesignating aappendix E to aappendix G.

§ 40.285 When is a SAP evaluation required?

In § 40.285, the word ''urine'' would be removed if oral fluid testing is added.

§ 40.345 In what circumstances may a C/TPA act as an intermediary in the transmission of drug and alcohol testing information to employers?

A conforming change, from aappendix F to aappendix H, would be made in § 40.345.

§ 40.355 What limitations apply to the activities of service agents?

In § 40.355(n) (Example 3), the word ''urine'' would be removed in light of the addition of oral fluid testing.

§ 40.291 What is the role of the SAP in the evaluation, referral, and treatment process of an employee who has violated DOT agency drug and alcohol testing regulations?

As discussed in the Principal Policy Considerations section, the Department is proposing to permit substance abuse professionals (SAPs) to conduct evaluations or assessments remotely. The proposed rule would amend §§ 40.291(a)(1) and (3) to remove the requirement that SAP evaluations be only ''face-to-face'' and to explain what is required for remote evaluations. Specifically, the technology must be able to allow real-time audio and visual interaction between the SAP and the employee. Telephone calls, therefore, would not be acceptable. In addition, the proposal would require that the quality of the technology be sufficient to allow the SAP to gather all visual and audible information that would be apparent in a face-to-face interaction.

§ 40.293 What is the SAP's function in conducting the initial evaluation of an employee?

The proposal would remove the words ''face-to-face'' from paragraph (a) this provision. This change, if adopted, would allow remote evaluations.

§ 40.301 What is the SAP's function in the follow-up evaluation of an employee?

The proposal would remove the words ''face-to-face'' from paragraph (b)(2) this provision. It would also add the words ''meeting the requirements of § 40.291(a)(1) of this part'', if adopted. This proposed change would allow remote evaluations.

§ 40.311 What are the requirements concerning SAP reports?

The proposal would add the words ''and format (*i.e.,* face-to-face or remote)'' to § 40.311(c)(4), (d)(4), and (e)(4). In addition, we would amend § 40.311 to direct SAPs to note on their SAP reports whether a given evaluation occurred face-to-face or remotely.

We also propose to change ''SSN'' to ''SSN or employee ID number'' in paragraphs § 40.311(c)(1), (d)(1) and (e)(1) for consistency of terms in Part 40 and to allow the use of additional identification numbers in SAP reports, instead of solely the Social Security Number.

§ 40.365 What is the Department's policy concerning starting a PIE proceeding?

We propose to amend § 40.365 to say that a PIE could occur because a SAP failed to conduct an evaluation using the means provided in § 40.291(a)(1), rather than because there was no face-to-face evaluation.

§ 40.327 When must the MRO report medical information gathered in the verification process?

In § 40.327, we would add a clarification that MROs are not to use the CCF to transmit information about safety concerns to employers or other authorized parties. Rather, a separate communication (*e.g.,* secure email, letter) is to be used. The communication should specify whether the MRO's safety concern relates to the use of a medication, the type of medical condition for which such a medication is typically prescribed, or some combination of the two. The purpose of

providing this information is to allow the employer and/or any third parties to focus on the MRO's specific concern, rather than having to make an open-ended inquiry. The Department seeks comment on this matter. This clarification would echo the Department's 2017 final rule preamble discussion that medical information is sent apart from the verified result report. (82 FR 52229, 52236; Nov. 13, 2017).

Appendices

Appendix A, concerning urine collection kits, would remain unchanged. The proposed rule would add a new aappendix B, establishing standards for oral fluid collection kits, based on material in the HHS OFMG and consistent with OTETA requirements for a split specimen. The Department seeks comments on the details of the proposed standards.

The remainder of the appendices would be renumbered and reordered. For a summary of these changes, see the redesignation table immediately preceding the discussion of subpart D in section V of the preamble. The Department seeks comment on the new organization of the appendices.

Current aappendix B, concerning semi-annual reports by laboratories to employers, would become aappendix D. The new version of the appendix would break out matters to be reported with respect to urine and oral fluid testing respectively. Current aappendix C, regarding semi-annual reports by laboratories to the Department, would become aappendix E. Meanwhile, the aappendix C slot would be reserved.

In the redesignated aappendix E (the former aappendix C), the Department proposes to amend the data elements that HHS/NLCP certified laboratories would submit to DOT semi-annually. Specifically, we propose to require laboratories to continue to provide the DOT with the drug testing data but to be broken out by specimen type (*i.e.,* urine and oral fluid), DOT agency (*i.e.,* FMCSA, FAA, FRA, FTA, PHMSA, U.S. Coast Guard) and test reason (*i.e.,* pre-employment, random, reasonable suspicion/cause, post-accident, return-to-duty, other, and follow-up). The proposal would require each laboratory to submit multiple data summaries as opposed to the one data summary they now provide. By providing the additional data elements, we hope to evaluate the efficacy of testing by oral fluid versus urine. We also hope to get a better understanding of any trends in drug testing by specimen type, DOT agency and/or test reason(s).

We do not anticipate that providing the amended data summaries will prove to be burdensome to the laboratories. It is our understanding that most, if not all of the HHS/NLCP-certified laboratories capture these data elements either as a result of implementing the electronic Federal Drug Testing Custody and Control Form, or in their Laboratory Information Management System, as part of tracking the specimens and reporting out test results to the Medical Review Officer. We would appreciate information from laboratories as to whether adding the new data elements would increase their costs or otherwise impose a quantifiable burden of what the costs of adding the new data elements would be.

Current aappendix D, concerning reports on split specimen failures to reconfirm, would become aappendix F. We propose to add the ''specimen type'' as another element to the information the MRO currently provides so we can track the two specimen types. Current aappendix E, on SAP equivalency requirements for certification organizations, would become aappendix G.

Current aappendix F, concerning drug and alcohol testing information can be transmitted by C/TPAs, would become appendix H. Current appendix G, the Alcohol Testing Form, would become aappendix I. Finally, aappendix H, the MIS data collection form, would be found in aappendix J.

VI. Regulatory Analyses and Notices

Executive Order 12866

The Secretary has examined the impact of the proposed Part 40 amendments under Executive Order 12866, which directs Federal agencies 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). This examination draws upon the evaluation performed by HHS in its final guidelines concerning oral fluid testing, published October 25, 2019 (84 FR 57554), as well as data reflecting the Department's experience in implementing its existing drug testing program.

According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. The proposed amendments do modify existing regulatory requirements and allow an activity that was formerly prohibited, but they do not meet the Executive Order's criteria for being a significant rule. Consequently, OMB has determined that this document proposes a nonsignificant rule.

Need for Regulation

The Department believes that this proposed rule is needed because it makes several improvements in the integrity and effectiveness of an important safety program, as well as potentially reducing some costs to regulated parties. The reasons for this belief include the following:

Enhanced Flexibility

The proposed rule, consistent with the HHS OFMG, would revise the requirement to collect only a urine specimen, which has existed since Part 40 was first published in 1988. Urine drug testing is subject to issues related to an employee's inability to produce a sufficient urine specimen. In such situations, the employee's inability to provide a sufficient urine specimen creates delays in getting a result to the employer because of the requirement to have the employee evaluated by a medical professional to assess the employee's inability to provide a sufficient specimen.

When the proposed amendments to Part 40 permitting oral fluid testing are used by a transportation employer, the employer will be authorized to collect an oral fluid specimen from an individual who is unable to provide a sufficient urine specimen. This added flexibility will reduce the need for the Medical Review Officer (MRO) to arrange a medical evaluation of an employee's inability to provide a specimen. Therefore, the proposed amendments would provide flexibility to address workplace drug testing needs of transportation employers by permitting the selection of the specimen type best suited for their needs and authorizing collection of an alternative specimen type when an employee is unable to provide a sufficient urine specimen. The added flexibility will also benefit employees, who should be able to provide one of the specimen types, thereby facilitating the drug test required for their employment.

Enhanced Versatility

Urine collection requires use of a collection facility, secured restrooms, and other special requirements. An oral fluid collection does not require an enclosure, the way that a urine collection does. With oral fluids, there

is more flexibility regarding the collection site. Specifically, an acceptable oral fluid collection site must allow the collector to observe the employee, maintain control of the collection device(s) during the process, maintain record storage, and protect employee privacy. This would provide employers with more flexibility about where to conduct a collection. For example, especially in the railroad and pipeline industries, where selected employees may be part of ''travelling gangs'' or in remote locations (*e.g.,* away from locations with traditional brick-and-mortar buildings) an enclosure is often difficult to find for collecting DOT-regulated specimens.

Having oral fluid testing as an option available to an employer provides flexibility for the employer to choose whether urine or oral fluid testing is better due to logistics, costs, and the specific facts of a situation. Among other things, when a problematic situation occurs at a collection site (*e.g.,* a urine specimen is out of temperature range), the ensuing directly observed test could be conducted using oral fluid. Choosing the oral fluid testing option in such situations can save the employer significant time and money.

Decreased Numbers of Substituted and Adulterated Tests

All unobserved specimen collections are at risk for substitution and adulteration. Per HHS's OFMG preamble, information from the drug testing industry indicates that 0.05 to 3% of urine specimens collected for drug use detection are determined to be substituted or adulterated. (84 FR 57571; Oct. 25, 2019). All oral fluid collections will occur under direct observation, which should substantially reduce the risks of specimen substitution and adulteration that has been associated with urine specimen collections, most of which are unobserved. With the above in mind, and to harmonize with HHS, we are proposing changes to §§ 40.91 and 40.93 to authorize laboratories to conduct specimen validity testing (*e.g.,* testing for a biomarker such as albumin or immunoglobulin G, IgG or for a specific adulterant).

Time and Cost Savings

Collecting an oral fluid specimen can require less time than collecting a urine specimen, and thereby reduce the employee's time away from the workplace and costs to the employer. First, most urine collections take place in separate facilities dedicated to collections, requiring employees to travel from their workplace to those facilities and back. Their time away from their workplace is a cost to their employers. On the other hand, most oral fluid collections are likely to take place at or near the workplace, making this travel time and cost unnecessary.

The Department does not currently have data on the percentage of urine collections that are conducted in dedicated collection facilities, or the percentage of oral fluid collections that would likely be conducted on-site. We request that commenters submit information that would help the Department approximate a calculation of the travel time savings that could result from making oral fluid testing available as an alternative to urine testing.

Second, some urine collection events involve the employee's inability to provide a sufficient specimen. In these cases, the current regulation affords the employee up to three hours to make a second attempt at providing a sufficient urine specimen. This wait period can be avoided by immediately switching to an oral fluid collection, saving up to three hours of time in such cases. From 2018 MIS data, about 334 insufficient specimen collections resulted in refusals, a number that does not include those instances in which the situation is resolved without a refusal being declared. The Department seeks comment on the incidence of ''shy bladder'' situations, to get a better sense of how much time and costs would be saved by eliminating them by the use of oral fluid testing.

In addition, fewer insufficient specimen situations would mean fewer medical evaluations, which could also result in time and cost savings. The option to collect a urine specimen in the event that the employee cannot provide an oral fluid specimen (and vice versa) will avoid the need for the MRO to arrange for a medical evaluation of an employee's inability to provide a sufficient specimen. We seek comment on what degree of time and cost savings might result from this proposal.

We also note that urine testing is subject to other events that may involve additional testing. For instance, if an initial urine specimen is out of temperature range, or the color or odor of a specimen may indicate an attempt to tamper with a specimen, there must be an immediate re-collection under direct observation. Many of these situations may well evolve into a ''shy bladder'' situation as, having just voided, the employee may be unable to produce another specimen quickly. These subsequent collections involve time and other costs. We seek comment on how frequently such subsequent collections occur, and how much time they add to the process.

Reduced Need for Collection Site Security Measures

Urine testing requires that access to water sources or to any potential adulterants or substituting products be secured and prohibited. This requires securing of the collection site to ensure the integrity of the unobserved testing process and protection against cheating. We are proposing substantially fewer steps for oral fluid collection site integrity and security because all oral fluid specimen collection is directly observed.

Providing urine is a bodily function that requires more privacy than having the employee place a collection device in the employee's mouth, in accordance with the collector's instructions. Consequently, oral fluid testing is less intrusive and time-consuming than even unobserved urine testing.

Versatility in Detection

Adding oral fluid as an alternate specimen type would allow an employer to select the specimen type based on the circumstances of the test. For example, in a reasonable suspicion/cause or post-accident test, an oral fluid test may show the presence of an active drug, which may indicate recent use of the drug, and which might not be detected in a urine drug test.

An oral fluid drug test can detect marijuana use in the past 24 hours, while a urine drug test detects use ranging from 3–67 days prior to collection (see preamble ''Understanding Windows of Detection''). Thus, oral fluid testing may give employers more interpretative insight into recent drug use.

Lower Likelihood of Adulteration, Substitution or Cheating

Urine was the original specimen of choice for workplace drug testing, and urine testing is expected to remain an established and reliable component of DOT's drug testing program. However, a major challenge to urine drug testing has been the proliferation and use of available commercial products used to adulterate or substitute an employee's urine specimen. Due to individual privacy rights, most urine collections are unobserved, allowing the opportunity to use such products. As under HHS Urine Mandatory Guidelines, laboratories have developed procedures to identify adulterated and/or substituted specimens, manufacturers have developed new products to avoid detection. The use of these products is expected to continue. Like HHS, DOT

believes that oral fluid testing is likely to be less susceptible to these problems because the oral fluid collection is a directly observed collection.

Costs and Benefits

Using data obtained from the Federal Workplace Drug Testing Programs and HHS-certified laboratories, HHS estimated that approximately 7% (or 10,500) of the 150,000 specimens tested in the Federal employee program per year would be oral fluid specimens and 93% would continue to be urine specimens. HHS further estimated that subsequent transition to oral fluid testing would be gradual and steady over the course of four years, when it could account for about 30% of all tests.

If, as the Department believes based on industry experience, the cost of a urine test is approximately $50, while the cost of an oral fluid test is $35, this means that each oral fluid test that is done in place of a urine test results in a saving of $15. By this calculation, oral fluid testing would cost $14.7 million in the first year and $63 million after the four-year transition period. This represents a potential savings of $6.3 million the first year and $27 million in the fourth year, compared to a scenario in which all the tests in question were urine tests. The Department seeks comment on whether the assumptions behind these calculations make sense and whether and how we should modify them.

It is possible that, over time, the proportion of tests conducted using oral fluid could increase beyond this projection, as employers take advantage of the lower costs and greater flexibility associated with oral fluid testing. If so, then the cost savings of these amendments would increase. We do not have data on which to base an estimate of how large and how quickly this trend might become. The Department seeks comment on this matter.

Employers and C/TPAs choosing to use oral fluid in their drug testing programs may incur collector training costs. Based on an average of the limited number of published training costs for oral fluid collectors in the non-DOT drug testing industry, oral fluid collection training would cost about $348 per collector trained.

The Department estimates that there are about 25,000 collectors currently participating in the DOT-regulated urine drug testing program. We assume, per HHS's projection, that after the first year of oral fluid testing, 7% of tests would use oral fluid and around 7% of collectors would be trained in oral fluid collection by that point. Seven percent of 25,000 collectors is 1,750. Their training would cost $609,000. By the same logic, by the end of the fourth year, 30% of those 25,000 collectors, or 7,500, would have been trained in collecting oral fluid. The cost for oral fluid testing training an additional 23% of the 25,000 collectors, or 5,750 individuals, in years 2–4 would be $2,001,000. The Department seeks information and comment on this approach and these projections.

As noted in the time savings discussion above, in a ''shy bladder'' situation, a collector can switch from urine to oral fluid collection. Likewise, in a ''dry mouth'' situation, a collector can switch from oral fluid to urine collection. This flexibility minimizes the required waiting period involved in ''shy bladder/dry mouth'' situations at the collection site. It also avoids costs and time expenses of subsequent medical evaluations to determine whether there is a medical explanation of employee's inability to provide a sufficient specimen. As noted above, we are seeking information on the number and costs of such evaluations. Table 1 summarizes the quantified economic effects of the proposed rule. The proposed rule has annual net cost savings (benefits) of $5,61,000 in the first year, increasing to $24,999,000 in the fourth and subsequent years.

TABLE 1—ECONOMIC EFFECTS OF PROPOSED RULE

Year	Costs	Cost savings	Net cost savings
1	$609,000	$6,300,000	$5,691,000
2	$957,000	$11,475,000	$10,518,000
3	$1,305,000	$11,475,000	$10,170,000
4 and beyond	$2,001,000	$27,000,000	$24,999,000

Regulatory Flexibility Act and SBREFA

This rule does affect small entities, including employees, small transportation companies and collection sites. DOT anticipates, however, that there will be an overall reduction in costs if drug testing is expanded to provide the option of oral fluid testing under Part 40. The added flexibility to use either specimen type will permit employers to select the specimen type best suited for their needs and to authorize collection of an alternative specimen type when an employee is unable to provide the specimen type originally authorized. This added flexibility will also benefit employees, who should be able to provide one of the specimen types, thereby facilitating the completion of drug tests required for their employment. For these reasons, and as explained in more detail in the preamble to this proposed rule, the Secretary has determined that the proposed rule would not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 605(b)). Consequently, an initial regulatory flexibility analysis is not required for this proposed rule.

The Secretary has determined that this NPRM is not a ''major rule'' for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of $100 million or more; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. The proposed rule does none of these things, and hence does not constitute a major rule under the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.

Unfunded Mandates

The Secretary has examined the impact of the proposed rule under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This notice does not trigger the requirement for a written statement under sec. 202(a) of the UMRA because this rulemaking does not impose a mandate that results in an expenditure of $100 million (adjusted annually for inflation) or more by either State, local, and tribal governments in the aggregate or by the private sector in any one year. In fact, by providing a lower cost alternative to urine drug testing, the NPRM would reduce costs to regulated parties, including State and local entities (*e.g.,*

public transit authorities, public works departments) whose employees are subject to testing.

Environmental Impact

The DOT has analyzed the environmental impacts of this action pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, ''Procedures for Considering Environmental Impacts'' (44 FR 56420, October 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). The purpose of this rulemaking is to amend the transportation industry drug testing program procedures regulation to include oral fluid testing. Paragraph 4(c)(5) of DOT Order 5610.1C incorporates by reference the categorical exclusions for all DOT Operating Administrations. This action is covered by the categorical exclusion listed in the Federal Transit Administration's implementing procedures, ''[p]lanning and administrative activities that do not involve or lead directly to construction, such as: . . . promulgation of rules, regulations, directives. . .'' 23 CFR 771.118(c)(4). The agency does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Executive Order 13132: Federalism

The Secretary has analyzed the proposed rule in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires Federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt State law. As defined in the Order, ''policies that have federalism implications'' refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that 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.

Most of the regulated parties under the Department's drug testing program are private entities. Some regulated entities are public entities (*e.g.,* transit authorities, public works departments); however, as noted above, this proposal would reduce costs of the Department's drug testing program and provide additional flexibility for regulated parties. Accordingly, the Secretary has determined that the proposed rules do not contain policies that have federalism implications.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 6, 2000) requires Federal agencies to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' as defined in the Executive Order, include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This proposed rule does not have tribal implications. Nor will they have substantial direct effects on tribal governments, 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, as specified in Executive Order 13175.

Information Collection/Record Keeping Requirements

The proposed rule would not impose additional information collection burdens. In August 2020, OMB approved the revised CCF (OMB Control No. 0930–0158). It is a single CCF that can be used for either urine or oral fluid testing. Collectors, laboratories, MROs and other parties in the DOT drug testing program are required to use the 2020 CCF for urine testing. Upon issuance of any final rule authorizing oral fluid testing, the 2020 CCF will be required for oral fluid testing.

Notwithstanding any other provision of law, no person is required 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 of information displays a currently valid OMB control number.

List of Subjects in 49 CFR Part 40

Administrative practice and procedures, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

For the reasons stated in the preamble, the Department proposes to amend 49 CFR part 40 as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

■ 1. The authority for part 40 continues to read as follows:

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

■ 2. In § 40.3:
■ a. Remove the definitions of ''Invalid drug test'' and ''Screening drug test'';
■ b. Remove the definition of ''Initial drug test (also known as ''Screening drug text'') and add a definition for ''Initial drug test'' in its place;
■ c. Remove the definition of ''Limit of Quantification'' and add a definition for ''Limit of Quantification (LOQ)'' in its place;
■ d. Add in alphabetical order definitions for ''Alternative specimen'', ''Commercial Driver's License Drug and Alcohol Clearinghouse (Clearinghouse)'', ''Cutoff'', ''Oral Fluid Specimen'', ''Specimen'', ''SSN or Employee ID No.'', ''Undiluted (neat) oral fluid'', and ''Urine Specimen''; and
■ e. Revise the definitions of ''Collection container'', ''Collection site'', ''Confirmatory drug test'', ''Initial drug test'', ''Initial specimen validity test'', ''Invalid Result'', ''Laboratory'', ''Limit of Detection (LOD)'', ''Limit of Quantitation (LOQ)'', ''Non-negative specimen'', ''Primary specimen'', ''Reconfirmed'', ''Shipping container'', ''Specimen bottle'', ''Split specimen'', ''Split specimen collection'', and ''Substituted specimen''.

The additions and revisions read as follows:

§ 40.3 What do the terms used in this part mean?

* * * * *

Alternative specimen. An authorized specimen, other than the type of specimen previously collected or attempted to be collected.

* * * * *

Collection container. A container used to collect a specimen.

Collection site. A place selected by the employer where employees present themselves for the purpose of providing a specimen for a drug test.

* * * * *

Commercial Driver's License Drug and Alcohol Clearinghouse (Clearinghouse). A database, administered by the Federal Motor Carrier Safety Administration, containing records of commercial motor vehicle drivers' violations of controlled

substances and alcohol testing program requirements, as set forth in part 382 of this title, as well as their return-to-duty status.

* * * * *

Confirmatory drug test. A second analytical procedure performed on a different aliquot of the original specimen to identify and quantify a specific drug or drug metabolite.

* * * * *

Cutoff. The analytical value (*e.g.,* drug or drug metabolite concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or substituted) or the need for further testing.

* * * * *

Initial drug test. The first test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

Initial specimen validity test. The first test used to determine if a specimen is adulterated, diluted, substituted, or invalid.

Invalid result. The result reported by a laboratory for a specimen in which the laboratory has not been able to complete testing or obtain a valid drug test result (*e.g.,* because of an unidentified adulterant, an interfering substance, or an abnormal physical characteristic).

Laboratory. Any U.S. laboratory certified by HHS under the National Laboratory Certification Program as meeting the minimum standards set by HHS; or, in the case of foreign laboratories, a laboratory approved for participation by DOT under this part.

Limit of Detection (LOD). The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

Limit of Quantitation (LOQ). For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

* * * * *

Non-negative specimen. A specimen that is reported as adulterated, substituted, positive (for drug(s) or drug metabolite(s)), or invalid.

* * * * *

Oral Fluid Specimen. A specimen that is collected from an employee's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

* * * * *

Primary specimen. In drug testing, the specimen bottle that is opened and tested by a first laboratory to determine whether the employee has a drug or drug metabolite in his or her system; and for the purpose of specimen validity testing. The primary specimen is the portion of the donor's subdivided specimen designated as the primary (''A'') specimen by the collector to distinguish it from the split (''B'') specimen, as defined in this section.

* * * * *

Reconfirmed. The result reported for a split (Bottle B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (Bottle A) specimen.

* * * * *

Shipping container. A container that is used for transporting and protecting specimen bottles and associated documents from the collection site to the laboratory.

Specimen. Fluid, breath, or other material collected from an employee at the collection site for the purpose of a drug or alcohol test.

Specimen bottle. The bottle that, after being sealed and labeled according to the procedures in this part, is used to hold a primary (''A'') or split (''B'') specimen during transportation to the laboratory. In the context of oral fluid testing, it may be referred to as a ''vial,'' ''tube,'' or ''bottle.''

Split specimen. In drug testing, the specimen that is sent to a first laboratory and stored with its original seal intact, and which is transported to a second laboratory for retesting at the employee's request following MRO verification of the primary specimen as positive, adulterated or substituted.

Split specimen collection. A collection in which the single specimen collected is divided into two separate specimen bottles, the primary specimen (Bottle A) and the split specimen (Bottle B).

SSN or Employee ID No. This number serves as a unique identifier that must be used on the Federal Drug Testing Custody and Control Form (CCF) or Alcohol Testing Form (ATF) for a donor, on the MRO's reports, on SAP reports, or on other documents that are required under this part. For all purposes of this part, this term means: Only the Commercial Driver's License (CDL) Number and State of issuance for drivers tested under the authority of the Federal Motor Carrier Safety Administration (FMCSA); and, for all drivers and other safety-sensitive employees tested under the authority of the other DOT agencies, this can be the individual's actual Social Security Number, a unique identifier issued by the employer, a State-issued identification card number, a State-issued driver's license number (including a CDL number) or any other State-issued or federally-issued identification number.

* * * * *

Substituted specimen. An employee's specimen not consistent with a normal human specimen, as determined by HHS (*e.g.,* a urine specimen, with creatinine and specific gravity values that are so diminished, or so divergent that they are not consistent with normal human urine).

* * * * *

Undiluted (neat) oral fluid. An oral fluid specimen to which no other solid or liquid has been added. For example: A collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.

Urine specimen. Urine collected from an employee at the collection site for the purpose of a drug test.

* * * * *

■ 3. In § 40.13, revise paragraphs (b), (c), and (d), redesignate paragraphs (e) and (f) as paragraphs (f) and (g), respectively, add new paragraph (e), and add paragraph (h).

The revisions and additions to read as follows:

§ 40.13 How do DOT drug and alcohol tests relate to non-DOT tests?

* * * * *

(b) DOT tests must take priority and must be conducted and completed before a non-DOT test is begun. When conducting a urine DOT drug test, you must discard any excess urine left over from a DOT test and collect a separate urine void for the subsequent non-DOT test.

(c) Except as provided in paragraph (d) of this section, you must not perform any tests on DOT specimens other than those tests specifically authorized by this part or DOT agency regulations. For example, you must not test a DOT specimen for additional drugs. In addition, a laboratory is prohibited from making a DOT specimen available for a DNA test or other types of specimen identity testing.

(d) When a DOT urine drug test collection is conducted as part of a physical examination required by DOT agency regulations, it is permissible to conduct medical tests related to this physical examination (*e.g.,* for glucose) on any specimen remaining in the collection container after the DOT portion has been sealed into the specimen bottles.

(e) A non-DOT drug or alcohol test administered, as part of a physical examination, is not a DOT drug or alcohol test for purposes of this part and

related DOT agency drug and alcohol testing rules, if that test was performed to determine if an employee is medically qualified for a license or certificate. Consequently, the results of such a test do not have consequences under this part.

* * * * *

(h) No one is permitted to conduct a DOT drug or alcohol test on an individual who is not a DOT-regulated employee, as defined by the DOT agency regulations.

■ 4. In § 40.14, revise paragraph (b) and add paragraphs (k) and (l) to read as follows:

§ 40.14 What information must employers provide to collectors?

* * * * *

(b) SSN or Employee ID No.'';

* * * * *

(k) Specimen type to be collected (*i.e.,* oral fluid or urine).

(l) If a urine specimen is to be collected under direct observation.

■ 5. In § 40.21:

■ a. In paragraph (c)(2)(vii)(B), remove the word ''and'' from the end;

■ b. Redesignate paragraph (c)(2)(vii)(C) as paragraph (c)(2)(vii)(D); and

■ c. Add a new paragraph (c)(2)(vii)(C).

The addition reads as follows:

§ 40.21 May an employer stand down an employee before the MRO has completed the verification process?

* * * * *

(c) * * *

(2) * * *

(vii) * * *

(C) For a verified negative result, the employee will not be required to submit an alternative specimen for the same testing action. For a cancelled result, the employee could be required to submit an alternative specimen on a re-collection; and

* * * * *

■ 6. In § 40.23, revise paragraphs (f) introductory text and (f)(1) and (5) to read as follows:

§ 40.23 What actions do employers take after receiving verified test results?

* * * * *

(f) As an employer who receives a drug test result indicating that the employee's test was cancelled because it was invalid and that a second collection must take place under direct observation—

(1) You must immediately direct the employee to provide a new specimen under direct observation (either an oral fluid specimen or a urine specimen under direct observation).

* * * * *

(5) You must ensure that the collector conducts the collection under direct observation (either an oral fluid specimen or a urine specimen under direct observation).

* * * * *

■ 7. In § 40.25, revise paragraph (a) to read as follows:

§ 40.25 Must an employer check on the drug and alcohol testing record of employees it is intending to use to perform safety-sensitive duties?

(a)(1) Yes, as an employer, you must, after obtaining an employee's written consent, request the information about the employee listed in paragraphs (b) through (j) of this section. This requirement applies only to employees seeking to begin performing safety-sensitive duties for you for the first time (*i.e.,* a new hire, an employee transferring into a safety-sensitive position). If the employee refuses to provide this written consent, you must not permit the employee to perform safety-sensitive functions.

(2) If you are an employer regulated by FMCSA, beginning January 6, 2023, you are not required to comply with the requirements of this section when checking an employee's testing history with other employers regulated by FMCSA. You must continue to comply with the requirements of section 40.25 when checking an employee's testing history with employers regulated by a DOT operating administration other than FMCSA.

(3) If you are an employer regulated by FMCSA, with a prospective employee subject to drug and alcohol testing with a DOT agency other than FMCSA, you must continue to request the information about the employee listed in in paragraphs (b) through (j) of this section. For example, if you are an employer regulated by both FMCSA and PHMSA, and you are hiring an employee to perform functions regulated by both DOT Agencies, then you must query FMCSA's Clearinghouse to satisfy FMCSA's requirements and you must request the information listed in in paragraphs (b) through (j) of this section to satisfy PHMSA's requirements.

* * * * *

§ 40.26 [Amended]

■ 8. In § 40.26, remove ''Appendix H'' and add in its place ''Appendix J''.

§ 40.29 [Removed]

■ 9. Remove § 40.29.

■ 10. In § 40.31,

■ a. Revise the section heading;

■ b. Revise paragraphs (b);

■ c. Redesignate paragraphs (c) and (d) as paragraphs (d) and (e)

■ d. Add new paragraph (c);

■ e. Revise newly redesignated paragraph (d); and

■ f. Add paragraph (f).

The revisions and additions read as follows:

§ 40.31 Who may collect specimens for DOT drug testing?

* * * * *

(b) A urine collector must meet training requirements of § 40.33.

(c) An oral fluid collector must meet the training requirements of § 40.35.

(d) To avoid the appearance of a conflict of interest, if you are the immediate supervisor of the employee being tested, you must not act as the collector when that employee is tested, unless no other collector is available and you are permitted to do so under DOT agency drug and alcohol regulations.

* * * * *

(f) Employees are not permitted to be their own collector.

(1) An employee who is a qualified collector is not permitted to be their own collector; another qualified collector must perform the collection in accordance with this part.

(2) To avoid a potential conflict of interest, a collector must not be related to the employee being tested (*e.g.,* spouse, ex-spouse, relative) or a close personal friend.

■ 11. In § 40.33, revise the section heading, introductory text, and paragraph (f) to read as follows:

§ 40.33 What training requirements must a collector meet for urine collection?

To be permitted to act as a urine collector in the DOT drug testing program, you must meet each of the requirements of this section:

* * * * *

(f) *Error correction training.* If you make a mistake in the collection process that causes a test to be cancelled (*i.e.,* a fatal or uncorrected flaw), you must undergo error correction training. This training must occur within 30 days of the date you are notified of the error that led to the need for retraining. Errors that cause cancellation but occur outside the collection process (*e.g.,* when a specimen is crushed or otherwise damaged during the transportation process, or is lost in transit), the cancellation would not be the result of an error by the collector during the collection process and does not require the collector to be retrained.

* * * * *

§ 40.35 [Redesignated as § 40.36]

■ 12. Redesignate § 40.35 as § 40.36.

■ 13. Add a new § 40.35 to read as follows:

§ 40.35 What training requirements must a collector meet for oral fluid collection?

To be permitted to act as an oral fluid collector in the DOT drug testing program, you must meet each of the requirements of this section:

(a) *Basic information.* You must be knowledgeable about this part, the current applicable guidelines and DOT agency regulations applicable to the employers for whom you perform collections. DOT agency regulations, guidelines, and other materials are available from ODAPC (Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, 202–366–3784, or on the ODAPC website (*https://www.transportation.gov/odapc*). You must keep current on any changes to these materials. You must subscribe to the ODAPC list-serve at: *https://www.transportation.gov/odapc/get-odapc-email-updates.*

(b) *Qualification training.* You must receive qualification training meeting the requirements of this paragraph. Qualification training must provide instruction on the following subjects:

(1) The oral fluid collection device manufacturer's training for each device the collector will use for DOT-regulated collections;

(2) All steps necessary to complete a collection correctly and the proper completion and transmission of the CCF;

(3) ''Problem'' collections (*e.g.,* situations like ''dry mouth'' and attempts to tamper with a specimen);

(4) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(5) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of employees being tested, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(c) *Initial proficiency demonstration.* Following your completion of qualification training under paragraph (b) of this section, you must demonstrate proficiency in collections under this part by completing five consecutive error-free mock collections.

(1) The five mock collections must include one uneventful collection scenario, one insufficient specimen quantity scenario; one scenario in which the employee has something in their mouth that might interfere with the collection; one scenario in which the employee attempts to tamper with the specimen; and one scenario in which the employee refuses to sign the CCF.

(2) Another person must monitor and evaluate your performance, in person or by a means that provides real-time observation and interaction between you and the qualified collector, who must attest in writing that the mock collections are ''error-free.'' This person must be a qualified collector who has demonstrated necessary knowledge, skills, and abilities by—

(i) Regularly conducting DOT drug test collections for a period of at least one year;

(ii) Conducting collector training under this part for at least one year; or

(iii) Successfully completing a ''train the trainer'' course.

(d) *Schedule for qualification training and initial proficiency demonstration.* You must meet the requirements of paragraphs (b) and (c) of this section before you begin to perform collector functions.

(e) *Refresher training.* No less frequently than every five years from the date on which you satisfactorily complete the requirements of paragraphs (b) and (c) of this section, you must complete refresher training that meets all the requirements of paragraphs (b) and (c) of this section.

(f) *Error correction training.* If you make a mistake in the collection process that causes a test to be cancelled (*i.e.,* a fatal or uncorrected flaw), you must undergo error correction training. This training must occur within 30 days of the date you are notified of the error that led to the need for retraining.

(1) Error correction training must be provided and your proficiency documented in writing by a person who meets the requirements of paragraph (c)(2) of this section.

(2) Error correction training is required to cover only the subject matter area(s) in which the error that caused the test to be cancelled occurred.

(3) As part of the error correction training, you must demonstrate your proficiency in the collection procedures of this part by completing three consecutive error-free mock collections. The mock collections must include one uneventful scenario and two scenarios related to the area(s) in which your error(s) occurred. The person providing the training must monitor and evaluate your performance and attest in writing that the mock collections were ''error-free.''

(g) *Documentation.* You must maintain documentation showing that you currently meet all requirements of this section. You must provide this documentation on request to DOT agency representatives and to employers and C/TPAs who are using or negotiating to use your services.

§ 40.37 [Removed]

■ 14. Remove § 40.37.

Subpart D [Amended]

■ 15. In the heading for subpart D, remove the word ''Urine''.

§ 40.41 [Redesignated as § 40.42]

■ 16. Redesignate § 40.41 as § 40.42.

§ 40.45 [Redesignated as § 40.40]

■ 17. Redesignate § 40.45 as § 40.40.

■ 18. In newly redesignated § 40.40:

■ a. Revise the section heading and paragraphs (a) and (b), (c) introductory text, and (c)(1) through (4); and

■ b. Amend paragraph (d) by removing the words ''social security number (SSN) or other employee identification (ID) number'' and adding in their place ''SSN or Employee ID No.''.

The revisions read as follows:

§ 40.40 What form is used to document a DOT collection?

(a) The Federal Drug Testing Custody and Control Form (CCF) must be used to document every collection required by the DOT drug testing program. You may view this form on the Department's website (*http://www.transportation.gov/odapc*) or the HHS website (*http://www.workplace.samhsa.gov*).

(b) You must not use a non-Federal form or an expired CCF to conduct a DOT collection. As a laboratory, C/TPA or other party that provides CCFs to employers, collection sites, or other customers, you must not provide copies of an expired CCF to these participants. You must also affirmatively notify these participants that they must not use an expired CCF.

(c) As a participant in the DOT drug testing program, you are not permitted to modify or revise the CCF except as follows:

(1) You may include, in the area outside the border of the form, other information needed for billing or other purposes necessary to the collection process.

(2) The CCF must include the names, addresses, telephone numbers and any other appropriate contact information (*e.g.,* an email address of the employer and the MRO), including the DER's name and contact information. All of this information must be preprinted, typed, or handwritten. Fax numbers may be included, but are not required. The MRO information must include the physician's name and address, as opposed to only a generic clinic, health care organization, or company name. This information is required, and an employer, collector, service agent or any other party is prohibited from omitting it. In addition, a C/TPA's name, address,

telephone and fax numbers, and any other appropriate contact information should be included, but is not required. The employer may use a C/TPA's address in place of its own, but must continue to include its name, telephone and fax numbers, and any other appropriate contact information.

(3) As an employer you may preprint the box in Step 1–D of the CCF for the DOT agency under whose authority the test will occur.

(4) As a collector, you may use a CCF with your name, address, telephone number, and fax number preprinted, but under no circumstances may you sign the form before the collection event. If a collection takes place at a clinic, the actual address of the clinic should be used, not a corporate address of the collection company. If the collection takes place onsite at the employer, the employer's address must be noted as the collection site address. If the collection takes place in a ''mobile unit'' or at an accident site, the collector must enter the actual location address of the collection or as near an approximation as possible. The collector must ensure that the required collector telephone number is the number that the laboratory, MRO, or employer may use to directly contact the individual collector and/or the collector's supervisor.

* * * * *

§ 40.47 [Redesignated as § 40.41]

■ 19. Redesignate § 40.47 as § 40.41.

§ 40.41 [Amended]

■ 20. In newly redesignated § 40.41, in paragraph (a), remove the word ''urine'' wherever it appears.

■ 21. In § 40.43, revise the section heading to read as follows:

§ 40.43 What steps must operators of collection sites and collectors take to protect the security and integrity of urine collections?

* * * * *

§ 40.49 [Redesignated as § 40.44]

■ 22. Redesignate § 40.49 as § 40.44.

§ 40.51 [Redesignated as § 40.45]

■ 23. Redesignate § 40.51 as § 40.45.

■ 24. Add §§ 40.47, 40.48, 40.49, and 40.51 to subpart D to read as follows:

* * * * *

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§ 40.47 Where does an oral fluid collection for a DOT drug test take place?

(a) An oral fluid collection for a DOT drug test must take place in a collection site meeting the requirements of this section.

(b) If you are operating an oral fluid collection site:

(1) You must ensure that it meets the security requirements of § 40.48;

(2) The site may be a permanent or temporary facility located either at the work site or at a remote site;

(3) The site may be in a medical facility, a mobile facility (*e.g.,* a van), a dedicated collection facility, or any other location meeting the requirements of this section; and

(4) You must have all necessary personnel, materials, equipment, and facilities that include privacy and supervision to provide for the collection, temporary storage, and shipping of specimens to a laboratory, and a suitable clean surface for writing.

(c) If a collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (*e.g.,* an accident investigation), another site may be used for the collection, if the collection is performed by a collector who has been trained to collect oral fluid specimens in accordance with this part and the manufacturer's procedures for the collection device.

§ 40.48 What steps must operators of collection sites and collectors take to protect the security and integrity of oral fluid collections?

(a) Collectors and operators of collection sites must take the steps listed in this section to prevent unauthorized access that could compromise the integrity of collections.

(b) As a collector, you must do the following before each collection to deter tampering with specimens:

(1) Ensure that access to collection materials and specimens is effectively restricted;

(2) Ensure that undetected access (*e.g.,* through a door not in your view) is not possible; and

(3) Secure facility against access during the procedure to ensure privacy to the employee and prevent distraction of the collector. Limited-access signs must be posted.

(c) As a collector, you must take the following additional steps to ensure security during the collection process:

(1) To avoid distraction that could compromise security, you are limited to conducting a collection for only one employee at a time. However, during the time one employee is in the period for drinking fluids in a ''dry mouth'' situation (see § 40.72(b)(1)), you may conduct a collection for another employee as long as the employee with ''dry mouth'' remains supervised.

(2) To the greatest extent practicable, keep an employee's collection container within view of both you and the employee between the time the employee has provided the oral fluid specimen and the specimen is sealed.

(3) Ensure you are the only person in addition to the employee who handles the specimen before it is sealed with tamper-evident seals.

(4) In the time between when the employee gives you the specimen and when you seal the specimen, remain within the collection site.

(5) Maintain personal control over each specimen and CCF throughout the collection process.

(d) If you are operating a collection site, you must implement a policy and procedures to prevent unauthorized personnel from entering any part of the site in which oral fluid specimens are collected or stored.

(1) Only employees being tested, collectors and other collection site workers, DERs, employee and employer representatives authorized by the employer (*e.g.,* employer policy, collective bargaining agreement), and DOT agency representatives are authorized persons for purposes of paragraph (e) of this section.

(2) You must ensure that all authorized persons are under the supervision of a collector at all times when permitted into the site.

(3) You or the collector may remove any person who obstructs, interferes with, or causes a delay in the collection process.

(e) If you are operating a collection site, you must minimize the number of persons handling specimens.

§ 40.49 What materials are used to collect oral fluid specimens?

For each DOT drug test, you must use a collection device meeting the requirements of appendix B of this part.

§ 40.51 What materials are used to send oral fluid specimens to the laboratory?

(a) Except as provided in paragraph (b) of this section, you must use a shipping container that adequately protects the specimen bottles from damage in the transport of specimens from the collection site to the laboratory.

(b) You are not required to use a shipping container if a laboratory courier hand-delivers the specimens

from the collection site to the laboratory.

Subpart E—[Amended]

■ 25. In the heading for subpart E, remove the word ''Urine''.

■ 26. In § 40.61, revise the section heading and paragraphs (a), (b)(1) introductory text, (b)(3) and (4), (e), and (f)(5)(i) to read as follows:

§ 40.61 What are the preliminary steps in the drug testing collection process?

* * * * *

(a) When a specific time for an employee's test has been scheduled, or the collection site is at the employee's work site, and the employee does not appear at the collection site at the scheduled time, contact the DER to determine the appropriate interval within which the DER has determined the employee is authorized to arrive. If the employee's arrival is delayed beyond that time, you must notify the DER that the employee has not reported for testing. In a situation where a C/TPA has notified an owner/operator or other individual employee to report for testing (other than for a pre-employment test) and the employee does not appear, the C/TPA must determine whether the employee has refused to test (see § 40.191(a)(1)).

(b) * * *

(1) If the employee is also going to take a DOT alcohol test, you must ensure, to the greatest extent practicable, that the alcohol test is completed before the drug testing collection process begins.

* * * * *

(3) You must not collect a specimen from an unconscious employee to conduct a drug test under this part.

(4) You must not catheterize a conscious employee for purposes of a urine test. However, you must inform an employee who normally voids through self-catheterization that the employee is required to provide a specimen in that manner. If an employee normally voids through self-catheterization, but declines to do so for the urine test, the collector should notify the DER of the circumstances, so that the employer can determine whether the situation constitutes a refusal to test by the employee.

* * * * *

(e) Explain the basic collection procedure to the employee, and notify the employee that instructions for completing the CCF can be found at the HHS (*www.samhsa.gov/workplace*) and DOT (*www.transportation.gov/odapc*) websites.

(f) * * *

(5) * * *

(i) Determine if the material appears to be brought to the collection site with the intent to alter the specimen, and, if it is, either conduct a directly observed urine collection using direct observation procedures (see § 40.67) or an oral fluid specimen collection, make a note on the CCF and continue with collection process; or

* * * * *

■ 27. In § 40.63, revise paragraph (a) to read as follows:

§ 40.63 What steps does the collector take in the collection process before the employee provides a urine specimen?

* * * * *

(a) Ensure all items under Step 1 of the CCF are complete and accurate (*e.g.,* if Step 1.D is not checked, put a check mark for the ''Specify DOT Agency'' under the authority of which the test will take place; if the address where the collection is actually taking place is not in Step 1.G, update that.)

* * * * *

■ 28. In § 40.65, revise the section heading and paragraphs (b)(5) and (6), and (c)(1) to read as follows:

§ 40.65 What does the collector check for when the employee presents a urine specimen?

* * * * *

(b) * * *

(5) If the specimen temperature is outside the acceptable range, you must immediately conduct a new urine collection using direct observation procedures (see § 40.67) or an oral fluid collection.

(6) In a case where a specimen is collected under direct observation because of the temperature being out of range, you must process both the original specimen and the specimen collected using direct observation (including oral fluid) and send the two sets of specimens to their respective laboratories. This is true even in a case in which the original specimen has insufficient volume and the temperature is out of range. You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

* * * * *

(c) * * *

(1) If it is apparent from this inspection that the employee has tampered with the specimen (*e.g.,* blue dye in the specimen, excessive foaming when shaken, or smell of bleach), you must immediately conduct a new urine collection using direct observation procedures (see § 40.67) or an oral fluid collection.

* * * * *

■ 29. In § 40.67:

■ a. Revise the section heading;

■ b. In paragraph (c)(1), remove ''paragraphs (a) and (b)'' and add ''paragraph (a)'' in its place;

■ c. Revise paragraph (d)(2);

■ d. In paragraph (e)(2), remove ''§ 40.67(b)'' and add in its place ''§ 40.67(c)(2) through (4)''; and

■ e. Revise paragraph (g).

The revisions and additions read as follows:

§ 40.67 When and how is a directly observed urine collection conducted?

* * * * *

(d) * * *

(2) As the collector, you must explain to the employee the reason, if known, under this part for a directly observed collection.

* * * * *

(g) As the collector, you must ensure that the observer is the same gender as the employee unless the observer is a medical professional (*e.g.,* nurse, doctor, physician's assistant, technologist, technician licensed or certified to practice in the jurisdiction in which the collection takes place). The observer can be a different person from the collector and need not be a qualified collector.

■ 30. In § 40.69, revise the section heading, redesignate paragraphs (a) through (g) as paragraphs (b) through (h); add new paragraph (a), and revise newly redesignated paragraph (e) to read as follows:

§ 40.69 How is a monitored urine collection conducted?

(a) As stated in § 40.42(f)(2), if you are conducting a urine collection in a multi-stall restroom and you cannot secure all sources of water and other substances that could be used for adulteration and substitution, you must conduct a monitored collection. This is the only circumstance in which you must conduct a monitored collection.

* * * * *

(e) As the monitor, you must not watch the employee urinate into the collection container. If you hear sounds or make other observations indicating an attempt to tamper with a specimen, there must be an additional collection under direct observation. See §§ 40.63(e), 40.65(c), and 40.67(c)(2)(3)).

* * * * *

■ 31. In § 40.71, revise the section heading and paragraph (b)(1) to read as follows:

§ 40.71 How does the collector prepare the urine specimen?

* * * * *

(b) * * *

(1) Check the box on the CCF (Step 2) indicating that this was a ''Urine'' and ''Split'' specimen collection.

* * * * *

§ 40.73 [Redesignated as § 40.79]

■ 32. Redesignate § 40.73 as § 40.79.

■ 33. Add new §§ 40.72 through 40.74 to read as follows:

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§ 40.72 What steps does the collector take in the collection process before the employee provides an oral fluid specimen?

(a) The collector requests that the employee open the employee's mouth, and the collector inspects the oral cavity to ensure that it is free of any items that could impede or interfere with the collection of an oral fluid specimen (*e.g.,* candy, gum, food, or tobacco) or could be used to adulterate, substitute, or alter the specimen.

(1) If the employee claims that he or she has a medical condition that prevents opening his or her mouth for inspection, the collector follows the procedure described in § 40.193(a).

(2) If the collector observes materials brought to the collection site or the employee's conduct clearly indicates an attempt to adulterate, substitute, or alter the specimen, the collector must terminate the collection, note the circumstances in the Remarks section of the CCF, and report the circumstances to the DER, so that the employer can decide whether to deem the situation a refusal in accordance with § 40.191(a).

(b) If an item is present that might impede or interfere with the collection of an oral fluid specimen, the collector must request the employee remove the item.

(1) If the employee removes any item that could impede or interfere with the collection of an oral fluid specimen, the employee has abnormally colored saliva, or the employee claims to have ''dry mouth,'' then the collector must give the employee water, up to 8 ounces, to rinse their mouth. The employee may drink the water. The collector must then wait 10 minutes before beginning the specimen collection.

(2) If the employee refuses to remove the item or rinse, the collector must terminate the collection, note the circumstances in the Remarks section of the CCF, and report the information to the DER to test as described in § 40.191(a)(8) (failure to cooperate), so that the employer can decide whether to deem the situation a refusal.

(c) If there is nothing of concern in the oral cavity and no ''dry mouth'' condition, the collector starts the 10-minute wait period and proceeds with the steps below before beginning the specimen collection as described in § 40.73.

(d) During the 10-minute wait:

(1) Review with the employee the procedures required for a successful oral fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(2) Complete all items under Step 1 of the CCF, and for clarification:

(i) In Step 1.D of the CCF, the collector must put a check mark for the ''Specify DOT Agency'' under whose authority the test will take place.

(ii) In Step 1.G of the CCF for the ''Collection Site Address'', the collector must provide the address where the collection took place.

(3) The collector will complete Step 2 of the CCF.

(i) Check ''Oral Fluid'',

(ii) For ''Oral Fluid: Split Type'' check ''Subdivided,'' and

(iii) Check ''Each Device Within Expiration Date?'' after ensuring that each device is within its expiration date.

(4) The collector must instruct the employee to use hand sanitizer, put on gloves, or wash and dry his or her hands.

(e) The collector will provide, or the employee may select, a specimen collection device that is clean, unused, and wrapped/sealed in original packaging. The collector must open the specimen collection device in view of the employee.

(f) To the greatest extent practicable, the collector must keep the employee's unwrapped collection device within view of both you and the employee, between the time the employee has provided a specimen and the specimen is sealed.

§ 40.73 How is an oral fluid specimen collected?

(a) The collector must be present and maintain visual contact with the employee during the procedures outlined in this section.

(b) The collector must note any unusual behavior or appearance of the employee on the CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* an attempt to bring into the collection site an adulterant or oral fluid substitute), the collector must terminate the collection and report the information to the DER so that the employer can decide whether to deem the situation a refusal.

(c) The employee and collector must complete the specimen collection in accordance with the manufacturer instructions for the collection device.

(1) The collector must ensure the collection is performed correctly (*i.e.,* using the oral fluid device in the manner described by its manufacturer), that the collection device is working properly, and that a sufficient specimen volume is collected.

(i) If there is a failure to collect the specimen, the collector must start the process again, beginning with § 40.72(e), using a new specimen collection device, and noting the failed collection attempt on the CCF.

(ii) If the employee states that he or she is unable to provide an oral fluid specimen during the collection process, or after multiple failures to collect the specimen, the collector follows the procedure in § 40.193.

(2) The collector must inspect the specimen for unusual color, presence of foreign objects or material, or other signs of tampering. If it is apparent from this inspection that the employee has tampered with the specimen, you must conduct a new collection.

(i) Document any unusual characteristics referenced above in the Remarks section of the CCF.

(ii) Proceed with obtaining the new oral fluid specimen from the donor. Note on the new CCF that this is another collection for the same testing event. (*i.e.,* Document in the remarks section that this is Specimen 2 of 2 and include the Specimen ID number of the other specimen. Make the same notation on the CCF of the suspect specimen.)

§ 40.74 How does the collector prepare the oral fluid specimens?

(a) The collector follows the manufacturer's instructions to package the split specimen collections.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube A'' and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube B''.

(c) In the presence of the employee, the collector places a tamper-evident seal from the CCF over the cap of each specimen container, taking care not to obstruct the expiration date on the collection containers. The collector must record the date of the collection on the tamper-evident seals, after they are affixed to the specimen containers.

(d) The collector instructs the employee to initial the tamper-evident seals on each specimen container. If the employee declines to do so, the collector must note this in the ''Remarks'' line of the CCF (Step 2) and complete the collection process.

§§ 40.75–40.78 [Reserved]

■ 34. Add reserved §§ 40.75 through 40.78.

■ 35. In newly redesignated § 40.79, revise paragraph (a)(1) to read as follows:

§ 40.79 How is the collection process completed?

* * * * *

(a) * * *

(1) Direct the employee to read and sign the certification statement on Copy 2 of the CCF and provide all information required in Step 5. If the employee declines to sign the CCF or to provide any of the required information, you must note this in the ''Remarks'' line (Step 2) of the CCF and complete the collection. If the employee declines to fill out any information, you must, as a minimum, print the employee's name in the appropriate place.

* * * * *

§ 40.81 [Amended]

■ 36. In § 40.81, in paragraph (a), remove the words ''all testing'' and add in their place the words ''each specimen testing methodology performed''.

§ 40.83 [Amended]

■ 37. In § 40.83:

■ a. In paragraph (c)(7), remove the word ''urine'' and add in its place the word ''specimen'';

■ b. In paragraph (f) introductory text, add the word ''urine'' before the word ''specimen'';

■ c. In paragraph (g) introductory text, remove the cross-reference ''40.45(a)'' and adding in its place ''40.40(a)'';

■ d. a. In paragraphs (h)(1)(i), (iii), and (iv), remove the word ''urine'' and add in its place the word ''specimen''; and

■ e. In paragraph (h)(2) removing the cross-reference ''(g)(1)'' and adding in its place ''(h)(1)''.

§ 40.99 [Redesignated as § 40.84]

■ 38. Redesignate § 40.99 as § 40.84.

§ 40.84 [Amended]

■ 39. In newly redesignated § 40.84:

■ a. In paragraph (a), remove the words ''one year'' and add, in their place, the words ''90 days'';

■ b. In the first sentence of paragraph (c) remove the words ''one-year'' and add in their the words ''90-day''; and

■ c. In the last sentence of paragraph (c) remove the word ''year'' and add in its place the words ''90-day period''.

§ 40.85 [Redesignated as § 40.82]

■ 40. Redesignate § 40.85 as § 40.82.

§ 40.87 [Redesignated as § 40.85]

■ 41. Redesignate § 40.87 as § 40.85.

§ 40.89 [Redesignated as § 40.86]

■ 42. Redesignate § 40.89 as § 40.86.

■ 43. In newly redesignated § 40.86, revise the section heading to read as follows:

§ 40.86 What is urine validity testing, and are laboratories required to conduct it?

* * * * *

§ 40.91 [Redesignaed as § 40.87]

■ 44. Redesignate § 40.91 as § 40.87.

■ 45. In newly redesignated § 40.87, revise the section heading, and in the introductory text, remove ''§ 40.89'' and add in its place ''§ 40.86''.

The revision reads as follows:

§ 40.87 What validity tests must laboratories conduct on primary urine specimens?

* * * * *

§ 40.93 [Redesignated as § 40.88]

■ 46. Redesignate § 40.93 as § 40.88.

■ 47. In newly redesignated § 40.88, revise the section heading to read as follows:

§ 40.88 What criteria do laboratories use to establish that a urine specimen is dilute or substituted?

* * * * *

§ 40.95 [Redesignated § 40.89]

■ 48. Redesignate § 40.95 as § 40.89.

■ 49. In newly redesignated § 40.89, revise the section heading to read as follows:

§ 40.89 What are the adulterant cutoff concentrations for initial and confirmation urine tests?

* * * * *

§ 40.96 [Redesignated as § 40.90]

■ 50. Redesignate existing § 40.96 as § 40.90.

■ 51. In newly redesignated § 40.90, revise the section heading to read as follows:

§ 40.90 What criteria do laboratories use to establish that a urine specimen is invalid?

* * * * *

■ 52. Add new §§ 40.91 through 40.93 to read as follows:

Sec.

* * * * *

40.91 What are the cutoff concentrations for undiluted (neat) oral fluid drug tests?

40.92 What is oral fluid validity testing, and are laboratories required to conduct it?

40.93 What validity tests must laboratories conduct on primary oral fluid specimens?

* * * * *

§ 40.91 What are the cutoff concentrations for undiluted (neat) oral fluid drug tests?

As a laboratory, you must use the cutoff concentrations displayed in table 1 to this section for initial and confirmatory drug tests for oral fluid specimens. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL).

TABLE 1 TO § 40.91—ORAL FLUID TESTING CUTOFF CONCENTRATIONS

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana (THC) [2]	4 ng/mL [3]	THC	2 ng/mL.
Cocaine/Benzoylecgonine	15 ng/mL	Cocaine	8 ng/mL.
		Benzoylecgonine	8 ng/mL.
Codeine/Morphine	30 ng/mL	Codeine	15 ng/mL.
		Morphine	15 ng/mL.
Hydrocodone/Hydromorphone	30 ng/mL	Hydrocodone	15 ng/mL.
		Hydromorphone	15 ng/mL.
Oxycodone/Oxymorphone	30 ng/mL	Oxycodone	15 ng/mL.
		Oxymorphone	15 ng/mL.
6-Acetylmorphine	4 ng/mL [3]	6-Acetylmorphine	2 ng/mL.
Phencyclidine	10 ng/mL	Phencyclidine	10 ng/mL.
Amphetamine/Methamphetamine	50 ng/mL	Amphetamine	25 ng/mL.
		Methamphetamine	25 ng/mL.

TABLE 1 TO § 40.91—ORAL FLUID TESTING CUTOFF CONCENTRATIONS—Continued

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff concentration
MDMA [4]/MDA [5]	50 ng/mL	MDMA	25 ng/mL.
		MDA	25 ng/mL.

[1] For grouped analytes (*i.e.*, two or more analytes that are in the same drug class and have the same initial test cutoff):
Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.
Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (*i.e.*, with concentrations equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.
[2] An immunoassay must be calibrated with the target analyte.
[3] *Alternate technology (THC and 6–AM):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (i.e., 2 ng/mL for THC, 2 ng/mL for 6–AM).
[4] Methylenedioxymethamphetamine (MDMA).
[5] Methylenedioxyamphetamine (MDA).

§ 40.92 What is oral fluid validity testing, and are laboratories required to conduct it?

(a) Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human oral fluid. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the oral fluid, if the oral fluid was altered.

(b) If a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then you may conduct validity testing.

(c) If you determine that the specimen is invalid and HHS guidelines direct you to contact the MRO, you must contact the MRO and together decide if testing the primary specimen by another HHS-certified laboratory would be useful in being able to report a positive or adulterated test result.

§ 40.93 What validity tests must laboratories conduct on primary oral fluid specimens?

As a laboratory, if you conduct validity testing under § 40.92, you must conduct it in accordance with the requirements of this section.

(a) You may test for a biomarker such as albumin or immunoglobulin G (IgG) or a test for a specific adulterant.

(b) You must follow the applicable HHS requirements for any additional validity testing.

■ 53. Revise § 40.97 to read as follows:

§ 40.97 What do laboratories report and how do they report it?

(a) As a laboratory, when reporting a result of any kind, you must report the specimen type.

(b) You must also report the results for each primary specimen, which will fall into one of the following three categories. As a laboratory, you must report the actual results (and not the categories):

(1) Category 1: Negative Results. As a laboratory, when you find a specimen to be negative, you must report the test result as being one of the following, as applicable:

(i) Negative, or

(ii) For urine only, negative-dilute, with numerical values for creatinine and specific gravity.

(2) Category 2: Non-negative Results. As a laboratory, when you find a specimen to be non-negative, you must report the test result as being one or more of the following, as applicable:

(i) Positive, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s).

(ii) Adulterated, with adulterant(s) noted, with confirmatory test values (when applicable), and with remarks(s);

(iii) For urine only, positive-dilute, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s) and with numerical values for creatinine and specific gravity;

(iv) For urine only, substituted, with confirmatory test values for creatinine and specific gravity; or

(v) For urine only, invalid result, with remark(s). Laboratories will report actual values for pH results.

(vi) For oral fluid only, invalid result, with remark(s). Laboratories must report numerical values of the specimen validity test results that support a specimen reported as invalid.

(3) Category 3: Rejected for Testing. As a laboratory, when you reject a specimen for testing, you must report the result as being Rejected for Testing, with remark(s).

(c) As a laboratory, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or a service agent (*e.g.,* a C/TPA).

(1) Negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully completed Copy 1 of the CCF which has been signed by the certifying scientist, or you may provide the laboratory results report electronically (*i.e.,* computer data file).

(i) If you elect to provide the laboratory results report, you must include the following elements, as a minimum, in the report format:

(A) Laboratory name and address;

(B) Employer's name (you may include I.D. or account number);

(C) Medical review officer's name;

(D) Specimen I.D. number;

(E) SSN or Employee ID from Step 1C of the CCF, if provided;

(F) Reason for test, if provided;

(G) Collector's name and telephone number;

(H) Date of the collection;

(I) For oral fluid only, collection device expiration date

(J) Date received at the laboratory;

(K) Date certifying scientist released the results;

(L) Certifying scientist's name;

(M) Results (*e.g.,* positive, adulterated) as listed in paragraph (a) of this section; and

(N) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(ii) You may release the laboratory results report only after review and approval by the certifying scientist. It must reflect the same test result information as contained on the CCF signed by the certifying scientist. The information contained in the laboratory results report must not contain information that does not appear on the CCF.

(iii) The results report may be transmitted through any means that ensures accuracy and confidentiality. You, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage (*e.g.,* see § 40.351).

(2) Non-negative and Rejected for Testing results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully completed Copy 1 of the CCF that has been signed by the certifying scientist. In addition, you may provide the electronic laboratory results report following the format and procedures set forth in paragraphs (b)(1)(i) and (ii) of this section.

(d) In transmitting laboratory results to the MRO, you, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage. If the results are provided by fax or other electronic means, the electronic communication must be accessible only to authorized individuals.

(e) You must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.

(f)(1) You must provide quantitative values for confirmed positive drug test results to the MRO.

(2) You must provide numerical values that support the adulterated (when applicable) or substituted result, without a request from the MRO.

(3) You must also provide the MRO numerical values for creatinine and specific gravity for the negative-dilute urine test result, without a request from the MRO.

(g) You must provide quantitative values for confirmed positive morphine and/or codeine urine results at or below 15,000 ng/mL, and for confirmed positive morphine or codeine oral fluid results at or below 150 ng/mL.

■ 54. In § 40.111, revise paragraphs (a) and (d) to read as follows:

§ 40.111 When and how must a laboratory disclose statistical summaries and other information it maintains?

(a) As a laboratory, you must transmit an aggregate statistical summary, by employer, of the data listed in appendix D of this part with respect to each specimen type for which you conduct tests to the employer on a semi-annual basis.

* * * * *

(d) As a laboratory, you must transmit an aggregate statistical summary listed in appendix E of this part for each specimen type for which you conduct testing to DOT on a semi-annual basis. The summary must be sent by January 31 of each year for July 1 through December 31 of the prior year. It must be sent by July 31 of each year for January 1 through June 30 of the current year. If you withdraw or are removed from NLCP's laboratory certification during a reporting period, you must provide the aggregate statistical summary to the DOT-regulated employers and to ODAPC for the last period in which you conducted DOT-regulated testing.

§ 40.121 [Amended]

■ 55. In § 40.121, in paragraph (c)(1)(i), remove the word ''urine''.

§ 40.123 [Amended]

■ 56. In § 40.123, in paragraph (c), remove the words ''invalid drug tests results'' and add in their place ''invalid results''.

§ 40.127 [Amended]

■ 57. In § 40.127, in paragraph (g)(2), add the words ''of all specimen types combined'' before the words ''in any quarter''.

§ 40.129 [Amended]

■ 58. In § 40.129, in paragraph (a) introductory text, remove the words ''invalid drug tests'' and add in their place ''invalid results''; in paragraph (d), remove ''drug test report'' and add ''result'' in its place.

§ 40.135 [Amended]

■ 59. In § 40.135, in paragraph (d) introductory text, remove the word ''test'' and add in its place the word ''result''.

■ 60. In § 40.139, revise paragraph (b), and in paragraph (c), remove the word ''urine''.

The revision reads as follows:

§ 40.139 On what basis does the MRO verify text results involving 6-acetylmorphine, codeine, and morphine?

* * * * *

(b) In the absence of 6–AM, if the laboratory confirms the presence of either morphine or codeine equal to or above 15,000 ng/mL (in urine) or equal to or above 150 ng/mL (in oral fluid), you must verify the test result as positive, unless the employee presents a legitimate medical explanation for the presence of the drug or drug metabolite in his or her system, as in the case of other drugs (see § 40.139). Consumption of food products (*e.g.,* poppy seeds) must not be considered a legitimate medical explanation for the employee having morphine or codeine at these concentrations.

* * * * *

§ 40.145 [Amended]

■ 61. In § 40.145, in paragraph (g)(3), remove the word ''urine'' and add the word ''drug'' in its place; and in paragraph (h) introductory text, add the word ''urine'' before the word ''result''.

■ 62. In § 40.151, revise paragraphs (a), (b), (g), and (i) to read as follows:

§ 40.151 What are MROs prohibited from doing as part of the verification process?

* * * * *

(a) You must not consider any evidence (verbal or written information) from any drug tests that are not collected or tested in accordance with this part. For example, if an employee tells you he went to his own physician, provided a urine specimen, sent it to a laboratory, and received a negative test result, you are required to ignore this test result.

(b) It is not your function to make decisions about factual disputes between the employee and the collector concerning matters occurring at the collection site that are not reflected on the CCF (*e.g.,* concerning allegations that the collector left the area or left open collection containers where other people could access them.)

* * * * *

(g) You must not accept an assertion that there is a legitimate medical explanation for the presence of PCP, 6–AM, MDMA, or MDA in a specimen.

* * * * *

(i) You must not accept, as a legitimate medical explanation for a substituted specimen, an assertion that an employee can produce a urine specimen for which the creatinine level is below the laboratory's limit of detection. There are no physiological means through which a person can produce a urine specimen having this characteristic.

■ 63. In § 40.159, revise paragraphs (a)(1) and (a)(5)(ii) to read as follows:

§ 40.159 What does the MRO do when a drug test result is invalid?

(a) * * *

(1) Discuss the laboratory results with a certifying scientist to determine if the primary specimen should be tested at another HHS-certified laboratory. If the laboratory did not contact you as required by §§ 40.91(e) and 40.96(b), you must contact the laboratory.

* * * * *

(5) * * *

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that a second collection must take

place immediately under direct observation. Recommend to the employer that an alternative specimen should be collected if practicable (*e.g.,* oral fluid, if the specimen was urine).

* * * * *

■ 64. In § 40.163, in paragraph (c)(2), remove the words ''donor SSN or employee ID number'' and add in their place the words ''SSN or employee ID No.'' and revise paragraph (e).

The revision reads as follows:

§ 40.163 How does the MRO report drug test results?

* * * * *

(e) If you use a written report as provided in paragraph (c) of this section to report results, you must retain a copy of the written report. If you use the electronic data file to report negatives, as provided in paragraph (d) of this section, you must retain a retrievable copy of that report in a format suitable for inspection and audit by a DOT representative. In either case, you must keep the completed Copy 2 of the CCF. When completing Copy 2, either the MRO must sign and date it (for both negatives and non-negatives) or MRO staff must stamp and date it (for negatives only).

* * * * *

■ 65. In § 40.177, revise paragraphs (a) through (c) to read as follows:

§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

* * * * *

(a) As the laboratory testing the split specimen, you must test the split specimen for the drug(s)/drug metabolite(s) confirmed in the primary specimen.

(b) You must conduct this test without regard to the cutoff concentrations of § 40.85 or § 40.91, as applicable.

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that were reported in the primary specimen, you must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/metabolite(s). You should conduct the same validity tests as you would conduct on a primary specimen set forth in § 40.87 or § 40.93, as applicable.

* * * * *

§ 40.179 [Amended]

■ 66. In § 40.179, in paragraph (a), remove ''§ 40.95'' and add in its place ''§ 40.89 or § 40.93, as applicable''.

■ 67. Revise § 40.181 to read as follows:

§ 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

As the laboratory testing a urine split specimen, you must test the split specimen using the confirmatory tests for creatinine and specific gravity, using the criteria set forth in § 40.88.

§ 40.187 [Amended]

■ 68. In § 40.187, in paragraphs (b)(1), (c)(1)(iii), and (c)(2)(iii), remove ''Appendix D'' and add in its place ''appendix F'', and in paragraph (e)(3), remove ''appendix D'' and add in its place ''appendix F''.

■ 69. In § 40.191, revise paragraphs (a)(2) through (9) and (d)(1) to read as follows:

§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?

(a) * * *

(2) *Fail to remain at the testing site until the testing process is complete.* Provided that an employee who leaves the collection site before the testing process commences (see § 40.63(c) or § 40.72(e), as applicable) for a pre-employment test is not deemed to have refused to test;

(3) Fail to provide a specimen for any drug test required by this part or DOT agency regulations. Provided that an employee who does not provide a specimen because he or she has left the testing site before the testing process commences (see § 40.63(c) or § 40.72(e), as applicable) for a pre-employment test is not deemed to have refused to test;

(4) In the case of a directly observed or monitored urine collection in a drug test, fail to permit the observation or monitoring of an employee's provision of a specimen (see §§ 40.67(m) and 40.69(g));

(5) Fail to provide a sufficient amount of specimen when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see § 40.193(d)(2));

(6) Fail or decline to take an additional drug test the employer or collector has directed you to take (see, for instance, § 40.197(b) as applicable);

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under § 40.193(c). In the case of a pre-employment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(8) Fail to cooperate with any part of the testing process (*e.g.,* refuse to empty pockets when directed by the collector, behave in a confrontational way that disrupts the collection process, fail to wash hands after being directed to do so by the collector, fail to remove objects from mouth, fail to permit inspection of the oral cavity, or fail to complete a rinse when requested);

(9) For an observed urine collection, fail to follow the observer's instructions to raise your clothing above the waist, lower clothing and underpants, and to turn around to permit the observer to determine if you have any type of prosthetic or other device that could be used to interfere with the collection process;

* * * * *

(d) * * *

(1) As the collector, you must note the refusal in the ''Remarks'' line (Step 2), and sign and date the CCF. The collector does not make the final decision about whether the employee's conduct constitutes a refusal to test; the employer has the sole responsibility to decide whether a refusal occurred, as stated in § 40.355(i), the employer has a non-delegable duty to make the decision about whether the employee has refused to test.

* * * * *

■ 70. Revise § 40.193 to read as follows:

§ 40.193 What happens when an employee does not provide a sufficient amount of specimen for a drug test?

(a) If an employee does not provide a sufficient amount of specimen to permit a drug test (*i.e.,* 45 mL of urine in a single void, or 2 mL oral fluid in a single sampling, as applicable) you, as the collector, must provide another opportunity to the employee to do so. This can be done using the same specimen type as the original collection or, if you are qualified to collect an alternative specimen, you may use an alternative specimen collection for this purpose.

(b)(1) As the collector, you must do the following when collecting a urine specimen:

(i) Discard the insufficient specimen, except where the insufficient specimen was out of temperature range or showed evidence of adulteration or tampering (see § 40.65(b) and (c)).

(ii) Urge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink. Document on the Remarks line of the CCF (Step 2), and inform the employee of the time at which the three-hour period begins and ends.

(iii) If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is complete, you must discontinue the collection, note that fact on the ''Remarks'' line of the CCF (Step 2), and immediately notify the DER of the conduct as provided in section 40.191(e)(1); the employer decides whether the situation is deemed to be a refusal.

(iv) If the employee has not provided a sufficient specimen within three hours of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the ''Remarks'' line of the CCF (Step 2), and immediately notify the DER. You must also discard any specimen the employee previously provided, including any specimen that is ''out of temperature range'' or shows signs of tampering. In the remarks section of the CCF that you will distribute to the MRO and DER, note the fact that the employee provided an ''out of temperature range specimen'' or ''specimen that shows signs of tampering'' and that it was discarded because the employee did not provide a second sufficient specimen.

(2) As the collector, you must do the following when collecting an oral fluid specimen:

(i) If the employee demonstrates an inability to provide a specimen after 15 minutes of using the collection device, and if the donor states that he or she could provide a specimen after drinking some fluids, urge the employee to drink (up to 8 ounces) and wait an additional 10 minutes before beginning the next specimen collection (a period of up to one hour must be provided, or until the donor has provided a sufficient oral fluid specimen, whichever occurs first). If the employee simply needs more time before attempting to provide an oral fluid specimen, the employee is not required to drink any fluids during the one-hour wait time. It is not a refusal to test if the employee declines to drink. The employee must remain at the collection site, in a monitored area designated by the collector, during the wait period.

(ii) If the employee has not provided a sufficient specimen within one hour of the first unsuccessful attempt to provide the specimen, you must discontinue the collection, note the fact on the ''Remarks'' line of the CCF (Step 2), and immediately notify the DER.

(iii) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must send or fax these copies to the MRO and DER within 24 hours or the next business day.

(c) As the DER, if the collector informs you that the employee has not provided a sufficient amount of specimen (see paragraph (b) of this section), you must, after consulting with the MRO, direct the employee to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the employee's failure to provide a sufficient specimen. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

(1) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the employee was required to take a DOT drug test, but was unable to provide a sufficient amount of specimen to complete the test;

(ii) The consequences of the appropriate DOT agency regulation for refusing to take the required drug test;

(iii) That the referral physician must agree to follow the requirements of paragraphs (d) through (g) of this section.

(2) [Reserved]

(d) As the referral physician conducting this evaluation, you must recommend that the MRO make one of the following determinations:

(1) A medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen. As the MRO, if you accept this recommendation, you must:

(i) Check ''Test Cancelled'' (Step 6) on the CCF; and

(ii) Sign and date the CCF.

(2) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen. As the MRO, if you accept this recommendation, you must:

(i) Check the ''Refusal to Test'' box and ''Other'' box in Step 6 on Copy 2 of the CCF and note the reason next to the ''Other'' box and on the ''Remarks'' lines, as needed.

(ii) Sign and date the CCF.

(e) For purposes of this paragraph, a medical condition includes an ascertainable physiological condition (*e.g.,* a urinary system dysfunction in the case of a urine test or autoimmune disorder in the case of an oral fluid test), or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of ''situational anxiety'' or dehydration.

(f) As the referral physician making the evaluation, after completing your evaluation, you must provide a written statement of your recommendations and the basis for them to the MRO. You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.

(g) If, as the referral physician making this evaluation in the case of a pre-employment, return-to-duty, or follow-up test, you determine that the employee's medical condition is a serious and permanent or long-term disability that is highly likely to prevent the employee from providing a sufficient amount of specimen for a very long or indefinite period of time, you must set forth your determination and the reasons for it in your written statement to the MRO. As the MRO, upon receiving such a report, you must follow the requirements of § 40.195, where applicable.

(h) As the MRO, you must seriously consider and assess the referral physician's recommendations in making your determination about whether the employee has a medical condition that has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of specimen. You must report your determination to the DER in writing as soon as you make it.

(i) As the employer, when you receive a report from the MRO indicating that a test is cancelled as provided in paragraph (d)(1) of this section, you take no further action with respect to the employee. If the test reason was 'random', the employee remains in the random testing pool.

■ 71. In § 40.195, revise the section heading to read as follows:

§ 40.195 What happens when an individual is unable to provide a sufficient amount of specimen for a pre-employment, follow-up, or return-to-duty test because of a permanent or long-term medical condition?

* * * * *

■ 72. In § 40.197, revise the section heading to read as follows:

§ 40.197 What happens when an employer receives a report of a dilute urine specimen?

* * * * *

■ 73. In § 40.199, revise paragraph (b)(7) and add paragraph (b)(8) to read as follows:

§ 40.199 What problems always cause a drug test to be cancelled?

* * * * *

(b) * * *

(7) Because of leakage or other causes, there is an insufficient amount of specimen in the primary specimen bottle for analysis and the specimens cannot be re-designated (see § 40.83(h)).

(8) For an oral fluid collection, the collector used an expired device at the time of collection.

* * * * *

§ 40.201 [Amended]

■ 74. In § 40.201, in paragraph (f), remove the word ''urine'' and add in its place the word ''specimen''.

■ 75. In § 40.207, add paragraph (d) to read as follows:

§ 40.207 What is the effect of a cancelled drug test?

* * * * *

(d) If a test is cancelled, only the MRO who cancelled the test can reverse the cancellation and must do so within 60 days of the cancellation. After 60 days, the MRO who cancelled the test cannot reverse the cancellation without the permission of ODAPC. For example, if an MRO cancels a test because the MRO did not receive a copy of the CCF, but later receives a copy of the CCF, the MRO may reverse the decision to cancel the test within 60 days. After 60 days, the MRO must contact ODAPC for permission to reverse the cancellation. A laboratory is not authorized to reverse a cancellation due to a fatal flaw, as described in § 40.199.

§ 40.209 [Amended]

■ 76. In § 40.209, in paragraph (b)(7), remove ''§ 40.41'' and add in its place ''§ 40.42''.

■ 77. Revise § 40.210 to read as follows:

§ 40.210 What kinds of drug tests are permitted under the regulations?

Both urine and oral fluid specimens are authorized for collection and testing under this part. An employer can use one or the other, but not both at the beginning of the testing event. For example, if an employee is sent for a test, either a urine or oral fluid specimen can be collected, but not both simultaneously. However, if there is a problem in the collection that necessitates a second collection (*e.g.,* insufficient quantity of urine, temperature out of range, or insufficient saliva), then a different specimen type could be chosen by the employer and its service agent to complete the collection process for the testing event. Only urine and oral fluid specimens screened and confirmed at HHS-certified laboratories (see § 40.81) are allowed for drug testing under this part. Point-of-collection (POC) urine, POC oral fluid drug testing, hair testing, or instant tests are not authorized.

§ 40.225 [Amended]

■ 78. In § 40.225, in paragraph (a), remove ''Appendix G'' and add in its place ''appendix I''.

■ 79. In § 40.261, redesignate paragraph (c) as paragraph (c)(1) and add paragraph (c)(2).

The addition reads as follows.

§ 40.261 What is a refusal to take an alcohol test?

* * * * *

(c) * * *

(2) As the BAT or STT, you must note the refusal in the ''Remarks'' line (Step 3), and sign and date the ATF. The BAT or STT does not make the final decision about whether the employee's conduct constitutes a refusal to test; the employer must decide whether a refusal occurred, as stated in § 40.355(i), the employer has a non-delegable duty to make the decision about whether the employee has refused to test.

§ 40.283 [Amended]

■ 80. In § 40.283, in paragraph (c), remove ''Appendix E'' and add in its place ''appendix G''.

§ 40.285 [Amended]

■ 81. In § 40.285, in paragraph (b), remove the word ''urine''.

■ 82. In § 40.291, revise paragraphs (a)(1) and (3) to read as follows:

§ 40.291 What is the role of the SAP in the evaluation, referral, and treatment process of an employee who has violated DOT agency drug and alcohol testing regulations?

(a) * * *

(1) Making a clinical assessment and evaluation to determine what assistance is needed by the employee to resolve problems associated with alcohol and/or drug use. This assessment or evaluation may be performed face-to-face or remotely. If a SAP is not prohibited from using technology within the parameters of the SAP's State-issued license, a remote evaluation must be must be conducted in accordance with the following criteria:

(i) The technology must permit real-time audio and visual interaction between the SAP and the employee; and

(ii) The quality of the technology (*e.g.,* speed of the internet connection and clarity of the video display) must be sufficient to allow the SAP to gather all the visual and audible information the SAP would otherwise gather in a face-to-face interaction, while providing security to protect the confidentiality of the communication.

* * * * *

(3) Conducting an evaluation to determine if the employee has actively participated in the education and/or treatment program and has demonstrated successful compliance with the initial assessment and evaluation recommendations. This assessment or evaluation may be performed face-to-face or remotely. A remote evaluation must be made by means that meet the criteria in paragraphs (a)(1)(i) and (ii) of this section.

* * * * *

§ 40.293 [Amended]

■ 83. In § 40.293, in paragraph (a), remove the words ''face-to-face'' and after the words ''clinical evaluation,'' add the words ''meeting the requirements of § 40.291(a)(1)''.

§ 40.301 [Amended]

■ 84. In § 40.301, in paragraph (b)(2), remove the words ''face-to-face'' and after the words ''clinical interview'', add the words ''meeting the requirements of § 40.291(a)(1)''.

§ 40.311 [Amended]

■ 85. In § 40.311, in paragraphs (c)(4), (d)(4), and (e)(4), after the word ''Date(s)'' add the words ''and format (*i.e.,* face-to-face or remote)''; in paragraphs (c)(1), (d)(1), and (e)(1) remove ''SSN'' and add in its place ''SSN or employee ID No.''.

■ 86. In § 40.327:

■ a. In paragraph (a), remove the reference ''paragraph (c)'' and add in its place ''paragraph (d)'';

■ b. Redesignate paragraph (c) as paragraph (d); and

■ c. Add a new paragraph (c).

The addition reads as follows:

§ 40.327 When must the MRO report medical information gathered in the verification process?

* * * * *

(c) The MRO must not report such medical information using the CCF. Instead, the MRO must provide the information in a separate written communication (*e.g.,* letter, secure email). The information must state the specific nature of the MRO's safety concern (*e.g.,* the effects of a medication the employee is taking, the employee's underlying medical condition which the employee disclosed to the MRO).

* * * * *

§ 40.345 [Amended]

■ 87. In § 40.345, in paragraph (b), remove ''Appendix F'' and add in its place ''appendix H''.

§ 40.355 [Amended]

■ 88. In § 40.355, in Example 3 to paragraph (n), remove the word ''urine''.

§ 40.365 [Amended]

■ 89. In § 40.365, in paragraph (b)(8), remove the words ''face to face interviews'' and add in their place the

words ''without interviews meeting the requirements of § 40.291(a)(1)''.

Appendices E Through H to Part 40 [Redesignated as Appendices G Through J to Part 40]

■ 90. Redesignate appendices E through H to part 40 as appendices G through J to part 40.

Appendix C to Part 40 [Redesignated as Appendix E to Part 40]

■ 91. Redesignate appendix C to part 40 as appendix E to part 40.

Appendix C to Part 40 [Reserved]

■ 92. Add reserved appendix C to part 40.

Appendix D to Part 40 [Redesignated as Appendix F to Part 40]

■ 93. Redesignate appendix D to part 40 as appendix F to part 40.

Appendix B to Part 40 [Redesignated as Appendix D to Part 40]

■ 94. Redesignate appendix B to Part 40 as appendix D to part 40.
■ 95. Add new appendix B to part 40 to read as follows:

Appendix B to Part 40—Oral Fluid Collection Kit Contents

1. Oral Fluid Collection Device

a. A single-use device made to simultaneously collect a total of at least 2 mL of undiluted (neat) oral fluid, which can be subdivided in the employee's presence, into an ''A'' and a ''B'' split sample of at least 1 mL ±10 percent undiluted (neat) oral fluid per each included specimen bottle; or a single-use device made to simultaneously collect a sufficient amount of oral fluid, which can be subdivided in the employee's presence, into an ''A'' and a ''B'' split sample sufficient for laboratory testing. For example, when two specimens are collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes; or when a device collects a specimen with a single pad, which can be subdivided into two separate collection tubes.

b. Must have unit markings or other indicators clearly noting that sufficient volume of oral fluid has been achieved.

c. Must be sufficiently transparent to permit a visual assessment of the contents without opening the specimen bottle.

d. Must be individually packaged in an easily visible tamper-evident system.

e. Must have the device's expiration date on the specimen bottles or vials sent to the laboratory.

f. Must not include any substance that would interfere with an accurate analysis of analytes per HHS OFMG.

g. Must include a way to seal specimens to prevent leakage and be engineered to withstand storage and shipping while maintaining the integrity of the specimen.

h. Must be designed so that the required tamper-evident bottle seals made available on the CCF fit with no damage to the seal when the employee initials it, and the seal overlap will not conceal printed information.

2. Instructions

a. Must include the manufacturer's instructions within the device's packaging. The instructions must provide sufficient detail to allow for an error-free collection when instructions are followed.

3. Leak-Resistant Plastic Bag

a. Must have two sealable compartments or pouches that are leak-resistant; one large enough to hold two specimen bottles and the other large enough to hold the CCF paperwork.

b. The sealing methodology must be such that once the compartments are sealed, any tampering or attempts to open either compartment will be evident.

4. Absorbent Material

Each kit must contain enough absorbent material to absorb the entire contents of both specimen bottles. Absorbent material must be designed to fit inside the leak-resistant plastic bag pouch into which the specimen bottles are placed.

5. Shipping Container

a. Must be designed to adequately protect the specimen bottles from damage during shipment of the specimens from the collection site to the laboratory (*e.g.,* standard courier box, small cardboard box, plastic container).

b. May be made available separately at collection sites rather than being part of an actual collection device sent to collection sites.

c. A shipping container is not necessary if a laboratory courier hand-delivers the specimen bottles in the leak-resistant plastic bags from the collection site to the laboratory.

■ 96. Revise the newly redesignated appendix D to read as follows:

Appendix D to Part 40—DOT Drug Testing Semi-Annual Laboratory Report to Employers

The following items are required on each laboratory report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
Employer Identification: (name; may include Billing Code or ID code)
C/TPA Identification: (where applicable; name and address)
A. *Urine Specimens*
1. Urine Specimen Results Reported (total number) By Test Reason
(a) Pre-employment (number)
(b) Post-Accident (number)
(c) Random (number)
(d) Reasonable Suspicion/Cause (number)
(e) Return-to-Duty (number)
(f) Follow-up (number)
(g) Type of Test Not Noted on CCF (number)
2. Urine Specimens Reported
(a) Negative (number)
(b) Negative and Dilute (number)
3. Urine Specimens Reported as Rejected for Testing (total number) By Reason
(a) Fatal flaw (number)
(b) Uncorrected Flaw (number)
4. Urine Specimens Reported as Positive (total number) By Drug
(a) Marijuana Metabolite (number)
(b) Cocaine Metabolite (number)
(c) Opioids (number)
(1) Codeine (number)
(2) Morphine (number)
(3) 6–AM (number)
(4) Hydrocodone (number)
(5) Hydromorphone (number)
(6) Oxycodone (number)
(7) Oxymorphone (number)
(d) Phencyclidine (number)
(e) Amphetamines (number)
(1) Amphetamine (number)
(2) Methamphetamine (number)
(3) MDMA (number)
(4) MDA (number)
5. Urine Adulterated (number)
6. Urine Substituted (number)
7. Urine Invalid Result (number)
B. *Oral Fluid Specimens*
1. Oral Fluid Specimen Results Reported (total number) By Test Reason
(a) Pre-employment (number)
(b) Post-Accident (number)
(c) Random (number)
(d) Reasonable Suspicion/Cause (number)
(e) Return-to-Duty (number)
(f) Follow-up (number)
(g) Type of Test Not Noted on CCF (number)
2. Oral Fluid Specimens Reported
(a) Negative (number)
(b) Negative and Dilute (number)
3. Oral Fluid Specimens Reported as Rejected for Testing (total number) By Reason
(a) Fatal flaw (number)
(b) Uncorrected Flaw (number)
4. Oral Fluid Specimens Reported as Positive (total number) By Drug
(a) Marijuana (number)
(b) Cocaine and/or Cocaine Metabolite (number)
(c) Opioids (number)
(1) Codeine (number)
(2) Morphine (number)
(3) 6–AM (number)
(4) Hydrocodone (number)
(5) Hydromorphone (number)
(6) Oxycodone (number)
(7) Oxymorphone (number)
(d) Phencyclidine (number)
(e) Amphetamines (number)
(1) Amphetamine (number)
(2) Methamphetamine (number)
(3) MDMA (number)
(4) MDA (number)
5. Oral Fluid Adulterated (number)
6. Oral Fluid Substituted (number)
7. Oral Fluid Invalid Result (number)

■ 97. Revise newly redesignated appendix E to part 40 to read as follows:

Appendix E to Part 40—Drug Testing Semi-Annual Laboratory Report to DOT

Mail, fax, or email to: U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE, Washington, DC 20590, Fax: (202) 366–3897. *Email: ODAPCWebMail@dot.gov.*

The following items are required on each report:

Reporting Period: (inclusive dates)
Laboratory Identification: (name and address)
1. Specimen Type:
—oral fluid or urine
2. DOT agency
—FMCSA, FAA, FRA, FTA, PHMSA, or USCG
3. Test Reason
—Pre-Employment, Random, Reasonable Suspicion/Cause, Post-Accident, Return-to-Duty, Other, and Follow-up
A. DOT Specimen Results Reported (total number)
B. Negative Results Reported (total number)
1. Negative (number)
2. Negative-Dilute (number)
C. Rejected for Testing Results Reported (total number) By Reason
1. Fatal flaw (number)
2. Uncorrected Flaw (number)
D. Positive Results Reported (total number) By Drug
1. Marijuana or Marijuana Metabolite (number)
2. Cocaine and/or Cocaine Metabolite (number)
3. Opioids (number)
a. Codeine (number)
b. Morphine (number)
c. 6–AM (number)
d. Hydrocodone (number)
e. Hydromorphone (number)
f. Oxycodone (number)
g. Oxymorphone (number)
4. Phencyclidine (number)
5. Amphetamines (number)
a. Amphetamine (number)
b. Methamphetamine (number)
c. MDMA (number)
d. MDA (number)
E. Adulterated Results Reported (total number) By Reason (number)
F. Substituted Results Reported (total number)
G. Invalid Results Reported (total number) By Reason (number)

■ 98. Revise newly redesignated appendix F to read as follows:

Appendix F to Part 40—Report Format: Split Specimen Failure To Reconfirm

Mail, fax, or submit electronically to: U.S. Department of Transportation, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE, Washington, DC 20590, Fax: (202) 366–3897.

Submit Electronically: *https://www.transportation.gov/odapc/mro-split-specimen-cancellation-notification.*

The following items are required on each report:

1. MRO name, address, phone number, and fax number.

2. Collection site name, address, and phone number.

3. Date of collection.

4. Specimen I.D. number.

5. Specimen type.

6. Laboratory accession number.

7. Primary specimen laboratory name, address, and phone number.

8. Date result reported or certified by primary laboratory.

9. Split specimen laboratory name, address, and phone number.

10. Date split specimen result reported or certified by split specimen laboratory.

11. Primary specimen results (*e.g.,* name of drug, adulterant) in the primary specimen.

12. Reason for split specimen failure-to-reconfirm result (*e.g.,* drug or adulterant not present, specimen invalid, split not collected, insufficient volume).

13. Actions taken by the MRO (*e.g.,* notified employer of failure to reconfirm and requirement for re-collection).

14. Additional information explaining the reason for cancellation.

15. Name of individual submitting the report (if not the MRO).

Appendix H to Part 40 [Amended]

■ 99. In newly redesignated appendix H, under ''Drug Testing Information,'' remove the reference ''§ 40.129(d)'' and add in its place the reference ''§ 40.129(e)''.

Signed in Washington, DC, on January 19, 2022.

Peter Paul Montgomery Buttigieg,

Secretary of Transportation.

[FR Doc. 2022–02364 Filed 2–25–22; 8:45 am]

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Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Endangered Species Status for Peppered Chub and Designation of Critical Habitat; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2019–0019; FF09E21000 FXES1111090FEDR 223]

RIN 1018–BD29

Endangered and Threatened Wildlife and Plants; Endangered Species Status for Peppered Chub and Designation of Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine endangered species status under the Endangered Species Act of 1973 (Act), as amended, for the peppered chub (*Macrhybopsis tetranema*), a freshwater fish species historically found in Colorado, Kansas, New Mexico, Oklahoma, and Texas, which is now extirpated from all but six percent of its historical range. We also designate critical habitat. In total, approximately 872 river miles (1,404 river kilometers) in New Mexico, Oklahoma, and Texas fall within the boundaries of the critical habitat designation. We are excluding approximately 197 river miles (317 river kilometers) of critical habitat in Kansas that was included in the proposed critical habitat designation. This rule adds the species to the List of Endangered and Threatened Wildlife and extends the Act's protections to the peppered chub designated critical habitat.

DATES: This rule is effective March 30, 2022.

ADDRESSES: This final rule is available on the internet at *https://www.regulations.gov* and *https://www.fws.gov/southwest/es/arlingtontexas.* Comments and materials we received, as well as supporting documentation we used in preparing this rule, are available for public inspection at *https://www.regulations.gov* at Docket No. FWS–R2–ES–2019–0019.

The coordinates or plot points or both from which the maps are generated are included in the decision file for this critical habitat designation and are available at *https://www.regulations.gov* at Docket No. FWS–R2–ES–2019–0019 and at *https://www.fws.gov/southwest/es/arlingtontexas.* Any additional tools or supporting information that we developed for this critical habitat designation will also be available at the Service's website set out above and at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Debra Bills, Field Supervisor, U.S. Fish and Wildlife Service, Arlington, Texas, Ecological Services Field Office, 2005 Northeast Green Oaks Boulevard, Suite 140, Arlington, TX 76006; telephone 817–277–1100. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, a species warrants listing if it meets the definition of an endangered species (in danger of extinction throughout all or a significant portion of its range) or a threatened species (likely to become endangered in the foreseeable future throughout all or a significant portion of its range). If we determine that a species warrants listing, we must list the species promptly and designate the species' critical habitat to the maximum extent prudent and determinable. We have determined that the peppered chub meets the definition of an endangered species; therefore, we are listing it as such and finalizing a designation of its critical habitat. Both listing a species as an endangered or threatened species and designating critical habitat can be completed only by issuing a rule through the Administrative Procedure Act rulemaking process.

What this document does. This rule lists the peppered chub (*Macrhybopsis tetranema*) as an endangered species and designates 872 river miles (1,404 river kilometers) in three units in Oklahoma, New Mexico, and Texas as critical habitat.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

We have determined that habitat degradation and fragmentation (Factor A), resulting from altered flow regimes, impoundments, and other stream fragmentation, adversely modified geomorphology, decreased water quality, and the introduction and proliferation of invasive species (aquatic and vegetative), pose the largest risk to the viability of the species. Changes in the hydrological regime are primarily related to habitat changes: The loss of flowing water, instream habitat fragmentation, disconnection of the floodplain, and impairment of water quality. The effects of climate change (Factor E) may be exacerbating habitat degradation and fragmentation.

Although habitat degradation and fragmentation are the primary stressors to the peppered chub, we present a broader discussion of the threats to the species below. Additionally, we found that the existing regulatory mechanisms do not adequately reduce or remove the threats acting on the species and the threats continue to affect the species such that it warrants listing (Factor D). We are aware of no conservation efforts at this time that sufficiently reduce or remove the identified threats to the species and the threats continue to affect the species such that listing is warranted. The Service, States (New Mexico and Texas), and academic partners are conducting monitoring efforts, and plans for captive propagation efforts are underway, but none are finalized yet.

Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary) to designate critical habitat concurrent with listing to the maximum extent prudent and determinable. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if she determines that the benefits of such exclusion outweigh the benefits of specifying such areas as part of critical habitat, unless she determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species.

Previous Federal Actions

Please refer to the proposed listing and critical habitat rule (85 FR 77108) for the peppered chub published on December 1, 2020, for a detailed description of previous Federal actions concerning this species.

Summary of Changes From the Proposed Rule

We reviewed the comments related to our proposed listing determination and critical habitat for the peppered chub (see Summary of Comments and Recommendations, below), completed our analysis of areas considered for exclusion under section 4(b)(2) of the Act, reviewed our analysis of the physical or biological features essential to the long-term conservation of the peppered chub, and finalized the economic analysis of the designation. This final rule incorporates changes from our 2020 proposed listing and critical habitat rule (85 FR 77108; December 1, 2020) based on the comments that we received and have responded to in this document and considers efforts to conserve the peppered chub.

Specifically, during the public comment period for the proposed rule, we received a request to exclude critical habitat from the State of Kansas because of an ongoing effort to include peppered chub in a candidate conservation agreement with assurances (CCAA) and a safe harbor agreement (SHA). The Kansas Aquatic Species Conservation Agreement: A Programmatic Safe Harbor Agreement and Candidate Conservation Agreement with Assurances for Fourteen Aquatic Species in Kansas (Agreement) was completed on December 15, 2021. The conservation efforts that will be undertaken because of the Agreement, and subsequent benefit to the species, outweigh the benefits of including these areas in the critical habitat designation. Based on our analysis, which incorporates the value of the Agreement, we are excluding Unit 3 and a portion of Unit 4 in Kansas, a net decrease of 196 river miles (rmi) from the proposed rule (table 3, below). More information can be found below in the Exclusions section.

Summary of Comments and Recommendations

In the proposed rule published on December 1, 2020 (85 FR 77108), we requested that all interested parties submit written comments on the proposal by February 1, 2021. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. Newspaper notices inviting general public comment were published in the USA Today on December 3, 2020. We did not receive any requests for a public hearing.

During the comment period on the proposed listing and critical habitat rule, we received approximately 22 written comment letters. All substantive information received during the comment period has either been incorporated directly into this final determination or addressed in our responses below.

Peer Reviewer Comments

As discussed in Supporting Documents above, we received comments from one peer reviewer. We reviewed all comments we received from the peer reviewer for substantive issues and new information regarding the information contained in the species status assessment (SSA report). The peer reviewer generally concurred with our methods and conclusions, and provided additional information, clarifications, and suggestions that improved the SSA report.

Comments From States

(1) Comment: Multiple State agency and industry commenters did not support designating unoccupied critical habitat within those States. Several indicated their view that the proposed unoccupied units would not support peppered chubs in their current conditions.

Our response: Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Unoccupied areas designated as critical habitat are not limited to areas that could support a self-sustaining population in their current condition but rather must contain at least one of the physical or biological features (PBFs) determined by the Secretary to be essential for the conservation of the species (50 CFR 424.12).

The areas that we have identified as critical habitat that are unoccupied contain at least one of the PBFs required by the peppered chub and are essential for the conservation of the species. The areas are more fully described below in the individual unit descriptions. Establishing healthy populations in these two currently unoccupied units (Unit 2 and Unit 4) would increase the resiliency, representation, and redundancy—and therefore, the viability—of the species. If established, each unoccupied unit contributes ecological diversity (representation) or guards against catastrophic events (redundancy) or both.

(2) Comment: A State and multiple public commenters stated that designation of both occupied and unoccupied critical habitat would discourage private landowners from allowing access for monitoring and habitat restoration, as well as participating in reintroduction efforts.

Our response: According to section 4(a)(3)(A) of the Act, the Secretary of the Interior shall, to the maximum extent prudent and determinable, concurrently with making a determination that a species is an endangered species or a threatened species, designate critical habitat for that species. As directed by the Act, we proposed as critical habitat those areas occupied by the species at the time of listing and that contain the physical or biological features essential for the conservation of the species, which may require special management considerations or protection. The Act does not provide for any distinction between land ownerships in those areas that meet the definition of critical habitat.

When prudent, the Service is required to designate critical habitat under the Act. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands.

The designation of critical habitat has little effect on private lands. This designation provides protection under section 7 of the Act and requires only Federal agencies to consult with the Service and ensure that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. Because of this, we hope that we can continue our partnerships with local landowners within the historical range of the

peppered chub and move collaboratively towards recovery of the species.

(3) Comment: Several commenters stated that the designation of critical habitat is unnecessary because it would not provide any additional benefit to the species, and that existing regulatory mechanisms and habitat restoration efforts (*e.g.,* the Arkansas River Shiner Management plan) are adequate for the conservation of the species.

Our response: The Service is not relieved of its statutory obligation to designate critical habitat based on the contention that it will not provide additional conservation benefit. In *Ctr. for Biological Diversity* v. *Norton,* 240 F. Supp. 2d 1090 (D. Ariz. 2003), the court held that the Act does not direct us to designate critical habitat only in those areas where ''additional'' special management considerations or protection is needed. See also *Cape Hatteras Access Preservation Alliance* v. *U.S. Dept. of Interior,* 731 F.Supp.2d (D.D.C. 2010). If any area provides the PBFs essential to the conservation of the species, even if that area is already well managed or protected, that area may still qualify as critical habitat under the statutory definition.

The Canadian River Municipal Water Authority's Arkansas River Shiner Management Plan aims to maintain minimum flows and control invasive vegetative (*e.g.,* saltcedar) encroachment in the South Canadian River upstream of Lake Meredith in Texas to Logan, New Mexico. Although we commend the Canadian River Municipal Water Authority and its partners for investing time, effort, and funding for conservation on the Canadian River, the habitat conservation efforts for Arkansas River shiner to date have not resulted in an improvement of the status of the peppered chub. In identifying critical habitat for peppered chub, we identified those areas that meet the definition of critical habitat under section 3(5)(A) of the Act. Although management actions for one listed species may overlap other species' habitat or be mutually beneficial to multiple listed species, our analysis indicates that habitat conditions such as adequate stream flow and appropriate stream geomorphology have continued to decline from the condition needed to conserve the peppered chub. As a result, we conclude that this conservation plan, in its current form, is not sufficient to reduce the threats to the last population of peppered chub. Even with this conservation plan in place, the current resiliency of the Upper South Canadian River Resiliency Unit is in low condition.

(4) Comment: Several commenters took issue with the SSA report not being peer reviewed at the time of the publication of the proposed rule. One commenter stated that the proposed rule format does not comply with the ESA and applicable implementing regulations in relying on an SSA that is not peer reviewed. The commenter cites the Service's peer review policy (59 FR 34270; July 1, 1994) and section II of the Office of Management and Budget's (OMB) December 16, 2004, Final Information Quality Bulletin for Peer Review (revised June 2012), which both require agencies to conduct peer review on influential scientific information prior to dissemination.

Our response: Section II of the OMB December 16, 2004, Final Information Quality Bulletin for Peer Review requires each agency to subject influential scientific information to peer review prior to dissemination. The document further requires that, for dissemination of influential scientific information, agencies have broad discretion in determining what type of peer review is appropriate and what procedures should be employed to select appropriate reviewers. The Service follows its peer review policy (59 FR 34270), also referenced by the commenter. Section A(1)(a) of the peer review policy states that the Service will solicit the expert opinions of three appropriate and independent specialists regarding pertinent scientific or commercial data and assumptions relating to the taxonomy, population models, and supportive biological and ecological information for species under consideration for listing. The policy does not state that the peer review must occur prior to the comment period for a proposed listing nor that the Service is required to receive responses from peer reviewers prior to the comment period provided for the proposed listing.

The Service actively sought peer review of the SSA and proposed rule as required by both the Final Information Quality Bulletin for Peer Review and the Service's peer review policy. We solicited peer review from nine independent peer reviewers on December 4, 2020. Since publication of the proposed rule, we solicited peer review a second time and received a response from one peer reviewer. Per the peer review policy, we summarize the peer review we received here in the *Peer Reviewer Comments* section.

(5) Comment: One commenter stated that current restoration efforts, which depend on Federal funding, include the treatment of nonnative invasive species, mastication of standing dead invasive species, installation of riparian fencing where necessary, and maintenance of previously treated areas. Due to the dependence on Federal funding, any successful restoration efforts would be delayed and constrained by the consultation requirements imposed by the peppered chub's listing and critical habitat designation.

Our response: The Act states that the Secretary shall make determinations required by subsection (a)(1) of the Act solely on the basis of the best scientific and commercial data available to her after conducting a review of the status of the species. Listing decisions are not dependent on possible funding delays caused by new consultation requirements imposed by the listing. However, critical habitat designations do consider the economic impacts including section 7 consultations. We conducted an economics analysis that found that there was likely to be no significant economic impact from this designation of critical habitat and that the additional costs are expected to be due to the additional incremental administrative costs from the consultation process in considering adverse modification of the critical habitat (IEc 2019, Section 6).

Additionally, as stated below in the Available Conservation Measures section, following publication of this final rule, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of Colorado, Kansas, New Mexico, Oklahoma, and Texas will be eligible for Federal funds to implement management actions that promote the protection or recovery of the peppered chub.

(6) Comment: Several States and one industry commenter raised concerns about how the listing and designation of critical habitat will affect deliveries of water from reservoirs and groundwater pumping for municipal use and agriculture, and the potential regulatory and financial burdens of the proposed action on water delivery and use.

Our response: Additional information about how we conducted our economic analysis, and how we incorporated water delivery and use, can be found in our screening memo (IEC 2019, entire) and our incremental effects memo (Service 2019, entire). The designation of critical habitat would not impose any such regulatory or financial burdens on non-Federal actions such as those indicated, where no Federal nexus

exists. Groundwater pumping that does not occur on Federal lands would not be subject to regulation under section 7, so long as there is no Federal nexus. Further, no reservoirs and dams occur within the designated critical habitat units and would only be subject to section 7 consultation if there is a Federal nexus and an upstream dam may adversely modify the critical habitat designation. Additionally, when there is a Federal nexus, under section 7 of the Act when evaluating the effects on critical habitat, we consider impacts from ongoing State water management operations that are not within the agencies' discretion to modify to be part of the baseline of an effects analysis. Service policy states that section 7 consultation should result in measures that minimize the impacts of incidental take to the extent reasonable and prudent (Endangered Species Consultation Handbook, 4–50 (March 1998)). They should be developed in coordination with the action agency and applicant, if any, to ensure that the measures are reasonable, that they cause only minor changes to the project, and that they are within the legal authority and jurisdiction of the agency or applicant to carry out. Therefore, they must be implementable under the legal regimes that apply in the situation being analyzed.

(7) Comment: Several commenters state that introducing section 10(j) experimental populations within the unoccupied critical habitat units stand a greater chance of making significant progress toward recovery of the species than does continued regulation of critical habitat and potential associated litigation.

Our response: The Service has determined that the areas being designated as unoccupied critical habitat units are essential for the conservation of the species. Therefore, they meet the Act's definition of critical habitat and should be designated as such. Further, we find that section 10(j) experimental population would not provide for the protection for the habitat within these areas that we have determined is needed for the conservation of the species.

(8) Comment: Two commenters raised concerns that the use of relative abundance as presented lacked scientific rigor and is being inappropriately interpreted. The commenters argued that conducting a trend analysis with relative abundance data provides weak evidence of one species' resiliency. Further, it is potentially misleading because it is affected by changes in abundance of other species in the catch, which may have no bearing on the status of the target species.

Our response: Using relative abundance (also referred to as percent composition) to infer species abundance is not appropriate and would be misleading, as it is inherently driven by the abundance of other species. Although measures of absolute abundance and densities would have provided additional useful metrics for our resiliency analysis, the analysis was not possible due to data limitations. Instead, we calculated relative abundance to standardize the data (Anderson et al. 1995, p. 315; Brewer et al. 2007, p. 328; Perkin and Gido 2011, p. 373). As discussed in our SSA report, we assessed relative abundance ''as one means to evaluate potential shifts in fish community structure'' (not overall abundance), which is well established in the literature (Mendelson and Jennings 1992, entire; Weaver and Garman 1994, pp. 163, 166; Bonner and Wilde 2000, pp. 192–194; Onorato et al. 2000, pp. 142, 145–152). Potential change in community structure is one important indicator of ecosystem change and has implications for species resiliency within that system. We also examined two relative abundance metrics (Baseline Condition and Trend Analysis), but only the former was included as a metric for assessing peppered chub resiliency. Due to limited data for peppered chub, we determined that the quasi-Poisson regression that we used for trend analysis (which does account for variability in the data) was not appropriate for that species.

Regarding the comment that the use of relative abundance data alone provides weak evidence of population resiliency, we agree. One should not draw conclusions from this measure alone assessing the resiliency of a population. As provided in our SSA, resiliency analyses for peppered chub considered eight metrics: Three examining population demographics and five examining habitat/flow metrics.

(9) Comment: One commenter noted that the SSA considered the decade with the highest capture ratios (1990s; 95 percent) to be the baseline condition and deemed ''good'' condition to be within 20 percent of that scenario. The commenter argued that capture ratios in no other decade approach 95 percent, suggesting that this may be an anomalously high number rather than a true baseline.

Our response: We evaluated the overall resiliency of each population of peppered chub using eight different metrics, one of those metrics was the capture ratio. Our capture ratio assessment was based on approximately 70 years of survey data, including 555 unique survey events. We separated the analysis by decade to evaluate differences over time, while still providing adequate number of surveys (per decade) to determine an ''optimal'' reference condition for this population resiliency metric. The decade referenced by the commenter included a total of 185 surveys spanning a ten-year period. Given the large number of surveys and relatively long span of time (particularly for a species that spawns annually), it is our determination that this decade serves as a reasonable representation of optimal capture ratios for a peppered chub population. We should also note that using the next best decade (2000s) as our optimal reference condition would still have resulted in a 'fair' resiliency score for this metric. Our database indicates a total of 185 fish collection surveys in the 1990s from the Upper South Canadian River between Ute Reservoir and Lake Meredith, of which 176 surveys collected at least one peppered chub, resulting in a capture ratio of 95 percent. This compares to the 2000s, at which time 142 of 189 surveys (75 percent) collected peppered chub, and the 2010s during which the survey results were 48 of 101 (48 percent). Two variables that could artificially inflate the likelihood of capturing a peppered chub, thus affecting capture ratios, are greater survey effort and/or surveying locations more likely to have peppered chub. Neither of these two variables apply to the 1990s surveys. The total number of fish collected per site, on average, was greater in both the 2000s and 2010s, indicating effort in those decades was greater than in the 1990s. Additionally, the geographical distribution of surveys was relatively similar among decades, indicating that the higher ratios in the 1990s were not artificially driven by surveying sites more likely to have peppered chub. Based on information from our survey database, capture ratios of 95 percent in the 1990s correctly represent peppered chub presence at that time.

(10) Comment: One commenter stated that the proposed rule overly relies on the SSA for an evaluation of species threats under each of the five listing factors, and neither the proposed rule nor SSA provides a systematic factor-by-factor evaluation of threats. The SSA is not intended to evaluate the identified threats for a species under each of the five listing factors, as is done in a 12-month finding and proposed rule under section 4(a)(1) of the Act. The commenter argues that the Service has failed to provide the most fundamental

evaluation of the listing factors from the 12-month findings, as provided in section 4(a)(1) of the ESA.

Our response: Under section 4(a)(1) of the Act, the Service may determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We are also required to consider any conservation measures made by any State or foreign nation regarding the species. The Service provided the evaluation of the listing factors in the proposed rule in *The basis for our action* section and the Determination of Peppered Chub Status section (85 FR 77108; December 1, 2020).

Using the SSA framework results in a biological risk assessment, the SSA report, which is designed to aid decisionmakers who must use the best available scientific information to make policy-guided decisions. The SSA informs, but is not, the decision. Using the conservation biology principles of representation, resiliency, redundancy, the SSA provides a scientifically rigorous characterization of species status that focuses on the likelihood that the species will sustain populations within in the wild beyond a biologically meaningful timeframe, its level of viability, along with key uncertainties in that characterization.

The Determination of Peppered Chub Status section clearly articulates how we arrived at our determination for an endangered status using the five factors from section 4 of the Act (16 U.S.C. 1533).

(11) Comment: One commenter asserted that the proposed rule relies on a paradigm that the peppered chub eggs and larvae need high water to keep the propagules suspended with subsequent return of fish to natal areas, tens or hundreds of miles upstream. The commenter argues that this paradigm ignores an alternative paradigm that the semi-buoyant eggs and larvae were historically retained near natal areas in laterally expansive floodplains and are now transported downstream because of a contemporary narrow and entrenched river channel. The commenter states that, in focusing on the perceived need to keep the propagules afloat with high water, the Service fails to recognize that, historically, most propagules probably did not drift longitudinally downstream but laterally into inundated floodplains and returned to the main channel with receding water levels.

Our response: The proposed rule and SSA report recognize the potential utility of wetted floodplain habitats to support larval nursery habitat for peppered chub. The semi-buoyant eggs of peppered chub remain suspended in water until hatching, and thereby require currents to maintain suspension in the water column until sufficient development to a free-swimming stage (Bottrell et al 1964, p. 398; Robison and Buchanan 1988 p. 183; Wilde et al. 2000, p. 107). In more lentic habitats, eggs may be deposited on sediment and covered, leading to lack of oxygen and suffocation. This requirement for flows of some velocity does not necessarily translate to a need for ''high water'' in all natal areas. However, discharges of likely increased magnitude would be required for inundation of floodplains to serve as nursery habitats. Restored floodplains and managed river flows have potential to benefit peppered chub habitats. However, in recent history, there is often less water in the system and because of this water less frequently reaches the floodplain.

Because the floodplains are less available for the reproduction of peppered chub, compared to historical conditions, river length is now more important for successful reproduction. The proposed rule and SSA use reach length as an indicator of habitat condition, since fish can successfully reproduce given adequate uninterrupted stream length as well. Sufficient reach length is needed to allow the time necessary for development of eggs and larvae floating downstream until they reach a motile, free-swimming stage. Larval fish may require strong currents to keep them suspended until they are capable of horizontal movement and are strong enough to leave the main channel. Physical barriers are likely unpassable by egg and larval fishes, and adults passing downstream remain isolated and unable to move downstream. This situation results in progressive impacts over time from upstream to downstream. Longer reach lengths may not be necessary to meet the needs of an individual peppered chub within its short lifetime. By facilitating reproduction and population growth, these unfragmented river segments guard against extirpation, and increase species resiliency. We are unaware of any data/information to conclude that a wetted floodplain in close proximity to natal areas would have the velocities to keep eggs buoyant for the appropriate amount of time necessary for fry development.

(12) Comment: One commenter notes the discrepancies among definitions of proposed critical habitat for peppered chub (up to bankfull) and existing definitions of critical habitat for Arkansas River shiner (300 feet on each side of the river channel at bankfull) and the sharpnose and smalleye shiners (areas beyond the bankfull river channel by 98 feet on each side). The commenter recommends that these discrepancies be better explained and justified, as areas above bankfull discharge are important to provide food sources and are subject to encroachment by saltcedar and other invasive vegetation that translate into impacts on river geomorphology, instream habitat for imperiled fishes, and stream flows.

Our response: Adjacent upland or terrestrial areas that are not below the ordinary bankfull (or high-water line) are not included in designated critical habitat. However, we would anticipate conducting section 7 consultations with Federal agencies for projects on Federal lands or for projects with a Federal nexus if a project had indirect impacts to the peppered chub's critical habitat or on the species itself. In general, activities in riparian areas should be conducted in such a manner as to protect adjacent streams. See Physical or Biological Features Essential to the Conservation of the Species (below). Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the landowner is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Public Comments

(13) Comment: One commenter stated that oil and gas activity is widespread and designation of unoccupied critical habitat would impose unnecessarily significant costs without providing measurable, probable benefits for the protection of the species. These costs may preclude or render economically impractical oil and gas activities preventing private landowners from developing their minerals. Another commenter was concerned that the Service had not clearly delineated in the proposed rule to what extent, in the geographic areas occupied by the species, that livestock production might be subject to a section 9 enforcement and what economic impact such a critical habitat designation might have.

Our response: The designation of critical habitat would not impose any such regulatory or financial burdens on non-Federal actions for private landowners such as those indicated, so long as there was no Federal nexus. If there is a Federal nexus and the action of the Federal agency may affect the species or its critical habitat designation, then the Federal agency would need to consult with the Service. We do identify oil and gas exploration and extraction activities as an activity that may require consultation to avoid adversely modifying critical habitat, under section 7(a)(2) of the Act and if there is a Federal nexus. If during consultation with a Federal agency, the Service finds that an activity is likely to adversely modify a critical habitat designation, the Service will work with the Federal agency to identify reasonable and prudent alternatives. Livestock production and exploration and extraction were taken into consideration during our economic analysis. For each unit, we found that there would be a non-significant incremental administrative cost from the designation to the Service and the Action agencies (IEc 2019, pg. 2). For further information, the full economic screening analysis can be viewed on *https://www.regulations.gov.*

Section 9 of the Act covers prohibited acts as they relate to endangered species. The actions outlined in section 9 of the Act are prohibited after the effective date of this rule (see **DATES**, above). However, in the Available Conservation Measures section (below), we identify activities that are unlikely to result in a violation of section 9, if these activities are carried out in accordance with existing regulations and permit requirements. In that list we include, normal livestock grazing and other standard ranching activities within riparian zones that do not destroy or significantly degrade peppered chub habitat. We had also included this in the proposed rule as well (85 FR 77108).

(14) Comment: One commenter noted that the proposed rule suggests the Act would allow normal livestock grazing and other standard ranching activities within riparian zones that do not destroy or significantly degrade peppered chub habitat. However, the proposed rule does not identify what livestock activities would not constitute normal livestock grazing.

Our response: We are not able to provide an exhaustive list of what activities would and would not constitute normal livestock grazing. However, activities that do not result in a violation of section 9 of the Act and are not subject to a Federal nexus would not be subject to section 11 (penalties and enforcement) of the Act. Based on our section 7 consultation experience within the historical range of peppered chub and because we contacted Federal agencies during our economics analysis and they did not comment on an increase in consultation for grazing (while they did anticipate increases in consultations for other activities; IEc 2019, entire), we anticipate consultations to be rare for grazing and ranching activities. We encourage all local landowners with questions specific to their property or project to contact their local Ecological Services Field Office. A list of field offices and their contact information can be found at: *https://www.fws.gov/ecological-services/map/directory.html.*

(15) Comment: One commenter stated that the economic impact analysis does not discuss what impact the proposed critical habitat designation would have on Confined Animal Feeding Operations that discharge under Clean Water Act section 402 permits. Typically, each feedyard with over 1,000 head of cattle will have and maintain a National Pollution Discharge Elimination System (NPDES) permit under section 402 of the Clean Water Act. These permits are subject to renewal every 5 years. Under the proposed rule, feedyards with NPDES permits in the river basins where critical habitat is being proposed would likely be required to undergo a section 7 consultation.

Our response: We considered animal feeding operations in our incremental effects memo (IEM) (IEM 2019, p. 9). Additionally, pollutant discharge and consultations with the Environmental Protection Agency were covered in the screening analysis that would cover the activity mentioned by the commenter (IEc 2019, pp. 7 & 8). The screening analysis found that the rule is unlikely to meet the threshold for an economically significant rule, with regard to costs (IEc 2019, pg. 2). Both documents can be found at: *https://www.regulations.gov;* Docket No. FWS–R2–ES–2019–0019.

Supporting Documents

A species status assessment (SSA) team prepared an SSA report for the Arkansas River shiner (*Notropis girardi*) and the peppered chub. The SSA team was composed of Service biologists, in consultation with other species experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of these species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species.

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought peer review of the SSA report. We sent the SSA report to nine independent peer reviewers during two separate peer review requests and received one response. We solicited peer review a second time because we received no responses to our first request. The purpose of peer review is to ensure that our listing determinations and critical habitat designations are based on scientifically sound data, assumptions, and analyses. The peer reviewer who responded has expertise in the biology, habitat, and threats to several broadcast-spawning fish species. The Service also sent the SSA report to 21 partners, including scientists with expertise in peppered chub threats and habitat, for review. We received review from eight partners (Colorado Parks and Wildlife, New Mexico Game and Fish, Texas Parks and Wildlife, two individuals from Oklahoma Department of Wildlife Conservation, and three individuals from universities in Oklahoma). Information received from the peer reviewer and partners is incorporated into this final rule and informed our determination. We also considered all comments and information received from the public during the comment period.

I. Final Listing Determination

Background

A full description of the species and its habitat can be found in chapter 2 of the SSA report. The peppered chub was historically known throughout the Arkansas River basin in Colorado, Kansas, New Mexico, Oklahoma, and Texas. Peppered chub were typically found in main channels of wide, shallow, sandy-bottomed rivers. The species prefers shallow channels where currents flow over clean fine sand, and, generally, adults avoid calm waters and silted stream bottoms. Peppered chub have adapted to tolerate the adverse conditions of the drought-prone prairie streams that they inhabit. The peppered chub is a small cyprinid minnow with a fusiform (tapering at both ends) body shape rapidly tapering to a conical head. It has a nearly transparent slender body with dark dots scattered on its back. Generally, adult fish reach a maximum length of 3 inches (in) (77 millimeters (mm)) and do not live beyond 2 years.

Gilbert first described the peppered chub in 1886 (pp. 208–209). Prior to Eisenhour's 1999 dissertation

(published 2004), the peppered chub was classified as one of six subspecies within the *Macrhybopsis aestivalis* (commonly: Speckled chub) complex. Eisenhour examined morphometrics (measurements of external shape), meristics (counts of features of fish), pigmentation, and tuberculation across the range of the complex. He concluded that the results supported the recognition of five individual species, including *Macrhybopsis tetranema,* or peppered chub. The American Fisheries Society also accepts the species as the peppered chub (Page et al. 2013, p. 28).

Habitat for the peppered chub historically consisted of the main channels of wide, shallow, sandy-bottomed rivers and larger streams of the Arkansas River basin, with a noted preference for river segments nearer the headwaters, as compared to other *Macrhybopsis* in the Arkansas River basin. Adults prefer shallow channels where currents flow over clean fine sand and generally avoid calm waters and silted river bottoms. Peppered chub have key adaptations that enable them to tolerate the adverse conditions of the drought-prone prairie rivers that they inhabit, including a relatively high capacity to endure elevated temperatures and low dissolved oxygen concentrations. They also appear to be often associated with turbid waters.

Peppered chub are members of a reproductive guild that broadcast-spawn semibuoyant eggs, which remain suspended in the water column by the current until hatching. This reproductive strategy appears to be an adaptation to highly variable environments where stream flows are unpredictable and suspended sediment deposition can cover eggs laid in nests or crevices. Without continuous stream flow of sufficient distance, eggs sink to the bottom where they may be covered with silt and suffocate due to the lack of oxygen. In addition to adequate stream discharge, an appropriate reach length is also needed to allow the time necessary for egg and larval development into a motile, free-swimming stage. After hatching, flowing water provides the extended development time needed by larval fish. Larval fish may require strong currents to keep them suspended in the water column until they are capable of horizontal movement and until the fish are strong enough to leave the main channel.

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an endangered species or a threatened species. The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Service can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain''; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent a decision by the Service on whether the species should be listed as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket

FWS–R2–ES–2019–0019 on *https://www.regulations.gov.*

To assess peppered chub viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm, or cold years), redundancy supports the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the individual species' life-history needs. The next stage involved an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involved making predictions about the species' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of a species to sustain populations in the wild over time. We use this information to inform our regulatory decision.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability. For a more detailed description, refer to the SSA report (Service 2022, entire) and the proposed rule (85 FR 77108; December 1, 2020).

Summary of Analysis

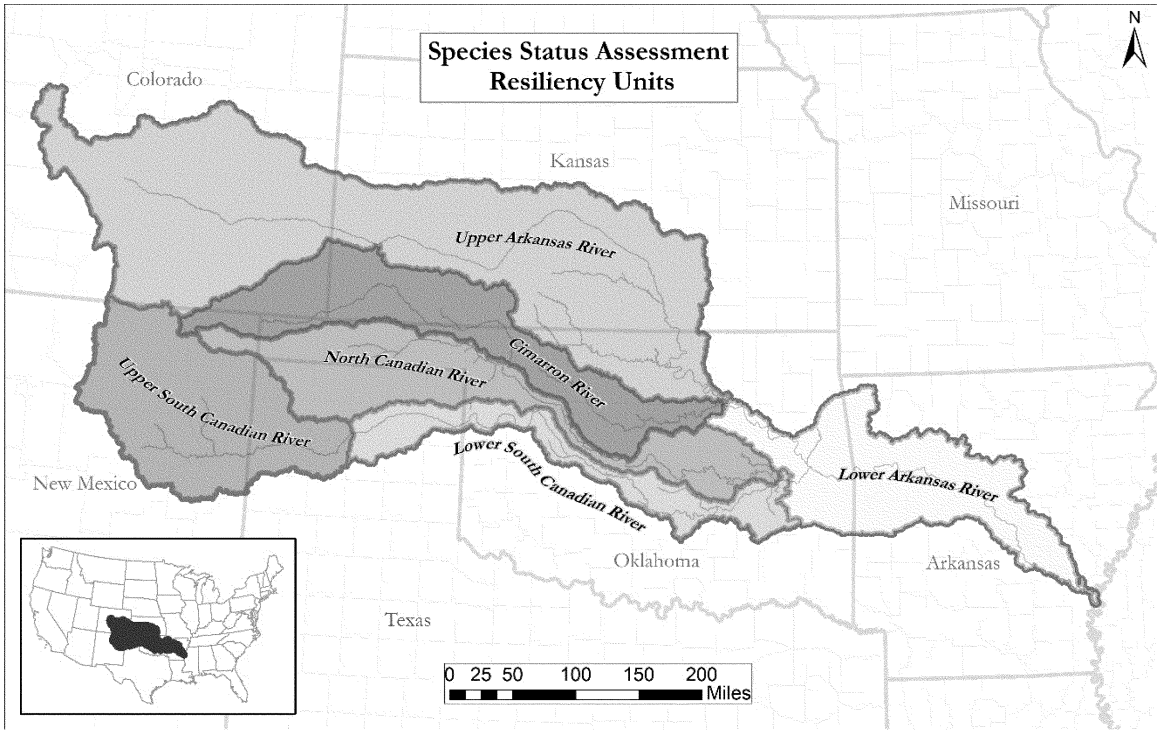
A full description of our analysis (analytical methods, threats, current condition, and future condition for the peppered chub can be found in the SSA report (Service 2022); below, we present a summary of the results of the SSA.

The peppered chub is a small cyprinid minnow once widespread and common in the western portion of the Arkansas River basin in Kansas, New Mexico, Oklahoma, Arkansas, and Texas.

Habitat historically consisted of the main channels of wide, shallow, sandy bottomed rivers and larger streams of the Arkansas River basin, with peppered chubs appearing more adapted for headwater areas. Adults prefer shallow channels where currents flow over clean fine sand, and generally avoid calm waters and silted stream bottoms. Peppered chub have adapted to tolerate the adverse conditions of the drought-prone prairie streams they inhabit, including a high capacity to endure elevated temperatures and low dissolved oxygen concentrations.

Peppered chub are members of a reproductive guild that broadcast spawns semibuoyant eggs, which are kept suspended until hatching in flowing water. This reproductive strategy appears to be an adaptation to highly variable environments where stream flows are unpredictable and suspended sediments and shifting sand can cover eggs laid in nests or crevices. Without stream flow, eggs sink to the bottom where they may be covered with silt and die. After hatching, adequate stream length likewise provides the extended flow time needed by larval fish which may require strong currents to keep them suspended in the water column until they are capable of horizontal movement and strong enough to leave the main channel. Channel complexity is also correlated with stream length resulting in slower transport rates in streams with wider and more braided channel morphology which allow more time for developing eggs and larva to reach their free-swimming stage.

The peppered chub historically inhabited numerous rivers of the Arkansas River basin and, without the presence of dams or other structures, it is likely that individuals within populations exhibited some level of genetic exchange among these rivers. To analyze population-level resiliency, we divided the range of the peppered chub into five ''resiliency units'' or populations (we use those terms interchangeably in this document) (see figure below; we do not include the Lower Arkansas River in the resiliency units for the SSA for the peppered chub because that portion of the watershed is not part of the current or historical range of the species). We described population resiliency and assessed representation and redundancy among these units. However, to assess conditions within each resiliency unit at a somewhat finer scale, we subdivided each resiliency unit into multiple subunits. This downscaling allows us to compare differences in conditions within a given resiliency unit and to understand the drivers affecting current condition (see the SSA report for further details).



Figure—Map depicting resiliency units (excluding Lower Arkansas River) for the Peppered Chub Species Status Assessment.

Maintaining representation in the form of genetic or ecological diversity is important to maintain the peppered chub's capacity to adapt to future environmental changes. The peppered chub must retain populations throughout its range to maintain the overall potential genetic and life-history attributes that can buffer the species' response to environmental changes over time. We define redundancy for the peppered chub as multiple, sufficiently resilient populations distributed throughout the species' historical range. Thus, multiple, adequately resilient populations, coupled with a relatively broad distribution, contribute to species-level viability.

Risk Factors for Peppered Chub

Stressors affecting the viability of the peppered chub include altered flow regimes (Factor A), impoundments and other stream fragmentation (Factor A), modified geomorphology (Factor A), decreased water quality (Factor A), and the introduction of invasive species (Factors A and C). The source of many of these stressors is the construction of dams and their impoundments (a body of water confined within an enclosure) which, in most cases, has drastically altered the natural flow regime and fragmented habitat. For example, a U.S. Geological Survey (USGS) stream gage on the Canadian River (near Amarillo, Texas) in the Lower South Canadian River resiliency unit has had a 69 percent decline in mean hydroperiod from pre-impoundment to post-impoundment, and the mean daily discharge (post-impoundment) is markedly lower (68 percent decline) since the completion of the reservoir. For a detailed description of the risk factors for peppered chub, see chapter 3 of the SSA report (Service 2022, pp. 22–38), below is only a summary of the risk factors.

Altered Flow Regimes

Peppered chub need a combination of varying flows (timing, duration, and magnitude) to support viable populations and maintain suitable habitat. Low flow periods (including isolated pooling) can impair or eliminate appropriate habitat for the species, and while adult peppered chub are adapted to and can typically survive these events for a short time, populations that regularly experience these conditions face compromised reproductive success and may not persist. Flow regime alterations that we considered during the SSA process include dams and their associated impoundments, the effects dams have on the natural flow regime, surface and groundwater extraction, and the effect of climate change on precipitation and drought.

Stream Fragmentation

Dams often fragment aquatic habitat and create impassable physical barriers to fish movement. Juvenile and adult peppered chub would likely be capable of passing downstream through small fish barriers such as weirs (low dams built to raise the level of water upstream), low-water crossings, and natural or manmade falls. However, no life stage of peppered chub is likely capable of successfully passing downstream through most reservoirs large enough to act as water supply or hydroelectric sources. Likewise, due to the small size and limited swimming ability of the peppered chub, upstream movement of adults (during spawning) would likely be prohibited by any impoundments (regardless of type or function), weirs, falls, pipeline reinforcements structures, and some low-water crossings.

It is unlikely that egg and larval stages of peppered chub are capable of passing over a fish barrier. When fish (typically adults only) pass downstream of a smaller barrier, they remain isolated below the barrier and are unable to return to spawning areas upstream. This often results in incremental and progressive extirpation from an upstream to downstream direction (Perkin and Gido 2011, p. 374). Because of its need for flowing water to reproduce, peppered chub have been

eliminated from shorter (generally less than 136 mi) reaches and typically persist only in river segments that are above a minimum threshold (Perkin and Gido 2011, p. 374). In addition, the blocking of movement of adult fish limits their ability to seek suitable habitat in more perennial, headwater reaches during drought conditions.

Modified Geomorphology

Decreases in stream flows in the South Canadian River have contributed to the decline or loss of wide, shallow sand-bed river channels that are characteristic of peppered chub habitat. Impoundments often reduce the magnitude and frequency of high flows, leading to bank stabilization and channel narrowing; alter streambank riparian communities; restrict downstream transport of nutrients that support ecosystem development; and alter river substrate (Poff et al. 1997, pp. 773–777; Mammoliti 2002, pp. 223–224). Impoundments also alter streamflow by reducing the availability or timing of water, leading to more frequent low-flow conditions, channel drying, pool isolation, and vegetative encroachment into the river channel. Reduction in flows reduces the peppered chub's reproductive success and decreases population resiliency.

Additional alteration of historical physical habitat occurs when dams release sediment-starved water that alters the composition and distribution of the bed substrate. River and stream water velocity slows rapidly where water enters the standing water of reservoirs, resulting in the settlement of suspended sediment within the reservoir (Poff et al. 1997, p. 773). The resulting release of low turbidity, high-velocity water from dams scours the downstream reaches, causing the channel to incise and become further isolated from its natural floodplain. Further, such dam releases remove sand and gravel substrate preferred by the peppered chub. Decreased turbidity provides a competitive advantage to fishes that are not as well adapted to the naturally turbid water. When water is released from a main channel reservoir, fish species adapted to naturally turbid conditions of the South Canadian River, such as the peppered chub, are displaced by fish with competitive advantage in less turbid conditions, resulting in a reduction in available habitat and increased predation (Bonner and Wilde 2002, pp. 1205–1206), thereby negatively influencing species distribution and abundance.

Degraded Water Quality

Suitable water quality is necessary for a healthy aquatic community. Water quality may become impaired through direct contamination or the alteration of freshwater chemistry. Contaminants enter the environment through both point and nonpoint sources including spills, industrial pathways, municipal effluents, and agricultural runoff. These sources may contribute organic compounds, heavy metals, pesticides, herbicides, and a wide variety of newly emerging contaminants to the aquatic environment. An additional type of water quality impairment is the alteration of water quality parameters such as dissolved oxygen, temperature, and salinity levels. Dissolved oxygen levels may be reduced due to increased nutrient levels (*i.e.,* nitrogen and phosphorous) from agricultural runoff or wastewater effluent (eutrophication). Increased water temperature from more frequent low-flow/drought conditions and climate change can also exacerbate low dissolved oxygen levels, particularly when low-flow conditions strand fish in isolated pools. Similarly, fish stranded in isolated pools can be subjected to naturally concentrated salinity. Additionally, many freshwater systems and shallow aquifers have become increasingly saline due to salinized water recharge (Hoagstrom 2009, p. 35). This effect largely stems from irrigation return flows that have flushed accumulated salts from irrigated lands back into the system.

Chloride concentrations have been increasing in the upper South Canadian River (Service 2022, p. 127). Additionally, arsenic levels in many of the rivers within the historical range of the peppered chub are above the Environmental Protection Agency's established levels for human health for the consumption of organisms but not above levels designed to protect freshwater aquatic communities. Arsenic levels have increased over time in the Cimarron River to the point that golden shiners (*Notemigonus crysoleucas*) exhibited avoidance behavior even though concentrations were below a toxic level (Hartwell et al. 1989, p. 452). It is a reasonable presumption that peppered chub would also demonstrate avoidance behavior at similar concentrations of arsenic, causing peppered chub distribution and movements to be disrupted, possibly further fragmenting or reducing the amount of available stream length necessary for all life stages.

Introduction of Invasive Species

The alteration of the hydrologic regime and geomorphology of rivers resulting from impoundments can cause the proliferation of larger, piscivorous fish not normally associated with unimpounded prairie rivers. This fish community conversion is exacerbated by the transfer or stocking of game species in areas that have undergone hydrologic regime or geomorphologic alterations. These species may include smallmouth bass (*Micropterus dolomieu*), largemouth bass (*Micropterus salmoides salmoides*), Florida largemouth bass (*Micropterus salmoides floridanus*), striped bass (*Morone saxatilis*), and channel catfish (*Ictalurus punctatus*) (Howell and Mauk 2011, pp. 11–12), which may prey upon peppered chubs. In a system similar to the Arkansas River Basin, eighteen fish species were introduced or immigrated into the Solomon River basin following impoundment and increased competition from these nonnative species may have contributed to the decline of native fish species (Eberle et al. 2002, p. 182, 188). While peppered chub declines throughout the species' range cannot be fully attributed to predation by invasive fishes, a shifting fish community (to more lentic (still water) adapted species) throughout the Lower South Canadian River has coincided with the extirpation of the peppered chub throughout this lower basin. The Upper South Canadian River (between Ute Reservoir and Lake Meredith) is an exception, where the natural fish community is still mostly intact (Service 2022, pp. 66–68).

Synergistic Effects

Many of the above-summarized risk factors may act synergistically or additively on the peppered chub. The combined impact of multiple stressors is likely more harmful than a single stressor acting alone. For example, resiliency of the peppered chub (in the Upper South Canadian River resiliency unit) is considered low due to river impoundment in combination with other stressors acting synergistically. The river is unimpeded for 179 river miles (288 river kilometers), which translates to a fair condition (see table 1, below). However, our flood frequency analysis in the Upper South Canadian River resiliency unit shows a decline to a level of null to fair, meaning flood events have significantly declined compared to historical conditions. As a result, the river channel has narrowed dramatically in many areas, resulting in unfavorable habitat for the peppered chub and a poor condition category for

this habitat metric. This condition limits the access to and formation of new habitat necessary for egg/larval retention and nursery. The hydroperiod (a comparison between pre-impoundment and post-impoundment discharge) has changed so that discharge is in a null (greater than 90 percent decrease in discharge) to fair condition for peppered chub. Lastly, the low-flow conditions in the stretch are in a poor to fair condition, meaning that low-flow days are common or increasing and some areas are vulnerable to drying in drought years, which could affect the length of unimpeded river and lead to additional channel narrowing. For a full explanation of our habitat factor analysis, see chapter 4 of the SSA report.

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the species, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the species. To assess the current and future condition of the species, we undertake an iterative analysis that encompasses and incorporates the threats individually and then accumulates and evaluates the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative effects analysis.

Current Condition of Peppered Chub

Our analysis of current condition of the peppered chub is based on numerous scientific publications from species experts who concluded that by the year 2000, the peppered chub had significantly declined and was isolated to the Ninnescah River in Kansas and the South Canadian River between Ute Reservoir in New Mexico and Lake Meredith in the Texas panhandle (Luttrell et al. 1999, p. 983; Eisenhour 1999, p. 975; Eisenhour 2004; Service 2022, pp. 53–57). More recently, we assessed the current condition using survey efforts from 1,826 collections (from 2013 to 2017) with only 38 of those (2 percent) containing the peppered chub. Extensive recent survey efforts show that the peppered chub distribution is currently limited to the South Canadian River between Ute Reservoir in New Mexico and Lake Meredith in the Texas panhandle, which represents 6 percent of its historical range. The capture ratio in the Upper South Canadian River dropped to 45 percent, and peppered chubs were not collected in the Ninnescah River during this time.

Historically, the peppered chub was known from five populations found in Colorado, Kansas, New Mexico, Oklahoma, and Texas. Several factors were responsible for the extirpation or abundance decline of the peppered chub in each of the resiliency units, as more fully set forth in the SSA report. However, habitat degradation and fragmentation has been primarily a result of water diversion and impoundments (*i.e.,* dams). Thus, the single remaining population (Upper South Canadian River) has low resiliency (see table 1, below).

We consider the peppered chub to have limited representation in the form of genetic and ecological diversity because only a single functioning population remains. Extirpated populations of peppered chub contained genetic and morphological variation that have been lost. The peppered chub has ''considerable stocks of genetic diversity'' within this single population; however, the species lacks the representation of species with multiple populations occurring across varying landscapes (Osborne 2017, p. 9). Despite restrictions of its range due to impoundments and other habitat alterations, and a decline in abundance, it is possible that genetic variation is sufficient to allow for survival in the naturally occurring conditions of the arid prairie stream environments in which the species evolved. However, it is unknown if this species has the genetic variability or the time required to adapt to continuing habitat and flow alterations.

To assess resiliency within each unit, we analyzed capture ratios, probability of capture trends, and relative abundance (demographic factors). We also analyzed habitat factors that were determined to have the most influence on the species: Stream fragment length, channel narrowing, flood frequency, hydroperiod (changes to the annual hydrograph most relevant to the species' lifecycle), and low flow conditions (habitat/flow factors). See table 1, below. Overall condition rankings for each resiliency unit were determined by combining the three demographic factors and five habitat/flow factors. For a more detailed description of the condition categories, see chapter 4 in the SSA report.

TABLE 1—CURRENT RESILIENCY OF THE PEPPERED CHUB

Population	Demographic factors			Habitat factors*					Current resiliency
	Capture ratio	Probability of capture trend	Relative abundance	Stream fragment length	Channel narrowing	Flood frequency	Hydroperiod	Low flow	
Upper Arkansas (includes Ninnescah and Salt Fork).	Ø**	Ø	Ø	Fair	Fair to Good.	Poor and Good.	Poor and Good.	Poor and Good.	Ø.
Cimarron	Ø	Ø	Ø	Good	Null to Good.	Null and Fair.	Poor and Fair	Poor and Good.	Ø.
North Canadian	Ø	Ø	Ø	Fair	Null	Null to Good.	Poor to Fair	Poor to Good.	Ø.
Lower South Canadian	Ø	Ø	Ø	Good	Null to Good.	Poor to Fair.	Poor to Fair	Fair and Good.	Ø.
Upper South Canadian	Fair	Good	Poor	Fair	Poor	Null to Fair.	Null to Fair	Poor to Fair.	Low.

*The habitat factors are presented as gradients (to) or multiple conditions (and) per population. Because of the great lengths of the stream stretches, the habitat quality can vary widely throughout the unit. (See the SSA report for further information.)

**The Ø symbol means null (having or associated with the value zero).

Because the peppered chub has been extirpated from all but one resiliency unit, it has a higher risk of extinction from a catastrophic event, due to a lack of redundancy across its range, compared to historical conditions. See the SSA report for the complete current condition analysis for the peppered chub (Service 2022).

Future Condition of Peppered Chub

As part of the SSA, we also developed multiple future condition scenarios to capture the range of uncertainties regarding future threats and the projected responses by the peppered chub. Our scenarios included a continuation of existing trends scenario and a water conservation with flow trends stabilizing scenario, which incorporated the current risk factors continuing the same trajectory that they are on now. These future scenarios project conditions that are worse for the peppered chub than the current condition or the water conservation with flow trends stabilizing scenario. Because we determined that the current condition of the peppered chub is consistent with an endangered species (see Determination of Peppered Chub Status, below), we are not presenting the results of the other future scenarios in this final rule. The other projected scenarios would also be endangered, as they forecast conditions that are the same or more at risk of extinction than the current condition. Please refer to the SSA report (Service 2022) for the full analysis of future scenarios.

Conservation Efforts and Regulatory Mechanisms

Since we proposed to list the peppered chub as endangered, The Kansas Aquatic Species Conservation Agreement: A Programmatic Safe Harbor Agreement and Candidate Conservation Agreement with Assurances for Fourteen Aquatic Species in Kansas (Agreement) was completed and includes the peppered chub. Further information about the agreement can be found in the Exclusions section below. The area of the range that is covered by the Agreement is currently unoccupied; therefore, the Agreement does not change our conclusions in the SSA report or the determination of status, outlined below.

This species is listed as endangered in Kansas and protected under the authority of the State's Nongame and Endangered Species Conservation Act of 1975. The Kansas Department of Wildlife, Parks and Tourism (KDWPT) finalized a recovery plan for the peppered chub in May 2005. The recovery plan outlines specific strategies and methods to recover and delist the peppered chub in Kansas. The recovery plan also includes designated critical habitat as required for endangered species conservation and recovery. Kansas Administrative Regulations (K.A.R.) 115–15–3 provides for review and a permit system for any alterations to the critical habitat administered by KDWPT Ecological Services Section.

The peppered chub has been listed as threatened in New Mexico since 1978 under the Wildlife Conservation Act (WCA). The State Game Commission is authorized and directed to establish such regulations as it may deem necessary to carry out all the provisions and purposes of the WCA. The WCA prohibits any person to take, possess, transport, export, process, sell or offer for sale, or ship the peppered chub, within the State of New Mexico.

The species is listed as threatened in Texas and protected under Texas Parks and Wildlife Department (TPWD) Code. Under chapter 67 of this Code, Texas Parks and Wildlife Commission is authorized to establish any limits on the taking, possession, propagation, transportation, importation, exportation, sale, or offering for sale of nongame fish or wildlife that TPWD considers necessary to manage the species. TPWD designation of the peppered chub as a threatened species prohibits take of the species.

As discussed in the proposed rule, the Canadian River Municipal Water Authority (in conjunction with several partners) has a management plan in place for the Arkansas River shiner, a similar species that shares many of the same life-history characteristics and habitat requirements as the peppered chub. However, the management plan includes no conservation efforts specific to the peppered chub.

Efforts are underway to begin a captive propagation program at the Kansas Aquatic Biodiversity Center and at the Tishomingo National Fish Hatchery in Oklahoma. However, these efforts are early in development and have not yet yielded improvements to the status of the species.

Approximately 95 percent of the adjacent land within the historical range of the peppered chub is private land. Except for those management activities included above, during the comment period for the proposed rule, we were not made aware of other conservation plans or management activities that are in place with private landowners that are specific to the peppered chub.

Despite the existing regulatory mechanisms and conservation efforts described above, the identified stressors continue to act on the species such that listing is warranted.

Determination of Peppered Chub Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an endangered species or a threatened species. The Act defines an ''endangered species'' as a species that is in danger of extinction throughout all or a significant portion of its range and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of endangered species or threatened species because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence.

The peppered chub faces threats from altered flow regimes (*e.g.,* dams and impoundments, groundwater extraction, and climate change effects on precipitation) (Factors A and E), stream fragmentation (Factor A), modified geomorphology (Factor A), poor water quality (Factor A), and introduction and proliferation of invasive species (Factors A and C). Because peppered chub rarely live beyond 2 years, the risk of species extinction from 2 (or more) successive years of low flow or drought conditions is high. These threats are currently acting on the peppered chub, and we expect them to continue or worsen into the future. We found no evidence of population- or species-level impacts from overutilization for commercial, recreational, scientific, or educational purposes (Factor B). In our analysis of the factors affecting the peppered chub, we found that despite the existing regulatory mechanisms and conservation efforts, the threats continue to affect the species such that listing is warranted (Factor D).

The range of the peppered chub once included Colorado, Kansas, New Mexico, Oklahoma, and Texas, with populations in several streams and rivers. The peppered chub is now confined to a single population in the upper portion of the South Canadian River in Texas and New Mexico, which represents approximately 6 percent of the species' historical range. The one remaining population has declined from an average of approximately 14 percent relative abundance (a component of biodiversity) historically, to a current relative abundance of under 2 percent, meaning the fish community structure has shifted significantly from its baseline condition. Explained in detail in the SSA report, the fish community

in this population is shifting away from its historical state, the peppered chub is becoming less common compared to other species in the community, and the species richness of the community is declining (Service 2022, pp. 63–68). This population has low resiliency, meaning that the population has a low probability of remaining extant and withstanding periodic or stochastic disturbances under its current condition. Representation has been reduced with the complete extirpation of populations in all but one resiliency unit and a range reduction of approximately 94 percent from its historical distribution. Species-level genetic and ecological diversity has been lost over time, as populations have become extirpated. Redundancy has declined dramatically because the peppered chub remains on the landscape in only one population. As such, the peppered chub is at greater risk of extinction due to a catastrophic event when compared to historical conditions.

Status Throughout All of Its Range

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats and the cumulative effect of the threats under the section 4(a)(1) factors to peppered chub. We find that the species' resiliency, representation, and redundancy are at levels that put the species at risk of extinction throughout its range. Thus, we conclude that the peppered chub meets the definition of an endangered species because it is in danger of extinction throughout all of its range. We find that a threatened species status is not appropriate for the peppered chub because it is currently at risk of extinction, based on the threats and their current impacts on the species and the resulting current condition of the species.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. We have determined that the peppered chub is in danger of extinction throughout all of its range and accordingly did not undertake an analysis of any significant portions of its range. Because the peppered chub warrants listing as endangered throughout all of its range, our determination is consistent with the decision in *Center for Biological Diversity* v. *Everson,* 2020 WL 437289 (D.D.C. Jan. 28, 2020), in which the court vacated the aspect of the Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578; July 1, 2014) that provided the Services do not undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range.

Determination of Status

Our review of the best available scientific and commercial information indicates that the peppered chub meets the definition of an endangered species. Therefore, we are listing the peppered chub as an endangered species in accordance with sections 3(6) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning consists of preparing draft and final recovery plans, beginning with the development of a recovery outline and making it available to the public within 30 days of a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened (''downlisting'') or removal from protected status (''delisting''), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (*http://www.fws.gov/endangered*), or from our Arlington, Texas, Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

Following publication of this final rule, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of Colorado, Kansas, New Mexico, Oklahoma, and Texas will be eligible for Federal funds to implement management actions that promote the protection or recovery of the peppered chub. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Please let us know if you are interested in participating in recovery efforts for the peppered chub. Additionally, we invite you to submit

any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of any endangered or threatened species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by the Service, U.S. Forest Service, Bureau of Land Management, and National Park Service; issuance of section 404 Clean Water Act (33 U.S.C. 1251 *et seq.*) permits by the U.S. Army Corps of Engineers; and construction and maintenance of roads or highways by the Federal Highway Administration.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to endangered wildlife. The prohibitions of section 9(a)(1) of the Act, codified at 50 CFR 17.21, make it illegal for any person subject to the jurisdiction of the United States to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these) endangered wildlife within the United States or on the high seas. In addition, it is unlawful to import; export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any species listed as an endangered species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22. With regard to endangered wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a final listing on proposed and ongoing activities within the range of a listed species. Based on the best available information, the following actions are unlikely to result in a violation of section 9, if these activities are carried out in accordance with existing regulations and permit requirements; this list is not comprehensive:

(1) Authorized taking of peppered chub in accordance with a permit issued by us pursuant to section 10 of the Act or with the terms of an incidental take statement pursuant to section 7 of the Act, or possessing specimens of this species that were collected prior to the effective date of this final regulation adding this species to the List of Endangered and Threatened Wildlife (see **DATES**).

(2) Normal, lawful recreational activities such as hiking, trail rides, camping, boating, hunting, and fishing, provided unused bait fish are not released back into the water.

(3) Normal livestock grazing and other standard ranching activities within riparian zones that do not destroy or significantly degrade peppered chub habitat.

(4) Routine implementation and maintenance of agricultural conservation practices specifically designed to minimize erosion of cropland (*e.g.,* terraces, dikes, grassed waterways, and conservation tillage).

(5) Existing discharges into waters supporting the peppered chub, provided these activities are carried out in accordance with existing regulations and permit requirements (*e.g.,* activities subject to sections 402, 404, and 405 of the Clean Water Act), and improvements to existing irrigation, livestock, and domestic well structures, such as renovations, repairs, or replacement.

Based on the best available information, the following activities may potentially result in a violation of section 9 of the Act if they are not authorized in accordance with applicable law; this list is not comprehensive:

(1) Unauthorized handling, collecting, possessing, selling, delivering, carrying, or transporting of the peppered chub, including interstate transportation across State lines and import or export across international boundaries.

(2) Capture, survey, or collection of peppered chub specimens without a permit from the Service under section 10(a)(1)(A) of the Act.

(3) Introduction of nonnative fish species that compete or hybridize with, displace, or prey upon peppered chub.

(4) Unauthorized destruction or alteration of peppered chub habitat by dredging, channelization, impoundment, diversion, recreational vehicle operation within the stream channel, sand or gravel removal, or other activities that result in the destruction or significant degradation of channel stability, streamflow/water quantity, substrate composition, and water quality used by the species for foraging, cover, and spawning.

(5) Unauthorized discharges (including violation of discharge permits), spills, or dumping of toxic chemicals, silt, household waste, or other pollutants (*e.g.,* sewage, oil and gasoline, heavy metals) into surface or ground waters or their adjoining riparian areas that support/sustain peppered chub.

(6) Applications of pesticides, herbicides, fungicides, and other chemicals, including fertilizers, in violation of label restrictions.

(7) Withdrawal of surface or ground waters to the point at which baseflows in water courses (*e.g.,* creeks, streams, rivers) occupied by the peppered chub diminish and habitat becomes unsuitable for the species.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Arlington, Texas, Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

II. Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely, by vagrant individuals). Additionally, our regulations at 50 CFR 424.02 define the word ''habitat,'' for the purposes of designating critical habitat only, as the abiotic and biotic setting that currently or periodically contains the resources and conditions necessary to support one or more life processes of a species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation also does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency would be required to consult with the Service under section 7(a)(2) of the Act. However, even if the Service were to conclude that the proposed activity would result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement ''reasonable and prudent alternatives'' to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (PBFs) (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those PBFs that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those PBFs that occur in specific occupied areas, we focus on the specific features that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. The implementing regulations at 50 CFR 424.12(b)(2) further delineate unoccupied critical habitat by setting out three specific parameters: (1) When designating critical habitat, the Secretary will first evaluate areas occupied by the species; (2) the Secretary will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied by the species would be inadequate to ensure the conservation of the species; and (3) for an unoccupied area to be considered essential, the Secretary must determine that there is a reasonable certainty both that the area will contribute to the conservation of the species and that the area contains one or more of those PBFs essential to the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2)

regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in section 9 of the Act. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of the species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available at the time of those planning efforts calls for a different outcome.

In our SSA report and the proposed listing determination for the peppered chub, we determined that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to the peppered chub and that those threats in some way can be addressed by section 7(a)(2) consultation measures. Accordingly, such a designation could be beneficial to the species. Therefore, because none of the circumstances enumerated in our regulations at 50 CFR 424.12(a)(1) has been met and because there are no other circumstances the Secretary has identified for which this designation of critical habitat would be not prudent, we have determined that the designation of critical habitat is prudent for the peppered chub. We have also reviewed the available information pertaining to the biological needs of the species and habitat characteristics where the species is located. This and other information represent the best scientific data available and led us to conclude that the designation of critical habitat is determinable for the peppered chub.

Physical or Biological Features Essential to the Conservation of the Species

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas we will designate as critical habitat from within the geographical area occupied by the species at the time of listing, we consider the physical or biological features that are essential to the conservation of the species and that may require special management considerations or protection. The regulations at 50 CFR 424.02 define ''physical or biological features essential to the conservation of the species'' as the features that occur in specific areas and that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions.

Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity. For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkaline soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic essential to support the life history of the species.

In considering whether features are essential to the conservation of the species, we may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; and habitats that are protected from disturbance.

We have analyzed: (1) The PBFs that are essential to the conservation of the species and which may require special management considerations or protection under the Act; (2) the criteria used to define the areas occupied at the time of listing for the species; and (3) the criteria used to identify critical habitat boundaries or unoccupied habitat suitable for designation. Any comments received on the proposed rule were taken into account when this analysis was undertaken to revise PBFs where necessary. Based on public comment we did not need to revise PBFs, identification criteria for the species, or where the PBFs exist on the landscape to determine the geographic extent of each critical habitat unit.

Summary of Essential Physical or Biological Features

We derive the specific PBFs essential to the conservation of peppered chub from studies of the species' habitat, ecology, and life history as described below. Additional information can be found in the SSA report (Service 2022, entire) and the discussion in the ''Summary of Essential Physical or Biological Features'' section of the preamble to the proposed rule (85 FR 77108; December 1, 2020).

We have determined that the following PBFs are essential to the conservation of peppered chub:

PBF 1: Unobstructed river segments greater than 127 river miles (rmi) (205 river kilometers (rkm)) in length that are characterized by a complex braided channel and substrates of predominantly sand, with some patches of silt, gravel, and cobble.

PBF 2: Flowing water with adequate depths to support all life stages and episodes of elevated discharge to facilitate successful reproduction, channel and floodplain maintenance, and sediment transportation.

PBF 3: Water of sufficient quality to support survival and reproduction, which includes, but is not limited to, the following conditions:

(i) Water temperatures generally less than 98.2 degrees Fahrenheit (°F) (36.8 degrees Celsius (°C));

(ii) Dissolved oxygen concentrations generally greater than 3.7 parts per million (ppm);

(iii) Conductivity generally less than 16.2 millisiemens per centimeter (mS/cm);

(iv) pH generally ranging from 5.6 to 9.0; and

(v) Sufficiently low petroleum and other pollutant concentrations such that reproduction and/or growth is not impaired.

PBF 4: Native riparian vegetation capable of maintaining river water quality, providing a terrestrial prey base, and maintaining a healthy riparian ecosystem.

PBF 5: A level of predatory or competitive, native or nonnative fish present such that any peppered chub population's resiliency is not affected.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the

species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. The features essential to the conservation of the peppered chub may require special management considerations or protections to reduce the following threats: (1) Altered flow regimes, including (but not limited to) dams and impoundments and groundwater extraction; (2) stream fragmentation; (3) modified geomorphology; (4) poor water quality; (5) impacts from introduction of invasive species (fish and vegetation) and the introduction of native competitors for sport fishing; and (6) other stressors including (but not limited to) gravel mining and dredging, commercial bait fish harvesting, and off-road vehicle use.

Management activities that could ameliorate these threats include, but are not limited to: Development of groundwater conservation strategies; removal of impoundments or creation of fish passage, development of water release strategies for reservoirs; minimization of in-channel work from utility or road projects; maintenance of bank stability and revegetation of impacted areas; incorporation of integrated pest management strategies (for saltcedar (*Tamarix* spp.) and other invasive plants); and development of best management practices to reduce pollutant discharges and to develop water conservation measures that reduce the need for water diversions.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat. We are designating critical habitat in areas within the geographical area occupied by the species at the time of listing. We also are designating specific areas outside the geographical area occupied by the species because we have determined that a designation limited to occupied areas would be inadequate to ensure the conservation of the species.

Designation of occupied areas alone is inadequate for conservation of the species because the current distribution of the species is much reduced from its historical range. We anticipate that recovery will require continued protection of the existing population and its habitat, as well as reintroduction of peppered chub into historically occupied areas, ensuring there are adequate numbers in stable populations and that these populations occur over a wide geographic area. This strategy will help to ensure that catastrophic events, such as the effects of drought, are unlikely to simultaneously affect all known populations. For these reasons, we are reasonably certain that these unoccupied areas will contribute to the conservation of the species. Moreover, both of the unoccupied areas that we are designating as critical habitat contain one or more of the PBFs required by the peppered chub and fall within the regulatory definition of ''habitat'' at 50 CFR 424.02. Additionally, rangewide recovery considerations, such as maintaining existing genetic diversity and striving for representation of all major portions of the species' current range, were considered in formulating this critical habitat designation.

Sources of data for this critical habitat designation include multiple databases maintained by Arkansas Game and Fish Commission; Fishes of Texas; Colorado Parks and Wildlife Department; Kansas Department of Wildlife, Parks and Tourism; New Mexico Department of Game and Fish; New Mexico Interstate Stream Commission; Oklahoma Department of Environmental Quality; Texas Parks and Wildlife Department; Oklahoma State University; University of New Mexico Museum of Southwestern Biology; and New Mexico Department of Game and Fish, as well as numerous survey reports on rivers and streams throughout the species' range (see SSA report). We have also reviewed available information that pertains to the habitat requirements of this species. Sources of information on habitat requirements include studies conducted at occupied sites and published in peer-reviewed articles and agency reports, and data collected during monitoring efforts.

Our review of occupied range of the peppered chub is based on numerous species experts who concluded that, by the year 2000, the peppered chub had significantly declined and was isolated to the South Fork Ninnescah River in Kansas and the South Canadian River between Ute Reservoir in New Mexico and Lake Meredith in the Texas panhandle (Luttrell et al. 1999, entire; Eisenhour 1999, entire; Eisenhour 2004, entire). Using data from more than 1,800 fish collections, we define ''currently occupied'' as river reaches with positive surveys from 2013 to 2017 (Service 2022, chapter 4). By the year 2013, the peppered chub was no longer being observed in the Ninnescah River in Kansas, despite extensive survey efforts. The peppered chub continues to be observed in surveys in the South Canadian River between the Ute Reservoir and Lake Meredith, and this is the only area we considered to be currently occupied. We are designating one occupied unit as critical habitat for the peppered chub in the upper South Canadian River.

In summary, for areas within the geographic area occupied by the species at the time of listing (Upper South Canadian River; Unit 1), we delineated the critical habitat unit boundary using the following criteria:

The one remaining population of peppered chub has a low level of resiliency (see table 1, above), and, because of its relatively short life cycle (~2 years), a series of back-to-back stochastic events could significantly reduce or extirpate the remaining population. The peppered chub range has been highly restricted (~6 percent remaining); therefore, its adaptive capacity (representation) has been dramatically reduced. The significantly reduced range reduces peppered chub exposure to ecologically diverse habitats and reduces its ability to adapt to changing environments over time.

A low-resiliency single population provides little redundancy for the species, and a single catastrophic event could cause species extinction. Consequently, we have determined that occupied areas alone are not adequate for the conservation of the species. We evaluated whether any unoccupied areas are essential for the conservation of the species, and we are designating critical habitat in two units that are currently unoccupied. We have determined that each is essential for the conservation of the species. Both units have at least one of the PBFs essential to the conservation of the species, and we are reasonably certain that each will contribute to the conservation of the species. Our specific rationale for each unit can be found below in the unit descriptions.

Peppered chub has been completely extirpated from all but a single river reach within its historical range. Additionally, the one remaining population was found to be in ''low'' condition in our resiliency analysis and protecting it alone would not sufficiently conserve the species. Additional healthy populations are needed because of the inherent threat from environmental stochasticity (such as a multiyear drought) and the

possibility that the species could be extirpated in a relatively short period of time, given a 2-year life cycle. Furthermore, a single catastrophic event could extirpate the last remaining population, resulting in species extinction.

As a result, additional healthy populations of the peppered chub must be established to increase its viability and to recover the species. Having at least two sufficiently resilient populations in the Canadian River and at least one population in each of the Ninnescah and Cimarron Rivers is essential for the conservation of the peppered chub. Representation and redundancy have both been dramatically reduced by the species' limited current range. Due to the species' constricted range, it currently has a limited scope of its historical ecological setting and, therefore, has little to no opportunity to adapt to a changing environment over time.

The specific areas in these units encompass the minimum area of the species' historical range within the critical habitat designation, while still providing ecological diversity so that the species has the ability to evolve and adapt over time (representation) and ensure that the species has an adequate level of redundancy to guard against future catastrophic events.

These areas also represent the areas within the historical range with the best potential for recovery of the species due to their current conditions and likely suitability for reintroductions, based on uninterrupted stream length, overall habitat condition, and the presence of some or all of the PBFs essential to the conservation of the species. The unoccupied units that we have selected to designate for the peppered chub represent the smallest number of units that could be designated while still capturing the widest range of historical ecological settings and increasing redundancy. We are finalizing a designation with only three units (see table 2, below), because one unit from the proposed rule is being excluded based on our analysis under section 4(b)(2) of the Act (see Exclusions section below).

In addition to representation concerns, redundancy has been dramatically reduced and must be improved in order for the species to maintain viability into the future. The peppered chub was once common among several streams throughout the Arkansas River Basin and was highly redundant because it existed in many streams across a range. The species now occurs in one river segment in a small portion of its historical range. The species needs healthy populations distributed across its historical range to guard against catastrophic events. The two unoccupied units that were selected to capture the species' historical ecological settings are also essential to increasing the redundancy of the species.

Accordingly, we designate one unoccupied unit in the Canadian River and one unoccupied unit in the Cimarron River. Establishing healthy populations in these two currently unoccupied units would increase the resiliency, representation, and redundancy (viability) of the species. If reintroduced populations become established, each unoccupied unit will contribute ecological diversity (representation) or guard against catastrophic events (redundancy) or both. As described below in the individual unit descriptions, each unit contains one or more of the PBFs and is reasonably certain to contribute to the conservation of the species and meet the definition of habitat at 50 CFR 424.02.

See table 2, below for a summary of the critical habitat unit boundaries for areas outside the geographic area occupied by the species at the time of listing.

When determining critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack the PBFs necessary for peppered chub. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this rule have been excluded by text in the rule and are not designated as critical habitat. Therefore, a Federal action involving these lands will not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the PBFs in the adjacent critical habitat.

We are designating as critical habitat three critical habitat units, totaling approximately 872 rmi (1,404 rkm), one unit of which is currently occupied by the peppered chub and two units that are unoccupied. All three units are designated based on one or more of the PBFs being present to support peppered chub's life-history processes. Some units contain all of the identified PBFs and support multiple life-history processes. Some units contain only some of the PBFs necessary to support the peppered chub's particular use of that habitat. We are designating two unoccupied units because we have determined that the single occupied area is inadequate to ensure the conservation of the species. Therefore, we have also identified and designated as critical habitat unoccupied areas that contain one or more of the PBFs that are essential to support life-history processes of the species and that are essential for the conservation of the species.

The critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document under Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on *https://www.regulations.gov* at Docket No. FWS–R2–ES–2019–0019 and on our internet site *https://www.fws.gov/southwest/es/ArlingtonTexas* (see **FOR FURTHER INFORMATION CONTACT**).

Final Critical Habitat Designation

We are designating three units as critical habitat for peppered chub. The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for peppered chub. The three areas we designate as critical habitat are: (1) Upper South Canadian River, (2) Lower South Canadian River, and (4) Cimarron River. Table 2, below shows the critical habitat units and the approximate area of each unit.

TABLE 2—FINAL CRITICAL HABITAT UNITS FOR PEPPERED CHUB

Critical habitat unit	Land ownership by type	Size of unit in river miles (kilometers)	Occupied?
1. Upper South Canadian River	Federal; State; Private; Other	197 (317)	Yes.
2. Lower South Canadian River	Federal; Tribal; Private; Other	400 (644)	No.

TABLE 2—FINAL CRITICAL HABITAT UNITS FOR PEPPERED CHUB—Continued

Critical habitat unit	Land ownership by type	Size of unit in river miles (kilometers)	Occupied?
4. Cimarron River	Federal; Tribal; State; Private; Other	275 (443)	No.
Total		872 (1,404)	

Notes: Area estimates reflect all land within critical habitat unit boundaries. Area sizes may not sum due to rounding.

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for peppered chub, below.

Unit 1: Upper South Canadian River, New Mexico and Texas

Unit 1 consists of approximately 197 river miles (rmi) (317 river kilometers (rkm)) comprising a portion of the South Canadian River originating below the Ute Dam west of Logan, New Mexico, and extending downstream to the delta of Lake Meredith, Texas; and a portion of Revuelto Creek originating at the Interstate Highway 40 bridge extending downstream to the confluence with the South Canadian River, New Mexico. Revuelto Creek is an important source of water and sediment for the Upper South Canadian River and is considered occupied. Unit 1 occurs largely within private land or land described as ''other,'' which is land with non-Federal ownership that could not be determined but is likely to be Tribal or private.

Approximately 21 rmi (34 rkm) of adjacent lands are federally owned and managed by the National Park Service, and the Bureau of Reclamation. In addition, several small segments of public lands occur at bridge crossings, road easements, and the like. There are state own lands adjacent to approximately 9 rmi (~15 rkm). The remaining lands are in private ownership status and are adjacent to approximately 167 rmi (~268 rkm) of the unit 1 designation.

This unit possesses those characteristics as described by PBF 1 (see Physical or Biological Features Essential to the Conservation of the Species, above). PBFs 2 and 3 are in degraded condition in this unit during some times of the year and are dependent upon water releases from Ute Reservoir, precipitation, and groundwater, but these PBFs are currently sufficient to maintain self-sustaining populations. Water management strategies could enhance PBFs 2 and 3 within this unit. Current management to address native riparian vegetation is ongoing throughout this unit as it pertains to PBF 4; however, additional efforts to improve streamflow and channel morphology/complexity (removal of flow obstructions, restoration of historical channel characteristics, etc.) could further benefit this species. Predatory and other fish that may compete with peppered chub are present in this unit, but any effect to peppered chub resiliency is unclear. Thus, management actions to achieve PBF 5 may be necessary if additional information indicates the species' resiliency is affected by predation or competition.

Unit 2: Lower South Canadian River, Texas and Oklahoma

Because we have determined occupied areas alone are not adequate for the conservation of the species, we have evaluated whether any unoccupied areas are essential for the conservation of the species and identified this area as essential for the conservation of the species. Unit 2 comprises approximately 400 rmi (644 rkm) consisting of the South Canadian River originating at the U.S. 83 bridge north of Canadian, Texas, and extending downstream to the U.S. 75 bridge northwest of Calvin, Oklahoma. Unit 2 occurs almost entirely within land under ''other'' land ownership, as described above under Unit 1. Approximately 13 rmi (21 rkm) is managed by the U.S. Army Corps of Engineers, and approximately >1 rmi (1 rkm) is held in trust by the Bureau of Indian Affairs as Cheyenne-Arapaho Trust Land. In addition, several small segments of public land occur at bridge crossings, road easements, and the like. Historically, peppered chubs were observed in the lower portions of the South Canadian River. Peppered chubs were last reported in the South Canadian River resiliency unit in 1999. Currently, this river supports other pelagic-spawning prairie fish, such as the threatened Arkansas River shiner. This unit has at least one of the PBFs essential to the conservation of the species, and we are reasonably certain that this unit will contribute to the conservation of the species.

Although it is considered unoccupied, portions of this unit contain some or all of the PBFs essential for the conservation of the species (see Physical or Biological Features Essential to the Conservation of the Species, above.) Unit 2 possesses those characteristics as described by PBF 1 and is the longest unfragmented river segment within the historical range of the peppered chub. Although we have determined that peppered chubs require 127 rmi of unobstructed river characterized by a complex braided channel and substrates of predominantly sand, with some patches of silt, gravel, and cobble, that is the minimum number of river miles required to adequately facilitate reproduction and maintain a population, assuming all of the physical habitat requirements exist throughout the stretch of river (Service 2022, pp. 32 & 116). In order to establish populations, peppered chub need a longer river length that will not only adequately facilitate reproduction but also population growth (Service 2022, p. 97). Additionally, the required habitat factors (from PBF 1) do not exist throughout the entire river segment and, because the peppered chub has an approximate 2-year life cycle, any additional stream length would guard against extirpation due to multiyear droughts.

PBF 2 is degraded in the upper portion of this unit during some times of the year and is dependent upon precipitation and groundwater. Based on available data (OWRB 2017, pp. 39–43), PBF 3 is present throughout this unit. Current management to address native riparian vegetation is ongoing throughout this unit as it pertains to PBF 4; however, these management efforts are not specifically directed at benefiting the peppered chub, and additional management efforts may be necessary. Management actions to control nonnative phreatophytic (deep rooted) vegetation upstream and within the upper portion of this unit could also improve PBF 2 by reducing evapotranspiration. Predatory and other fish that may compete with peppered chub are present in this unit, but any effect to peppered chub resiliency is unclear. Thus, management actions to achieve PBF 5 may be necessary if additional information suggests the species'

resiliency is affected by predation or competition.

If a healthy population is established in this unit, it would likely be a moderately to highly resilient population due to longer stream length compared to other units and would increase the species' redundancy by one population. This unit is essential for the conservation of the species because it will provide habitat for range expansion in portions of known historical habitat that is necessary to increase viability of the species by increasing its resiliency, redundancy, and representation. A portion (approximately 238.2 rmi (383.3 rkm)) of listed Arkansas River shiner critical habitat is present in Unit 2.

For these reasons, we are reasonably certain that this unit will contribute to the conservation of the species. Additionally, the need for conservation efforts is recognized and is being discussed by our conservation partners, and researchers are working on methods for restoring and reintroducing the species into unoccupied habitat. The State of Oklahoma has identified the peppered chub as a tier III species of greatest conservation need (moderate level of conservation need) in the Oklahoma Comprehensive Wildlife Conservation Strategy (ODWC 2016, p. 399). The State strategy was developed to articulate the conservation strategies necessary to conserve their rare and declining wildlife species and maintain Oklahoma's rich biological heritage for present and future generations (ODWC 2016, p. 3). The strategy identifies several general conservation actions that would improve PBFs 2, 3, and 4 and benefit the peppered chub, if a population were established and if the actions were implemented, such as providing funding to landowners to restore channel morphology, water conservation, coordinating further with the Service, and public education (ODWC 2016, pp. 45–46). State and Federal partners have shown interest in propagation and reintroduction efforts for the peppered chub in this area. As previously mentioned, efforts are underway regarding a captive propagation program for peppered chub at the Tishomingo National Fish Hatchery in Oklahoma. The State of Kansas, Tishomingo National Fish Hatchery, and the Oklahoma Fish and Wildlife Conservation Office collaborate regularly on conservation actions.

The State of Texas also recognizes the peppered chub as a species of greatest conservation need and gives the species a rank of S1 (*i.e.,* at very high risk of extirpation in the jurisdiction due to very restricted range, very few populations or occurrences, very steep declines, severe threats, or other factors). Texas is one of only two States where the species remains extant. The State has also identified the portion of the Canadian River within the boundaries of the State of Texas (portions of which are currently occupied and unoccupied areas inside this unit) as an ecologically significant stream because it has threatened and endangered species/unique communities present (Texas Water Development Board (TWDB) 2016, p. 8–2). The Canadian River segment in the panhandle of Texas is also significant because of the presence of unique, exemplary, or unusually extensive natural communities upon which water development projects would have significant detrimental effects (TWDB 2016, p. 8–2).

Proposed Unit 3: Arkansas/Ninnescah River, Kansas and Oklahoma

Proposed Unit 3 comprised approximately 179 rmi (288 rkm) consisting of the South Fork Ninnescah River originating at the Highway 54/400 bridge east of Pratt, Kansas, and extending downstream to the River Road Bridge east of Newkirk, Oklahoma. The proposed unit occurs almost entirely on land under ''other'' land ownership, as described above under Unit 1. A small amount of this unit is publicly owned in the form of bridge crossings, road easements, and the like. Peppered chub were observed in the Ninnescah River in surveys between the years 2000 and 2013. We have excluded the entire unit from the final designation (see Exclusions, below). A description and map of this unit is maintained in the proposed rule for this designation (85 FR 77108).

Approximately 93 percent of this unit is located in the State of Kansas and contains the PBFs essential for the conservation of the species. In 2021, the State of Kanas signed The Kansas Aquatic Species Conservation Agreement: A Programmatic Safe Harbor Agreement and Candidate Conservation Agreement with Assurances for Fourteen Aquatic Species in Kansas (Agreement) that includes the peppered chub and covers the entire portion of this unit that falls within the boundaries of the State of Kansas. Because of the existence of the Agreement, the remaining 12 miles (less than seven percent) of the unit in Oklahoma no longer meets our criteria for designating critical habitat, we have excluded the entire unit from the final critical habitat designation (see Exclusions, below).

Unit 4: Cimarron River and Oklahoma

Because we have determined that occupied areas alone are not adequate for the conservation of the species, we evaluated whether any unoccupied areas are essential for the conservation of the species and identified this area as essential for the conservation of the species. Unit 4 comprises approximately 275 rmi (443 rkm) consisting of the Cimarron River originating at the border of Kansas and Oklahoma and extending downstream to the OK 51 bridge northeast of Oilton, Oklahoma. This unit occurs almost entirely on land under ''other'' land ownership, as described above under Unit 1. Approximately 0.86 rmi (1.38 rkm) is managed by the U.S. Army Corps of Engineers; approximately 0.56 rmi (0.91 rkm) is managed by the Bureau of Land Management; and approximately 0.94 rmi (1.51 rkm) is held in trust by the Bureau of Indian Affairs as Sac and Fox Nation Trust Land and Pawnee Trust Land. In addition, small amounts of the unit are publicly owned in the form of bridge crossings, road easements, and the like. Historically, peppered chubs were observed in the Cimarron River. The peppered chub was last observed in the Cimarron River resiliency unit in 2011. This unit has at least one of the PBFs essential to the conservation of the species, and we are reasonably certain that it will contribute to the conservation of the species. Our specific rationale for this unit can be found below in this unit description.

Unit 4 is considered unoccupied; however, portions of this unit contain some or all of the PBFs necessary for the conservation of the species (see Physical or Biological Features Essential to the Conservation of the Species, above.) PBF 1 is present within this unit, as described in the Unit 2 description. PBF 2 is degraded in upstream portions of this unit during some times of the year (absent during elevated drought conditions) and is dependent upon precipitation and groundwater. Based on available data, PBF 3 is present throughout this unit with the exception of PBF 3(iii) (conductivity generally less than 16.2 mS/cm) along an approximate 79-mile portion upstream of Waynoka to Ames, Oklahoma. Management actions would likely be necessary to reduce conductivity in this area (OWRB 2017, pp. 49–56). Current management to enhance native riparian vegetation is ongoing throughout this unit as it pertains to PBF 4 and involves the removal/control of nonnative phreatophytic vegetation such as saltcedar, common reed, etc. Management actions to control

nonnative phreatophytic vegetation upstream and within the upper portion of this unit could also improve PBFs 2 and 3 by reducing evapotranspiration. Phreatophytic plants such as saltcedar have high water consumption (increasing evapotranspiration) and stress aquatic habitats by lowering groundwater levels. Predatory and other fish that may compete with peppered chub are present in this unit, but any effect to peppered chub resiliency is unclear. Thus, management actions to achieve PBF 5 may be necessary if additional information indicates the species' resiliency is affected by predation or competition.

As discussed above, peppered chub currently has little to no representation and redundancy. If established in this unit, a population would increase redundancy by one population, thereby guarding against catastrophic events, and would increase the species' ecological diversity (representation). This unit is essential for the conservation of the species because it will provide habitat for range expansion in portions of known historical habitat that is necessary to increase viability of the species by increasing its resiliency, redundancy, and representation. Critical habitat for the Arkansas River shiner is present within a portion (approximately 201.5 rmi (324.30 rkm)) of Unit 4 and, accordingly, similar conservation activities are already ongoing.

For these reasons, we are reasonably certain that this unit will contribute to the conservation of the species. Additionally, the need for conservation efforts has been recognized and is being discussed by our conservation partners, and methods for restoring and reintroducing the species into unoccupied habitat are ongoing. The State of Oklahoma has identified the peppered chub as a tier III species of greatest conservation need in the Oklahoma Comprehensive Wildlife Conservation Strategy (ODWC 2016, p. 399). The Oklahoma strategy was developed to articulate the conservation strategies necessary to conserve their rare and declining wildlife species and maintain Oklahoma's rich biological heritage for present and future generations (ODWC 2016, p. 3). The strategy identifies several general conservation actions that would improve PBFs 2, 3, and 4 and benefit the peppered chub, if a population were established and if the actions were implemented, such as providing funding to landowners to restore channel morphology, water conservation, coordinating further with the Service, and public education (ODWC 2016, pp. 45–46). Also, in Oklahoma, State and Federal partners have shown interest in propagation and reintroduction efforts for the peppered chub. As previously mentioned, efforts are underway regarding a captive propagation program for peppered chub at the Tishomingo National Fish Hatchery in Oklahoma.

It is possible that significant drought conditions in the late 1980s and early 1990s led to the peppered chub decline and eventual extirpation in the Cimarron River (in Unit 4). The current condition of the unit, however, is likely to support populations once again (Service 2022, p. 150). Consequently, the shoal chub *(Macrhybobsis hyostoma),* a species in the same genus as the peppered chub, has reestablished populations and continues to persist in the Cimarron River after previously experiencing significant declines (Lutrell et al. 1999, pp. 984–985), demonstrating that this unit would similarly be suitable for the peppered chub.

A relatively small portion of Unit 4 extends into the State of Kansas (approximately six percent) and is covered by The Kansas Aquatic Species Conservation Agreement: A Programmatic Safe Harbor Agreement and Candidate Conservation Agreement with Assurances for Fourteen Aquatic Species in Kansas. We have excluded approximately 17 miles (27 kilometers) of this unit from the final critical habitat designation because the benefits of exclusions outweigh the benefits of inclusion (see Exclusions, below).

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species.

We published a final rule revising the definition of destruction or adverse modification on August 27, 2019 (84 FR 44976). Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation.

Compliance with the requirements of section 7(a)(2) is documented through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 set forth requirements for Federal agencies to reinitiate formal consultation on previously reviewed actions. These requirements apply when the Federal agency has retained discretionary

involvement or control over the action (or the agency's discretionary involvement or control is authorized by law) and, subsequent to the previous consultation: (1) If the amount or extent of taking specified in the incidental take statement is exceeded; (2) if new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered; (3) if the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion; or (4) if a new species is listed or critical habitat designated that may be affected by the identified action.

In such situations, Federal agencies sometimes may need to request reinitiation of consultation with us, but the regulations also specify some exceptions to the requirement to reinitiate consultation on specific land management plans after subsequently listing a new species or designating new critical habitat. See the regulations for a description of those exceptions.

Application of the ''Adverse Modification'' Standard

The key factor related to the destruction or adverse modification determination is whether implementation of the proposed Federal action directly or indirectly alters the designated critical habitat in a way that appreciably diminishes the value of the critical habitat as a whole for the conservation of the listed species. As discussed above, the role of critical habitat is to support PBFs essential to the conservation of a listed species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may violate section 7(a)(2) of the Act by destroying or adversely modifying such habitat, or that may be affected by such designation.

Activities that the Service may, during a consultation under section 7(a)(2) of the Act, consider likely to destroy or adversely modify critical habitat include, but are not limited to:

(1) Replacement and maintenance of river crossings and bridges;

(2) Construction, replacement, maintenance, or removal of pipelines, or abandonment of pipelines or electrical lines crossing streams;

(3) Park maintenance and authorization of recreational activities by the U.S. National Park Service (*e.g.,* permitting recreational off-road vehicle use at Lake Meredith Recreational Area);

(4) Operation and maintenance of salinity control programs;

(5) Dam maintenance, water releases from dams, and flow management via dams;

(6) Water withdrawals and groundwater withdrawals from reservoirs;

(7) Water development projects (such as new impoundments, diversions, or reservoir projects);

(8) Watershed restoration activities;

(9) Stream restoration and habitat improvement;

(10) Stocking of nonnative fish or native fish that compete with the peppered chub;

(11) Oil and gas exploration and extraction; and

(12) New or expanded development of municipal or agricultural water supplies.

Exemptions

Application of Section 4(a)(3) of the Act

Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that the Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense (DoD), or designated for its use, that are subject to an integrated natural resources management plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation. There are no DoD lands with a completed INRMP within the final critical habitat designation.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. In considering whether to exclude a particular area from the designation, we identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and evaluate whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise discretion to exclude the area only if such exclusion would not result in the extinction of the species. In making the determination to exclude a particular area, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor. We describe below the process that we undertook for taking into consideration each category of impacts and our analyses of the relevant impacts.

On December 18, 2020, we published a final rule in the **Federal Register** (85 FR 82376) revising portions of our regulations pertaining to exclusions of critical habitat. These final regulations became effective on January 19, 2021, and apply to critical habitat rules for which a proposed rule was published after January 19, 2021. Consequently, these new regulations do not apply to this final rule.

The Act affords a great degree of discretion to the Services in implementing section 4(b)(2). This discretion is applicable to a number of aspects of section 4(b)(2) including whether to enter into the discretionary 4(b)(2) exclusion analysis and the weights assigned to any particular factor used in the analysis. Most significant is that the decision to exclude is always discretionary, as the Act states that the Secretaries ''may'' exclude any areas. Under no circumstances is exclusion required under the second sentence of section 4(b)(2). There is no requirement to exclude, or even to enter into a discretionary 4(b)(2) exclusion analysis for any particular area identified as critical habitat. Accordingly, per our discretion, we have only done a full discretionary exclusion analysis when we received clearly articulated and reasoned rationale to exclude the area from this critical habitat designation.

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. In order to consider economic impacts, we prepared an incremental effects memorandum (IEM) and screening analysis which, together with our narrative and interpretation of effects, we consider our draft economic analysis (DEA) of the proposed critical habitat designation and related factors (IEc 2019, entire). The analysis, dated February 19, 2019, was made available for public review from December 1, 2020, through February 1, 2021 (85 FR 77108). The DEA addressed probable

economic impacts of critical habitat designation for peppered chub. Following the close of the comment period, we reviewed and evaluated all information submitted during the comment period that may pertain to our consideration of the probable incremental economic impacts of this critical habitat designation. Information relevant to the probable incremental economic impacts of the critical habitat designation for the peppered chub is summarized below and available in the screening analysis for the peppered chub (IEc 2019, entire), available at *https://www.regulations.gov.*

The full description of the findings from the DEA are outlined in the proposed rule (85 FR 77108; December 1, 2020). No more than 153 peppered chub consultations (148 informal and 5 formal) are anticipated in any given year (IEc 2019, p. 17). Proposed Unit 3 (Arkansas/Ninnescah River) had the highest potential costs, due in part to the fact that there is no overlapping critical habitat designation with the Arkansas River shiner in this unit. However, the Service is excluding proposed Unit 3 from the final critical habitat designation (see Exclusions, below). The estimated incremental costs of the total proposed critical habitat designation for the peppered chub in the first year was found to be unlikely to exceed $900,000, with proposed Unit 3 accounting for $500,000 of the total costs (2018 dollars) (IEc 2019, p. 17). Therefore, with the exclusion of proposed Unit 3, the estimated incremental costs of the total proposed critical habitat designation for the peppered chub within the first year is unlikely to exceed $400,000. Thus, the annual administrative burden would not reach $100 million and, therefore, would not be significant (see Executive Order 12866: Regulatory Planning and Review).

Consideration of Impacts on National Security and Homeland Security

The Service must consider impacts on national security, including homeland security, under section 4(a)(3)(B)(i) and on those DoD lands or areas not covered by section 4(a)(3)(B)(i), because section 4(b)(2) requires the Service to consider those impacts whenever it designates critical habitat. Accordingly, if DoD, Department of Homeland Security (DHS), or another Federal agency has requested exclusion based on an assertion of national-security or homeland-security concerns, or we have otherwise identified national-security or homeland-security impacts from designating particular areas as critical habitat, we generally have reason to consider excluding those areas.

Consideration of Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security discussed above. Other relevant impacts may include, but are not limited to, impacts to Tribes, States, local governments, public health and safety, community interests, the environment (such as increased risk of wildfire or pest and invasive species management), Federal lands, and conservation plans, agreements, or partnerships. To identify other relevant impacts that may affect the exclusion analysis, we consider a number of factors, including whether there are permitted conservation plans covering the species in the area—such as habitat conservation plans (HCPs), safe harbor agreements (SHAs), or candidate conservation agreements with assurances (CCAAs)—or whether there are non-permitted conservation agreements and partnerships that may be impaired by designation of, or exclusion from, critical habitat (see Policy Regarding Implementation of Section 4(b)(2) of the Endangered Species Act: 81 FR 7226; February 11, 2016). In addition, we look at whether Tribal conservation plans or partnerships, Tribal resources, or government-to-government relationships of the United States with Tribal entities may be affected by the designation. We also consider any State, local, public-health, community-interest, environmental, or social impacts that might occur because of the designation.

Exclusions

Exclusions Based on Economic Impacts

The Service considered the economic impacts of the critical habitat designation as described above. Based on this information, the Secretary has determined not to exercise her discretion to exclude any areas from this designation of critical habitat for the peppered chub based on economic impacts.

Exclusions Based on Impacts on National Security and Homeland Security

In preparing this rule, we have determined that the lands within the designation of critical habitat for peppered chub are not owned or managed by DoD or DHS. We also received no requests for exclusion from DoD or DHS. Therefore, we anticipate no impact on national security or homeland security. Based on this information, the Secretary has determined not to exercise her discretion to exclude any areas from this designation of critical habitat for the peppered chub based on impacts on national security or homeland security.

Exclusions Based on Other Relevant Impacts

When analyzing other relevant impacts of including a particular area in a designation of critical habitat, we weigh those impacts relative to the conservation value of the particular area. To determine the conservation value of designating a particular area, we consider a number of factors, including, but not limited to, the additional regulatory benefits that the area would receive due to the protection from destruction or adverse modification as a result of actions with a Federal nexus, the educational benefits of mapping essential habitat for recovery of the listed species, and any benefits that may result from a designation due to State or Federal laws that may apply to critical habitat.

In the case of peppered chub, the benefits of critical habitat include public awareness of the presence of peppered chub and the importance of habitat protection, and, where a Federal nexus exists, increased habitat protection for peppered chub due to protection from destruction or adverse modification of critical habitat. Continued implementation of an ongoing management plan that provides conservation equal to or more than the protections that result from a critical habitat designation would reduce those benefits of including that specific area in the critical habitat designation.

We evaluate the existence of a conservation plan when considering the benefits of inclusion. We consider a variety of factors, including, but not limited to, whether the plan is finalized; how it provides for the conservation of the essential PBFs; whether there is a reasonable expectation that the conservation management strategies and actions contained in a management plan will be implemented into the future; whether the conservation strategies in the plan are likely to be effective; and whether the plan contains a monitoring program or adaptive management to ensure that the conservation measures are effective and can be adapted in the future in response to new information.

After identifying the benefits of inclusion and the benefits of exclusion, we carefully weigh the two sides to evaluate whether the benefits of exclusion outweigh those of inclusion.

If our analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, we then determine whether exclusion would result in extinction of the species. If exclusion of an area from critical habitat will result in extinction, we will not exclude it from the designation.

Based on the information provided by entities seeking exclusion, as well as any additional public comments we received, we evaluated whether certain lands in the proposed critical habitat Units 3 and 4 are appropriate for exclusion from the final designation under section 4(b)(2) of the Act. This analysis indicates that the benefits of excluding lands from the final designation outweigh the benefits of designating those lands as critical habitat; thus, the Secretary is exercising her discretion to exclude the lands from the final designation.

Based on the existence of private or non-Federal conservation plans, as discussed below, we are excluding the following areas under section 4(b)(2) of the Act from the final critical habitat designation for peppered chub. Table 3, below provides approximate areas (rmi, rkm) that meet the definition of critical habitat but which we are excluding under section 4(b)(2) of the Act from the final critical habitat designation.

TABLE 3—AREAS EXCLUDED BY CRITICAL HABITAT UNIT FOR THE PEPPERED CHUB

Proposed critical habitat unit	Proposed critical habitat (rmi (rkm))	Area excluded (rmi (rkm))	Final critical habitat (rmi (rkm))
3: Arkansas/Ninnescah River	179 (288)	179 (288)	0
4: Cimarron River	292 (470)	17 (27)	275 (443)

Private or Other Non-Federal Conservation Plans Related to Permits Under Section 10 of the Act

HCPs for incidental take permits under section 10(a)(1)(B) of the Act provide for partnerships with non-Federal entities to minimize and mitigate impacts to listed species and their habitat. In some cases, HCP permittees agree to do more for the conservation of the species and their habitats on private lands than designation of critical habitat would provide alone. We place great value on the partnerships that are developed during the preparation and implementation of HCPs.

CCAAs and SHAs are voluntary agreements designed to conserve candidate and listed species, respectively, on non-Federal lands. In exchange for actions that contribute to the conservation of species on non-Federal lands, participating property owners are covered by an ''enhancement of survival'' permit under section 10(a)(1)(A) of the Act, which authorizes incidental take of the covered species that may result from implementation of conservation actions, specific land uses, and, in the case of SHAs, the option to return to a baseline condition under the agreements. The Service also provides enrollees assurances that we will not impose further land-, water-, or resource-use restrictions, or require additional commitments of land, water, or finances, beyond those agreed to in the agreements.

When we undertake a discretionary section 4(b)(2) exclusion analysis based on permitted conservation plans such as CCAAs, SHAs, and HCPs, we consider the following three factors:

(i) Whether the permittee is properly implementing the conservation plan or agreement;

(ii) Whether the species for which critical habitat is being designated is a covered species in the conservation plan or agreement; and

(iii) Whether the conservation plan or agreement specifically addresses the habitat of the species for which critical habitat is being designated and meets the conservation needs of the species in the planning area. See Policy Regarding Implementation of Section 4(b)(2) of the Endangered Species Act: 81 FR 7226; February 11, 2016.

We have determined that The Kansas Aquatic Species Conservation Agreement: A Programmatic Safe Harbor Agreement and Candidate Conservation Agreement with Assurances for Fourteen Aquatic Species in Kansas (Agreement) fulfills the above criteria, and we are excluding non-Federal lands covered by this plan that provide for the conservation of peppered chub, as further explained below.

Proposed Units 3 and 4—The Kansas Aquatic Species Conservation Agreement: A Programmatic Safe Harbor Agreement and Candidate Conservation Agreement With Assurances for Fourteen Aquatic Species in Kansas

In 2021, the Secretary of the Kansas Department of Wildlife, Parks and Tourism signed The Kansas Aquatic Species Conservation Agreement: A Programmatic Safe Harbor Agreement and Candidate Conservation Agreement with Assurances for Fourteen Aquatic Species in Kansas (hereafter, the ''Agreement''). The Agreement was part of an application for an enhancement-of-survival permit under section 10(a)(1)(A) of the Federal Endangered Species Act. The Agreement facilitates the introduction, reintroduction, augmentation, and translocation of, and conserves the habitat of, imperiled native aquatic species in the State of Kansas. The Agreement, a programmatic SHA and a CCAA, is between the Kansas Department of Wildlife, Parks and Tourism (KDWPT) and the Service, collectively, ''the Parties.''

The Agreement covers all eligible, non-Federal lands in the State of Kansas, for all eligible non-Federal landowners who wish to participate in the Agreement (Cooperator). Non-Federal lands are those lands owned by non-Federal landowners which include, but are not limited to, State, Tribal, regional, or local governments; private or nonprofit organizations; or private citizens. By entering into this Agreement, the Parties are using the Service's SHA and CCAA programs to further the conservation of the Nation's fish and wildlife. Both components of this Agreement and their associated permits target non-Federal lands in Kansas, whose owners or land managers are willing to engage in habitat management actions to benefit the species covered by the Agreement (Covered Species).

For a Cooperator to obtain an enhancement-of-survival permit under the Agreement, the Service must determine that there is a reasonable expectation of a net conservation benefit to the Covered Species (50 CFR 17.32(c)(2)(ii) and (e)(2)(ii)). The duration of the Agreement is 50 years from its effective date. Each participating landowner, or Cooperator, will enroll in the SHA, CCAA, or both, through a Landowner Management

Agreement (Landowner Agreement). Once the Landowner Agreement is signed, KDWPT will issue the Cooperator a Certificate of Inclusion (COI). The duration of the Landowner Agreements entered into under the Agreement and the associated COI will be for the remaining duration of the permit unless another time period is agreed upon by the Parties and the Cooperator.

The conservation goals of the Agreement are to increase the resiliency, redundancy, and representation of the Covered Species' populations through reintroductions and protect, enhance, and expand habitat availability (stream bed and banks). Under the Agreement, Cooperators will maintain habitat available to the Covered Species and will assist with habitat conservation for the remainder of the term of the Agreement. Cooperators will facilitate the ability to reintroduce and augment populations, and manage enrolled lands, as agreed to in their Landowner Agreement, in a manner that maintains existing habitat and improves and restores habitat for the Covered Species.

Expected outcomes of implementing the Agreement include the protection, enhancement, and restoration of instream habitat, improved water quality, reduced erosion and sedimentation, improved riparian habitat, and improved land use practices on enrolled lands during the term of the Agreement. The reintroduction activities included in the Agreement will increase probability that Covered Species will expand their range and survive and recruit new cohorts in reintroduced areas. Criteria for eligible landowners with land neighboring peppered chub habitat is: ''Mainstem of waterbody where reintroduction occurs extending onto adjoining parcels, plus direct tributaries containing suitable habitat. Eligible property must support suitable habitat (*i.e.,* permanently flowing channels with sandy substrates)'' per the Agreement. The Agreement in its entirety can be found at: *https://www.fws.gov/mountain-prairie/ea/newsAndReleases.php*.

Benefits of Inclusion—State of Kansas (Proposed Units 3 and 4): The principal benefit of including an area in critical habitat designation is the requirement of Federal agencies to ensure that actions that they fund, authorize, or carry out are not likely to result in the destruction or adverse modification of any designated critical habitat, which is the regulatory standard of section 7(a)(2) of the Act under which consultation is completed. In areas where a listed species occurs, Federal agencies must consult with the Service on actions that may affect a listed species, and refrain from actions that are likely to jeopardize the continued existence of such species. The analysis of effects to critical habitat is a separate and different analysis from that of the effects to the species. Therefore, the difference in outcomes of these two analyses represents the regulatory benefit of critical habitat. For some cases, the outcome of these analyses will be similar, because effects to habitat will often result in effects to the species. However, in this case, peppered chubs do not occur in the areas of proposed Units 3 and 4 (unoccupied units) considered for exclusion. Critical habitat designation may provide a regulatory benefit for the peppered chub on lands covered under the Agreement when there is a Federal nexus present for a project that might adversely modify critical habitat. However, the areas that were considered for exclusion do not contain a large amount of Federal land where such a nexus would exist.

Another possible benefit of including lands in critical habitat is public education regarding the potential conservation value of an area that may help focus conservation efforts on areas of high conservation value for certain species. We consider any information about the peppered chub and its habitat that reaches a wide audience, including parties engaged in conservation activities, to be valuable. Designation of critical habitat would provide educational benefits by informing Federal agencies and the public about the presence of listed species for all units.

In summary, we find that the benefits of inclusion of approximately 196 rmi (315 rkm) in proposed Units 3 and 4 of waterways within the State of Kansas are: (1) A regulatory benefit when there is a Federal nexus present for a project that might adversely modify critical habitat; and (2) educational benefits for the peppered chub and its habitat.

Benefits of Exclusion—State of Kansas (Proposed Units 3 and 4): The benefits of excluding 196 rmi (315 rkm) in Kansas waterways under the Agreement from the designation of critical habitat for the peppered chub are substantial and include: (1) Continuance and strengthening of our effective working relationship with private landowners to promote voluntary, proactive conservation of the peppered chub and its habitat as opposed to reactive regulation; (2) allowance for continued meaningful collaboration and cooperation in working toward species recovery, including conservation benefits that might not otherwise occur; (3) the State of Kansas reviewed the Agreement as a partner in development and has ensured required determinations are necessary and advisable; (4) the Agreement has a monitoring program to ensure conservation measures are effective; and (5) encouragement of developing additional conservation easements and other conservation and management plans in the future for other federally listed and sensitive species.

Many landowners perceive critical habitat as an unfair and unnecessary regulatory burden. According to some, the designation of critical habitat on (or adjacent to) private lands may reduce the likelihood that landowners will support and carry out conservation actions (Main et al. 1999, pp. 1,263–1265; Bean 2002, p. 412). The magnitude of this negative outcome is greatly amplified in situations where active management measures (such as reintroduction, fire management, and control of invasive species) are necessary for species conservation (Bean 2002, pp. 412–414). We find that the exclusion of this specific area of non-federally owned lands from the critical habitat designation for peppered chub can contribute to the species recovery and provide a superior level of conservation than critical habitat can provide alone. We find that, where consistent with the discretion provided by the Act, it is necessary to implement policies that provide positive incentives to private landowners to voluntarily conserve natural resources and that remove or reduce disincentives to conservation (Wilcove et al. 1996, pp. 1–15; Bean 2002, entire).

Additionally, partnerships with non-Federal landowners are vital to the conservation of listed species, especially on non-Federal lands; therefore, the Service is committed to supporting and encouraging such partnerships through the recognition of positive conservation contributions. In the case considered here, excluding these areas from critical habitat will help foster the partnerships the landowners and land managers in question have developed with Federal and State agencies and local conservation organizations; will encourage the continued implementation of voluntary conservation actions for the benefit of the peppered chub and its habitat on these lands; and may also serve as a model and aid in fostering future cooperative relationships with other parties here and in other locations for the benefit of other endangered or threatened species. Therefore, we consider the positive effect of excluding from critical habitat areas managed by

active conservation partners to be a significant benefit of exclusion.

Benefits of Exclusion Outweigh the Benefits of Inclusion—State of Kansas, Proposed Units 3 and 4: We evaluated the exclusion of 196 rmi (315 rkm) of waterways adjacent to private land within the areas covered by the Agreement from our designation of critical habitat, and we determined the benefits of excluding these lands outweigh the benefits of including them as critical habitat for the peppered chub.

We conclude that the additional regulatory and educational benefits of including these lands as critical habitat are relatively small, because of the unlikelihood of a Federal nexus on these private lands. These benefits are further reduced by the existence of the Agreement. We anticipate that there would be little additional Federal regulatory benefit to the taxon on private land because there is a low likelihood that those parcels will be negatively affected to any significant degree by Federal activities requiring section 7 consultation, and ongoing management activities indicate there would be no additional requirements pursuant to a consultation that addresses critical habitat.

Furthermore, the potential educational and informational benefits of critical habitat designation on areas containing the PBFs essential to the conservation of the peppered chub would be minimal, because the landowners and land managers under consideration have demonstrated their knowledge of the species and its habitat needs in the process of developing their partnerships with the Service.

In contrast, the benefits derived from excluding the areas managed by these owners and enhancing our partnership with these landowners and land managers is significant. Because voluntary conservation efforts for the benefit of listed species on non-Federal lands are so valuable, the Service considers the maintenance and encouragement of conservation partnerships to be a significant benefit of exclusion. The development and maintenance of effective working partnerships with non-Federal landowners for the conservation of listed species is particularly important in areas such as Kansas, a State with relatively little Federal landownership, but many species of conservation concern. Excluding these areas from critical habitat will help foster the partnerships the landowners and land managers in question have developed with Federal and State agencies and local conservation organizations, and will encourage the continued implementation of voluntary conservation actions for the benefit of the peppered chub and its habitat on these lands. The current active conservation efforts on some of these areas contribute to our knowledge of the species through monitoring and scientific research. In addition, these partnerships not only provide a benefit for the conservation of these species, but may also serve as a model and aid in fostering future cooperative relationships with other parties in this area of Kansas and in other locations for the benefit of other endangered or threatened species.

We find that excluding areas from critical habitat that are receiving both long-term conservation and management for the purpose of protecting the habitat that supports the peppered chub will preserve our partnership with the private landowners in the State of Kansas and will encourage future collaboration towards conservation and recovery of listed species. The partnership benefits are significant and outweigh the small potential regulatory, educational, and ancillary benefits of including the land in the final critical habitat designation for the peppered chub. Therefore, the Agreement provides greater protection of habitat for the peppered chub than could be gained through the project-by-project analysis of a critical habitat designation.

Exclusion Will Not Result in Extinction of the Species—State of Kansas; Proposed Units 3 and 4: We determined that the exclusion of 196 rmi (315 rkm) of waterways within the boundaries of the State of Kansas covered by the Agreement will not result in extinction of the taxon. Protections afforded to the species and its habitat by the Agreement provide assurances that the species will not go extinct as a result of excluding these lands from the critical habitat designation.

An important consideration as we evaluate these exclusions and their potential effect on the species in question is that critical habitat does not carry with it a regulatory requirement to restore or actively manage habitat for the benefit of listed species; the regulatory effect of critical habitat is only the avoidance of destruction or adverse modification of critical habitat should an action with a Federal nexus occur. It is, therefore, advantageous for the conservation of the species to support the proactive efforts of non-Federal landowners who are contributing to the enhancement of essential habitat features for listed species through exclusion. The jeopardy standard of section 7 of the Act will also provide protection in these occupied areas when there is a Federal nexus. Therefore, based on the above discussion, the Secretary is exercising her discretion to exclude approximately 196 rmi (315 rkm) of waterways from the designation of critical habitat for the peppered chub.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine whether potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

Under the RFA, as amended, and as understood in light of recent court decisions, Federal agencies are required to evaluate only the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself; in other words, the RFA does not require agencies to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies will be directly regulated by this designation. The RFA does not require evaluation of the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities will be directly regulated by this rulemaking, the Service certifies that this critical habitat designation will not have a significant economic impact on a substantial number of small entities, and a regulatory flexibility analysis is not required.

During the development of this final rule, we reviewed and evaluated all information submitted during the comment period that may pertain to our consideration of the probable incremental economic impacts of this critical habitat designation. Based on this information, we affirm our certification that this final critical habitat designation will not have a significant economic impact on a substantial number of small entities, and a regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare statements of energy effects when undertaking certain actions. We do not find that this critical habitat designation will significantly affect energy supplies, distribution, or use, as the areas identified as critical habitat are along riparian corridors in mostly remote areas with little energy supply, distribution, or infrastructure in place. Therefore, this action is not a significant energy action, and no statement of energy effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or Tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or Tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule will significantly or uniquely affect small governments because the lands being designated for critical habitat are owned by the States of New Mexico, Texas, and Oklahoma and the Federal Government (National Park Service, Bureau of Land Management, Bureau of Reclamation, and Service). We have determined that this rule will not significantly or uniquely affect small governments because it will not produce a Federal mandate of $100 million or greater in any year; that is, it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act. The designation of critical habitat imposes no obligations on State or local governments. By definition, Federal agencies are not considered small entities, although the activities they fund or permit may be proposed or carried out by small entities.

Consequently, we have determined that this critical habitat designation will not significantly or uniquely affect small government entities. As such, a small government agency plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the peppered chub in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership or establish any closures or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed and concludes that this designation of critical habitat for the peppered chub does not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this rule does not have significant federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of the critical habitat designation with, the appropriate State resource agencies. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the rule does not have substantial direct effects either on the State, or on the relationship between the Federal Government and the State, or on the distribution of powers and responsibilities among the various levels of government. The designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the PBFs of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist these State and local governments in long-range planning because these local governments no longer have to wait for case-by-case section 7 consultations to occur.

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) will be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We are designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, this rule identifies the physical or biological features essential to the conservation of the species. The designated areas of critical habitat are presented on maps, and the rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)). However, when the range of the species includes States within the Tenth Circuit, such as that of the peppered chub, under the Tenth Circuit ruling in *Catron County Board of Commissioners* v. *U.S. Fish and Wildlife Service,* 75 F.3d 1429 (10th Cir. 1996), we undertake a NEPA analysis for critical habitat designation.

We performed the NEPA analysis, and the draft environmental assessment was made available for public comment on April 21, 2021, on the Arlington Ecological Services Field Office website (below). We emailed notices to 39 individuals, agencies, organizations, and Tribes that were likely to be interested in and/or potentially affected by the proposed action. We accepted public comments through May 24, 2021, and received comments from the Kansas Farm Bureau, Oklahoma Farm Bureau, New Mexico Department of Game and Fish, New Mexico Interstate Stream Commission, the Petroleum Alliance of Oklahoma, and the Texas Commission on Environmental Quality. The final environmental assessment and finding of no significant impact have been completed and are available for review with the publication of this final rule. You may obtain a copy of the documents online at *https://www.regulations.gov,* by mail from the Arlington, Texas, Ecological Services Field Office (see **ADDRESSES**), or by visiting our website at *https://www.fws.gov/southwest/es/ArlingtonTexas/.*

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal

Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes.

In a letter dated September 7, 2017, we informed the Tribal leadership of nine Tribal nations (Pueblo of Cochiti, Pueblo of Isleta, Pueblo of Jemez, Pueblo of Tesuque, Pueblo of Zuni, Hopi Tribe, Jicarilla Apache Nation, Mescalero Apache Tribe, and the Navajo Nation) near or within the range of the peppered chub in the State of New Mexico of our intent to conduct a status assessment for the peppered chub. In a letter sent October 18, 2017, we informed all Tribal entities in the State of Oklahoma of our intent to conduct a status assessment. In a letter dated November 6, 2018, we sought the input of the Sac and Fox Nation and the Cheyenne and Arapaho Tribes of Oklahoma for their input on the potential economic impact of designating critical habitat for the peppered chub. We received a response from the Sac and Fox Nation providing input for a potential critical habit designation and incorporated the information into our screening analysis.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov* and upon request from the Arlington, Texas, Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this final rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Arlington, Texas, Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.11, amend the table in paragraph (h) by adding an entry for ''Chub, peppered'' to the List of Endangered and Threatened Wildlife in alphabetical order under FISHES to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
FISHES				
*	*	*	*	*
Chub, peppered	*Macrhybopsis tetranema*	Wherever found	E	87 FR [INSERT ***FEDERAL REGISTER*** PAGE WHERE THE DOCUMENT BEGINS]; 2/28/2022; 50 CFR 17.95(e).[CH]
*	*	*	*	*

■ 3. In § 17.95, amend paragraph (e) by adding an entry for ''Peppered Chub (*Macrhybopsis tetranema*)'' after the entry for ''Owens Tui Chub (*Gila bicolor snyderi*)'' to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(e) *Fishes.*

* * * * *

Peppered Chub (*Macrhybopsis tetranema*)

(1) Critical habitat units are depicted for Quay County, New Mexico; Hemphill, Moore, Oldham, and Potter Counties, Texas; and Blaine, Caddo, Canadian, Cleveland, Creek, Custer, Dewey, Ellis, Grady, Harper, Hughes, Kingfisher, Logan, Major, McClain, Payne, Pontotoc, Pottawatomie, Roger Mills, Seminole, Woods, and Woodward Counties, Oklahoma, on the maps in this entry. The critical habitat units include Units 1, 2, and 4 as Unit 3 was excluded during the rulemaking process.

(2) Within these areas, the physical or biological features essential to the conservation of peppered chub consist of the following components:

(i) Unobstructed river segments greater than 127 river miles (205 river kilometers) in length that are characterized by a complex braided channel and substrates of predominantly sand, with some patches of silt, gravel, and cobble.

(ii) Flowing water with adequate depths to support all life stages and episodes of elevated discharge to facilitate successful reproduction, channel and floodplain maintenance, and sediment transportation.

(iii) Water of sufficient quality to support survival and reproduction, which includes, but is not limited to, the following conditions:

(A) Water temperatures generally less than 98.2 °F (36.8 °C);

(B) Dissolved oxygen concentrations generally greater than 3.7 parts per million (ppm);

(C) Conductivity generally less than 16.2 millisiemens per centimeter (mS/cm);

(D) pH generally ranging from 5.6 to 9.0; and

(E) Sufficiently low petroleum and other pollutant concentrations such that reproduction and/or growth is not impaired.

(iv) Native riparian vegetation capable of maintaining river water quality, providing a terrestrial prey base, and maintaining a healthy riparian ecosystem.

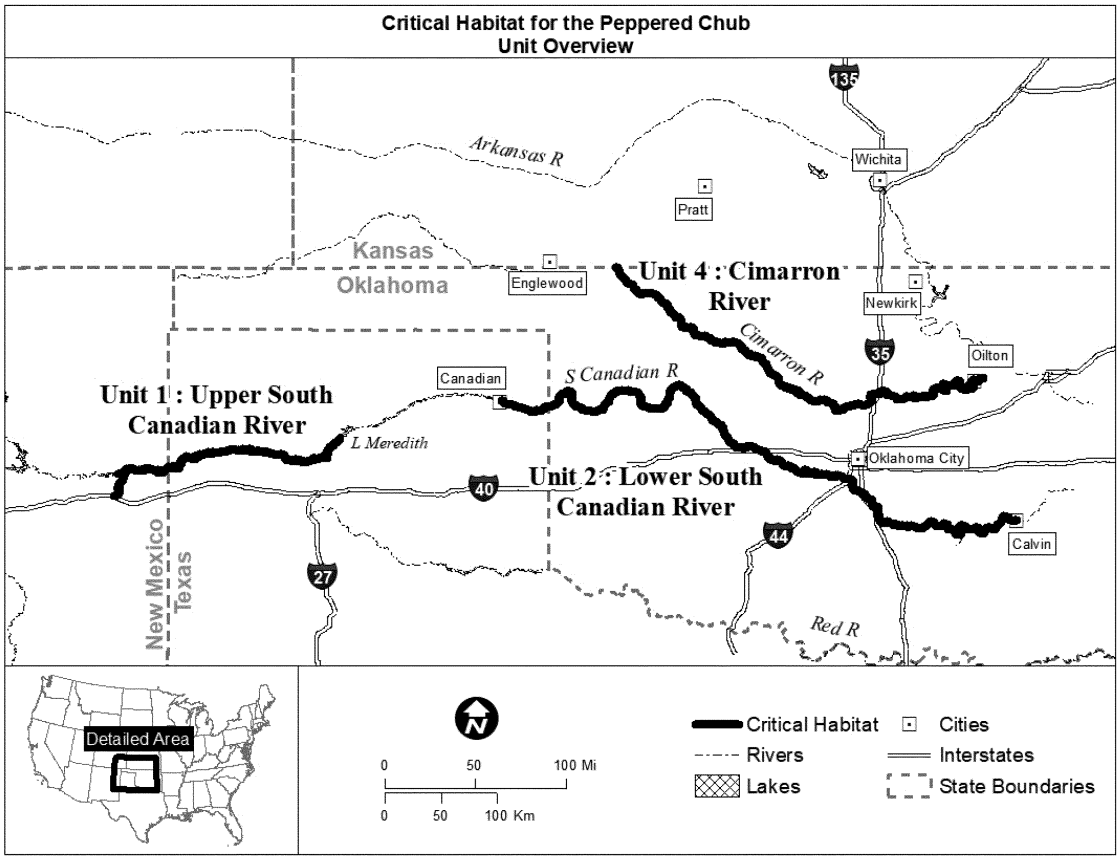
(v) A level of predatory or competitive, native or nonnative fish present such that any peppered chub population's resiliency is not affected.

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on March 30, 2022.

(4) Data layers defining map units were created using fish distribution data provided by State agencies and sourced on the FishNet2 online database. Hydrologic data for stream reaches were sourced from the U.S. Geological Survey online database. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service's internet site at *https://www.fws.gov/southwest/es/ArlingtonTexas/* and at *https://www.regulations.gov* under Docket No. FWS–R2–ES–2019–0019 and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Note: Index map follows:

Figure 1 to Peppered Chub (*Macrhybopsis tetranema*) paragraph (5)

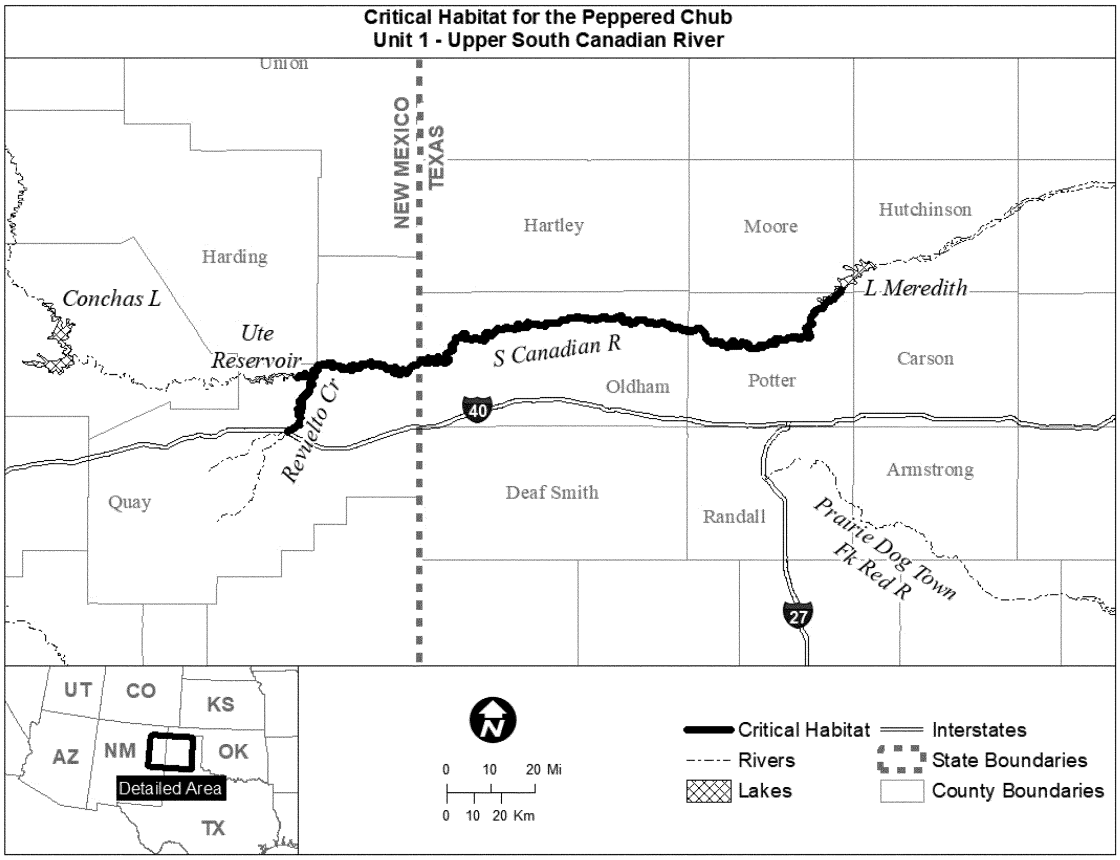


(6) Unit 1: Upper South Canadian River, New Mexico and Texas.

(i) This unit consists of approximately 197.2 river miles (317.3 river kilometers) of habitat in the South Canadian River from Revuelto Creek at Interstate 40 in New Mexico downstream to the inundated portion of Lake Meredith in Texas. Unit 1 includes river habitat up to bank full height.

(ii) Map of Unit 1 follows:

Figure 2 to Peppered Chub (*Macrhybopsis tetranema*) paragraph (6)(ii)

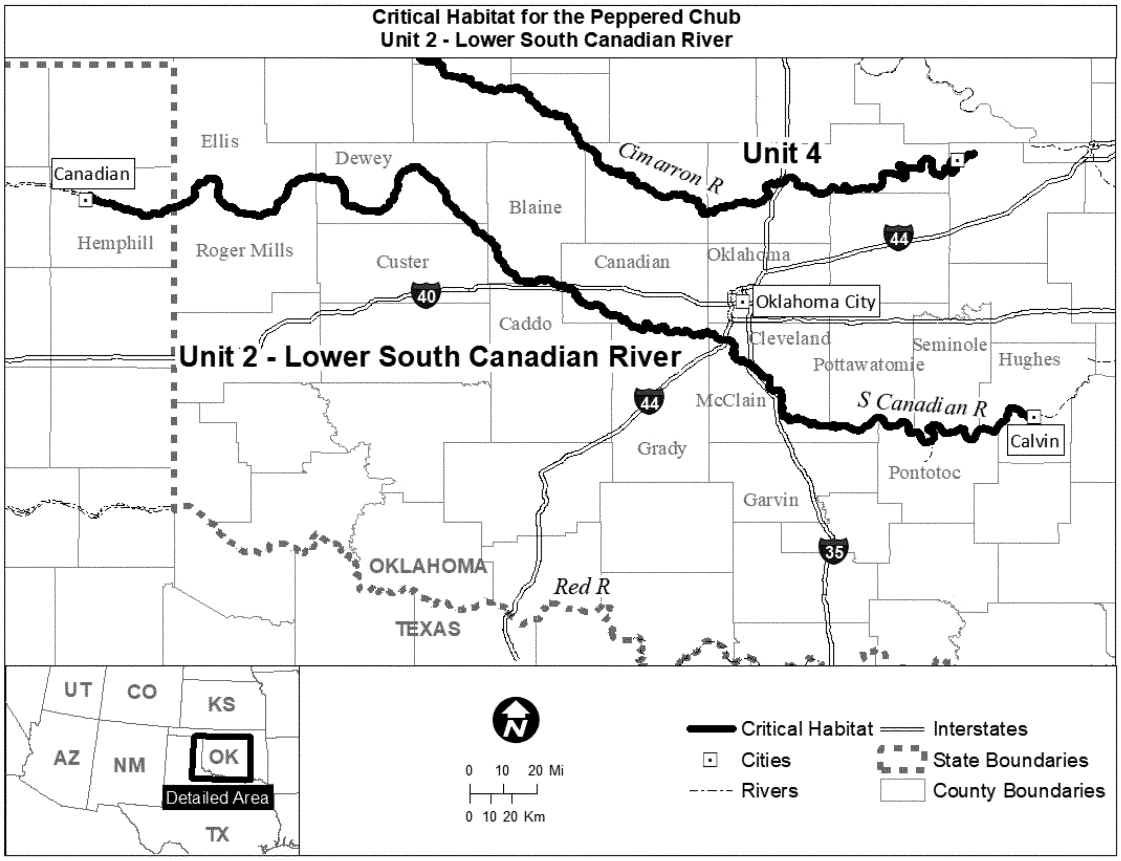


(7) Unit 2: Lower South Canadian River, Texas and Oklahoma.

(i) This unit consists of approximately 399.9 river miles (643.6 river kilometers) of unoccupied habitat in the lower portion of the South Canadian River from the U.S. 83 bridge north of Canadian, Texas, downstream to the U.S. 75 bridge northwest of Calvin, Oklahoma. Unit 2 includes river habitat up to bank full height.

(ii) Map of Unit 2 follows:

Figure 3 to Peppered Chub (*Macrhybopsis tetranema*) paragraph (7)(ii)

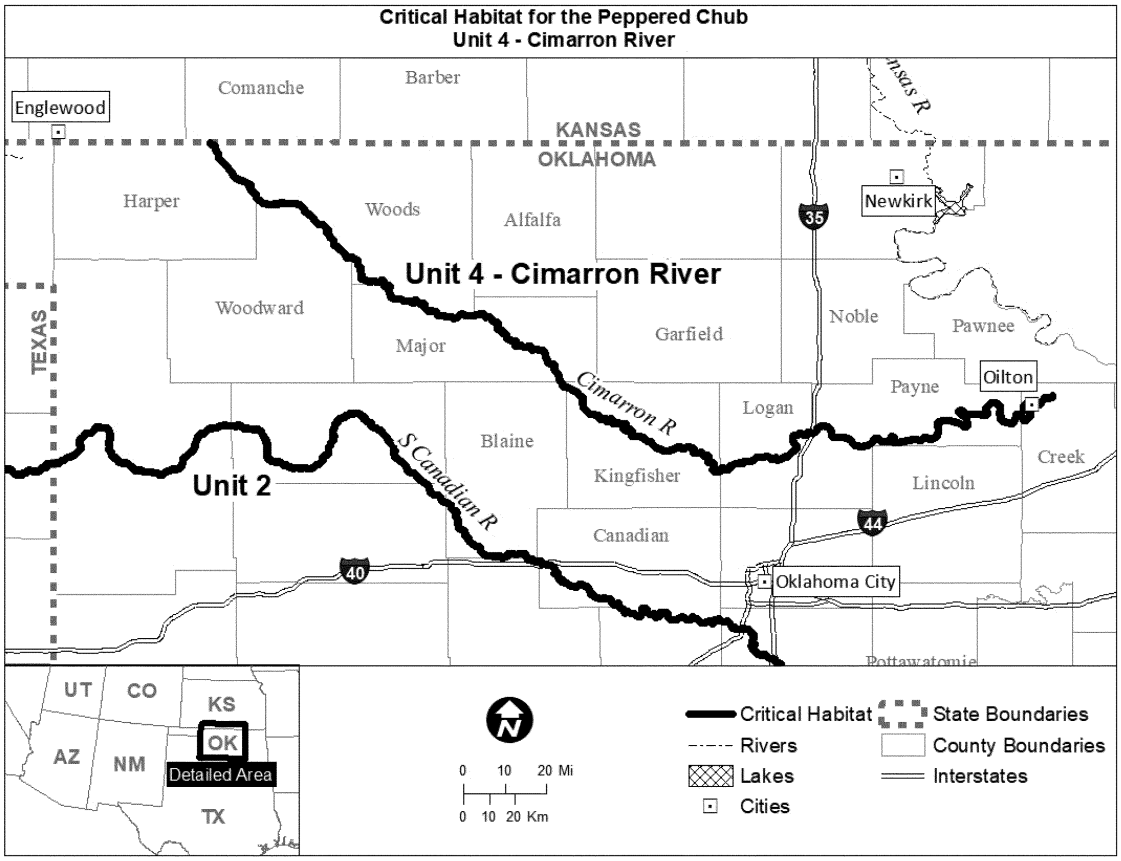


(8) Unit 4: Cimarron River, Oklahoma.

(i) Unit 4 consists of approximately 275.3 river miles (443.1 river kilometers) of unoccupied habitat in portions of the Ninnescah River and the Arkansas River, originating at the border of Kansas and Oklahoma, and extending downstream to OK 51 bridge northeast of Oilton, Oklahoma. Unit 4 includes river habitat up to bank full height.

(ii) Map of Unit 4 follows:

Figure 4 to Peppered Chub (*Macrhybopsis tetranema*) paragraph (8)(ii)



* * * * *

Martha Williams,

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

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Part IV

Environmental Protection Agency

40 CFR Part 180
Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0523; 5993–05–OCSPP]

Chlorpyrifos; Final Order Denying Objections, Requests for Hearings, and Requests for a Stay of the August 2021 Tolerance Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Order.

SUMMARY: In response to EPA's August 2021 final rule revoking all tolerances for the insecticide chlorpyrifos under the Federal Food, Drug, and Cosmetic Act (FFDCA), several objections, hearing requests, and requests for stay were filed by numerous parties representing a wide variety of growers and pesticide users. In this Order, EPA denies all objections to, requests for hearing on those objections, as well as requests for stay of the final rule.

DATES: The Order is effective February 28, 2022.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0523, 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.

Due to public health concerns related to COVID–19, the EPA/DC and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Elissa Reaves, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: 202–566–0700; email address: *OPPChlorpyrifosInquiries@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

In this document, EPA denies all objections to, requests for hearing on those objections, and requests for stay of EPA's August 2021 final rule (Ref. 1) revoking all tolerances for the insecticide chlorpyrifos under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346(d). This action may be of interest to all parties filing objections, requests for hearing on those objections, and requests for stay. This action may also be of interest to agricultural producers, food manufacturers or pesticide manufacturers, and others interested in food safety issues generally. 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).

Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What action is the Agency taking?

In this Order, EPA denies all objections to, requests for hearing on those objections, as well as requests for stay of the August 2021 final rule (Ref. 1). This Order is issued under FFDCA section 408(g)(2)(C), 21 U.S.C. 346a(g)(2)(C)).

Based on information available as of August 20, 2021—the date by which the U.S. Court of Appeals for the Ninth Circuit (Ninth Circuit) ordered EPA to issue a final rule concerning chlorpyrifos tolerances—EPA was unable to conclude that the tolerances for chlorpyrifos residues were safe in accordance with the FFDCA safety standard. In other words, EPA could not determine that there was a reasonable certainty that no harm would result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency's analysis indicated that aggregate exposures (*i.e.,* exposures from food, drinking water, and residential exposures), resulting from currently registered uses, exceeded safe levels. This decision relied on the well-established 10% red blood cell acetylcholinesterase (RBC AChE) inhibition as an endpoint for risk assessment and included the default Food Quality Protection Act (FQPA) tenfold (10X) margin of safety to account for uncertainties related to the potential for neurodevelopmental effects to infants, children, and fetuses. Accordingly, EPA issued a final rule revoking all tolerances for chlorpyrifos contained in 40 CFR 180.342. (*See* 86 FR 48315, Aug. 30, 2021) The prepublication of the final rule was issued on August 18, 2021, the final rule was published in the **Federal Register** on August 30, 2021, and the final rule became effective on October 29, 2021.

Pursuant to the procedures set forth in FFDCA section 408(g)(2), objections to, requests for evidentiary hearings on those objections, and/or requests for stays of, the final rule were filed by the persons listed in Unit V. (each, an Objector, and collectively, the Objectors) on or before the close of the objections period on October 29, 2021. (Ref. 1) The Objectors raised challenges to the final rule, including, for example, objections relating to the scope of the revocations in the final rule, retention of the additional FQPA Safety Factor, and use of the 2016 drinking water assessment, as well as raising procedural or other irrelevant concerns that do not change the basis for the final rule itself.

Four Objectors requested a hearing on their objections. The American Soybean Association, American Sugarbeet Growers Association and U.S. Beet Sugar Association (collectively, ''Sugarbeet Associations''), and Cherry Marketing Institute each submitted requests for evidentiary hearings to dispute EPA's revocation of tolerances for the 11 ''high-benefit'' uses identified in the ''Proposed Interim Decision for the Registration Review of Chlorpyrifos'' (2020 PID) (Ref. 31)—including soybean uses, sugarbeet uses, and the Michigan tart cherry industry's use. Gharda also submitted a request for an evidentiary hearing on an issue related to the assessment of chlorpyrifos oxon in EPA's aggregate assessment.

Finally, EPA received several written requests for EPA to stay the effective date of the final rule due to impacts on the agricultural industry and in order to provide more time for EPA to fully consider the objections filed.

This Order denies all of the objections, requests for evidentiary hearings on those objections, and requests for stays of the final rule. EPA has undertaken a comprehensive analysis of the merits of each of the Objectors' objections, hearing requests, and requests for stay. That analysis shows, as set out in Units VI., VII., and VIII. of this document, respectively, that none of the Objectors' objections support the claims raised, none of the Objectors' requests for hearing meet the

regulatory standard for granting a hearing, and none of the Objectors' requests for stay warrant staying the effective date of the final rule. There are numerous reasons for EPA's conclusions, for which additional detail is provided in Units VI., VII., and VIII. of this document.

C. What is the Agency's authority for taking this action?

The procedure for filing objections and requests for hearings thereon to EPA's final rule and EPA's authority for acting on such objections is contained in FFDCA section 408(g)(2) (21 U.S.C. 346a(g)(2)) and EPA's regulations at 40 CFR part 178.

II. Statutory and Regulatory Background

In this Unit, EPA provides background on the relevant statutes and regulations governing pesticides and tolerances, objections, requests for hearing, and requests for a stay, as well as on pertinent Agency policies and practices.

Unit II.A. summarizes the requirements and procedures in FFDCA section 408 and applicable regulations pertaining to pesticide tolerances, including the procedures for objecting to EPA tolerance actions and the substantive standards for evaluating the safety of pesticide tolerances. This unit also discusses the closely-related statute under which EPA regulates the sale, distribution, and use of pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*).

Unit II.B. provides an overview of EPA's Office of Pesticide Programs (OPP) risk assessment process. It contains an explanation of how EPA identifies the hazards posed by pesticides, how EPA determines the level of exposure to pesticides that pose a concern (level of concern), how EPA measures human exposure to pesticides, and how hazard, level of concern conclusions, and human exposure estimates are combined to evaluate risk. Further, this unit presents background information on the Agency's policy on the FQPA safety factor and acetylcholinesterase (AChE) inhibition.

A. FFDCA/FIFRA and Applicable Regulations

1. General

EPA establishes, modifies, or revokes tolerances for pesticide residues in food under FFDCA section 408. (21 U.S.C. 346a) A ''tolerance'' represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, pesticide residues in or on food are considered unsafe (21 U.S.C. 346a(a)(1)), and such food, which is then rendered ''adulterated'' under FFDCA section 402(a) (21 U.S.C. 342(a)), may not be distributed in interstate commerce. (21 U.S.C. 331(a)) Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). FFDCA section 408 was substantially rewritten by the Food Quality Protection Act of 1996 (FQPA), which added the provisions establishing a detailed safety standard for pesticides and additional protections for infants and children, among other things. (Pub. L. 104–170, 110 Stat. 1489 (1996))

EPA also regulates pesticides under FIFRA. (7 U.S.C. 136 *et seq.*) While FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires the approval of pesticides prior to their sale and distribution (*Id.* at section 136a(a)), and establishes a registration regime for regulating the use of pesticides. In order for a pesticide to be registered, EPA must determine that a pesticide ''will not generally cause unreasonable adverse effects on the environment'', among other things. (*Id.* at section 136a(c)(5)) The term ''unreasonable adverse effects on the environment'' is defined to include ''a human dietary risk from residues that results from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21.'' (*Id.* at section 136(bb)) The FFDCA safety standard was integrated into the FIFRA registration standard in the FQPA, which also directed that EPA coordinate, to the extent practicable, revocations of tolerances with pesticide cancellations under FIFRA. (21 U.S.C. 346a(l)(1))

Also under FIFRA, EPA is required to re-evaluate existing registered pesticides every 15 years in a process called ''registration review.'' (7 U.S.C. 136(a)(g)) The purpose of registration review is ''to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration,'' (40 CFR 155.40(a)(1)) taking into account changes that have occurred since the last registration decision, including any new relevant scientific information and any changes to risk-assessment procedures, methods, and data requirements. (40 CFR 155.53(a)) To ensure that a pesticide continues to meet the standard for registration, EPA must determine, based on the available data, including any additional information that has become available since the pesticide was originally registered or re-evaluated, that the pesticide does not cause ''unreasonable adverse effects on the environment.'' (7 U.S.C. 136a(c)(1), (5); *see also* 40 CFR 152.50)

2. Safety Standard for Pesticide Tolerances

FFDCA section 408(b)(2) directs that EPA may establish or leave in effect a tolerance for a pesticide only if it finds that the tolerance is safe and that EPA must revoke or modify tolerances determined to be unsafe. (21 U.S.C. 346a(b)(2)(A)(i)) FFDCA section 408(b)(2)(A)(ii) 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.'' (*Id.* At section 346a(b)(2)(A)(ii)) FFDCA section 408(b)(2)(D) directs EPA, in making a safety determination, to consider, among other relevant factors ''available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources.'' (*Id.* at section 346a(b)(2)(D)(vi)) As the language indicates, this includes exposure through food, drinking water, and all non-occupational exposures (*e.g.,* in residential settings), but does not include occupational exposures to workers (*i.e.,* occupational).

Risks to infants and children are given special consideration. Specifically, pursuant to FFDCA section 408(b)(2)(C), EPA must assess the risk of the pesticide chemical based on ''available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of *in utero* exposure to pesticide chemicals''; and available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity. (21 U.S.C. 346a(b)(2)(C)(i)(II) and (III))

This provision also creates a presumption that EPA will use an additional safety factor for the protection of infants and children. Specifically, it directs that ''in the case of threshold effects, ... an additional

tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.'' (21 U.S.C. 346a(b)(2)(C)) EPA is permitted to ''use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.'' (*Id.*) Due to Congress's focus on both pre- and postnatal toxicity, EPA has interpreted this additional safety factor as pertaining to risks to infants and children that arise due to prenatal exposure as well as to exposure during childhood years. This section providing for the special consideration of infants and children in section 408(b)(2)(C) was added to the FFDCA by the FQPA in 1996; therefore, this additional margin of safety is referred to throughout this Order as the ''FQPA safety factor (SF)''.

3. Procedures for Establishing, Amending, or Revoking Tolerances

Tolerances are established, amended, or revoked by rulemaking under the unique procedural framework set forth in FFDCA. Generally, a tolerance rulemaking is initiated by the party seeking to establish, amend, or revoke a tolerance by means of filing a petition with EPA. (*See* 21 U.S.C. 346a(d)(1)) EPA publishes in the **Federal Register** a notice announcing the filing of a petition filing and requesting public comment. (*Id.* at section 346a(d)(3)) After reviewing the petition, and any comments received on it, EPA may issue a final rule establishing, amending, or revoking the tolerance; issue a proposed rule subject to public comments and then finalize a rule to do the same; or deny the petition. (*Id.* at section 346a(d)(4))

Once EPA takes final action on the petition by either establishing, amending, or revoking the tolerance or denying the petition, any person may file objections with EPA and seek an evidentiary hearing on those objections. (21 U.S.C. 346a(g)(2)) Objections and hearing requests must be filed within 60 days after EPA takes that action. (*Id.*) The statute provides that EPA shall ''hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections.'' (*Id.* at section 346a(g)(2)(B)) EPA regulations make clear that hearings will only be granted where it is shown that there is ''a genuine and substantial issue of fact,'' the requestor has identified evidence ''which, if established, resolve one or more of such issues in favor of the requestor,'' and the issue is ''determinative'' with regard to the relief requested. (40 CFR 178.32(b)) EPA's final Order on the objections and requests for hearing is subject to judicial review. (21 U.S.C. 346a(h)(1)) The statute directs that tolerance regulations shall take effect upon publication unless EPA specifies otherwise. (*Id.* at section 346a(g)(1)) EPA is authorized to stay the effectiveness of the tolerance if objections are filed. (*Id.*) Because EPA does not have its own regulations governing stay requests, EPA typically evaluates requests for stay under the criteria set out in FDA's regulations at 21 CFR 10.35(e) due to the fact that the FFDCA provisions governing EPA's objections and hearings process were adapted from the similar parallel statutory process governing FDA objections and hearings.

B. EPA Risk Assessment—Policy and Practice

1. The Safety Determination—Risk Assessment

To assess risk of a pesticide tolerance, EPA combines information on pesticide toxicity with information regarding the route, magnitude, and duration of exposure to the pesticide. The risk assessment process involves four distinct steps, which are discussed in further detail in this section: (1) Identification of the toxicological hazards posed by a pesticide; (2) determination of the ''level of concern'' with respect to human exposure to the pesticide, which includes choosing a point of departure (PoD) that reflects the adverse health endpoint that is most sensitive to the pesticide and uncertainty factors; (3) estimation of human exposure to the pesticide through all applicable routes; and (4) characterization of risk posed to humans by the pesticide based on comparison of human exposure to the level of concern. For tolerances, characterization of risk involves determining whether the tolerances are safe; if aggregate exposure to humans is greater than the Agency's determined level of concern, the Agency's determination is that the tolerances are not safe.

a. Hazard Identification

Any risk assessment begins with an evaluation of a chemical's potential to cause adverse effects, and whether those properties have the potential to cause adverse effects (*i.e.,* a hazard identification). In evaluating toxicity or hazard, EPA reviews toxicity data, typically from studies with laboratory animals, to identify any adverse effects on the test subjects. Where available and appropriate, EPA will also take into account studies involving humans, including human epidemiological studies. For most pesticides, the animal toxicity database usually consists of studies investigating a broad range of endpoints including potential for carcinogenicity, mutagenicity, developmental and reproductive toxicity, and neurotoxicity. These studies include gross and microscopic effects on organs and tissues; functional effects on bodily organs and systems; effects on blood parameters (such as red blood cell count, hemoglobin concentration, hematocrit, and a measure of clotting potential); effects on the concentrations of normal blood chemicals (including glucose, total cholesterol, urea nitrogen, creatinine, total protein, total bilirubin, albumin, hormones, and enzymes such as alkaline phosphatase, alanine aminotransferase, and cholinesterases); and behavioral or other gross effects identified through clinical observation and measurement. EPA examines whether adverse effects are caused by different durations of exposure ranging from short-term (acute) to long-term (chronic) pesticide exposure and different routes of exposure (oral, dermal, inhalation). For chlorpyrifos, the Agency examined acute and steady-state durations because of the potential to cause adverse effects based on acute (single day, 24 hours) and steady-state (21-day) exposures. The latter duration is based on the observation in the available studies for organophosphates (OPs) indicating a consistent pattern of AChE inhibition that reaches a steady-state (or comes to an equilibrium) around 2–3 weeks and does not change in studies of longer duration. (Ref. 2 at pg. 7) Further, EPA evaluates potential adverse effects in different age groups (adults as well as fetuses and juveniles). (Ref. 3 at pgs. 8 through 10)

EPA also considers whether the adverse effect has a threshold—a level below which exposure has no appreciable chance of causing the adverse effect. For effects that have no threshold, EPA assumes that any exposure to the substance increases the risk that the adverse effect may occur.

b. Level of Concern/Dose-Response Analysis

Once a pesticide's potential hazards are identified, EPA determines a toxicological level of concern for evaluating the risk posed by human exposure to the pesticide. In this step of the risk assessment process, EPA

essentially evaluates the levels of exposure to the pesticide at which effects might occur. An important aspect of this determination is assessing the relationship between exposure (dose) and response (often referred to as the dose-response analysis). EPA follows differing approaches to identifying a level of concern for threshold and non-threshold hazards.

i. Threshold effects. In examining the dose-response relationship for a pesticide's threshold effects, EPA evaluates an array of toxicity studies on the pesticide. In each of these studies, EPA attempts to identify the lowest observed adverse effect level (LOAEL) and the no observed adverse effect level (NOAEL), which by definition is the next lower tested dose level below the LOAEL. Generally, EPA will use a NOAEL from the available studies as a starting point (called ''the Point of Departure'' or ''PoD'') in estimating the level of concern for humans. At times, however, EPA will use a LOAEL from a study as the Point of Departure when no NOAEL is identified in that study and the LOAEL is close to, or lower than, other relevant NOAELs. PoDs are selected to be protective of the most sensitive adverse toxic effect for each exposure scenario and are chosen from toxicity studies that show clearly defined NOAELs or LOAELs and dose-response relationships. The Point of Departure is, in turn, used in choosing a level of concern. EPA will make separate determinations as to the Points of Departure, and corresponding levels of concern, for both short and long exposure periods as well as for the different routes of exposure (oral, dermal, and inhalation).

EPA has also used other approaches for choosing the Point of Departure. One approach, called a benchmark dose, or BMD, estimates a point along a dose-response curve that corresponds to a specific response level. (Ref. 4) For example, a BMD_{10} represents a 10% change from the background or typical value for the response of concern. In contrast to the NOAEL/LOAEL approach, a BMD is calculated using a range of dose-response data and thus better accounts for the variability and uncertainty in the experimental results due to characteristics of the study design, such as dose selection, dose spacing, and sample size. In addition to a BMD, EPA generally also calculates a ''confidence limit'' in the BMD. Confidence limits express the uncertainty in a BMD that may be due to sampling and/or experimental error. The lower confidence limit on the dose used as the BMD is termed the BMDL, which the Agency often uses as the PoD. Use of the BMDL for deriving the PoD rewards better experimental design and procedures that provide more precise estimates of the BMD, resulting in tighter confidence intervals. It also provides a health protective conservative estimate of the safe dose. Numerous scientific peer review panels have supported the Agency's application of the BMD approach as a scientifically supportable method for deriving PoDs in human health risk assessment, and as an improvement over the historically applied approach of using NOAELs or LOAELs. (Refs. 5 and 6)

Another approach for deriving Points of Departure uses a sophisticated model called a physiologically based pharmacokinetic-pharmacodynamic (PBPK–PD) model. PBPK models are mathematical descriptions of how a chemical enters the body (*e.g.,* breathing, drinking, eating); the amount of chemical that gets into the blood; how the chemical moves between body tissues (*e.g.,* fat, brain) and the blood; and how the body alters (*i.e.,* metabolizes) and eliminates the chemical (*e.g.,* via urine, feces). PBPK models incorporate information about the body's anatomical and physiological structure as well as biochemical processes into the model structure. EPA uses PBPK models to better translate animal toxicity data to potential human risks (*i.e.,* extrapolation). A PBPK model that describes a chemical in a laboratory animal species can be used for humans by changing the physiological parameters. In the case of chlorpyrifos assessment, the PBPK–PD model is used to derive age-, duration-, and route-specific PoDs that would have resulted in a maximum RBC AChE inhibition level at 10% in humans. Rather than converting an animal BMDL to derive a human POD, the PBPK–PD modeling approach accounts for human physiology, biochemistry, life-stage, and exposure scenarios to derive human PODs based on predicted AChE inhibition in humans. (Ref. 7) Numerous Federal Advisory Committees and external review panels have encouraged the use of such a modeling approach to reduce inherent uncertainty in the risk assessment and facilitate more scientifically sound extrapolations across studies, species, routes, and dose levels. The PBPK–PD model for chlorpyrifos has undergone extensive peer review by various individual and groups, including the FIFRA Scientific Advisory Panel (SAP) (discussed in Unit III.A.3.) Significant improvements have been made to the model over the years in response to recommendations from the 2008, 2011, and 2012 FIFRA SAPs and comments from both internal and external peer reviewers. (Ref. 2 at pg. 20)

In estimating and describing the level of concern, the Point of Departure is at times used differently depending on whether the risk assessment addresses dietary or non-dietary exposures. For dietary risks, EPA uses the PoD to calculate an acceptable level of exposure or reference dose (RfD). The RfD is calculated by dividing the PoD by all applicable safety or uncertainty factors. Typically, EPA uses a baseline safety/uncertainty factor of 100X in assessing pesticide risk. That value includes a factor of 10 (10X) where EPA is using data from laboratory animals to account for the possibility that humans potentially have greater sensitivity to the pesticide than animals (also known as the ''inter-species factor'' or ''inter-species extrapolation factor'') and another factor of 10X to account for potential variations in sensitivity among members of the human population (also known as the ''intra-species factor'' or ''intra-species extrapolation factor''). These factors may vary if data is available to indicate that another extrapolation factor would be appropriate and protective. For example, where a PBPK–PD model using human parameters is used for deriving Points of Departure, there is no need for an interspecies factor since the model directly predicts human Points of Departure based on human physiology and biochemistry, rather than animal studies. Moreover, because the PBPK–PD model used for assessing chlorpyrifos accounts for differences in metabolism and toxicity response across the human population for some age groups and some subpopulations, the intraspecies extrapolation factor can be refined in accordance with EPA's 2014 *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation.* (Ref. 8)

Additional safety factors may be added to address data deficiencies or concerns raised by the existing data. Under the FQPA, an additional safety factor of 10X is presumptively applied to protect infants and children, unless reliable data support selection of a different factor. This FQPA additional safety factor largely replaces EPA's pre-FQPA practice regarding additional safety factors (*e.g.,* LOAEL to NOAEL factor or database uncertainty factor), but it might also account for residual concerns related to pre- and postnatal toxicity or exposure. (Ref. 9 at pgs. 4 through 11)

In implementing FFDCA section 408, EPA's Office of Pesticide Programs, also calculates a variant of the RfD referred to as a Population Adjusted Dose (PAD). A PAD is the RfD divided by the FQPA safety factor. (*Id.* at pgs. 13 through 16) RfDs and PADs are generally calculated for both acute and chronic dietary risks. Throughout this document, general references to OPP's calculated safe dose are denoted as an RfD/PAD.

For non-dietary, and combined dietary and non-dietary, risk assessments of threshold effects, the toxicological level of concern is not expressed as an RfD/PAD but rather in terms of an acceptable (or target) margin of exposure (MOE) between human exposure and the Point of Departure. The ''margin'' of interest is the ratio between human exposure and the Point of Departure, which is calculated by dividing human exposure into the Point of Departure. An acceptable MOE is generally considered to be a margin at least as high as the product of all applicable safety factors for a pesticide. For example, if a pesticide needs a 10X factor to account for potential inter-species differences, 10X factor for potential intra-species differences, and 10X factor for the FQPA children's safety provision, the safe or target MOE would be an MOE of at least 1,000. What that means is that for the pesticide in the example to meet the safety standard, human exposure to the pesticide would generally have to be at least 1,000 times smaller than the Point of Departure. Like RfD/PADs, specific target MOEs are selected for exposures of different durations. For non-dietary exposures, EPA typically examines short-term, intermediate-term, and long-term exposures. Additionally, target MOEs may be selected based on both the duration of exposure and the various routes of non-dietary exposure—dermal, inhalation, and oral.

ii. Non-threshold effects. For risk assessments for non-threshold effects, EPA does not use the RfD/PAD or MOE approach to choose a level of concern if quantification of the risk is deemed appropriate. Rather, EPA calculates the slope of the dose-response curve for the non-threshold effects from relevant studies frequently using a linear, low-dose extrapolation model that assumes that any amount of exposure will lead to some degree of risk. This dose-response analysis will be used in the risk characterization stage to estimate the risk to humans of the non-threshold effect.

c. Estimating Human Exposure

Risk is a function of both hazard and exposure. Thus, equally important to the risk assessment process as determining the hazards posed by a pesticide and the toxicological level of concern for those hazards is estimating human exposure. Under FFDCA section 408, EPA must evaluate the aggregate exposure to a pesticide chemical residue. This means that EPA is concerned not only with exposure to pesticide residues in food but also exposure resulting from pesticide contamination of drinking water supplies and from use of pesticides in the home or other non-occupational settings. (See 21 U.S.C. 346a(b)(2)(D)(vi)) This statutory requirement specifically clarifies that the assessment of dietary exposures includes exposure under the tolerances at issue, as well as ''all other tolerances in effect for the pesticide chemical residue''. (Id.) Additionally, EPA must take into account exposure from ''other related substances.'' (Id.)

i. Exposure from food. There are two critical variables in estimating exposure in food: (1) The types and amount of food that is consumed and (2) the residue level in that food. Consumption is estimated by EPA based on scientific surveys of individuals' food consumption in the United States conducted by the USDA. (Ref. 3 at pg. 12) Information on residue values comes from a range of sources including crop field trials, data on pesticide reduction (or concentration) due to processing, cooking, and other practices, information on the extent of usage of the pesticide, and monitoring of the food supply. (Ref. 3 at pg. 17)

In assessing exposure from pesticide residues in food, EPA, for efficiency's sake, follows a tiered approach in which it, in the first instance, assesses exposure using the worst-case assumptions that 100% of the crop or commodity in question is treated with, or exposed to, the pesticide and 100% of the food from that crop or commodity contains pesticide residues at the tolerance level. (Ref. 3 at pg. 11) When such an assessment shows no risks of concern, a more refined risk assessment is unnecessary. By using worst-case assumptions as a starting point for risk assessment, EPA's resources are conserved, and regulated parties are spared the cost of any additional studies that may be needed. The risk assessments produced using the worst-case assumptions yield conservative and health-protective outcomes; however, if a first-tier assessment suggests there could be a risk of concern, EPA then attempts to refine its exposure assumptions to yield a more realistic picture of residue values through use of data on the percent of the crop or commodity actually treated with, or exposed to, the pesticide and data on the level of residues that may be present on the treated crop or commodity. These latter data are used to estimate what has been traditionally referred to by EPA as ''anticipated residues''.

Use of percent crop/commodity treated data and anticipated residue information is appropriate because EPA's worst-case assumptions of 100% treatment and residues at tolerance value significantly overstate residue values. There are several reasons why this is true. First, all growers of a particular crop would rarely choose to apply the same pesticide to that crop (some may apply no pesticide; some may apply an alternative pesticide); generally, the proportion of the crop treated with a particular pesticide is significantly below 100%. (70 FR 46706, 46731, August 10, 2005) (FRL–7727–4) Second, the tolerance value represents a high-end or worst-case value. Tolerance values are chosen only after EPA has evaluated data from experimental trials in which the pesticide has been used in a manner, consistent with the draft FIFRA label, that is likely to produce the highest residue in the crop or food in question (*e.g.,* maximum application rate, maximum number of applications, minimum pre-harvest interval between last pesticide application and harvest). (Refs. 3 and 10) These experimental trials are generally conducted in several locations and involve multiple samples. (Ref. 10 at pgs. 5 and 7 and Tables 1 and 5) The results from such experimental trials invariably show that the residue levels for a given pesticide use will vary from as low as non-detectable to measurable values in the parts per million (ppm) range with the majority of the values falling at the lower part of the range. (70 FR 46706 at 46731) EPA uses a statistical procedure to analyze the experimental trial results and identify the upper bound of expected residue values. This upper bound value is typically used as the tolerance value. There may be some commodities for which pesticide residues come close to the tolerance value where the maximum label rates are followed, but most generally fall significantly below the tolerance value. If less than the maximum legal rate is applied, residues will be even lower. Third, residue values measured at the time of treatment do not take into account the lowering of residue values that frequently occurs as a result of degradation over time and through food processing and cooking.

EPA uses several techniques to refine residue value estimates. (Ref. 3 at pgs. 17 through 28) First, where appropriate, EPA will take into account all the

residue values reported in the experimental trials, either through an average of all the field trials or consideration of individual field trials. Second, EPA will consider data showing what portion of the crop or commodity is not treated with, or exposed to, the pesticide. Third, data can be produced showing pesticide degradation and decline over time, and the effect of commercial and consumer food handling and processing practices. Finally, EPA can consult monitoring data gathered by the FDA, the USDA, or pesticide registrants, on pesticide levels in food at points in the food distribution chain distant from the farm, including retail food establishments. Monitoring data, including data gathered by USDA's Pesticide Data Program (PDP), generally provide a characterization of pesticide residues in or on foods consumed by the U.S. population that closely approximates real-world exposures because they are sampled closer to the point of consumption in the chain of commerce than field trial data, which are generated to establish the maximum level of legal residues that could result from maximum permissible use of the pesticide immediately after harvest.

Another critical component of the exposure assessment is how data on consumption patterns are combined with data on pesticide residue levels in food. Traditionally, EPA has calculated exposure by simply multiplying average consumption by average residue values for estimating chronic risks and high-end consumption by maximum residue values for estimating acute risks. Using average residues is a realistic approach for chronic risk assessment due to the fact that variations in residue levels and consumption amounts average out over time, especially given the nationwide market for food in the United States. Using average values is inappropriate for acute risk assessments, however, because in assessing acute exposure situations it matters how much of each treated food a given consumer eats in the short-term and what the residue levels are in the particular foods consumed. Yet, using maximum residue values for acute risk assessment tends to greatly overstate exposure because it is unlikely that a person would consume at a single meal multiple food components bearing high-end residues. To take into account the variations in short-term consumption patterns and food residue values for acute risk assessments, EPA uses probabilistic modeling techniques for estimating exposure when more simplistic models appear to show risks of concerns.

In practice, EPA uses a computer program known as the Dietary Exposure Evaluation Model and Calendex software with the Food Commodity Intake Database (DEEM–FCID version 3.16/Calendex) to estimate dietary exposure from pesticide residues in food by combining data on human consumption amounts with residue values in food commodities. The model used for assessment of chlorpyrifos in the 2020 human health risk assessment (HHRA) incorporated 2003–2008 consumption data from USDA's National Health and Nutrition Examination Survey/What We Eat in America database (NHANES/WWEIA). The data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods ''as consumed'' (*e.g.,* apple pie) are linked to EPA-defined food commodities (*e.g.,* apples, peeled fruit—cooked; fresh or N/S (Not Specified); baked; or wheat flour—cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA Agricultural Research Service (ARS) and EPA. For chronic exposure assessment (or in the case of chlorpyrifos, for steady-state exposure assessment), consumption data are averaged for the entire U.S. population and within population subgroups; however, for acute exposure assessment, consumption data are retained as individual consumption events. Using this consumption information and residue data, the exposure estimates are calculated for the general U.S. population and specific subgroups based on age, sex, ethnicity, and region.

All of these refinements to the exposure assessment process, from use of food monitoring data through probabilistic modeling, can have dramatic effects on the level of exposure predicted, typically reducing worst-case estimates by at least 1 or 2 orders of magnitude. (Ref. 11 at pgs. 16 through 17; 70 FR 46706 at 46732)

For chlorpyrifos, EPA has calculated potential risk by using probabilistic techniques to combine distributions of potential exposures in sentinel populations. The resulting probabilistic assessments present a range of dietary exposure/risk estimates. Because probabilistic assessments generally present a realistic range of residue values to which the population may be exposed, EPA's starting point for estimating exposure and risk for such assessments is the 99.9th percentile of the population under evaluation. When using a probabilistic method of estimating acute dietary exposure, EPA typically assumes that, when the 99.9th percentile of acute exposure is equal to or less than the acute PAD (aPAD), the level of concern for acute risk has not been exceeded. By contrast, where the analysis indicates that estimated exposure at the 99.9th percentile exceeds the aPAD, EPA would generally conduct one or more sensitivity analyses to determine the extent to which the estimated exposures at the high-end percentiles may be affected by unusually high food consumption or residue values. (The same assumptions apply to estimates for steady-state dietary exposure and the steady-state PAD (ssPAD).) To the extent that one or a few values seem to ''drive'' the exposure estimates at the high-end of exposure, EPA would consider whether these values are reasonable and should be used as the primary basis for regulatory decision making. (Ref. 11)

ii. Exposure from water. (a) Modeling and monitoring data. EPA may use either or both field monitoring data and mathematical water exposure models to generate pesticide exposure estimates in drinking water. Monitoring and modeling are both important tools for estimating pesticide concentrations in water and can provide different types of information. Monitoring data can provide estimates of pesticide concentrations in water that are representative of specific agricultural or residential pesticide practices and under environmental conditions associated with a sampling design. Although monitoring data can provide a direct measure of the concentration of a pesticide in water, it does not always provide a reliable estimate of exposure because sampling may not occur in areas with the highest pesticide use, and/or the sampling may not occur when the pesticides are being used. When monitoring data meet certain data quantity criteria, EPA has tools available to quantify the uncertainty in available monitoring data such that it can be used quantitively to estimate pesticide concentrations in drinking water. (Ref. 12) Furthermore, monitoring data can be used in a weight of evidence (WOE) approach with model estimated concentrations to increase confidence in the conclusions of a drinking water assessment.

Due often to the limitations in many monitoring studies, EPA uses mathematical water exposure models to estimate pesticide exposure levels in drinking water. EPA's models are based on extensive monitoring data and detailed information on soil properties, crop characteristics, and weather patterns to estimate water concentrations in vulnerable locations where the pesticide could be used according to its label. (Ref. 13 at pgs. 27 and 28) (*See also* 69 FR 30042, 30058

through 30065, May 26, 2004) (FRL–7355–7) These models calculate estimated environmental concentrations of pesticides using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment. The modeling provides an estimate of pesticide concentrations in ground water and surface water. Depending on the modeling algorithm (*e.g.,* surface water modeling scenarios), daily concentrations can be estimated continuously over long periods of time, and for places that are of most interest for any particular pesticide. Modeling is a useful tool for characterizing vulnerable sites and can be used to estimate peak concentrations from infrequent, large rain events.

EPA relies on models it has developed for estimating pesticide concentrations in both surface water and groundwater. The most common model used to conduct drinking water assessments is the Pesticide in Water Calculator (PWC). PWC couples the Pesticide Root Zone Model (PRZM) and Variable Volume Water Model (VVWM) together to simulate pesticide fate and transport from the field of application to an adjacent reservoir. (Ref. 13 at pgs. 27 and 28) The PWC estimates pesticide concentrations for an index reservoir that is modeled for site-specific scenarios (*i.e.,* weather and soil data) in different areas of the country. A detailed description of the models routinely used for exposure assessment is available from the EPA OPP Aquatic Models website: *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#aquatic.*

In modeling potential surface water concentrations, EPA attempts to model areas of the country that are vulnerable to surface water contamination rather than simply model ''typical'' concentrations occurring across the nation. EPA models exposures occurring in small highly agricultural watersheds in different growing areas throughout the country, over a 30-year period. The scenarios are designed to capture residue levels in drinking water from reservoirs with small watersheds with a large percentage of land use in agricultural production. EPA believes these assessments are likely reflective of a small subset of the watersheds across the country that maintain drinking water reservoirs, representing a drinking water source generally considered to be more vulnerable to frequent high concentrations of pesticides than most locations that could be used for crop production.

(b) Drinking Water Level of Comparison (DWLOC). The drinking water level of comparison (DWLOC) is an estimate of the maximum concentration of the pesticide (and other residues of concern) that may be in drinking water without triggering a risk concern for human health. (Ref. 13 at pg. 10) The DWLOC is a benchmark that can be used to guide refinements of the drinking water assessment (DWA). This value relates to the concept of the ''risk cup,'' which EPA developed to facilitate risk refinement when considering aggregate human health risk to a pesticide. (Ref. 14) The risk cup is the total exposure allowed for a pesticide considering its toxicity and required safety factors. The risk cup is equal to the maximum safe exposure for the duration and population being considered. Exposures exceeding the risk cup are of potential concern. There are risk cups for each pertinent duration of exposure (*e.g.,* acute, short-term, chronic). The exposure durations most commonly of interest for acute or short-term pesticide exposure risk assessments are 1-day, 4-day, and 21-day averages. For example, the relevant exposure duration for AChE reversible inhibition from exposure to *N*-methyl carbamate insecticides is 1-day, while AChE irreversible inhibition resulting from exposure to OP insecticides is usually 21-days based on steady-state kinetics. (Ref. 5)

When using the DWLOC approach, EPA calculates the total exposure from food consumption and residential (or other non-occupational) exposures and subtracts this value from the maximum safe exposure level. The resulting value is the allowable remaining exposure without the potential for adverse health effect, and this allowable remaining exposure becomes the remaining space in the ''risk cup'' for pesticide exposures in drinking water. Knowing this allowable remaining exposure and the water consumption for each population subgroup (*e.g.,* infants), the Agency can calculate the DWLOC, which is the estimate of safe concentrations of pesticides in drinking water. Using this process of DWLOC calculation allows EPA to determine a target maximum safe drinking water concentration, which makes it easier to identify instances where drinking water estimates require refinement. (Ref. 13 at pgs. 19 and 20)

(c) Scale of drinking water assessment. Although food is distributed nationally, and residue values are therefore not expected to vary substantially throughout the country, drinking water is locally derived and concentrations of pesticides in source water fluctuate over time and location for a variety of reasons. Pesticide residues in water fluctuate daily, seasonally, and yearly because of the timing of the pesticide application, the vulnerability of the water supply to pesticide loading through runoff, spray drift and/or leaching, and changes in the weather. Concentrations are also affected by the method of application, the location, characteristics of the sites where a pesticide is used, the climate, and the type and degree of pest pressure, which influences the application timing, rate used, and number of treatments in a crop production cycle.

EPA may conduct a drinking water assessment (DWA) for a national scale depending on the pesticide use under evaluation. A national-scale DWA may use a single upper-end pesticide concentration as a starting point for assessing whether additional refinements are needed or estimated pesticide concentrations for certain site-specific scenarios that are associated with locations in the United States vulnerable to pesticide contamination based on pesticide use patterns. (Ref. 13 at pg. 22)

EPA may also conduct a regional-scale DWA to focus on areas where pesticide concentrations may be higher than the DWLOC. Under this type of assessment, EPA estimates pesticide concentrations across different regions in the United States that correspond with specific hydrologic units identified by a unique hydrologic unit code (HUC). For purposes of assessing chlorpyrifos, EPA evaluated concentrations in the 21 major geographic areas (or regions) used that comprise the United States. These areas contain either the drainage area of a major river or a combined drainage of a series of rivers. This information can be found at: *https://water.usgs.gov/GIS/huc.html.* Estimated pesticide concentrations under this approach would be associated with a vulnerable pesticide use area somewhere within the evaluated region. (Ref. 13 at pg. 23)

(d) Refinements to drinking water assessments. Much like the tiered approach used for assessing exposures of pesticides in food, EPA has defined four tiers for drinking water assessments. Lower-tiered assessments are more conservative based on the defaults or upper bound assumptions and may compound conservatisms, while higher tiers integrate more available data and provide more realistic estimates of environmental pesticide concentrations.

These four tiers are generally based on the level of effort, the amount of data considered, the spatial scale, and the

certainty in the estimated pesticide concentration. Each successive tier integrates more focused pesticide, spatial, temporal, agronomic, and crop-specific information. Tier 1 requires the least amount of effort and the least amount of data, whereas Tier 4 is resource intensive, considers a wide range of sources and types of data, and is spatially explicit. The order in which refinements are considered (*i.e.,* the order in which the assessment is refined) is pesticide-specific and depends on the nature and quality of the available data used to support the refinement. Additional information on the conduct of drinking water assessments can be found in EPA's ''Framework for Conducting Pesticide Drinking Water Assessment for Surface Water'' (Drinking Water Framework) (Ref. 13).

As discussed in the Drinking Water Framework, EPA can incorporate several refinements in higher tiered modeling. Two such refinements are the percent cropped area (PCA) and the percent crop treated (PCT). The PCA refers to the amount of area in a particular community water system that is planted with the crop of interest (*e.g.,* the default assumption is that the entire watershed is planted with a crop of interest). The PCT refers to the amount of the cropped area that is treated with the pesticide of interest (*e.g.,* the default is that the entire cropped area is treated with the pesticide of interest). With additional use and usage data, EPA can refine assumptions about the application rate and PCT for use in modeling to generate estimated drinking water concentrations (EDWCs) that are appropriate for human health risk assessment and more accurately account for the contribution from individual use patterns in the estimation of drinking water concentrations. The goal of the PCA and PCT refinements are to generate EDWCs that are appropriate for human health risk assessment that reduce the magnitude of overestimation due to variability in crops and actual pesticide usage. (Ref. 15)

iii. Non-occupational (Residential) exposures. Residential assessments examine exposure to pesticides in non-occupational or residential settings (*e.g.,* homes, parks, schools, athletic fields, or any other areas frequented by the general public), based on registered uses of the pesticide. Exposures to pesticides may occur to persons who apply pesticides (which is referred to as residential handler exposure) or to persons who enter areas previously treated with pesticides (which is referred to as post-application exposure). Such exposures may occur through oral, inhalation, or dermal routes and may occur over different exposure durations (*e.g.,* short-term, intermediate-term, long-term), depending on the type of pesticide and particular use pattern.

Residential assessments are conducted through examination of significant exposure scenarios (*e.g.,* children playing on treated lawns or homeowners spraying their gardens) using a combination of generic and pesticide-specific data. To standardize this process, EPA has prepared Standard Operating Procedures (SOPs) for conducting residential assessments on a wide array of scenarios that are intended to address all major possible means by which individuals could be exposed to pesticides in a non-occupational environment. (Ref. 16) SOPs have been developed for many common exposure scenarios including pesticide treatment of lawns, garden plants, trees, swimming pools, pets, and indoor surfaces including crack-and-crevice treatments.

The SOPs identify relevant generic data and construct algorithms for calculating application and post-application exposures in a residential or non-occupational setting using these generic data in combination with pesticide-specific information. The generic data typically involve survey data on behavior patterns (*e.g.,* activities conducted on turf and time spent on these activities) and transfer coefficient data (*i.e.,* data measuring the amount of pesticide that transfers from the environment to humans during some activity). Specific information on pesticides can include information on residue levels as well as information on environmental fate such as degradation data.

Once EPA assesses all the potential exposures from all applicable residential exposure scenarios, EPA selects the highest exposure scenario for each exposed population to calculate representative risk estimates for use in the aggregate exposure assessment. Those specific exposure values are then combined with the life-stage appropriate exposure values provided for food and drinking water to determine whether a safety finding can be made.

iv. Aggregate exposures. The aggregate exposure assessment process considers exposure through multiple pathways or routes of exposure (*e.g.,* food, water, and residential) for different sub-populations (*e.g.,* infants, children ages 1 through 6) and exposure duration or types of effects (*e.g.,* acute noncancer effects (single dose), chronic noncancer effects, and cancer). The aggregated exposure assessments can be deterministic (levels of exposure for each pathway are point estimates), probabilistic (levels of exposure are a distribution for a given population), or a combination of the two and are dependent on the level of refinement or assessment tier.

EPA evaluates aggregate exposure by comparing combined exposure from all relevant sources to the safe level. Where exposures exceed the safe level, those levels exceed the risk cup and are of potential concern. There are risk cups for each pertinent duration of exposure for a pesticide because the amount of exposure that can be incurred without adverse health effects will vary by duration (*e.g.,* acute, short-term, chronic, steady-state). The size of the risk cup is dependent on the maximum safe exposure for the different relevant durations (*e.g.,* acute, short-term, intermediate-term, long-term, steady-state).

d. Risk Characterization

The final step in the risk assessment is risk characterization. In this step, EPA combines information from the first three steps (hazard identification, level of concern/dose-response analysis, and human exposure assessment) to quantitatively estimate the risks posed by a pesticide. Separate characterizations of risk are conducted for different durations of exposure. Additionally, separate and, where appropriate, aggregate characterizations of risk are conducted for the different routes of exposure (dietary and non-dietary).

Whether exposures will exceed the available space in the risk cup (*i.e.,* whether exposures are expected to exceed safe levels) is expressed differently, depending on the type of level of concern (*i.e.,* RfD/PAD or MOE) the Agency has identified. For dietary assessments for which EPA calculates an RfD/PAD, the risk is expressed as a percentage of the acceptable dose (*i.e.,* the dose which EPA has concluded will be ''safe''). Dietary exposures greater than 100% of the percentage of the acceptable dose are generally cause for concern and would be considered ''unsafe'' within the meaning of FFDCA section 408(b)(2)(B). For non-dietary (and combined dietary and non-dietary) risk assessments of threshold effects, the toxicological level of concern is typically not expressed as an RfD/PAD, but rather in terms of an acceptable (or target) Margin of Exposure (MOE) between human exposure and the PoD. Non-dietary (and combined) exposures that result in an MOE equal to or exceeding the product of all applicable

safety factors would not generally be of concern.

As a conceptual matter, the RfD/PAD and MOE approaches are fundamentally equivalent. For a given risk and given exposure of a pesticide, if exposure to a pesticide were found to be acceptable under an RfD/PAD analysis it would also pass under the MOE approach, and vice-versa. However, for any specific pesticide, risk assessments for different exposure durations or routes may yield different results. This is a function not of the choice of the RfD/PAD or MOE approach but of the fact that the levels of concern and the levels of exposure may differ depending on the duration and route of exposure.

Where EPA has calculated a DWLOC, the Agency can assess risk by comparing estimated pesticide concentrations in drinking water to the DWLOC. As noted previously, an aggregate DWLOC represents the amount of maximum safe residues of pesticide in drinking water because it represents the room remaining in the risk cup for drinking water exposures, after accounting for the food and residential exposures. When the EDWC is less than the DWLOC, there are no risk concerns for aggregate exposures because the Agency can conclude that the contribution from drinking water, when aggregated with food and non-occupational exposures, will not exceed safe levels of exposure. Conversely, an EDWC at or exceeding the DWLOC would indicate a risk of concern, as pesticide exposures in drinking water, when aggregated with exposures from food and residential exposures, would exceed safe levels of exposure. (Ref. 14)

For non-threshold risks (generally, cancer risks), EPA uses the slope of the dose-response curve for a pesticide in conjunction with an estimation of human exposure to that pesticide to estimate the probability of occurrence of additional adverse effects. Under FFDCA section 408, for non-threshold cancer risks, EPA generally considers cancer risk to be negligible if the probability of increased cancer cases falls within the range of 1 in 1 million. EPA describes this quantitative standard as a ''range'' because it does not want to impart a false precision to numerical cancer risk estimates. EPA seeks to identify risks differing significantly from a 1 in 1 million risk, and that involves both a quantitative as well as qualitative assessment of what a risk estimate represents.

2. EPA Policy on the FQPA Children's Safety Factor

As the summary of EPA's risk assessment practice indicates, the use of safety factors plays a critical role in the process. This is true for traditional safety factors to account for potential differences between animals and humans when relying on studies in animals (inter-species factor) and potential differences among humans (intra-species factor), as well as the FQPA's additional 10X children's safety factor.

In implementing the children's safety factor provision, EPA has interpreted it as imposing a presumption in favor of applying a 10X safety factor, in addition to the traditional safety factors for inter- and intra-species extrapolation. (Ref. 9 at pgs. 4 and 11) Thus, EPA generally refers to the FQPA 10X factor as a presumptive or default 10X factor. EPA has also made clear, however, that this presumption or default in favor of the FQPA 10X safety factor is only a presumption. The presumption can be overcome if reliable data demonstrate that a different factor is safe for children. (*Id.*) In determining whether a different factor is safe for children, EPA focuses on the three factors listed in section 408(b)(2)(C) of the FFDCA—the completeness of the toxicity database, the completeness of the exposure database, and potential pre- and postnatal toxicity. In examining these factors, EPA strives to make sure that its choice of a safety factor, based on a WOE evaluation, does not understate the risk to children. (*Id.* at pgs. 24 through 25 and 35)

3. Acetylcholinesterase Inhibition

Acetylcholinesterase (AChE) inhibition is a disruption of the normal process in the body by which the nervous system chemically communicates with muscles and glands. Communication between nerve cells and a target cell (*i.e.,* another nerve cell, a muscle fiber, or a gland) is facilitated by the chemical, acetylcholine. When a nerve cell is stimulated, it releases acetylcholine into the synapse (or space) between the nerve cell and the target cell. The released acetylcholine binds to receptors in the target cell, stimulating the target cell in turn. As EPA has explained, ''the end result of the stimulation of cholinergic pathway(s) includes, for example, the contraction of smooth (*e.g.,* in the gastrointestinal tract) or skeletal muscle, changes in heart rate or glandular secretion (*e.g.,* sweat glands) or communication between nerve cells in the brain or in the autonomic ganglia of the peripheral nervous system.'' (Ref. 17 at pg. 10)

AChE is an enzyme that breaks down acetylcholine and terminates its stimulating action in the synapse between nerve cells and target cells. When AChE is inhibited, acetylcholine builds up prolonging the stimulation of the target cell. This excessive stimulation potentially results in a broad range of adverse effects on many bodily functions including muscle cramping or paralysis, excessive glandular secretions, or effects on learning, memory, or other behavioral parameters. Depending on the degree of inhibition, these effects can be serious or even fatal.

EPA's cholinesterase inhibition policy statement explains EPA's approach to evaluating the risks posed by AChE-inhibiting pesticides such as chlorpyrifos. (*Id.*) The policy focuses on three types of effects associated with AChE-inhibiting pesticides that may be assessed in animal and human toxicological studies: (1) Physiological and behavioral/functional effects; (2) AChE inhibition in the central and peripheral nervous system; and (3) AChE inhibition in red blood cells and blood plasma. The policy discusses how such data should be integrated in deriving an acceptable dose (*e.g.,* RfD/PAD) for an AChE-inhibiting pesticide.

After clinical signs or symptoms, AChE inhibition in the nervous system provides the next most important endpoint for evaluating AChE-inhibiting pesticides. Although AChE inhibition in the nervous system is not itself regarded as a direct adverse effect, it is ''generally accepted as a key component of the mechanism of toxicity leading to adverse cholinergic effects.'' (*Id.* at pg. 25) As such, the policy states that it should be treated as ''direct evidence of potential adverse effects'' and ''data showing this response provide valuable information in assessing potential hazards posed by anticholinesterase pesticides.'' (*Id.*) Unfortunately, useful data measuring AChE inhibition in the peripheral nervous system tissues has only been relatively rarely captured by standard toxicology testing. For central nervous system effects, however, more recent neurotoxicity studies ''have sought to characterize the time course of inhibition in * * * [the] brain, including brain regions, after acute and 90-day exposures.'' (*Id.* at pg. 27)

AChE inhibition in the blood is one step further removed from the direct harmful consequences of AChE-inhibiting pesticides. According to the policy, inhibition of blood AChEs ''is not an adverse effect, but may indicate a potential for adverse effects on the nervous system.'' (*Id.* at pg. 28) The policy states that ''[a]s a matter of science policy, blood cholinesterase data are considered appropriate surrogate measures of potential effects on peripheral nervous system

acetylcholinesterase activity in animals, for CNS [central nervous system] acetylcholinesterase activity in animals when CNS data are lacking and for both peripheral and central nervous system acetylcholinesterase in humans.'' (*Id.* at pg. 29) The policy notes that ''there is often a direct relationship between a greater magnitude of exposure [to an AChE-inhibiting pesticide] and an increase in incidence and severity of clinical signs and symptoms as well as blood cholinesterase inhibition.'' (*Id.* at pg. 30) Thus, the policy regards blood AChE data as ''appropriate endpoints for derivation of reference doses or concentrations when considered in a weight-of-the-evidence analysis of the entire database * * *.'' (*Id.* at pg. 29) Between AChE inhibition measured in red blood cell (''RBC'') or blood plasma, the policy states a preference for reliance on RBC AChE measurements because plasma cholinesterase is composed of a mixture of acetylcholinesterase and butyrylcholinesterase, and inhibition of the latter is less clearly tied to inhibition of acetylcholinesterase in the nervous system. (*Id.* at pgs. 29 and 32)

In the Agency's analysis for chlorpyrifos, EPA used a response level of 10% RBC AChE inhibition; this value represents the estimated dose where AChE is inhibited by 10%, compared to untreated animals. For the last several years EPA has used the 10% value to regulate AChE-inhibiting pesticides, including other organophosphorous pesticides. For a variety of toxicological and statistical reasons, EPA chose 10% RBC AChE inhibition as the response level for use in its PBPK–PD modeling. (Ref. 2 at pg. 7) EPA analyses have demonstrated that 10% is a level that can be reliably measured in the majority of rat toxicity studies; is generally at or near the limit of sensitivity for discerning a statistically significant decrease in AChE activity across the brain compartment; and is a response level close to the background.

III. Chlorpyrifos Background

A. Regulatory Background

1. General

a. Chlorpyrifos Uses

Chlorpyrifos (0,0-diethyl-0–3,5,6-trichloro-2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated organophosphate (OP) insecticide that has been registered for use in the United States since 1965. (The OPs are a group of closely related pesticides that affect functioning of the nervous system.) Pesticide products containing chlorpyrifos are registered for use on many agricultural crops, including, but not limited to, corn, soybeans, alfalfa, oranges, wheat, and walnuts. Additionally, chlorpyrifos products are registered for use on nonfood sites such as ornamental plants in nurseries, golf course turf, and as wood treatment. There are also public health uses including aerial and ground-based mosquito adulticide fogger treatments, use as fire ant control in nursery stock grown in USDA-designated quarantine areas, and for some tick species that may transmit diseases such as Lyme disease. The majority of uses in residential settings were voluntarily canceled over two decades ago (*e.g.,* 65 FR 76233, December 6, 2000 (FRL–6758–2); 66 FR 47481, September 12, 2001 (FRL–6799–7)).

b. Chlorpyrifos Risks

i. Acetylcholinesterase (AChE) inhibition. Chlorpyrifos, like other OP pesticides, affects the nervous system by inhibiting AChE, an enzyme necessary for the proper functioning of the nervous system, and ultimately leading to signs of neurotoxicity. This mode of action, in which AChE inhibition leads to neurotoxicity, is well-established, and thus has been used as basis for the PoD for OP human health risk assessments, including chlorpyrifos. This science policy is based on decades of work, which shows that AChE inhibition is the initial event in the pathway to acute cholinergic neurotoxicity. (Ref. 17 at pg. 14)

The Agency has conducted a comprehensive review of the available data and public literature regarding this adverse effect from chlorpyrifos. (Ref. 18 at pgs. 25 through 27) There are many chlorpyrifos studies evaluating RBC AChE inhibition or the brain in multiple lifestages (gestational, fetal, postnatal, and non-pregnant adult); multiple species (rat, mouse, rabbit, dog, human); methods of oral administration (oral gavage with corn oil, dietary, gavage via milk); and routes of exposure (oral, dermal, inhalation via vapor and via aerosol). In addition, chlorpyrifos is unique in the availability of AChE data from peripheral tissues in some studies (*e.g.,* heart, lung, liver). There are also literature studies comparing the *in vitro* AChE response to a variety of tissues that show similar sensitivity and intrinsic activity. Across the database, brain AChE tends to be less sensitive than RBC AChE or peripheral AChE. In oral studies, RBC AChE inhibition is generally similar in response to peripheral tissues. Thus, the *in vitro* data and oral studies combined support the continued use of RBC AChE inhibition as the critical effect for quantitative dose-response assessment.

Female rats tend to be more sensitive than males to these AChE effects. For chlorpyrifos, there are data from multiple studies which provide robust RBC AChE data in pregnant, lactating, and non-pregnant female rats from oral exposure (*e.g.,* developmental neurotoxicity (DNT), reproductive, and subchronic data).

In addition, studies are available in juvenile pups that show age-dependent differences, particularly following acute exposures, in sensitivity to chlorpyrifos and its oxon metabolite. This sensitivity is not derived from differences in the AChE enzyme itself but instead are derived largely from the immature metabolic clearance capacity in the juveniles.

ii. Neurodevelopmental toxicity. In addition to information on the effects of chlorpyrifos on AChE, there is an extensive body of information (in the form of laboratory animal studies, epidemiological studies, and mechanistic studies) studying the potential effects on neurodevelopment in infants and children following exposure to OPs, including chlorpyrifos.

There are numerous laboratory animal studies on chlorpyrifos in the literature that have evaluated the impact of chlorpyrifos exposure in pre- and postnatal dosing on the developing brain. These studies vary substantially in their study design, but all involve gestational and/or early postnatal dosing with behavioral evaluation from adolescence to adulthood. The data provide qualitative support for chlorpyrifos to potentially impact the developing mammalian brain with adverse outcomes in several neurological domains including cognitive, anxiety and emotion, social interactions, and neuromotor function. It is, however, important to note that there is little consistency in patterns of effects across studies. In addition, most of these studies use doses that far exceed EPA's 10% benchmark response level for RBC AChE inhibition. There are only a few studies with doses at or near the 10% brain or RBC AChE inhibition levels; among these only studies from Carr laboratory at Mississippi State University are considered by EPA to be high quality. EPA has concluded that the laboratory animal studies on neurodevelopmental outcomes are not sufficient for quantitatively establishing a PoD. (Ref. 2 at pgs. 88 and 89)

EPA evaluated numerous epidemiological studies on chlorpyrifos and other OP pesticides in accordance with the Agency's ''Framework for

Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment'' (''Epidemiologic Framework''). (Ref. 19) The most robust epidemiologic research comes from three prospective birth cohort studies. These include: (1) The Mothers and Newborn Study of North Manhattan and South Bronx performed by the Columbia Children's Center for Environmental Health (CCCEH) at Columbia University (''CCCEH study''); (2) the Mount Sinai Inner-City Toxicants, Child Growth and Development Study (''Mt. Sinai study''); and (3) the Center for Health Assessment of Mothers and Children of Salinas Valley (CHAMACOS) conducted by researchers at University of California Berkeley (''CHAMACOS study''). (Ref. 20 at pgs. 32 through 43)

In the case of the CCCEH study, which specifically evaluated the possible connections between chlorpyrifos levels in cord blood and neurodevelopmental outcomes on a specific cohort, there are a number of notable associations. (*Id.* at pgs. 35 through 38) Regarding infant and toddler neurodevelopment, the CCCEH study authors reported statistically significant deficits of 6.5 points on the Psychomotor Development Index at three years of age when comparing high to low exposure groups. Notably, these decrements persist even after adjustment for group and individual level socioeconomic variables. These investigators also observed increased odds of mental delay and psychomotor delay at age three when comparing high to low exposure groups. The CCCEH study authors also report strong, consistent evidence of a positive association for attention disorders, attention deficit hyperactivity disorder (ADHD), and pervasive development disorder (PDD) when comparing high to low chlorpyrifos exposure groups. Moreover, it was reported that for children in the CCCEH study cohort at age seven for each standard deviation increase in chlorpyrifos cord blood exposure, there is a 1.4% reduction in Full-Scale IQ and a 2.8% reduction in Working Memory. In addition, the CCCEH study authors evaluated the relationship between prenatal chlorpyrifos exposure and motor development/movement and reported elevated risks of arm tremor in children around 11 years of age in the CCCEH cohort.

Notwithstanding the observed associations, EPA and the 2012 and 2016 FIFRA SAPs identified multiple uncertainties in the CCCEH epidemiology studies. (Refs. 21 and 22) Some of these include the relatively modest sample sizes, which limited the statistical power; exposure at one point in prenatal time with no additional information regarding postnatal exposures; representativeness of a single-point exposure where time-varying exposures or the ability to define cumulative exposures would be preferable; lack of specificity of a critical window of effect and the potential for misclassification of individual exposure measures; and lack of availability of the raw data from the studies that would allow verification of study conclusions.

One of the notable uncertainties in the CCCEH epidemiology studies identified by EPA and the 2016 FIFRA SAP is the lack of specific exposure information on the timing, frequency, and magnitude of chlorpyrifos application(s) in the apartments of the women in the study. Despite extensive effort by EPA to obtain or infer this exposure information from various sources, the lack of specific exposure data remains a critical uncertainty. EPA made efforts in 2014 and 2016 to develop dose reconstruction of the exposures to these women. These dose reconstruction activities represent the best available information and tools but are highly uncertain. In addition, the pregnant women and children in the CCCEH studies were exposed to multiple chemicals, including multiple potent AChE inhibiting OPs and *N*-methyl carbamates. Moreover, using EPA's dose reconstruction methods from 2014 suggest that the pregnant women likely did not exhibit RBC AChE inhibition above 10%. The 2012 and 2016 FIFRA SAP reports expressed concern that it is likely that the CCCEH findings occurred at exposure levels below those that result in 10% RBC AChE inhibition. (Refs. 21 and 22) However, given the available CCCEH exposure information and the exposures to multiple potent AChE inhibiting pesticides, EPA cannot definitively attribute all AChE inhibition to chlorpyrifos. EPA remains unable to make a causal linkage between chlorpyrifos exposure and the outcomes reported by CCCEH investigators. (Ref. 20 at pg. 43) Moreover, given the uncertainties, particularly in the exposure information available from CCCEH (single timepoints, lack of time varying exposure, lack of knowledge about application timing), uncertainties remain about the dose-response relationships from the epidemiology studies.

Finally, there are several lines of evidence for actions of chlorpyrifos distinct from the classical mode of action of AChE inhibition. This information has been generated from model systems representing different levels of biological organization and provide support for molecular initiating events (binding to the morphogenic site of AChE, muscarinic receptors, or tubulin), cellular responses (alterations in neuronal proliferation, differentiation, neurite growth, or intracellular signaling), and responses at the level of the intact nervous system (serotonergic tone, axonal transport). Among the many *in vitro* studies on endpoints relevant to the developing brain available for chlorpyrifos, only three have identified outcomes in picomole concentrations, including concentrations lower than those that elicit AChE inhibition *in vitro.* However, as is the case for many other developmental neurotoxicants, most of these studies have not been designed with the specific goal of construction or testing an adverse outcome pathway. Thus, there are not sufficient data available to test rigorously the causal relationship between effects of chlorpyrifos at the different levels of biological organization in the nervous system. (*Id.* at pgs. 27 through 31)

Due to the complexity of nervous system development involving the interplay of many different cell types and developmental timelines, it is generally accepted that no single *in vitro* screening assay can recapitulate all the critical processes of neurodevelopment. As a result, there has been an international effort to develop a battery of new approach methodologies (NAMs) to inform the DNT potential for individual chemicals. This DNT NAM battery is comprised of *in vitro* assays that assess critical processes of neurodevelopment, including neural network formation and function, cell proliferation, apoptosis, neurite outgrowth, synaptogenesis, migration, and differentiation. In combination the assays in this battery provide a mechanistic understanding of the underlying biological processes that may be vulnerable to chemically-induced disruption. It is noteworthy, however, that the quantitative relationship between alterations in these neurodevelopmental processes and adverse health outcomes has, to date, not been fully elucidated. Moreover, additional assays evaluating other critical neurodevelopmental processes such as myelination are still being developed. (Ref. 23)

In September 2020, EPA convened a FIFRA SAP on developing and implementing NAMs using methods such as *in vitro* techniques and computational approaches. Included in that consideration was use of the DNT NAM battery to evaluate OP compounds as a case study. These methods

presented to the 2020 FIFRA SAP provide a more systematic approach to evaluating pharmacodynamic effects on the developing brain compared to the existing literature studies. Initial data from the NAM battery were presented to the SAP for 27 OP compounds, including chlorpyrifos and its metabolite, chlorpyrifos-oxon, and, when possible, compared to *in vivo* results (by using *in vitro* to *in vivo* extrapolation). On December 21, 2020, the SAP released its final report and recommendations on EPA's proposed use of the NAMs data. (Ref. 24) The advice of the SAP is currently being taken into consideration as EPA develops a path forward on NAMs. The Agency is continuing to explore the use of NAMs for the OPs, including chlorpyrifos, and intends to make its findings available as soon as it completes this work.

2. Reregistration and Registration Review

In 2006, EPA completed FIFRA section 4 (7 U.S.C. 136a–1) reregistration (a program under which EPA reregisters older pesticides that continue to meet the standard for registration) and FFDCA tolerance reassessment (21 U.S.C. 346a(q)) for chlorpyrifos and the OP class of pesticides. EPA concluded that process by determining that those tolerances were safe and should be left in effect. That decision relied on an endpoint based on 10% RBC AChE inhibition. (Ref. 25)

Given ongoing scientific developments in the study of the OPs generally, in March 2009 EPA announced its decision to prioritize the FIFRA section 3(g) (7 U.S.C. 136a(g)) registration review of chlorpyrifos by opening a public docket and releasing a preliminary work plan to complete the chlorpyrifos registration review by 2015. Despite the ambitions of that original work plan, the registration review of chlorpyrifos has proven to be far more complex than originally anticipated, and thus, chlorpyrifos is currently still undergoing registration review, which must be completed by October 1, 2022. (7 U.S.C. 136a(g)(1)(A)(iv)) For information about the ongoing registration review process for chlorpyrifos, see *https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0850.*

Reflecting that complexity, the Agency has engaged in extensive and ongoing analyses of the available science since initiating registration review in 2009, including multiple human health risk assessments and drinking water assessments, development of a new model for deriving points of departure to assess risks of chlorpyrifos, development of a framework for incorporating human epidemiology information into risk assessments as well as conducting an in-depth epidemiology and literature review, and in the process convening the FIFRA SAP at least six times. The following lays out the major milestones of the chlorpyrifos registration review process.

In 2011, EPA released its preliminary human health risk assessment (2011 HHRA) for the registration review of chlorpyrifos. (Ref. 18) The 2011 HHRA used 10% RBC AChE inhibition from laboratory rats as the critical effect (or PoD) for extrapolating risk. It also used the default 10X uncertainty factors for inter- and intra-species extrapolation. The 10X FQPA safety factor was reduced to 1X with a note to the public that a WOE analysis evaluating available epidemiological studies would be forthcoming. Also, in 2011, EPA released its Revised Chlorpyrifos Preliminary Registration Review Drinking Water Assessment. (Ref. 26) This assessment provided estimated drinking water concentrations (EDWCs) based on Tier I groundwater and Tier II surface water model simulations for registered uses of chlorpyrifos and considered monitoring data from several different programs. Based on data demonstrating the impacts of drinking water treatment on chlorpyrifos, EPA concluded that chlorpyrifos in drinking water would convert to chlorpyrifos-oxon, a metabolite, when going through chlorinated drinking water treatment systems. Based on modeling results, EDWCs for chlorpyrifos and chlorpyrifos-oxon generated from surface water sources provided higher estimates of the potential exposure to either of these chemicals in drinking water than those from groundwater.

In 2014, following the development of the PBPK–PD model and 2012 SAP's review of EPA's epidemiology review, EPA released a revised human health risk assessment (2014 HHRA). (Ref. 20) Using the chlorpyrifos PBPK–PD model for deriving human PoDs for RBC AChE inhibition, which obviated the need for the inter-species extrapolation factor and allowed for data-derived intra-species extrapolation factors (as described in Unit II.B.1.b.i.), the revised risk assessment identified highly refined PoDs that accounted for gender, age, duration and route-specific exposure considerations. In addition, the revised risk assessment retained the 10X FQPA SF, based on EPA's WOE analysis concerning the potential for neurodevelopmental outcomes that followed a draft of EPA's Epidemiologic Framework (Ref. 19), and incorporated recommendations from the 2012 SAP. Also in 2014, EPA released its Updated Drinking Water Assessment for Registration Review (''2014 DWA''). (Ref. 27) As an update to the 2011 DWA, the 2014 DWA included several additional analyses focusing on: (1) Clarifying labeled uses, (2) evaluating volatility and spray drift, (3) revising aquatic modeling input values, (4) comparing aquatic modeling and monitoring data, (5) summarizing the effects of drinking water treatment, and (6) updating model simulations using current exposure tools. The additional analyses did not change the exposure assessment conclusions reported in the preliminary DWA. The 2014 HHRA, taken together with the Agency's drinking water assessment, identified estimated aggregate risks exceeding the level of concern for chlorpyrifos.

In 2016 EPA issued a revised human health risk assessment using a dose-reconstruction approach to derive the PoD based on the neurodevelopmental effects observed in the CCCEH study based on advice from the 2016 SAP. (Ref. 28) Although the 2016 HHRA found that risks from food alone exceeded the safe level for chlorpyrifos, EPA also issued a revised drinking water assessment (2016 DWA). (Ref. 29) This refined drinking water assessment served to combine, update, and complete the work presented in the 2011 and 2014 drinking water assessments for chlorpyrifos as part of the registration review process. Even with the additional refinements, the results were consistent and suggested potential exposure to chlorpyrifos or chlorpyrifos-oxon in finished drinking water based on labeled uses. The assessment noted that depending on the drinking water level of concern, measured concentrations of chlorpyrifos and chlorpyrifos-oxon may exceed the level of concern in some locations across the country, which warranted comparison of EDWCs to the established drinking water level of concern. EPA issued a Notice of Data Availability seeking public comment on the 2016 HHRA and 2016 DWA. (81 FR 81049, November 17, 2016) (FRL–9954–65)

In September 2020, EPA issued the ''Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review'' (2020 HHRA) (Ref. 2) and the ''Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review'' (2020 DWA) (Ref. 30). In the 2020 HHRA, EPA utilizes the same endpoint and PoDs as those used in the 2014 HHRA. This was done because the Agency concluded that the

unresolved nature of the science addressing neurodevelopmental effects warranted further evaluation of the science during the remaining time for completion of registration review. Due to the uncertainties concerning neurodevelopmental effects, the 2020 HHRA retained the default 10X FQPA safety factor; the 2020 HHRA also presented potential risk estimates at a reduced 1X FQPA safety factor to reflect the range of estimates possible, although it did not adopt or explain why the 1X FQPA safety factor would be safe for infants and children. While in the 2020 HHRA the Agency determined that risks from exposures to chlorpyrifos residues in food combined with residential exposures were not of concern, drinking water exposures significantly add to those risks. The 2020 DWA built upon the analysis in the 2016 DWA but focused on a subset of currently registered chlorpyrifos uses for high benefit crops to growers in specific areas of the country, *i.e.,* alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat. This assessment utilized new surface water model scenarios (*i.e.,* soil, weather, and crop data), integrated the entire distribution of community water system percent cropped area (PCA) adjustment factors and state-level percent crop treated (PCT) data, and considered the quantitative use of available surface water monitoring data. The 2020 DWA noted that concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water were not likely to exceed the drinking water level of comparison (DWLOC) even with the retention of the 10X FQPA safety factor for the subset of uses considered; however, that assessment noted that adding additional uses could change estimated drinking water concentrations, which could ultimately result in changes to the risk conclusion relative to the drinking water level of comparison(s).

In December 2020, EPA released the ''Proposed Interim Decision for the Registration Review of Chlorpyrifos'' (2020 PID) for a 60-day public comment period (85 FR 78849, December 7, 2020) (FRL–10017–1). The 2020 PID concluded that ''[w]hen considering all currently registered agricultural and non-agricultural uses of chlorpyrifos, aggregate exposures are of concern.'' (Ref. 31 at pg. 19) However, the 2020 PID also noted that if one considered only the uses that result in EDWCs below the DWLOC, then aggregate exposures would not be of concern. (*Id.*) Accordingly, the 2020 PID proposed to limit applications of chlorpyrifos in this country to only 11 uses in certain regions of the United States; EPA had focused its review on those 11 geographically limited uses due to potential benefits from those uses and concluded that the EDWCs for those uses alone were below the DWLOC. This proposed path forward was intended to offer to stakeholders a way to mitigate the aggregate risk from chlorpyrifos, although as a proposal, it was not a final Agency determination and could be subject to change following public comment and stakeholder interest, perhaps in an Agency determination on a different subset of uses. Along with comments on the 2020 PID, EPA invited comments on the benefits assessments, the 2020 HHRA, draft ecological risk assessment, and 2020 DWA. EPA extended the 60-day comment period by 30 days, which then closed on March 7, 2021. EPA is currently reviewing public input and will respond to comments prior to issuing an interim decision.

3. Scientific Issues and SAPs

As noted previously, the registration review of chlorpyrifos has proven to be far more complex than originally anticipated. The OPs have presented EPA with numerous novel scientific issues that the Agency has taken to multiple FIFRA Scientific Advisory Panel (SAP) meetings since the completion of reregistration in 2006. (*Note:* The SAP is a federal advisory committee created by FIFRA section 25(d), 7 U.S.C. 136w(d), and serves as EPA's primary source of peer review for significant regulatory and policy matters involving pesticides. EPA may convene an SAP meeting to present significant regulatory, science, or policy matters involving pesticides and request that the SAP provide comments, evaluations, and recommendations on the matters submitted for its review.)

These FIFRA SAP meetings, which have included the review of new worker and non-occupational exposure methods, experimental toxicology and epidemiology, and the evaluation of a chlorpyrifos-specific PBPK–PD model, have resulted in significant developments in EPA's risk assessments generally, and, more specifically, in the study of chlorpyrifos's effects. In particular, and partly in response to issues raised in the 2007 Petition (discussed in Unit III.B. of this document), EPA has conducted extensive reviews of available data to evaluate the possible connection between chlorpyrifos and adverse neurodevelopmental effects and to assess whether the neurodevelopmental effects could be used to determine PoDs for assessing chlorpyrifos. On this particular topic, EPA has convened multiple FIFRA SAP meetings.

In 2008, the Agency presented to the FIFRA SAP a preliminary review of available literature and research on epidemiology in mothers and children following exposures to chlorpyrifos and other OPs, laboratory studies on animal behavior and cognition, AChE inhibition, and mechanisms of action. (Ref. 32) The 2008 FIFRA SAP recommended that AChE inhibition remain as the source of data for the PoDs but noted that despite some uncertainties, the CCCEH epidemiologic studies ''is epidemiologically sound'' and ''provided extremely valuable information'' for evaluating the potential neurodevelopmental effects of chlorpyrifos.

The 2010 FIFRA SAP favorably reviewed EPA's 2010 draft epidemiology framework. (Ref. 33) This draft framework, titled ''Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments in Pesticides,'' (''Epidemiologic Framework'') described the use of the Bradford Hill Criteria as modified in the Mode of Action Framework to integrate epidemiology information with other lines of evidence. As suggested by the 2010 FIFRA SAP, EPA did not immediately finalize the draft framework but instead used it in several pesticide evaluations prior to making revisions and finalizing it. EPA's Office of Pesticide Program's (OPP) finalized this Epidemiologic Framework in December 2016. (Ref. 19)

In 2012, the Agency convened another meeting of the FIFRA SAP to review the latest experimental data related to RBC AChE inhibition, cholinergic and non-cholinergic adverse outcomes, including neurodevelopmental studies on behavior and cognition effects. The Agency also performed an in-depth analysis of the available chlorpyrifos biomonitoring data and of the available epidemiologic studies from three major children's health cohort studies in the United States, including those from the CCCEH, Mount Sinai, and University of California, Berkeley. The Agency explored plausible hypotheses on mode of actions/adverse outcome pathways (MOAs/AOPs) leading to neurodevelopmental outcomes seen in the biomonitoring and epidemiology studies.

The 2012 FIFRA SAP described the Agency's epidemiology review as ''very clearly written, accurate'' and a ''very thorough review.'' (Ref. 21 at pgs. 50–52, 53) It went further to note that it ''believes that the [Agency's] epidemiology review appropriately

concludes that the studies show some consistent associations relating exposure measures to abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7 through 9 years, and attention and behavior problems at 3 and 5 years of age. . . .'' The 2012 FIFRA SAP concluded that the RBC AChE inhibition remained the most robust dose-response data, though expressed concerns about the degree to which 10% RBC AChE inhibition is protective for neurodevelopmental effects, pointing to evidence from epidemiology, *in vivo* animal studies, and *in vitro* mechanistic studies, and urged the EPA to find ways to use the CCCEH data.

Taking that recommendation into consideration, the Agency prepared a proposal for using cord blood data from the CCCEH epidemiology studies as the source of data for the PoDs, which it presented to the FIFRA SAP in April 2016. The 2016 SAP did not support the ''direct use'' of the cord blood and working memory data for deriving the regulatory endpoint, due in part to insufficient information about timing and magnitude of chlorpyrifos applications in relation to cord blood concentrations at the time of birth, uncertainties about the prenatal window(s) of exposure linked to reported effects, lack of a second laboratory to reproduce the analytical blood concentrations, and lack of raw data from the epidemiology study. (Ref. 22) Despite its critiques of uncertainties in the CCCEH studies, the 2016 FIFRA SAP stated that it ''agrees that both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% RBC AChE inhibition (*i.e.,* toxicity at lower doses).'' (*Id.* at pg. 18)

B. FFDCA Petition and Associated Litigation

1. 2007 Petition Seeking Revocation of Chlorpyrifos Tolerances

As described previously, in 2006, EPA issued the Reregistration Eligibility Decision (RED) for chlorpyrifos, which concluded that chlorpyrifos was eligible for reregistration as it continued to meet the FIFRA standard for registration. In September 2007, Pesticide Action Network North America (PANNA) and Natural Resources Defense Council (NRDC) (collectively, the Petitioners) submitted to EPA a petition (the Petition) seeking revocation of all chlorpyrifos tolerances under FFDCA section 408 and cancellation of all chlorpyrifos pesticide product registrations under FIFRA. (Ref. 34) That Petition raised several claims regarding EPA's 2006 FIFRA reregistration decision for chlorpyrifos and the active registrations in support of the request for tolerance revocations and product cancellations. Those claims are described in detail in EPA's earlier Order denying the Petition (82 FR 16581, April 5, 2017) (FRL–9960–77).

2. Agency Responses and 2017 Order Denying Petition

Ultimately, EPA denied the Petition in full on March 29, 2017 (82 FR 16581, April 5, 2017) (FRL–9960–77). Prior to issuing that Order, however, EPA issued two interim responses and a proposed rule in response to the Petition.

EPA provided the Petitioners with two interim responses on July 16, 2012, and July 15, 2014, which denied six of the Petition's claims. EPA made clear in both the 2012 and 2014 responses that, absent a request from Petitioners, EPA's denial of those six claims would not be made final until EPA finalized its response to the entire Petition. Petitioners made no such request, and EPA therefore finalized its response to those claims in the March 29, 2017 Order Denying Petition.

As background, three of the Petition's claims all related to the same issue: Whether the potential exists for chlorpyrifos to cause neurodevelopmental effects in children at exposure levels below EPA's existing regulatory standard (10% RBC AChE inhibition). Because the claims relating to the potential for neurodevelopmental effects in children raised novel, highly complex scientific issues, EPA originally decided it would be appropriate to address these issues in connection with the registration review of chlorpyrifos under FIFRA section 3(g) and decided to expedite that review, intending to finalize it in 2015, well in advance of the October 1, 2022 registration review deadline. (Ref. 35) EPA decided as a policy matter that it would address the Petition claims regarding these matters on a similar timeframe. (82 FR 16581 at 16583)

As noted earlier in this Unit, the complexity of these scientific issues precluded EPA from finishing its review according to EPA's original timeline, and the Petitioners brought legal action in the Ninth Circuit Court of Appeals to compel EPA to either issue an Order denying the Petition or to grant the Petition by initiating the tolerance revocation process. The result of that litigation was that on August 10, 2015, the Court ordered EPA to ''issue either a proposed or final revocation rule or a full and final response to the administrative [P]etition by October 31, 2015.'' (*In re Pesticide Action Network N. Am.,* 798 F.3d 809, 815 (9th Cir. 2015))

In response to that Court's order, EPA issued a proposed rule in 2015 to revoke all tolerances for chlorpyrifos (80 FR 69080, November 6, 2015) (FRL–9935–92) (2015 proposed rule), based on its unfinished registration review risk assessment. EPA acknowledged that it had had insufficient time to complete its drinking water assessment and its review of data addressing the potential for neurodevelopmental effects. Although EPA noted that further evaluation might enable more tailored risk mitigation, EPA was unable to conclude, based on the information before EPA at the time, that the tolerances were safe, since the aggregate exposure to chlorpyrifos exceeded safe levels.

On December 10, 2015, the Ninth Circuit issued a further order, in response to additional legal challenge by Petitioners, requiring EPA to take final action on its proposed revocation rule and issue its final response to the Petition by December 30, 2016. *In re Pesticide Action Network N. Am.,* 808 F.3d 402 (9th Cir. 2015). In response to EPA's request for an extension of the deadline in order to be able to fully consider the July 2016 FIFRA SAP report regarding chlorpyrifos toxicology, the Ninth Circuit ordered EPA to complete its final action by March 31, 2017. *In re Pesticide Action Network of North America* v. *EPA,* 840 F.3d 1014 (9th Cir. 2016). Following that Court's order, EPA published a Notice of Data Availability (NODA), seeking comment on EPA's revised risk assessment and water assessment and reopening the comment period on the proposal to revoke tolerances. (81 FR 81049, November 17, 2016) (FRL–9954–65)

On March 29, 2017, the EPA issued the 2017 Order Denying Petition. (82 FR 16581, April 5, 2017) (FRL–9960–77) The specific responses are described in full in that 2017 Order Denying Petition (and summarized again in the Agency's denial of objections. (84 FR 35555, July 24, 2019) (FRL–9997–06) EPA's 2017 Order Denying Petition did not contain a determination concerning the safety of chlorpyrifos. Rather, EPA concluded that, despite several years of study, the science addressing neurodevelopmental effects remained unresolved and that further evaluation of the science on this issue during the remaining time for completion of registration review was warranted. EPA therefore denied the remaining Petition claims, concluding that it was not required to complete—and would not complete—the human

health portion of the registration review or any associated tolerance revocation of chlorpyrifos without resolution of those issues during the ongoing FIFRA registration review of chlorpyrifos.

3. Objections and EPA's Denial of Objections

In June 2017, several public interest groups and states filed objections to the 2017 Order Denying Petition pursuant to the procedures in FFDCA section 408(g)(2). Specifically, Earthjustice submitted objections on behalf of the following 12 public interest groups: Petitioners PANNA and NRDC, United Farm Workers, California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, GreenLatinos, Labor Council for Latin American Advancement, League of United Latin American Citizens (LULAC), Learning Disabilities Association of America, National Hispanic Medical Association and Pineros y Campesinos Unidos del Noroeste. Another public interest group, the North Coast River Alliance, submitted separate objections. With respect to the states, New York, Washington, California, Massachusetts, Maine, Maryland, and Vermont submitted a joint set of objections. (Ref. 34), These objectors asserted that EPA erred in not making the requisite safety finding in denying the Petition and that EPA should revoke all tolerances because the available record supported a conclusion that the tolerances were unsafe.

On July 18, 2019, EPA issued a final Order denying all objections to the 2017 Order Denying Petition and thereby completing EPA's administrative denial of the petition (2019 Order Denying Objections to Petition Denial) (84 FR 35555, July 27, 2019) (FRL–9997–06). Again, the 2019 Order Denying Objections to Petition Denial did not issue a determination concerning the safety of chlorpyrifos. Rather, EPA denied the objections on the grounds that the data concerning neurodevelopmental toxicity were not sufficiently valid, complete, and reliable to meet the Petitioners' burden to present evidence supporting the request for revocation.

4. Judicial Challenge to 2019 Order Denying Objections To Petition Denial and 2021 Ninth Circuit Order

On August 7, 2019, the objectors (LULAC Petitioners) and States petitioned the Ninth Circuit for review of the 2017 Order Denying Petition and the 2019 Order Denying Objections to Petition Denial. The LULAC Petitioners and States argued that EPA was compelled to grant the 2007 Petition and revoke chlorpyrifos tolerances because: (1) EPA lacked authority to maintain chlorpyrifos tolerances without an affirmative finding that chlorpyrifos is safe; (2) EPA's findings that chlorpyrifos is unsafe in the Agency's 2014 and 2016 risk assessments compel revocation of the chlorpyrifos tolerances; and (3) The Petition provided a sufficient basis for EPA to reconsider the question of chlorpyrifos's safety and was not required to prove that a pesticide is unsafe.

On April 29, 2021, the Ninth Circuit issued its decision, finding that when EPA denied the 2007 Petition to revoke chlorpyrifos tolerances, it was essentially leaving those chlorpyrifos tolerances in effect, which, the Court noted, the FFDCA only permits if EPA has made an affirmative determination that such tolerances were safe. (*League of United Latin Am. Citizens (LULAC)* v. *Regan,* 996 F.3d. 673 (9th Cir. 2021)) Although EPA argued that it was not compelled to reconsider its safety determination because the 2007 Petition had failed to meet the threshold requirement of providing reliable evidence that the tolerances were unsafe, the Court found that the Petition provided the necessary ''reasonable grounds,'' which triggered EPA's duty to ensure the tolerances were safe. (*Id.* at pg. 695) Since the 2017 Order Denying Petition and 2019 Order Denying Objections to Petition Denial failed to make any safety determinations for chlorpyrifos, the Court concluded that EPA violated the FFDCA by leaving those tolerances in place without the requisite safety findings. (*Id.* at pgs. 678, 695 and 696 (declaring that EPA's action was a ''total abdication of EPA's statutory duty under the FFDCA'')) Moreover, in light of the record before the Court, including the 2016 HHRA indicating that the current chlorpyrifos tolerances were not safe, the Court found EPA's denial of the 2007 Petition to be arbitrary and capricious. (*Id.* at pg. 697) Based on the available record, the Court concluded that EPA must grant the Petition and issue a final rule modifying or revoking the tolerances under FFDCA section 408(d)(4)(A)(i). (*Id.* at pg.701)

The Court recognized that, since the litigation had commenced, EPA had been continuing to evaluate chlorpyrifos in registration review and had issued the 2020 PID and convened another FIFRA SAP; the Court noted that such information could be relevant to a safety determination. (*Id.* at pg. 703) The Court allowed that if the new information could support a safety determination, EPA might issue a final rule modifying chlorpyrifos tolerances rather than revoking them. But the Court warned that EPA was to act ''immediately'' and not engage in ''further factfinding.'' (*Id.*) The Court chided that taking ''nearly 14 years to publish a legally sufficient response to the 2007 Petition'' was an ''egregious delay'' and ''EPA's time is [ ] up.'' (*Id.*) As a result, the Court ordered EPA to: (1) Grant the 2007 Petition; (2) Issue a final rule within 60 days of the issuance of the mandate that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances, provided that such modification is supported by a safety finding, and (3) Modify or cancel related FIFRA registrations for food use in a timely fashion. (*Id.* at 703 and 704) Since the mandate was issued on June 21, 2021, the deadline for issuing the final rule was August 20, 2021, less than four months from the date the Court issued its decision.

IV. The Final Rule

As noted in the previous Unit, the Ninth Circuit directed EPA to act on the 2007 Petition by granting it and issuing a final rule concerning the chlorpyrifos tolerances. The Court allowed that that rule could either revoke all tolerances or modify tolerances, as long as EPA issued, concurrently with such modification, a determination that such modified tolerances were safe. The Court, impatient with EPA's failure to comply with the FFDCA when it left chlorpyrifos tolerances in place without the requisite safety finding, directed EPA to issue that final rule very quickly, *i.e.,* 60 days after the issuance of the mandate.

Given the limited window for issuing the rule and the Court's directive not to engage in additional fact-finding or further delay, the Agency focused in its rulemaking on the data and completed assessments available at the time and whether they were adequate to support a safety finding for the chlorpyrifos tolerances. EPA did not conduct additional analyses or engage in any additional fact-finding or scientific review, due to the limited time. Thus, the rule was based on available information that EPA had already reviewed and incorporated into risk assessments and/or regulatory documents.

The most recent risk assessments and regulatory documents were the 2020 HHRA (Ref. 2), 2020 DWA (Ref. 30), and the 2020 PID (Ref. 31). These documents were not in the record before the Ninth Circuit, although as noted previously, the Court allowed that the new information could be used in support of

a safety finding as appropriate. Thus, the Agency considered, in addition to other previously developed documents on chlorpyrifos as cited in the final rule (Ref. 1), whether the 2020 documents would support a safety finding for the chlorpyrifos tolerances.

EPA's final rule follows the Agency's practice of assessing risk described in Unit II.B. of this document. Relying on the Agency's existing analyses on chlorpyrifos, EPA examined the toxicological profile of chlorpyrifos to identify potential hazards and identify PoDs for assessing risk. The Agency considered the appropriate uncertainty factors, including the appropriate FQPA safety factor, for setting the level of concern. EPA also examined potential exposures of chlorpyrifos in food and drinking water, as well as from uses that might result in exposure to residues in residential settings. Finally, EPA aggregated all anticipated exposures to determine if the existing tolerances would meet the safety standard of the FFDCA. The rest of this Unit summarizes the analysis and conclusions of the 2021 final rule. For further detail, see Ref. 1.

In the 2021 final rule, EPA described the two primary toxicological effects associated with chlorpyrifos: Acetylcholinesterase inhibition and neurodevelopmental effects. These effects are discussed in greater detail in Unit III.A.1.b. of this document. As EPA noted, the mode of action of chlorpyrifos of affecting the nervous system through inhibition of AChE is well-established, as well as its use as the basis for PoD for assessing risks from chlorpyrifos as well as other OPs. In addition, EPA acknowledged and addressed the extensive body of information studying the potential effects on neurodevelopment in infants and children following exposure to OPs, including chlorpyrifos. EPA recognized that available data provide qualitative support for chlorpyrifos to potentially impact the developing mammalian brain and acknowledged the observed associations between prenatal chlorpyrifos exposure and neurodevelopmental outcomes in the epidemiological data. But EPA also noted that due to uncertainties in the data, including the lack of specific exposure information, EPA was precluded from being able to make a causal linkage between chlorpyrifos exposure and the outcomes found in the epidemiological studies. As a result, while there is a lot of information about the potential association between chlorpyrifos and neurodevelopmental outcomes in infants and children, there was insufficient information at the time of the final rule to draw conclusions about the dose-response relationship between chlorpyrifos and those outcomes.

As a result, EPA relied on the RBC AChE inhibition results from laboratory animals to derive PoD, consistent with the 2006 chlorpyrifos RED, the 2006 OP cumulative risk assessment, and other single chemical OP risk assessments. To account for the unresolved scientific uncertainties associated with the potential for neurodevelopmental effects—and to be protective of those effects—the Agency retained the default 10X FQPA safety factor. As noted earlier, EPA is required to apply this tenfold margin of safety to account for potential pre- and postnatal toxicity, unless it has reliable data to support a determination that a different margin of safety would be protective. (21 U.S.C. 346a(b)(2)(C)) EPA explained that the Agency's WOE analysis indicates there is qualitative evidence of a potential effect on the developing brain associated with chlorpyrifos exposures; however, uncertainties remain about the levels at which those neurodevelopmental outcomes may occur. Therefore, EPA retained the 10X FQPA safety factor in recognition of the fact that despite extensive analysis of the available data, the science concerning neurodevelopmental effects remains unresolved and thus presents an uncertainty concerning the potential pre- and postnatal toxicity. EPA did not believe it had sufficient reliable data to determine that a lower safety factor would be protective of infants and children.

To assess risk, EPA estimated exposures to chlorpyrifos from approved uses. As the FFDCA requires, EPA examined exposures for chlorpyrifos uses that resulted in residues of chlorpyrifos in or on food, in drinking water, and in residential (or non-occupational) settings. EPA's assessment of dietary (food only) exposures relied on the Agency's Dietary Exposure Evaluation Model and Calendex software with the Food Commodity Intake Database (DEEM–FCID version 3.16/Calendex) to estimate exposure by combining data on human consumption amounts with residue values in food commodities. These food-only exposure assessments were highly refined, based both on field trial data and monitoring data.

In drinking water, EPA estimated exposures of chlorpyrifos and chlorpyrifos-oxon, a metabolite of chlorpyrifos. The most recent drinking water assessment that examined all approved uses of chlorpyrifos was conducted in 2016; thus, the Agency relied on that assessment in evaluating the safety of the chlorpyrifos tolerances. While a more recent drinking water assessment had been conducted in 2020, that newer assessment only evaluated a subset of the approved uses and thus was incomplete for purposes of assessing the aggregate exposures of chlorpyrifos. Based on the 2016 drinking water assessment then, EPA evaluated estimated concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water resulting from approved uses of chlorpyrifos.

There are few remaining uses of chlorpyrifos that result in residential or non-occupational exposures. EPA evaluated those uses and used estimated exposures from use on golf courses in the overall aggregate risk assessment since golf course uses result in the highest estimated exposures among remaining residential (non-occupational) uses.

In accordance with the requirements of the FFDCA, EPA considered aggregate exposures of chlorpyrifos in all food, drinking water, and residential settings. EPA used a DWLOC approach, in which EPA compared estimated drinking water exposures to a DWLOC, *i.e.,* a value corresponding to the maximum amount of chlorpyrifos exposures that may be present in drinking water without resulting in aggregate exposures of chlorpyrifos that would result in unsafe exposures. Where the estimated drinking water concentrations for chlorpyrifos exceed the DWLOC, the Agency concluded that aggregate exposures would be unsafe because the chlorpyrifos residues in drinking water, when combined with food and residential exposures, would exceed safe levels of chlorpyrifos exposure. For chlorpyrifos and chlorpyrifos-oxon, the Agency calculated DWLOCs for acute and steady-state exposures for several population subgroups. (Ref. 2 at pgs. 15, and 44 through 47)

As noted in the final rule, EPA's assessment concluded that exposures to chlorpyrifos from food and residential exposures individually or together did not exceed EPA's levels of concern. However, the Agency found that when combined with the exposures in drinking water from all registered uses of chlorpyrifos, the aggregate exposure to chlorpyrifos exceeded safe levels. The estimated drinking water concentrations calculated in the 2016 drinking water assessment exceeded the DWLOC. The Agency recognized that the 2020 PID proposed a subset of uses that might result in exposures below the Agency's level of concern if uses were eliminated and significant changes to the labels were made, including use cancellations

and geographic limitations, among others. However, as no registration or label changes had been effectuated such that EPA could rely on them at the time of the final rule, EPA assessed aggregate exposures expected from all registered uses.

Ultimately, EPA concluded that, based on the information before the Agency and taking into consideration all the registered uses for chlorpyrifos at the time, it was unable to determine that the chlorpyrifos tolerances were safe, since aggregate exposures to chlorpyrifos exceeded safe levels. Therefore, EPA issued a final rule revoking all tolerances for chlorpyrifos contained in 40 CFR 180.342. The prepublication copy of the final rule was posted on the EPA website on August 18, 2021, and the final rule published in the **Federal Register** on August 30, 2021 (Ref. 1). The final rule became effective on October 29, 2021. EPA provided a grace period of six months to ease the transition for growers and accommodate international trade considerations, by setting an expiration date for the chlorpyrifos tolerances of February 28, 2022.

The final rule provided that, pursuant to FFDCA section 408(g), 21 U.S.C. 346a, any person could file an objection to any aspect of the regulation, request a hearing on those objections, and requests for stay of the final rule. The objections, requests for hearing, and requests for stay received are summarized in Units V. and VI. of this document.

V. Objections, Requests for Hearing, and Requests for Stay

The Agency received several filings of objections, four requests for hearing on those objections, and several requests seeking a stay or extension of the rule. EPA briefly summarizes the objections, hearing requests, and stay requests, and responds to them in the next three units of this document.

Individual objections were filed by the following: The Amalgamated Sugar Company; the American Crystal Sugar Company; the American Farm Bureau Federation; the American Soybean Association; the California Citrus Quality Council; the Cherry Marketing Institute; the Coalition of Organophosphate (OP) Registrants; Gharda Chemicals International, Inc.; the Michigan Vegetable Council. Inc.; the Minor Crop Farmer Alliance; the Republic of Colombia; the Southern Minnesota Beet Sugar Cooperative; and 99 independent growers of soybean, corn, wheat, cotton, rice, alfalfa, and sugarbeet. Several entities also filed objections jointly in response to the final rule as follows: American Sugarbeet Growers Association and U.S. Beet Sugar Association (collectively, Sugarbeet Associations) CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE) (collectively, CLA/RISE); two sugarbeet farmers filed a joint objection; numerous growers, retailers, co-ops, applicators, refiners, crop consultants, and other agricultural stakeholders signed on to a set of objections (collectively, the Agricultural Retailers Association, *et al.*).

The Agency has grouped the objections submitted into the following five categories:

(i) *Objections to the scope of EPA's final rule revoking tolerances.* Several Objectors objected to the final rule revoking all chlorpyrifos tolerances. Rather than revoke all tolerances, the Objectors assert that EPA should have modified tolerances by retaining the tolerances for those 11 high-benefit crops identified in the 2020 PID. Some of those objectors also argued that EPA had an obligation to harmonize its tolerance revocations with action under FIFRA (*e.g.,* canceling uses) in order to allow for the retention of the 11 tolerances identified in the PID. Finally, a number of Objectors requested that EPA retain ''import tolerances'' for chlorpyrifos commodities, on the grounds that those tolerances would not contribute to drinking water exposures, which are driving risks.

(ii) *Retention of the 10X FQPA safety factor.* Several objectors assert that EPA should not have retained the 10X FQPA safety factor due to scientific uncertainties tied to epidemiological data that objectors believe is invalid, incomplete, and unreliable. Objectors argue that EPA should have reduced the FQPA safety factor to 1X based on the rest of the available data for assessing the toxicity of chlorpyrifos.

(iii) *Objections related to drinking water.* Several objectors assert that EPA erred in relying on the 2016 Drinking Water Assessment (DWA), instead of the more refined 2020 DWA for assessing drinking water exposures. Objectors believe the Agency's approach is highly conservative and inaccurate. In addition, Gharda asserts that the Agency erred in assessing chlorpyrifos-oxon in the aggregate assessment of chlorpyrifos.

(iv) *Procedural considerations.* A number of objectors argue that EPA has failed to provide adequate due process by not addressing comments submitted on the 2015 proposed rule to revoke chlorpyrifos tolerances, and in the chlorpyrifos registration review process. Moreover, an objector raised due process concerns with the delayed opening of the Agency's Federal eRulemaking Portal for submitting objections electronically. Finally, some objectors argued that the Agency failed to provide meaningful opportunity for interagency input under Executive Order 12866.

(v) *Objections that, as a matter of law, do not provide a basis for leaving the tolerances in place.* Several Objectors requested that EPA rescind the final rule due to the impacts on growers and the environment from the loss of the pesticide. One objector believes that EPA improperly considered occupational exposure in the final rule based on an Agency press statement. Other objectors assert that the final rule is improper because it deviates from an unspecified Codex Alimentarius international standard of 0.05 mg/kg for chlorpyrifos. Some objectors assert that the implementation timeline specified by EPA was too short and that the final rule should have provided guidance for chlorpyrifos products in the channels of trade and considered the implications for existing stocks of chlorpyrifos. Finally, Gharda objects that the final rule violates their substantive due process rights.

Four objectors also included requests for evidentiary hearings. Three of these requesters—the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute—each request evidentiary hearings to demonstrate that the best available science, including the 2020 PID, supports a finding that chlorpyrifos tolerances can remain in effect for soybeans, sugarbeets, and Michigan tart cherries, respectively. Gharda submitted the fourth request for an evidentiary hearing on its objection that the chlorpyrifos-oxon was not relevant to the Agency's aggregate risk assessment. While Gharda believes the Agency has all the evidence necessary to make this determination, it still requests a hearing ''[t]o the extent that EPA believes that a fact issue is presented by this data.''

Finally, EPA received written requests to stay the effective date of the final rule from several objectors. The Sugarbeet Associations and Gharda both argue that the criteria set out in the FDA's regulations regarding stays of administrative proceedings at 21 CFR 10.35 require that EPA stay the effectiveness of the final rule. Specifically, these Objectors argue that they will suffer irreparable injury absent a stay, that their objections are not frivolous and are undertaken in good faith, that the public interest favors a stay, and the delay caused by a stay is not outweighed by the public health or public interest. Several other Objectors

do not specifically address the regulatory criteria set forth at 21 CFR 10.35, but request that EPA stay the effectiveness of the final rule until EPA can address the issues raised in their various objections. Some objectors simply request an extension of the timeframe for implementation of the rule.

VI. Response to Requests for Hearing

EPA denies each of the four requests for evidentiary hearing on objections. Three objectors requested an evidentiary hearing on their objection that EPA should have retained tolerances for certain crops based on the conclusions of the 2020 PID; these requests are denied for failure to make a sufficient evidentiary proffer. Gharda also requested a hearing on its objection to EPA's assessment of chlorpyrifos-oxon exposures in drinking water; this request is denied as unnecessary for the purpose of receiving evidence and because the likely factual issue has no material impact on Agency's decision to revoke tolerances. EPA's substantive responses to the underlying objections follow in the next Unit, *i.e.,* Unit VII.C.1. and VII.C.3.b., respectively. Under EPA's regulations, EPA may treat these objections as a group and rule on them only after ruling on the request for an evidentiary hearing on that objection. 40 CFR 178.30(c)(2) Therefore, EPA is addressing these hearing requests before responding to objections in the next Unit.

A. The Standard for Granting an Evidentiary Hearing

EPA has established regulations governing objections to tolerance rulemakings and tolerance petition denials and requests for hearings on those objections. (40 CFR part 178; 55 FR 50282, December 5, 1990) (FRL–3688–4)) Those regulations prescribe both the form and content of hearing requests and the standard under which EPA is to evaluate requests for an evidentiary hearing.

As to the form and content of a hearing request, the regulations specify that a hearing request must include: (1) A statement of the factual issues on which a hearing is requested and the requestor's contentions on those issues; (2) A copy of any report, article, or other written document ''upon which the objector relies to justify an evidentiary hearing;'' (3) A summary of any other evidence relied upon to justify a hearing; and (4) A discussion of the relationship between the factual issues and the relief requested by the objection. (40 CFR 178.27)

The standard for granting a hearing request is set forth in 40 CFR 178.32. That section provides that a hearing will be granted if EPA determines that the ''material submitted'' shows all of the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. An evidentiary hearing will not be granted on issues of policy or law.

(2) There is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary. An evidentiary hearing will not be granted on the basis of mere allegations, denials, or general descriptions of positions and contentions, nor if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged.

(3) Resolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought. (40 CFR 178.32(b))

This provision essentially imposes four requirements upon a hearing requestor. First, the requestor must show it is raising a question of fact, not one of law or policy. Hearings are for resolving factual issues, not for debating law or policy questions. Second, the requestor must demonstrate that there is a genuine dispute as to the issue of fact. If the facts are undisputed or the record is clear that no genuine dispute exists, there is no need for a hearing. Third, the requestor must show that the disputed factual question is material, *i.e.,* that it is outcome determinative with regard to the relief requested in the objections. Finally, the requestor must make a sufficient evidentiary proffer to demonstrate that there is a reasonable possibility that the issue could be resolved in favor of the requestor. Hearings are for the purpose of providing objectors with an opportunity to present evidence supporting their objections as the regulation states, hearings will not be granted on the basis of ''mere allegations, denials, or general descriptions of positions or contentions.'' (40 CFR 178.32(b)(2))

The Court in *National Corn Growers Ass'n* v. *EPA* noted that the FFDCA and EPA's regulations ''establish a 'summary-judgment type' standard for determining whether to hold a hearing: The EPA must hold a hearing if it determines an objection raises a material issue of fact.'' (613 F.2d 266, 271 (DC Cir. 2010)) In addition, the Court applied a ''necessarily deferential'' standard of review in determining whether an issue was material, looking to whether the agency ''has given adequate consideration to all relevant evidence in the record.'' (*Id.* at pgs. 271 and 272) ''Mere difference in the weight or credence given to particular scientific studies . . . are insufficient'' to overturn an agency conclusion regarding whether an objection raises a material issue of fact. (*Id.* at pg. 271)

EPA's hearing request requirements are based heavily on FDA regulations establishing similar requirements for hearing requests filed under other provisions of the FFDCA (53 FR 41126, 41129, October 19, 1988) (FRL–8372–5). FDA pioneered the use of summary judgment-type procedures to limit hearings to disputed material factual issues and thereby conserve agency resources. FDA's use of such procedures was upheld by the Supreme Court in 1972, (*Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609 (1973)), and, in 1975, FDA promulgated generic regulations establishing the standard for evaluating hearing requests (40 FR 22950, May 27, 1975). It is these regulations upon which EPA relied in promulgating its hearing regulations in 1990.

Unlike EPA, FDA has had numerous occasions to apply its regulations on hearing requests. FDA's summary of the thrust of its regulations, which has been repeatedly published in the **Federal Register** in Orders ruling on hearing requests over the last 24 years, is instructive on the proper interpretation of the regulatory requirements. That summary states:

> A party seeking a hearing is required to meet a threshold burden of tendering evidence suggesting the need for a hearing.' [ ] An allegation that a hearing is necessary to sharpen the issues' or fully develop the facts' does not meet this test. If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one.
>
> A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held. [ ] FDA need not grant a hearing in each case where an objection submits additional information or posits a novel interpretation of existing information. [ ] Stated another way, a hearing is justified only if the objections are made in good faith and if they 'draw in question in

a material way the underpinnings of the regulation at issue.' Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy.

(49 FR 6672 at 6673, February 22, 1984; 72 FR 39557 at 39558, July 19, 2007 (citations omitted) EPA has been guided by FDA's application of its regulations in this proceeding.

Congress confirmed EPA's authority to use summary judgment-type procedures with hearing requests when it amended FFDCA section 408 in 1996. Although the statute had been silent on this issue previously, the FQPA added language specifying that when a hearing is requested, EPA ''shall . . . hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections'' (21 U.S.C. 346a(g)(2)(B)). This language grants EPA broad discretion to determine whether a hearing is ''necessary to receive factual evidence'' to objections (H.R. Rep. No. 104–669, at pg. 49 (1996)).

B. American Soybean Association, Sugarbeet Associations, and Cherry Marketing Institute Hearing Requests

1. Summary of Hearing Request

Three Objectors—the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute—requested evidentiary hearings based on their objections that EPA erred in revoking tolerances covering chlorpyrifos residues for their particular commodity, *i.e.,* soybean, sugarbeet, and cherry, respectively. (Refs. 36 through 38) These Objectors root this claim in statements made in the 2020 PID, in which EPA proposed a subset of 11 registered uses for retention as an option to mitigate dietary risks from uses of chlorpyrifos. The 2020 PID noted that if uses were limited in accordance with that proposal, EPA would be able to determine that such uses would ''not pose potential risks of concern.'' Because, at the time of the final rule, uses were not so limited, EPA revoked all tolerances. These Objectors assert that such a conclusion was inconsistent with the conclusions in the 2020 PID and thus not supported by factual evidence. As a result, these Objectors request a hearing on that objection to dispute the underlying factual basis for EPA's decision to revoke all tolerances and, in particular, for their tolerance of interest.

Specifically, the American Soybean Association notes that soybeans were included among the 11 high-benefit crop uses of chlorpyrifos that the 2020 PID described as ''not pos[ing] potential risks of concern with a Food Quality Protection Act (FQPA) safety factor of 10X.'' (Ref. 36 at pg. 4) In addition, the American Soybean Association asserts that EPA has determined ''elsewhere in its administrative record'' that it is reasonably certain soybean uses will not pose harm from aggregate dietary exposures. (*Id.*) Therefore, the American Soybean Association challenges EPA's determination in the final rule that soybean uses of chlorpyrifos might pose dietary risks of concern as factually inaccurate and contrary to the finding in the 2020 PID, and requests an evidentiary hearing ''to dispute this underlying factual inaccuracy.'' (*Id.*) Similarly, the Sugarbeet Associations argue that EPA's decision to revoke tolerances for the 11 high-benefit crop uses of chlorpyrifos identified in the 2020 PID is arbitrary and capricious and request an evidentiary hearing ''to demonstrate that the best available science, including the 2020 PID, supports a finding that tolerances for sugarbeets can remain in effect.'' (Ref. 37 at pg. 6) Lastly, the Cherry Marketing Institute argues that EPA's decision to revoke tolerances for chlorpyrifos in the Michigan tart cherry industry due to dietary risks is factually inaccurate, in light of EPA's identification of tart cherries among the 11 high-benefit crop uses of chlorpyrifos identified in the 2020 PID. (Ref. 38 at pg. 2) The Cherry Marketing Institute allege that an unspecified ''drinking water assessment and a dietary assessment'' provide that the Michigan tart cherry industry's use of chlorpyrifos meets FFDCA safety standards. (*Id.* at pg. 1) The Cherry Marketing Institute therefore requests an evidentiary hearing ''to further convey [its] concerns with EPA's determination'' to revoke chlorpyrifos tolerances. (*Id.* at pg. 2)

2. Denial of Hearing Request

The evidentiary hearing requests submitted by the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute do not meet the regulatory standard for granting an evidentiary hearing request set forth in 40 CFR 178.32 and are therefore denied.

As noted previously, the purpose for holding hearings is ''to receive factual evidence.'' (21 U.S.C. 346a(g)(2)(B); 53 FR 41126 at 41129 (''Hearings are for the purpose of gathering evidence on disputed factual issues . . . .'')) Therefore, at a bare minimum, a requestor must identify evidence relied upon to justify a hearing and either submit copies of that evidence or summarize it. (40 CFR 178.27)

None of these Objectors proffers any factual evidence to support their request for an evidentiary hearing. Other than offering that the Agency's determinations in the final rule were inconsistent with the 2020 PID, these Objectors refer to a hearing as an opportunity to dispute the Agency's factual conclusions regarding the risks posed by the use of chlorpyrifos on their particular commodity. As noted previously, ''[a]n allegation that a hearing is necessary to sharpen the issues' or fully develop the facts' does not meet this test. If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one.'' (49 FR 6672 at 6673, February 22, 1984; 72 FR 39557 at 39558, July 19, 2007) (citing *Georgia Pacific Corp* v. *EPA,* 671 F.2d 1235, 1241 (9th Cir. 1982)) The statute requires that the objector identify actual evidence; however, the Objectors point to no additional factual evidence that they would offer for review in this evidentiary hearing. Failing to identify any factual evidence that the Objectors would like to be considered in a hearing, the Objectors' hearing request fails to proffer the requisite evidence.

Even viewed in the most favorable light, these Objectors merely proffer the Agency's own statements in its risk assessments and the 2020 PID and unspecified references to statements ''elsewhere in the administrative record.'' As a result, EPA concludes that this submission is sufficiently lacking to be considered an evidentiary proffer. Given that the purpose of a hearing is to gather or receive evidence, proffering evidence already considered and relied upon by EPA is not grounds for holding a hearing. Furthermore, EPA has already considered and found inadequate the evidence in the record to support retaining individual tolerances without a change in registrations, and it is difficult to understand, how, as a matter of law, this same evidence would justify the opposite conclusion, given the same underlying facts. At bottom, these objectors' proffer fails to ''identify'' evidence which would, if established, resolve an issue in the objectors' favor.

Moreover, the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute have all failed to demonstrate that there is a ''genuine and substantial issue of fact for resolution at a hearing.'' (40 CFR 178.32(b)(1)) Whether EPA was arbitrary and capricious in revoking the soybean, sugarbeet, and cherry tolerances is a question of law, not of fact. Contrary to what these objectors assert, EPA does

not assess safety of tolerances based upon the risks posed by use on a single commodity. Under the FFDCA, EPA is required to assess aggregate exposures, *i.e.,* exposure to the pesticide from use on that particular commodity, as well as use on all other commodities, contributions to drinking water from all registered uses, and exposures in non-occupational settings. Furthermore, to the extent there is a factual question here, it is not in dispute. EPA does not dispute its own scientific conclusions and findings in the 2020 PID that the Agency could support a safety determination for the very limited and specific subset of uses identified in that document. The problem is that at the time of the final rule, the Agency did not have a basis for assuming that uses would be limited in accordance with the 2020 PID mitigation proposal. Thus, as a legal matter, EPA could not rely on those scientific findings to support leaving the tolerances in place at the time of the final rule. Ultimately, this issue comes down to whether EPA properly interpreted its obligation under the FFDCA in assessing aggregate exposure to chlorpyrifos, and that is ultimately a question of law and not one of fact. Hearings are not granted on legal questions. (40 CFR 178.32(b)(1)) Accordingly, the hearing requests of the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute are denied.

EPA responds to the objection concerning whether EPA was justified in revoking all chlorpyrifos tolerances in Unit VII.C.1.a. of this document.

C. Gharda Chemicals International, Inc. Hearing Request

1. Summary of Hearing Request

In a footnote in a section of its objections alleging that EPA failed to adequately consider certain relevant scientific information, Gharda says, ''Gharda respectfully submits that EPA has all of the scientific data at its disposal to find that chlorpyrifos oxon is not relevant to EPA's aggregate exposure assessment under the FFDCA. To the extent that EPA believes that a fact issue is presented by this data, Gharda respectfully requests a hearing.'' (Ref. 39 at pg. 34) Although the first sentence of Gharda's footnote indicates that Gharda does not believe that a hearing is necessary, which should settle the matter, the second sentence introduces some ambiguity that compels a response as a matter of completeness. So, as discussed later in this document, EPA considers whether an evidentiary hearing on Gharda's objection to EPA's assessment of chlorpyrifos-oxon is warranted and determines that it is not.

On its face, Gharda's request for a hearing fails to proffer any evidence that Gharda believes warrants an evidentiary hearing. The specific request refers simply to ''scientific data'', which is so vague as to not be an evidentiary proffer at all. Nevertheless, taking into consideration the whole of Gharda's objection concerning the assessment of chlorpyrifos-oxon, EPA notes that Gharda references two documents: (i) A drinking water study submitted to EPA by Corteva in December 2020 (*Study of Cholinesterase Inhibition in Peripheral Tissues in Sprague Dawley Rats Following Exposure to Chlorpyrifos Oxon in Drinking Water for 21 Days* (MRID 51392601) (''Corteva Oxon Study'')) and (ii) A Declaration of Dr. Richard Reiss, dated October 21, 2021 and included as an exhibit attached to Gharda's Objections to the final rule, offering opinions on the meaning of the Corteva Oxon Study (''Reiss Declaration''). (*Id.* at pg. 32) Also mentioned within the same section of Gharda's submission as its objection relating to chlorpyrifos-oxon are two other documents: (i) Comments filed by Dow AgroSciences LLC (DAS) (now doing business as Corteva Agriscience) on January 17, 2017 on the *Chlorpyrifos: Tolerance Revocations; Notice of Data Availability and Request for Comment* (81 FR 81049) and its accompanying assessments, including the 2016 DWA; and (ii) A Response to Objections document filed by DAS on April 18, 2019 regarding objections submitted by PANNA, NRDC, and others to EPA's March 29, 2017 Order denying the 2007 Petition. (*Id.* at 31) Because Gharda refers to these documents only in the context of challenging the Agency's use of the 2016 DWA in general and not with regard to the chlorpyrifos-oxon objection specifically, EPA concludes that Gharda is not proffering those documents in support of its objection on the assessment of chlorpyrifos-oxon.

Gharda points to the Corteva Oxon Study as support for its objection that the chlorpyrifos-oxon was not relevant to, and should not have been included in, EPA's aggregate risk assessment. Gharda asserts, quoting from the Reiss Declaration, that the Corteva Oxon Study found ''(a) no detectable circulating chlorpyrifos oxon in blood, (b) no statistically significant AChE inhibition in either RBC or brain, and (c) an absence of clinical signs of toxicity or markers of exposure,'' and therefore nullified EPA's assumption in the 2020 DWA ''that chlorpyrifos oxon is more toxic that the parent chlorpyrifos for drinking water exposure purposes.'' (*Id.* at pg. 32) As a result, Gharda argues that this study shows that ''drinking water risks associated with the oxon are not a risk concern for any agricultural uses of chlorpyrifos and should not be part of the EPA's aggregate risk assessment or serve as a basis for limiting uses of chlorpyrifos.'' (*Id.* at pgs. 32 and 33) According to Gharda, EPA has received this study but has failed to review it. Gharda argues that EPA's failure to consider this study means that the final rule rests on incomplete information and is arbitrary and capricious. (*Id.* at pgs. 33 through 34) Therefore, giving Gharda the benefit of the doubt, EPA finds that the Corteva Oxon Study is being proffered by Gharda for the Agency's consideration in determining whether a factual issue is raised that warrants an evidentiary hearing. Similarly, because Gharda relies heavily on the Reiss Declaration for its allegations concerning the Corteva Oxon Study, EPA finds that Gharda is proffering that declaration as evidence as well.

2. Denial of Hearing Request

EPA denies Gharda's hearing request under both its broad discretionary authority found in FFDCA section 408(g)(2) and under the regulatory standard in 40 CFR 178.32. As an initial matter, the equivocating and vague nature of Gharda's hearing request makes it difficult to discern whether Gharda has submitted a request for an evidentiary hearing that meets even the basic form and content criteria of EPA's regulations. (40 CFR 178.27) First, EPA's regulations require a specific request for an evidentiary hearing and a statement of the factual issue on which the hearing is requested. (40 CFR 178.27(a) and (b)) While Gharda ''respectfully requests a hearing,'' it is only to the extent EPA finds a factual issue warranting one. (Ref. 39 at pg. 34) Gharda asserts many things in this particular objection concerning what Gharda believes is EPA's failure to consider relevant scientific data, including failure to consider the Corteva Oxon Study, which Gharda asserts would support a conclusion that chlorpyrifos-oxon in drinking water is not relevant for chlorpyrifos risk assessment purposes. That is not a clear statement of the factual issue on which EPA should evaluate the request for a hearing. (40 CFR 178.27(b)) Moreover, as discussed previously, it is difficult to discern exactly what evidence Gharda is proffering—''all scientific data'' in EPA's files or just the Corteva Oxon Study. (40 CFR 178.27(c)) Finally, Gharda makes no attempt to ''include a discussion of the relationship between

the factual issues and the relief requested by the objection.'' (40 CFR 178.27(e)) Gharda seems to be arguing that if the chlorpyrifos-oxon was not relevant to the Agency's assessment, it would somehow change the outcome of the final rule, but Gharda fails to explain how consideration of that study would ultimately impact the Agency's conclusions concerning the safety of chlorpyrifos. In order to evaluate this ''hearing request'', EPA has had to discern from context what the factual issue is and what Gharda specifically hopes to accomplish with this evidence. This is contrary to EPA's regulations, which place the burden of presenting evidence upon which the objector relies to justify an evidentiary hearing on the objector, not on EPA. (40 CFR 178.27(c) and (d)) It appears that Gharda in its comment is trying to flip the burden for demonstrating whether an evidentiary hearing is necessary onto EPA; as such EPA believes that Gharda has failed to meet a threshold burden of submitting a hearing request that meets the basic criteria for such submissions under 40 CFR 178.27.

Significantly, by its own terms, Gharda does not believe that a hearing is necessary for the Agency to receive factual evidence, since the Agency already ''has all of the scientific data at its disposal'' to evaluate this objection. (Ref. 39 at pg. 34) As noted previously, FFDCA directs EPA to ''hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections'' (21 U.S.C. 346a(g)(2)(B)) This language was added to the FFDCA by the FQPA in 1996, after EPA promulgated its evidentiary hearing regulations, and EPA views it as providing broad discretion to evaluate whether a hearing is necessary, even if the requirements in 40 CFR 178.32 are met. EPA does not interpret this language as requiring it to hold a hearing in any instance where factual evidence relevant to a material issue of fact is proffered (essentially the standard set forth in 40 CFR 178.32); rather, EPA construes the statutory language as requiring it to hold a hearing only where it determines a hearing is necessary to receive such proffered evidence. In other words, a party wishing to obtain a hearing must not only satisfy the requirements of 40 CFR 178.32, it must also show that an evidentiary hearing is necessary for the presentation of proffered evidence to the Agency.

In this particular instance, Gharda states that EPA already has all the scientific data necessary to evaluate this issue and thus does not believe that a hearing is necessary to address the relevance of the oxon issue. EPA agrees. Because EPA already has the Corteva Oxon Study in its files, EPA has determined that a hearing is not necessary to receive that evidence. This conclusion is bolstered by EPA's determination that ultimately, consideration of this study would not materially impact EPA's conclusions regarding the safety of chlorpyrifos, since (as discussed later in this unit) EPA could not support a safety finding for chlorpyrifos based on consideration of only the chlorpyrifos (and not the oxon) concentrations in drinking water.

Moreover, in examining the evidentiary proffer of the Reiss Declaration, EPA concludes that a hearing would not be appropriate for receiving that evidence. ''An evidentiary hearing will not be granted on the basis of mere allegations . . . or general descriptions of positions and contentions. . . .'' (40 CFR 178.32(b)(2)) The Reiss Declaration contains a composite of conclusory statements of interpretation of the Corteva Oxon Study, with no elucidation of how Dr. Reiss arrived at those conclusions. (Ref. 39 at pgs. 113 through 132) One paragraph simply refers to a ''prior study'' to illustrate an example of the oxon causing lower levels of brain AChE inhibition than chlorpyrifos, but no citation to that study is provided. (*Id.* at pg. 120, paragraph 26) Paragraph 27, which Gharda quotes for its objections, concludes that the Corteva Oxon Study ''found (a) no detectable circulating chlorpyrifos oxon in blood, (b) no statistically significant AChE inhibition in either RBC or brain, and (c) an absence of clinical signs of toxicity or markers of exposure.'' (*Id.* at pg. 121, paragraph 27) But that is it. There is no explanation of how Dr. Reiss came to those conclusions based on the study or what information provided in the study that supports these conclusions. Therefore, with regard to the Corteva Oxon Study, EPA finds that a hearing is not warranted to receive the Reiss Declaration, since the statements contained therein appear to contain mere allegations and conclusions.

In applying the criteria for granting a hearing, EPA looks first to the question of whether there is a genuine and substantial issue of fact. (40 CFR 178.32(b)(1)) As noted previously, Gharda has failed to provide a clear statement of the factual issue to be resolved at an evidentiary hearing. However, EPA recognizes Gharda's assertion that chlorpyrifos-oxon is not relevant for risk assessment purposes due to the lack of toxicity allegedly demonstrated in the Corteva Oxon Study is at odds with EPA's assessment of chlorpyrifos-oxon residues in drinking water and in the aggregate risk assessment. Whether there is valid scientific data supporting a different conclusion about the toxicity of chlorpyrifos-oxon is likely to be a factual question, rather than one of law or policy.

Nevertheless, EPA's hearing regulations also require that the ''[r]esolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action request.'' (40 CFR 178.32(b)(3)) Under this prong, Gharda's request for a hearing fails. As noted previously, Gharda has failed to provide a discussion of how resolution of this factual issue would assist in granting the relief of their objection. For that matter, Gharda has not even clarified how their objection (*i.e.,* failure to consider relevant scientific information) supports a change to the Agency's safety determination in the final rule.

Assuming *arguendo* that Gharda (and Dr. Reiss) has correctly interpreted the Corteva Oxon Study and assuming also that chlorpyrifos-oxon is less toxic than chlorpyrifos and is not therefore the relevant exposure measurement for assessing risks of chlorpyrifos in drinking water as EPA had assumed, Gharda's request for an evidentiary hearing still fails. This is because this assumption would not ultimately change the outcome of the final rule; EPA would still be unable to conclude that the chlorpyrifos tolerances were safe because the estimated concentrations of chlorpyrifos itself (rather than chlorpyrifos-oxon) in drinking water still exceed the relevant DWLOC.

In the 2020 PID, EPA calculated a DWLOC for both chlorpyrifos and chlorpyrifos-oxon. The DWLOCs used for comparison to residues of chlorpyrifos in drinking water in the final rule were associated with chlorpyrifos-oxon, as that was considered the residue of concern: 4.0 ppb for steady-state exposures and 23 ppb for acute exposures. Based on the 2016 DWA, EPA determined that there were likely to be estimated concentrations of chlorpyrifos-oxon in drinking water that exceeded those DWLOCs. As indicated in Unit II.B.1.d., where the concentrations of pesticide in drinking water exceed the DWLOC, the Agency concludes that the aggregate exposures are not safe. If, as Gharda asserts, the chlorpyrifos-oxon residues are not relevant, there would still be exposures to chlorpyrifos in drinking

water, and EPA would need to consider whether those exposures to chlorpyrifos would be safe. The DWLOCs calculated for chlorpyrifos were 17 ppb for steady-state exposures and 100 ppb for acute exposures. (Ref. 31 at pg. 15) Relative to the DWLOCs for chlorpyrifos-oxon, the DWLOCs for chlorpyrifos are larger, providing slightly more room in the risk cup for residues of chlorpyrifos, relative to chlorpyrifos-oxon. Nevertheless, the 2016 DWA indicates that for the majority of HUC regions assessed, the estimated concentrations of chlorpyrifos alone in drinking water still exceed the higher DWLOC of 17 ppb, *i.e.,* Table 25 of the 2016 DWA indicates that the range of chlorpyrifos concentrations in drinking water have the potential to exceed the DWLOC for all HUC regions except one (HUC 16b). (Ref. 29 at pgs. 73–74) As long as there are certain vulnerable watersheds where the concentrations of chlorpyrifos exceed the maximum amount allowed for residues in drinking water to ensure that aggregate chlorpyrifos exposures stay below safe levels, the Agency cannot make a safety finding to support the chlorpyrifos tolerances. Thus, Gharda has failed to raise a material factual issue for which an evidentiary hearing would be appropriate. ''An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought.'' (40 CFR 178.32(b)(3))

The absence of a material issue of fact here is fatal to Gharda's request for a hearing. As noted previously, the Corteva Oxon Study, even if it supported Gharda's assertion that chlorpyrifos-oxon residues were not relevant for EPA's risk assessment, does not ultimately support a finding that the chlorpyrifos tolerances are safe. Therefore, EPA concludes that a hearing is not justified to receive that evidence for the purposes of evaluating Gharda's claim concerning the consideration of chlorpyrifos-oxon in the Agency's risk assessment. This conclusion also reinforces EPA's earlier determination that a hearing is not necessary to receive the evidence since the study is already in the Agency's files. Furthermore, because the Reiss Declaration offers nothing more than conclusory statements about how to interpret the Corteva Oxon Study, it also fails to provide a basis for determining that the chlorpyrifos tolerances are safe and changing the final rule. Conclusory statements indicating a potential difference of scientific interpretation of a study that, even in the most favorable light, is not outcome determinative, does not create a material issue of fact. (*See National Corn Growers Ass'n,* 613 F.3d at 274 (finding that ''[m]ere differences in the weight or credence given to particular scientific studies'' would not be a sufficient basis to overturn an Agency conclusion that there is no material issue of fact)) Therefore, EPA has determined that Gharda has failed to proffer evidence warranting an evidentiary hearing on its objection concerning the Agency's assessment of chlorpyrifos-oxon.

D. Summary of Reasons for Denial of Hearing Requests

EPA is denying the requests for evidentiary hearing submitted by the American Soybean Association, the Sugarbeet Associations, and the Cherry Marketing Institute because those entities failed to proffer any evidence for which a hearing would be appropriate. The statute clearly states that a hearing is appropriate when ''necessary to receive material evidence.'' (21 U.S.C. 346a(g)(2)(B)) Moreover, these Objectors ultimately disagree with EPA's application of the FFDCA statutory standard for assessing exposures, which is a legal question, rather than a factual one, and thus not appropriate for a hearing. (40 CFR 178.32(b)(1))

EPA is denying Gharda's request for an evidentiary hearing for lack of necessity since, as Gharda concedes, EPA already has the evidence proffered and for lack of materiality, since even if Gharda's factual assertions are correct and supported by the evidence proffered, those issues are not determinative with regard to the Agency's conclusions in the final rule, *i.e.,* they would not provide a basis for leaving the chlorpyrifos tolerances in place at this time.

VII. Response to Objections

A. Overview

EPA denies each of the objections to the final rule. As noted in Unit V. of this document, EPA received several objections from many different entities, including trade associations, farm bureaus, individual growers, and registrants. EPA has grouped these objections into five different categories, which are described later in this unit. After a brief description of each objection or objection subissue, EPA responds to each in this unit.

B. Denial of Objections Not Properly Filed

As a preliminary matter, EPA notes that several parties submitted documents to the Federal eRulemaking Portal that are styled as objections but that do not comply with the requirements of 40 CFR 178.25. As EPA noted in the final rule—and as required in EPA's regulations—objections must be submitted in writing and filed with the Office of the Hearing Clerk in accordance with the procedures in 40 CFR 178.25. While the regulations specify that objections are to be mailed or hand-delivered to the Hearing Clerk, due to the pandemic the Office of Administrative Law Judges (OALJ), where the Office of the Hearing Clerk is housed, is directing parties to file electronically. (Ref. 40) The final rule provided instructions for filing online as well as what to do in the event that online filing was not available. (Ref. 1 at pgs. 48315–16)

The following parties did not submit their objections to the Office of the Hearing Clerk either through the OALJ e-filing system or through mail or hand delivery as required by 40 CFR 178.25(b): The Colombia Ministry of Trade, Industry and Tourism; Drexel Chemical Company; the International Pepper Community; Oregonians for Food and Shelter; and the Republic of Ecuador. (Refs. 41 through 45) EPA also notes that the National Association of Wheat Growers submitted two sets of objections: One as a standalone document, which was not properly filed with the Office of the Hearing Clerk (Ref. 46), and one as a signatory to objections submitted by numerous growers, retailers, co-ops, applicators, refiners, crop consultants, and other agricultural stakeholders (which EPA is referring to as the Agricultural Retailers Association, *et al.* objections (Ref. 47)), which was properly filed with the Office of the Hearing Clerk. EPA's regulations require EPA to deny each objection that is found not to conform with 40 CFR 178.25. (40 CFR 178.30(a)(1)) As a result, EPA denies the previously-described objections that were not submitted to the Office of the Hearing Clerk and will not be considering them in this Order.

C. Responses to Specific Issues Raised in Objections

1. Objections to the Scope of EPA's Final Rule Revoking Tolerances

One theme running through several objections was an assertion that EPA's revocation of all chlorpyrifos tolerances was unlawful and unnecessary. Some Objectors argued that EPA should have

retained some of the chlorpyrifos tolerances, rather than revoking them all, based on EPA's mitigation proposal in the 2020 PID to limit uses to 11 high-benefit crops in certain geographic locations. Relatedly, some Objectors believed that EPA should have coordinated the tolerance revocations with actions under FIFRA to cancel uses in order to avoid revoking all tolerances. Finally, some Objectors asserted that EPA should have retained import tolerances since imported commodities would not contribute to drinking water exposures, which were driving risk concerns. These objections and EPA's responses are discussed in further detail in this sub-unit.

a. EPA's Proposal for Limiting Uses to 11 High-Benefit Crops in the 2020 Proposed Interim Decision (PID) for Chlorpyrifos

i. Objection. Nearly all Objectors assert that revoking all chlorpyrifos tolerances was unlawful and unnecessary based on statements in the 2020 PID where EPA proposed a subset of chlorpyrifos tolerances for retention, provided certain restrictions were implemented. (The objections, requests for hearing on objections, and stay requests submitted in response to the final rule are available at *https://www.regulations.gov* in docket ID number EPA–HQ–OPP–2021–0523.) Some Objectors' claims are general, asserting that EPA should have retained all 11 tolerances, and some are specific to their own commodity of interest (*e.g.,* the American Soybean Association focuses on EPA's determination in the 2020 PID as it relates to soybeans, specifically). (Ref. 36 at pg. 4) In each case, however, these Objectors rely on EPA's proposed finding in the 2020 PID to demonstrate that EPA's record contains sufficient information to determine that at least some tolerances and uses satisfy the FFDCA safety standard. The objectors conclude that, therefore, revocation of all tolerances was inconsistent with the FFDCA requirement to consider aggregate exposure from all ''anticipated dietary exposures''.

The Objectors point to the Ninth Circuit's April 29, 2021, decision for support that EPA was not required to revoke all chlorpyrifos tolerances. The Objectors note that the Court gave EPA the option to ''either revoke all chlorpyrifos tolerances or modify chlorpyrifos tolerances,'' as long as the modification was supported by a safety determination, as well as a direction to ''modify or cancel related FIFRA registrations for food use in a timely fashion consistent with the requirements of [FFDCA 408(a)].'' (*LULAC,* 996 F.3d at 703–04) Consequently, the Objectors assert that EPA should have modified tolerances by retaining the 11 uses rather than revoking all.

ii. Denial of objection. EPA denies this objection. The Objectors' claim is primarily based on a misunderstanding of the FFDCA's requirement to consider aggregate exposure, a misreading of the 2020 PID, and a disregard of the facts at the time of the final rule. When one corrects for each of those factors, it is clear that EPA's revocation of all chlorpyrifos tolerances was entirely consistent with the Agency's obligations under the FFDCA.

Before diving into the rationale for why the Objectors' argument is legally flawed, it is worth providing context for the PID, or proposed registration review decision. Under EPA's regulations, a proposed (interim) registration review decision lays out the Agency's proposed findings, identifies proposed risk mitigation measures or other remedies as needed, identifies any missing or needed data, specifies proposed labeling changes, and identifies any anticipated deadlines. (*See* 40 CFR 155.58(b)) EPA publishes notice of the availability of this proposed decision and provides for at least a 60-day comment period. (40 CFR 155.58(a)) After consideration of those comments, EPA will issue an interim or final registration review decision, which can be very similar to the proposed decision or incorporates changes based on those comments. (40 CFR 155.58(c)) As noted in Unit II.A., the purpose of registration review is to determine whether the registered pesticide continues to meet the standard for registration. Where EPA identifies potential unreasonable risks from use of a pesticide, EPA considers whether there are any options or measures for reducing or mitigating those risks that would enable the pesticide to meet the standard for registration. Where such mitigation measures are available, EPA will propose those in the proposed registration review decision in conformance with its regulations. But consistent with the nature of any proposal, the findings in the proposed decision are just proposals and subject to change based upon public comment or other developments that may occur before the final decision is issued.

For the 2020 PID for chlorpyrifos, EPA followed the process laid out in its regulations. EPA summarized the findings of its aggregate risk assessment and concluded that ''[w]*hen considering all currently registered agricultural and non-agricultural uses of chlorpyrifos,* aggregate exposures are of concern. *If considering only the uses that results in DWLOCs below the EDWCs,* aggregate exposures are not of concern.'' (Ref. 31 at pg. 19 (emphases added)) In other words, EPA found that the universe of currently registered chlorpyrifos uses presented aggregate exposures that exceeded the Agency's determined safe level of exposure. As a result, EPA proposed mitigation to address the dietary and aggregate risks of concern that were posed by use of chlorpyrifos as currently registered. (*Id.* at pg. 40)

To mitigate these risks, EPA proposed that chlorpyrifos applications be limited to the following 11 specific uses in only those specific geographic areas where the estimated concentrations of chlorpyrifos in drinking water from those uses were lower than the DWLOC, *i.e.,* the maximum amount of chlorpyrifos residues that could be present in water and still ensure that aggregate exposures would be safe: Alfalfa, apple, asparagus, tart cherry, citrus, cotton, peach, soybean, strawberry, sugar beet, and spring and winter wheat. (*Id.* at pgs. 40 and 41) For this mitigation proposal to reduce aggregate exposures to safe levels, all other existing uses of chlorpyrifos that contribute to aggregate exposures (*i.e.,* food, drinking water, and residential exposures) would need to be cancelled and the labels for products containing the identified subset of uses would need to be amended to ensure that applications would be limited to those specifically identified geographic areas. Moreover, some revisions to labeled application rates would also be required since the conclusions in the 2020 PID that drinking water contributions were safe in these areas from these uses was based on usage data rather than maximum labeled application rates. It is also important to emphasize that the act of proposing to limit chlorpyrifos applications to this subset of uses did not, in fact, automatically result in the elimination of all uses beyond those identified uses; that would require separate actions under FIFRA to cancel uses and to amend labels, which has not occurred.

EPA proposed this particular list of uses as critical and high-benefit uses of those uses currently registered for chlorpyrifos. (Ref. 30, Attachment 2) Although the ''reasonable certainty of no harm'' standard in the FFDCA, which is strictly a risk-based standard, allows no consideration of benefits, except in one very limited circumstance not relevant here (*see* 21 U.S.C. 346a(b)(2)(B)), FIFRA's ''unreasonable adverse effects'' standard incorporates a consideration of economic costs or benefits, which EPA took into

consideration when identifying this proposed list of retainable uses as part of the FIFRA registration review process. But this is likely not the only combination of uses that could have resulted in safe levels of aggregate exposure. To conserve resources (and because previous analyses had indicated risks of concern when considering all chlorpyrifos uses), EPA's 2020 DWA focused solely on the areas where these particular crops were grown that had the highest benefit to growers to determine if there were areas where the EDWCs were below the DWLOC; it is possible that a different set of crops and a different range of geographic areas could also result in safe aggregate exposures. The Agency expressly noted that it would ''consider registrant and stakeholder input on the subset of crops and regions from the public comment period and may conduct further analysis to determine if any other limited uses may be retained.'' (Ref. 31 at pg. 40) The 2020 PID was made available for public comment, and the Agency did, in fact, receive hundreds of comments, although none committed to making changes to the chlorpyrifos registrations necessary to implement the 2020 PID as proposed, nor were any requests for voluntary cancellation of registered uses submitted under FIFRA in response to the 2020 PID.

Turning now to the legal standard, as noted in Unit II.A., FFDCA section 408(b)(2)(A)(i) permits EPA to leave tolerances in place only if the Agency can determine that the tolerance is safe. If the Agency determines that the tolerances, which must be based on aggregate exposures, are not safe (or cannot determine that tolerances are safe), the Agency must modify or revoke them. (21 U.S.C. 346a(b)(2)(A)(i); see also *LULAC,* 996 F.3d at pgs. 693–94 (concluding that when EPA receives a petition raising substantive questions concerning safety, FFDCA provides no middle ground in which EPA can leave tolerances in place if EPA is unwilling or unable to make a safety finding)) The FFDCA also defines safe as requiring EPA to determine 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.*'' (21 U.S.C. 346a(b)(2)(A)(ii) (emphases added)) Congress understood the phrase ''aggregate exposure'' to include dietary exposures under all tolerances for the pesticide chemical residue, H.R. Rep. 104–669(II) at 1279, and codified that understanding among the factors EPA must consider when establishing, modifying, leaving in effect, or revoking tolerances. (21 U.S.C. 346a(b)(2)(D)(vi)) In FFDCA section 408(b)(2)(D)(vi), EPA must consider ''available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, *including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue,* and exposure from other non-occupational sources.'' (*Id.* (emphasis added))

The requirement to consider ''aggregate exposure'' was added to the FFDCA through the FQPA amendments in 1996. (Food Quality Protection Act of 1996, Pub. L. 104–170) Prior to the enactment of the FQPA, when assessing risk, EPA treated exposures from different pathways as independent events and made no concerted effort to evaluate potential exposures simultaneously. In reality, however, exposures to pesticides do not occur as single, isolated events, but rather as a series of sequential or concurrent events that may overlap or be linked in time and space. Congress, in enacting the FQPA, was concerned with ensuring that the Agency's assessments under the FFDCA would be strictly health-protective and risk-based, and as a result, made a number of significant amendments to the FFDCA, including the new risk-only safety standard, the FQPA children's safety factor, and, of most relevance here, a new requirement for EPA to consider exposures in the aggregate rather than independently.

Following the enactment of the FQPA, EPA developed guidance on how to conduct aggregate exposure and risk assessment. (Ref. 14) That guidance describes the aggregate exposure and risk assessment as involving ''the analysis of exposure to a single chemical by multiple pathways [food, drinking water, residential] and routes of exposure [oral, dermal, inhalation] . . . . All potential, relevant routes of exposure are analyzed with an aggregate exposure assessment.'' (*Id.* at pg. 4) That guidance also defines aggregate risk as ''[t]he likelihood of the occurrence of an adverse health effect resulting from all routes of exposure to a single substance.'' (*Id.* at pg. 72) In describing how EPA intends to conduct such aggregate risk assessments, EPA states that ''[t]he starting point for identifying the exposure scenarios for inclusion in an aggregate exposure assessment is the universe of proposed and approved uses for the pesticide,'' which are determined by looking to labeled allowable use patterns. (*Id.* at pgs. 24, 44 and 45) Moreover, the guidance directs that aggregate exposure and risk should be estimated for major identifiable subgroups of the population, which the Agency typically does through considerations of demographics (*e.g.,* age, gender, racial/ethnic background) and temporal (season) and spatial (geographics) characteristics of potentially exposed individuals. (*Id.* at pgs. 12, 24)

The Aggregate Exposure Guidance describes an approach for assessing aggregate exposures that recognizes such exposures to hypothetical individuals in the population: ''(1) may occur by more than one route (*i.e.,* oral, dermal and/or inhalation); (2) may originate from more than one source and/or pathway (*i.e.,* food, drinking water, and residential); (3) may occur within a time-frame that corresponds to the period of exposure required in an appropriately designed toxicity study to elicit an adverse toxicological effect; (4) should occur at a spatially relevant set of locations that correspond to an individual's potential exposure; and (5) should be consistent with the individual's demographic and behavioral attributes.'' (*Id.* at pg. 26) In practice, this means that the Agency might consider whether different populations of individuals are more or less likely to eat different kinds of food over different time periods; whether pesticide concentrations in drinking water vary temporally due to the growing season calendar or spatially due to the nature of applications generally being localized or regional; and/or whether different populations are likely to use or be exposed to pesticides in non-occupational settings. Generally, EPA would utilize upper-end estimates to ensure protection for the most vulnerable populations, unless other factors warranted a different approach.

From there, the Agency assesses the aggregate exposure through relevant routes of exposure for hypothetical individuals among these major identifiable subgroups (including food, drinking water, and residential exposures to which that individual is likely exposed), taking into consideration the various factors for co-occurrence of exposures in the various exposure pathways. (*Id.* at pg. 26) Where risks from aggregate exposures exceed safe levels, EPA will examine whether refinements can be made to the assessment. (*Id.* at pg. 13)

In the final rule, EPA assessed aggregate exposure based on all currently registered uses of chlorpyrifos as required by the FFDCA and consistent with its guidance. That

assessment considered exposure through oral, dermal, and inhalation routes of exposure that could result from exposures in food, drinking water, and residential uses. Taking into consideration the registered use patterns for chlorpyrifos, EPA assessed the universe of potential exposures from all currently approved uses of chlorpyrifos because no formal steps had been taken to limit those uses.

In demanding that EPA retain tolerances for the 11 uses, the Objectors essentially argue that EPA should have presumed that individuals would only be exposed to chlorpyrifos from the 11 uses because EPA proposed those 11 uses as an option for mitigation in the 2020 PID proposal. However, that argument ignores the premise in the PID that the safety finding for those uses is contingent on all other uses being cancelled and the remaining 11 uses being restricted both geographically and with lowered use rates. Exposures from those uses alone could not reasonably be considered as ''anticipated'' since they did not yet (nor did EPA have reason to believe that they would) reflect the exposures people would be exposed to in the real world. The FFDCA requires EPA to determine whether tolerances *are* safe, requiring consideration of aggregate exposures, including ''anticipated dietary exposures''; it does not allow EPA to leave tolerances in place if they *would be* safe at some unspecified time in the future based on certain mitigation that may not be implemented.

At the time of the final rule, no concrete steps had been taken by registrants under FIFRA to implement the PID proposal: No uses had been cancelled, nor had any labels been revised to geographically limit applications or limit maximum application rates. Although there were discussions with registrants and indications of a willingness to mitigate uses (see discussion in next sub-unit), the Agency had not received prior to the issuance of the final rule from registrants any formal requests under FIFRA for voluntary cancellation or applications to amend labels, to which the Agency could point as directionally supportive for a conclusion that exposures would at some future time be limited to that subset of chlorpyrifos applications. Until such uses cease—or at least until EPA has a reasonable basis to believe that they will cease—the Agency could not ignore the exposures from those uses. In sum, the 2020 PID proposal, without more, is just a proposal; it does not support an EPA assumption that aggregate exposures would be limited to that subset of uses instead of an assessment based on the actual registered uses and ongoing real-world applications of chlorpyrifos.

While the Objectors claim that EPA could have modified tolerances, as per the Court's order, by leaving in place only those identified in the 2020 PID, doing so, without accompanying registration actions under FIFRA, would have put EPA in the position of picking ''winners and losers'' among the tolerances. While, under FIFRA, EPA might be able to make an argument that some uses contribute relatively lower risks or higher benefits than other uses and thus meet the FIFRA standard of no unreasonable adverse effects on the environment whereas others may not, considerations of those relative benefits is not a factor for consideration under the FFDCA when determining which tolerances are safe or not. As noted previously, the 2020 PID proposal reflected one possible subset of uses that might warrant retention based on economic considerations. In circumstances where aggregate exposures exceed safe levels, there are potentially multiple variations of the potential subset of tolerances that might meet the safety standard and that EPA did not analyze. As such, EPA's general policy is to defer to the pesticide registrant and the public to determine which of the various subsets of tolerances are of sufficient importance to warrant retentions since not all parties might agree on the particular combination that should be retained. For example, one comment submitted on the 2020 PID requested that EPA retain tolerances on cranberries (Ref. 48), which was not listed among the 11 uses in the PID. Without some reasonable basis to believe that the uses would be limited as had been proposed, EPA did not have a basis to assume anticipated exposures would be limited to that particular subset of uses for purposes of modifying the tolerances.

Some Objectors made this same argument but focused more specifically on their crop of interest (*e.g.,* cherry, citrus, soybean, sugarbeet). These objectors assert that EPA could not have revoked the specific commodity tolerance because that crop was included in the list of crops EPA proposed to retain and thus EPA did not have a basis for concluding that those tolerances themselves were unsafe. However, the Agency does not assess tolerances for each crop in a vacuum; whether one tolerance is safe depends on whether aggregate exposure from that tolerance and all other tolerances in effect are safe. (21 U.S.C. 346a(b)(2)(D)(vi)) The consequence of the FFDCA requirement for EPA to assess the safety of tolerances as an aggregate is that, when one tolerance is unsafe, all tolerances are equally unsafe until aggregate exposures have been reduced to acceptable levels. At the time the final rule was issued, there were over 80 tolerances in effect, which the Agency was required to consider in its aggregate exposure assessment, unless there had been a reasonable basis to exclude exposures from those tolerances. The list in the 2020 PID was only a proposed mitigation measure, necessary because the aggregate exposures from chlorpyrifos, which included exposures from use of chlorpyrifos on these three commodities, exceeded safe levels.

It is also worth noting that tolerances themselves are broadly applicable rules that regulate the amount of pesticide residues on a food commodity. As such, they are not limited in geographic scope, and the Agency must be able to determine that all aggregate exposures from any registered uses (including all relevant geographic areas) that would be covered by a particular tolerance would be safe. For example, the tolerance covering residues of chlorpyrifos on cherry applies to the pesticide residues on the crop regardless of the location of application. In practice, this means that EPA needs to be able to determine that use of chlorpyrifos in any place permitted by the FIFRA label would be safe. For cherries, EPA's 2020 PID proposal only concluded that use on cherry could be safe in Michigan, if the other aforementioned mitigation measures were implemented; whether cherry use could be safe in other areas was not assessed. In order to conclude that cherry use was safe based on the 2020 PID proposal, the labels would need to restrict chlorpyrifos use to cherries only in Michigan. Since the uses on cherry were not so restricted under FIFRA at the time of the final rule, EPA could not assume that chlorpyrifos would be used only in the limited geographical regions without some progress being made on the label revisions.

In conclusion, while the 2020 PID proposed that there is at least one subset of chlorpyrifos uses that could be safe if additional restrictions were adopted and all other uses contributing to aggregate exposures were cancelled under FIFRA, that is not a basis for maintaining tolerances when the Agency does not have a reasonable basis to believe that the registrations would be so amended. Based on the factual realities at the time of the final rule, EPA was required to consider aggregate exposures resulting from approved labelling and all currently registered

uses. The Objectors' claim incorrectly relies on the proposal in the 2020 PID as a basis for limiting the aggregate exposure assessment, and the request to limit EPA's safety assessment to a subset of actual exposures based on a proposal would reflect an incorrect application of the statutory standard under the FFDCA. EPA recognizes that the practice of identifying mitigation measures to address risks of concern in the proposed or interim decisions in registration review is common, and the expectation is that registrants will make adjustments to retain registrations. However, this is not always the case; some registrants may suggest alternative means of mitigating risks, which the Agency then needs to evaluate, or may refuse due to a disagreement with the Agency's underlying rationale for its decision. When mitigation measures are not implemented (or it is unclear that such risks will be mitigated), the risks that EPA initially identified remain. Therefore, the objection is denied.

b. Coordination With FIFRA Under FFDCA Section 408(l)(1)

i. Objection. Objectors assert that the revocation of tolerances should not have been undertaken without coordination of use cancellations under FIFRA. The Sugarbeet Associations and Gharda argue that EPA had a statutory duty under section 408(l)(1) of the FFDCA to harmonize the chlorpyrifos tolerance revocation with necessary actions under FIFRA. (Refs. 37 and 39) They argue that EPA offers no explanation for why it was not practicable for EPA to cancel the FIFRA registrations and revoke tolerances for the food uses for which EPA would be unable to make a safety finding while maintaining the registrations and tolerances that the 2020 PID proposed for retention. The Sugarbeet Associations also argue that because the Ninth Circuit also ordered EPA to ''correspondingly modify or cancel related FIFRA registrations for food use in a timely fashion,'' EPA's failure to harmonize its revocations with FIFRA actions is therefore also inconsistent with the Court's order. (Ref. 37 at pg. 7) Gharda acknowledges that EPA did engage in negotiations with registrants to attempt this harmonization but alleges that EPA was acting in bad faith in those negotiations and disregarded Gharda's commitment to modify its registration. (Ref. 39 at pgs. 28 through 31) The Minor Crop Farmers Alliance notes that EPA did not follow ''its traditional FIFRA/FQPA sequencing of taking the necessary tolerance actions only after first finalizing its decision in a cancellation action under Section 6 of FIFRA.'' (Ref. 49 at pg. 4) Finally, CLA/RISE requests guidance on how EPA intends to harmonize the tolerance revocation under FIFRA to reduce confusion among growers and industry. (Ref. 50)

ii. Denial of objection. EPA denies this objection on the following legal and factual grounds. FFDCA 408(l)(1) states that ''[t]o the extent practicable . . . , in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under [FIFRA].'' (21 U.S.C. 346a(l)(1)) While the statutory language includes the word ''shall,'' this provision clearly contemplates that there may be circumstances in which coordination is not practicable and thus such coordination is not required. Even when such coordination would be practicable, the statute does not require that this coordination be concurrent or occur in any predetermined order.

EPA has previously opined on this provision in a final rule revoking carbofuran tolerances in which this same comment was raised. (See 74 FR 23046, 23069–70, May 15, 2009 (FRL–8413–3)) In that rule, EPA found that the requirement to ''coordinate'' is a direction to ensure that the substance of actions taken under FIFRA and the FFDCA are consistent, and that the Agency make a determination as to the proper order of action under the two statutes. It cannot be read as a requirement that actions under FIFRA precede actions under the FFDCA, or that any particular order for EPA actions is necessarily required. Accordingly, there is no support for the notion that, as a matter of law, the Agency lacks the legal authority to revoke pesticide tolerances under the FFDCA that do not meet the safety standard of that statute unless the Agency has first canceled—or simultaneously cancels—associated pesticide registrations under FIFRA.

In this instance, the Ninth Circuit itself prioritized EPA's taking action on the chlorpyrifos tolerances above the action necessary under FIFRA, when it set a very short and specific deadline for addressing pesticide tolerances (*i.e.,* within 60 days of the issuance of the mandate) and allowed flexibility for EPA to ''modify or cancel related FIFRA registrations for food use in a timely fashion.'' (*LULAC,* 996 F.3d at 703–04) Under the Court's timeframe, it was not practicable for EPA to take action under FIFRA to cancel registered food uses of chlorpyrifos concurrently with the final rule. Cancellation of uses under FIFRA section 6(b) requires several steps, including drafting a notice of intent to cancel, interagency coordination and SAP review, as well as possible administrative hearings, and can take several years to complete. (See 7 U.S.C. 136d(b)) Even the process to obtain and act on voluntary cancellation requests can be a time-consuming process with statutorily set comment periods before a cancellation can be ordered. (7 U.S.C. 136d(f))

In any event, in this particular instance, EPA did attempt to harmonize its tolerance revocation actions with cancellation actions under FIFRA. As the Minor Crop Farmer Alliance pointed out, EPA traditionally, as part of the registration review process, identifies the relative risks and benefits of particular uses and works with registrants to eliminate uses that no longer meet the FIFRA standard, including for safety risks. Under that approach, EPA and the registrant(s) can mutually agree on terms for the smooth phase-out of the product, and the product or use cancellations can be coordinated with tolerance revocations under the FFDCA. After the Ninth Circuit's decision was issued, EPA engaged in discussions with the four registrants of technical chlorpyrifos products (*i.e.,* those that are used to manufacture the chlorpyrifos pesticide products sold to end users) to discuss possible voluntary use cancellations and label restrictions, although EPA did not initiate any discussions with the dozens of registrants of end-use products. (Ref. 51) Despite the progress made in those discussions, no registrant submitted under FIFRA a request for voluntary cancellation of any uses or application to amend existing chlorpyrifos labels to reduce application rates and geographically limit uses. One of those registrants, Gharda, asserts that EPA acted in bad faith in the negotiations with Gharda and disregarded a commitment from Gharda to modify its registration. EPA disagrees with Gharda's characterization of the negotiations.

Prior to the issuance of the final rule, EPA entered into discussions with Gharda, as well as several other registrants, in a good-faith effort to determine if the safety issues identified in EPA's record on chlorpyrifos by the Ninth Circuit could be resolved in a sufficient and timely manner to allow for the modification of tolerances by the Court's imposed timeline. EPA held several meetings with each of the technical registrants, including Gharda, to discuss their interests and concerns as EPA considered its response to the Court's directive to issue a final rule. (*Id.*) The meetings with Gharda occurred on May 27, June 3, June 17, June 24, July

14, and August 16, 2021. As Gharda's objection filing indicates, there was an extensive amount of back-and-forth between EPA and Gharda concerning restrictions to the current registrations and an attempt to work out mutually agreeable terms (*e.g.,* uses to be retained, geographic limitations on uses, retention of import tolerances, timing for phase-out of existing uses) to provide a reasonable basis for assuming aggregate exposures could be limited to the 11 uses proposed for retention in the 2020 PID.

Gharda asserts, in its objection, that EPA disregarded a written commitment to voluntarily cancel uses and therefore, the Agency's decision to revoke all tolerances was arbitrary and capricious. (Ref. 39 at pgs. 28 and 29) EPA acknowledges that Gharda submitted two such letters to the Agency; however, the question is whether those letters provided a legal basis for any EPA regulatory determination, *e.g.,* whether to retain tolerances for the 11 uses assessed in the PID. EPA concludes that they did not.

On their face, Gharda's letters fall far short of actually requesting voluntary cancellation of their registered uses. Gharda's first letter says that it is ''willing to work with EPA to negotiate the voluntary cancellation of many currently approved uses of chlorpyrifos on mutually acceptable terms and in a manner that minimizes disruption on growers and other users.'' Gharda requests that any agreement with EPA to voluntarily cancel uses include several key terms, including further discussion of the geographic restrictions set forth in the PID as to the 11 crops, allowing use on crops in addition to the 11 uses in the PID, phase-out schedules that would allow some uses to continue until 2026 (5 years after the Court ordered EPA to issue a final rule revoking or modifying tolerances), additional existing stocks orders that would allow additional time for phase-out, retention of all import tolerances, etc. (Ref. 39 at Exhibit B to Gharda's objection, Letter from Gharda to EPA (May 12, 2021)) Gharda's second letter states that ''Gharda commits to voluntarily cancel all currently approved agricultural uses of chlorpyrifos other than uses for the 11 high-benefit agricultural crops in select regions that the Agency has identified [in the PID] . . . . subject to [several] conditions.'' Those conditions included allowing use on cotton in Texas (which the Agency had not determined would be safe under the limited conditions presented in the 2020 PID), existing stocks terms that allowed for sale of all finished Gharda technical product in the United States and overseas to be processed and sold until stocks were exhausted, retention of all ''import tolerances,'' and allowing food treated with chlorpyrifos to clear the channels of trade. (*Id.* at Exhibit C, Letter from Gharda to EPA (June 7, 2021)) As Gharda's objection filing indicates, there were several other emails exchanged in which terms continued to be negotiated, and Gharda continued to seek agreement on various terms prior to submission of a voluntary cancellation request. (*Id.* at Exhibits D through J)

Contrary to Gharda's assertions, a conditional proposal does not provide a sufficient basis for EPA to conclude that uses will be cancelled and exposures will be reduced. By their terms the letters simply indicate an intent to keep discussing the issue and a willingness to initiate the process to cancel uses provided other conditions can be agreed upon. The implication in Gharda's letter was that if agreement could not be reached on the other conditions, then no such voluntary cancelation request would be forthcoming. And as indicated previously, Gharda's proposal was initially contingent upon EPA allowing use on crops beyond the 11 identified in the PID, which EPA had not assessed and proposed to find safe if other conditions were met. Although Gharda's subsequent email traffic indicated a willingness to drop those additional uses, given the Agency's safety concerns with the tolerances, EPA continued to express a concern about whether an extended existing stocks period would be considered consistent with the Ninth Circuit's order.

Typically, a formal request for voluntary cancellation of a pesticide registration or registered uses would involve the submission of a letter requesting cancelation of a product or uses and would also, in the case of deletions of certain uses, need to be accompanied with applications to amend relevant labels. (See *https://www.epa.gov/pesticide-registration/voluntary-cancellation-pesticide-product-or-use*) While Gharda's letters indicate a willingness to continue negotiations with EPA, they do not constitute an actual request to cancel uses and thus do not provide a sufficient basis for EPA to conclude that aggregate exposures to chlorpyrifos would be limited to the 11 geographically limited uses identified in the 2020 PID proposal.

It should also be noted that Gharda's voluntary cancellation request alone would not be sufficient to support a conclusion that all registered uses would be cancelled since other products are registered for those uses as well. Other registrants would have also needed to submit voluntary cancellation requests and label amendments, and as indicated previously, that has not happened.

Unlike negotiations that are typically conducted as part of registration review, this situation involved a tight deadline for a final Agency rulemaking and thus a very short period of time to resolve differences and allow EPA to develop a final rule that incorporated any such resolution. In light of the Ninth Circuit's impending deadline for issuing a final rule and the lack of a mutually agreeable resolution to the remaining issues in a timely manner, it simply was not practicable for EPA to continue negotiating these terms.

While it is understandable for Gharda to be disappointed, Gharda erroneously asserts now, based on the lack of resolution in time for the final rule to be completed by the Court's deadline, that EPA's rule is arbitrary and capricious. This simply is not true. Whether a rule revoking tolerances is legally valid is strictly dependent on whether EPA had substantial evidence to support its conclusion that the tolerances were not safe; how negotiations proceed regarding use cancellations and label amendments under FIFRA is irrelevant to that safety question. As noted in the denial of the previous objection, EPA determined that the tolerances were not safe, based on the assessments EPA had completed at the time and aggregate exposures resulting from the uses in place at the time of the final rule.

It is worth noting that, although the Agency/registrant negotiations prior to the final rule ended without resulting in use cancellations or label amendments under FIFRA, any registrant is authorized at any time, without prior EPA consent, to take initiative and submit a request to voluntarily cancel uses on its registration or to submit an application seeking amendments to its label to restrict uses. Upon submission of such a request, EPA would consider that request and publish a notice of receipt of a voluntary cancellation request, and for situations like chlorpyrifos, take into consideration whether that request would have an impact on the Agency's ability to support a safety finding, in light of uses remaining on other registered products. For chlorpyrifos, however, no such submissions were submitted to with the Agency prior to the issuance of the final rule. While there were communications from Gharda indicating an intent to amend registrations and cancel uses, with an extended existing stocks period to allow for continued sale and distribution of their chlorpyrifos inventory, no formal steps were taken

under FIFRA to put those processes in action.

c. Import Tolerances

i. Objection. Gharda, the Agricultural Retailers Association, *et al.,* and CLA/RISE argue that EPA should have retained import tolerances (*i.e.,* tolerances covering pesticide residues for commodities that are imported into the United States) for chlorpyrifos commodities. (Refs. 39, 47 and 50) These Objectors assert that because EPA's final rule noted that food exposures and non-occupational exposures do not exceed levels of concern—rather, risks are driven by exposures to chlorpyrifos in drinking water—EPA could conclude that import tolerances, which would not contribute to drinking water exposures, would be safe. The Objectors assert that there is no science-based reason to revoke tolerances as they apply to food imported with chlorpyrifos residues. CLA/RISE cites to EPA's guidance entitled, ''Pesticides; Guidance on Import Tolerances & Residue Data for Imported Food'' ((65 FR 35069, June 1, 2000) (FRL–6559–3)), and legal precedent for support for the retention of import tolerances. (Ref. 50)

ii. Denial of objection. This objection is denied because, as a matter of law, where aggregate exposures from pesticide use exceed safe levels, EPA cannot leave tolerances in place, even if those tolerances just cover residues in imported foods.

As a legal matter, tolerances established under the FFDCA apply to pesticide residues in or on food moving through interstate commerce, regardless of whether those residues came from use of a domestically registered pesticide or from application of a pesticide overseas to a food that is then imported into the United States. As a matter of law, EPA does not separately establish ''import tolerances'' that apply exclusively to imported commodities. The term ''import tolerance'' is a term of convenience that refers to tolerances for pesticide residues in an imported food where there is no corresponding U.S. registration for that pesticide on that particular commodity; however, there is no statutory or regulatory distinction between a tolerance covering pesticide residues in imported commodities and tolerances covering pesticide residues from use of a pesticide product registered in the United States. Once established, that tolerance would cover pesticide residues in that particular commodity, regardless of how residues came to be present in the food.

It is correct that imported food treated with a pesticide would only contribute to aggregate exposures through the residues that are present on the imported commodity. Imported foods do not result in additional drinking water and residential contributions to exposure because the pesticides are used overseas, not domestically. Nevertheless, the pesticide residues on the imported food must be aggregated with all the other food, drinking water, and residential exposures to that pesticide that occur in the United States, as part of the safety determination and consideration of aggregate exposures for that pesticide. If the domestic uses of that particular pesticide already exceed safe levels, EPA would not be able to approve the new import tolerance, even if the relative contributions from the imported commodities was very minor because the safety assessment of that tolerance requires a consideration of ''aggregate exposures'' from all other tolerances in effect.

For chlorpyrifos, since domestic use of chlorpyrifos in accordance with currently approved labeling results in aggregate exposures that exceed safe levels, due to drinking water concerns, all tolerances, including those covering imported commodities, are unsafe and must be revoked. Until domestic use ceases—or EPA has a reasonable basis to believe that it will cease—the risks from drinking water need to be assessed in EPA's risk assessment. Once domestic uses are cancelled and aggregate exposures are reduced below the Agency's levels of concern for safety, EPA could consider whether risks from exposures in or on imported food would be safe. Again, this is a consequence of the requirement under the FFDCA to consider aggregate exposures from all uses; when one tolerance is unsafe, all are equally unsafe until aggregate exposures have been reduced to levels that are below the Agency's level of concern.

CLA/RISE cite EPA's *Guidance on Import Tolerances* to encourage EPA to consider and approve requests to retain import tolerances. This guidance, however, does not provide a legal basis for retaining import tolerances under the current circumstances. Rather the guidance document describes how EPA may consider requests for modifying or maintaining tolerances to allow the continue import of food treated with a pesticide, where ''domestic uses are canceled . . . for any other reason (other than dietary risk)'' as long as EPA can make the required safety finding. (65 FR at 35072) For chlorpyrifos, no domestic uses have been cancelled to date, which precludes EPA from making the required safety finding.

CLA/RISE also point to the D.C. Circuit Court's decision in *National Corn Growers Ass'n* v. *EPA,* 613 F.3d 266, as instructive here. In that case, the Court ordered EPA to reinstate import tolerances for the pesticide carbofuran because the Agency had received requests for retaining those tolerances and because EPA had concluded that exposure from imported foods alone was safe. (*Id.* at pg. 275)

This present case is distinguishable in that for the carbofuran situation, the import tolerances at issue had no domestic registrations for the commodities covered by those tolerances. This fact was specifically identified by footnotes to the tolerances for those commodities. For chlorpyrifos, there are no specifically designated import tolerances, although the Agency notes that there is a tolerance for chlorpyrifos on banana, for which there are no U.S. registrations. To the extent there were requests for retention of import tolerances prior to the issuance of the final rule, such requests were to leave *all* current tolerances in place, in order to accommodate chlorpyrifos use in other countries on any of the commodities for which tolerances were set. Because those uses would overlap with domestic uses, the Agency could not exclude other non-food exposures associated with those uses until those domestic uses were cancelled.

EPA recognizes that the Republic of Colombia, in its objections, requested the retention of the banana tolerance; however, EPA denies that request since EPA is unable, at this time with the existing domestic uses still being registered, to make a safety finding for the banana tolerance. While after *National Corn Growers Ass'n* was decided, the import tolerances were reinstated for commodities that had no domestic uses, that reinstatement occurred after the other domestic uses that had resulted in unsafe aggregate exposure levels had been cancelled, thus obviating the need to tackle a potential aggregate exposure issue involving residues from both domestic and imported food. (*See* Carbofuran; Product Cancellation Order ((74 FR 11551, March 18, 2009) (FRL–8403–6)) (announcing FMC Corporation's voluntary cancelation of its carbofuran registrations for all but six crops); Carbofuran; Reinstatement of Specific Tolerances and Removal of Expired Tolerances ((80 FR 21187, Apr. 17, 2015) (FRL–9925–70)) (EPA reinstatement of import tolerances for carbofuran for banana; coffee, bean, green; rice, grain; and sugarcane, cane))

Here, all registrations of chlorpyrifos remain intact and uses in accordance with the labels are still contributing to drinking water concentrations that result in aggregate exposures exceeding safe levels. Therefore, for chlorpyrifos, the Agency cannot make the safety finding for leaving tolerances in place to accommodate imports until sufficient uses are cancelled that reduce aggregate exposures to acceptable levels.

2. Retention of the 10X Food Quality Protection Act (FQPA) Safety Factor

a. Objection

Several Objectors (Sugarbeet Associations, Gharda, the Agricultural Retailers Association, *et al.,* Minor Crop Farmer Alliance, California Citrus Quality Council, and Coalition of OP Registrants) claim that EPA acted unlawfully in retaining the 10X FQPA safety factor based on the epidemiology data. (Refs. 37, 39, 47, 49, 52 and 53) Objectors assert that the epidemiological data was invalid and unreliable and should not been considered nor should it have been relied upon to introduce ''scientific uncertainties'' into the Agency's assessment of chlorpyrifos. In light of the alleged defects with the epidemiological studies, the Objectors assert EPA had no basis to retain the 10X FQPA safety factor, given the balance of toxicity data on chlorpyrifos.

b. Denial of Objection

As an initial matter, EPA points out that the Objectors have failed to identify an issue that supports a retention of the chlorpyrifos tolerances or changing the EPA's final rule, even if what the objectors assert is correct. Even if the Agency agreed that the epidemiological data should not have been considered by the Agency or that available data support a reduction of the FQPA safety factor to 1X, as indicated in the 2020 PID, EPA would not have been able to determine that chlorpyrifos tolerances were safe without some uses being cancelled and other uses being modified.

The 2020 PID provided estimates of potential risks based on retention of the 10X FQPA safety factor and on a reduced FQPA safety factor of 1X. The previous sub-unit discussed the need to cancel all uses besides the 11 uses identified for retention and the need for label amendments to geographically restrict applications and to reduce maximum application rates, if EPA retained the 10X FQPA safety factor. For the 1X scenario, EPA concluded that ''the majority of labeled chlorpyrifos uses result in drinking water concentrations below the DWLOC.'' (Ref. 31 at pg. 41) The ''majority,'' however, is not all, and thus, EPA noted that three uses still resulted in EDWCs above the DWLOC (peppers, trash storage bins, and wood treatment), and six uses would need to be restricted to certain states and application rates adjusted consistent with assessed usage data in order to ensure that concentrations of chlorpyrifos in drinking water did not exceed safe levels. (*Id.*) In other words, uses as registered at the time EPA issued the 2020 PID—and at the time of the final rule—still resulted in aggregate exposures that were not safe under a scenario in which EPA applied a 1X FQPA safety factor. Since some uses would result in exposures of chlorpyrifos that exceeded the Agency's safe levels, EPA would not have been able to determine that the tolerances were safe, even with the FQPA safety factor being reduced to 1X. If EPA had had a reasonable basis to assume that such uses resulting in exceedances would cease, EPA may have been able to aggregate only those uses that were expected to continue. As there was no such basis at the time the final rule was issued—and, indeed at this time, there is still no such basis, EPA was required to look at aggregate exposures from all currently registered uses, as those exposures were anticipated to continue. Therefore, since the Objectors have failed to state a claim upon which the relief they seek (leaving the tolerances in place) can be granted, this objection is denied.

Notwithstanding this denial, EPA disagrees with the assertions made by Objectors with regard to the Agency's decisions to rely on the epidemiological data and retain the 10X FQPA safety factor as discussed in this unit. For ease of addressing this claim, EPA is breaking this objection into two subissues: (1) Whether it was reasonable for EPA to use the epidemiology data as part of its weight-of-the evidence analysis for assessing the potential pre- and postnatal toxicity relating to neurodevelopmental effects and (2) Whether EPA had ''reliable data'' to support a different margin of safety to protect infants and children based on the available record.

c. Background

Before responding to these objections, it is helpful to provide some background on the FQPA safety factor EPA used in the final rule to clarify the statutory standard, and to provide some background on EPA's FQPA safety factor policy.

i. Final rule. In the final rule, EPA retained the 10X FQPA safety factor due to uncertainty around the levels at which potential neurodevelopmental outcomes may occur in infants and children exposed to chlorpyrifos. The decision was based on the Agency's weight-of-evidence (WOE) analysis, which took into consideration the totality of available information on the toxicity of chlorpyrifos and the potential for neurodevelopmental outcomes associated with chlorpyrifos exposure. That information included laboratory animal studies, epidemiological studies, and available mechanistic data, as described in Unit III.A.1.b. of this document.

In essence, the WOE analysis concluded that there was qualitative evidence of a potential effect on the developing brain; however, due to insufficient clarity on the levels at which these neurodevelopmental outcomes occur relative to levels at which cholinesterase inhibition occurs, the science addressing neurodevelopmental outcomes remained unresolved in a manner sufficient to quantify these effects. Due to the remaining uncertainties, EPA was unable to conclude at the time of the final rule that a different safety factor would be sufficient to protect infants and children from potential pre- and postnatal toxicity related to neurodevelopmental effects. (Ref. 1 at pg. 48327)

ii. FFDCA section 408(b)(2)(C) and EPA's FQPA safety factor policy. Through the FQPA, Congress significantly amended the FFDCA, to establish a new stringent health-based standard (''reasonable certainty of no harm'') and add a new provision providing heightened protections for infants and children. (21 U.S.C. 346a(b)(2)(C)) That provision directs EPA to consider available data on, among other things, the ''special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of *in utero* exposure to pesticide chemicals.'' (21 U.S.C. 346a(b)(2)(C)(i)(II)) Moreover, EPA is required to ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide. (21 U.S.C. 346a(b)(2)(C)(ii)(I)) When making that safety determination for infants and children, EPA is required to apply, in the case of threshold effects, an additional tenfold margin of safety ''to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.'' (21 U.S.C. 346a(b)(2)(C)) This provision

permits a different margin of safety ''only if, on the basis of reliable data, such margin will be safe for infants and children.'' (*Id.*) Thus, EPA interprets this provision as establishing a presumption in favor of applying the default 10X safety factor, which can be departed from only if reliable evidence show that a different factor would be protective of infants and children.

In 2002, EPA issued guidance on how OPP intends to make determinations regarding the FQPA safety factor when developing risk assessments for pesticides (''FQPA Policy Paper'') (Ref. 9) While not binding, that document provides helpful background and clarification on the process for determining the appropriate FQPA safety factor. Ultimately, the decision to retain the default 10X FQPA safety factor or use a different factor depends on level of confidence in the risk assessment and the degree of concern for any susceptibility or residual uncertainties in the toxicity and exposure databases. (*Id.* at 50) A lower level of confidence and a higher degree of concern will support retention of the default 10X FQPA safety factor. Because the chlorpyrifos 10X FQPA safety factor decision relates primarily to the concern for potential pre- and postnatal toxicity, this discussion focuses on those aspects of the guidance, although it also covers concerns related to the completeness of the toxicity and exposure databases.

Before making any determination on the FQPA safety factor, OPP will review all available and relevant toxicological data and determine whether the chemical has any potential to cause adverse effects in infants and children, *i.e.,* potential pre- and postnatal toxicity or special susceptibility. (*Id.* at pg. 8) The FQPA Policy Paper states, ''In general terms, there is increased susceptibility or sensitivity when data demonstrate unique effects (*e.g.,* a different pattern of effects of concern) or adverse effects in the young that are of a type similar to those seen in adults, but occur either at doses lower than those causing effects in adults, occur more quickly, or occur with greater severity or duration than in adults.'' (*Id.* at pg. 30) If the toxicity data indicate no concern for pre- and postnatal toxicity or special susceptibility, then the presumption for the 10X factor should be treated as obviated with respect to the potential for pre- and postnatal toxicity. In contrast, if the toxicity data indicate pre- and postnatal toxicity, then OPP will assess the level or degree of concern for the potential for those effects, taking into consideration the degree to which the traditional uncertainty factors provide protection for infants and children. (*Id.* at pg. 29)

EPA typically uses a WOE approach for making judgments about the degree of concern for potential pre- and postnatal toxicity, in the context of the entire database, taking into consideration the quality and adequacy of the data, and the consistency of responses induced by the chemical across different studies. (*Id.* at pg. 30) The FQPA Policy Paper notes that this integrative approach is important because ''for example, positive animal findings may be diminished by other key data (*e.g.,* toxicokinetic or mechanism of toxicity information), or likewise, a weak association found in epidemiological studies may be bolstered by experimental findings in animal studies.'' (*Id.* at pg. 31) Moreover, it is important to consider other factors concerning the biological responses observed in the young relative to the adult effects, such as ''progression, severity, recovery time or persistence, and dose-response . . . . For example, there would be greater concern for effects that were irreversible and of a greater potential consequence to the young compared to observed effects in adults that are of a transient and minimal nature, even when they occur at the same dose.'' (*Id.* at pg. 33) The FQPA Policy Paper notes that ''[w]hen sufficient human data are available to judge that an adverse developmental outcome is related to exposure, the degree of concern increases,'' although ''sufficient human evidence is very difficult to obtain.'' (*Id.*) Another factor influencing the degree of concern is the relationship between dose and response. Where the dose-response relationship is well-characterized, there is a lower degree of concern, whereas in cases where the opposite is the case, the degree of concern may increase. (*Id.* at pg. 34) Finally, mechanistic data can be helpful in evaluating the degree of concern. (*Id.*)

In some cases, concerns regarding pre- and postnatal toxicity can be addressed by calculating a protective reference dose or margin of exposure based on relevant endpoints in the offspring or through the use of traditional uncertainty factors. (*Id.* at pg. 35) OPP risk assessors will consider whether the developmental and offspring effects are well-characterized in the toxicity database and if other appropriate uncertainty factors are already applied for calculating a protective RfD; if so, then ''there would normally be no need for an additional FQPA safety factor to address potential pre- and postnatal toxicity.'' (*Id.*) However, in some instances, ''data may raise uncertainties or a high concern for infants or children which cannot be addressed in the derivation of an RfD or MOE''. (*Id.* at pg. iv) If so, ''those residual concerns or uncertainties should be addressed through retention of the default FQPA safety factor . . . .'' (*Id.* at pg. 35)

If there is a high level of confidence that the combination of the hazard and exposure assessments is adequately protective of infants and children, then the presumption in favor of the additional 10X default FQPA safety factor would be obviated and the risk assessor should recommend that a different FQPA safety factor be applied . . . . Conversely, if the risk assessor finds evidence of pre- or postnatal toxicity or problems with the completeness of the toxicity or exposure databases and these uncertainties have not been adequately dealt with in the toxicity and/or exposure assessments (through use of traditional uncertainty factors or conservative exposure assumptions), then the default additional 10X safety factor should be retained.'' (*Id.* at pgs. 51 and 52)

If the degree of concern for the potential pre- or postnatal uncertainty is high, the default 10X FQPA safety factor will typically be retained, unless there is ''reliable data'' to account for and describe the level of uncertainty regarding the potential for pre- or postnatal toxicity. (*Id.* at pg. 30) ''If the uncertainty can be addressed by reliable data, the risk assessor should recommend use of a different FQPA safety factor . . . to protect the safety of infants and children.'' (*Id.*) In the FQPA Policy Paper, EPA explains that ''reliable data'' must ''be sufficiently sound such that OPP could routinely rely on such information in taking regulatory action.'' (*Id.* at pg. A–5) As part of determining whether a different margin of safety would be safe, the paper indicates that the risk assessment should focus on whether the ''combination of data and reasonable scientific judgment,'' taking into account relevant information and data, would lead to a conclusion that the ''hazard or exposure . . . will not be underestimated.'' (*Id.* at pg. A–8)

d. Reliance on Epidemiological Data

i. Objection subissue. The Objectors assert that EPA's retention of the 10X FQPA safety factor to account for scientific uncertainties in the epidemiological data was unlawful. Citing the lack of underlying data and EPA's inability to reproduce or verify the conclusions of the studies, the Objectors claim that the epidemiological data are incomplete, invalid, and unreliable. As a result, Objectors argue

that the ''scientific uncertainties'' in those epidemiological data cannot be used to justify retention of the 10X FQPA safety factor. Gharda also asserts that the FFDCA does not allow application of the 10X FQPA safety factor based on unreliable epidemiological studies, ''particularly where a 10X safety factor results in the elimination of many important crop uses.'' (Ref. 39 at pg. 48) In essence, the Objectors are arguing that EPA acted arbitrarily and capriciously in considering the epidemiological studies in its WOE analysis.

ii. Denial of objection subissue. To the extent the Objectors are arguing that EPA cannot, as a matter of law, rely on epidemiological studies where the underlying raw data is unavailable or EPA cannot independently verify or reproduce the studies' conclusions, that objection is denied. There is no requirement for epidemiological studies to be supported by the raw data before the Agency can rely on them. On the contrary, a rule promulgated in January 2021, which would have required EPA to give heightened consideration to studies for which underlying data were publicly available, was judicially vacated one month after its issuance. (*EDF* v. *EPA,* 515 F. Supp. 3d 1135 (D. Mt. Jan. 27, 2021); 86 FR 29515, June 2, 2021 (FRL–10024–32–ORD) (removal of regulatory provisions from Code of Federal Regulations))

Significantly, the idea that these epidemiological studies are unreliable without the raw data was soundly rejected by the Ninth Circuit as applied to the chlorpyrifos studies. In a departure from its previous statements about the epidemiological studies, in the 2019 Denial Order and in the attendant litigation, EPA argued that the epidemiological data was invalid, incomplete, and unreliable due to the lack of underlying data and thus should not be considered by the Agency in assessing chlorpyrifos. The Ninth Circuit rejected EPA's reasoning as follows:

''[W]hile the EPA might reasonably conclude that divergences from international protocols and lack of access to raw data might affect the weight the EPA accords to these studies, they are nowhere near enough to show that the studies are entirely unreliable. The FFDCA requires the EPA to consider the ''information'' that is ''available'' and to make a safety determination based on that information. In this case, live animal studies showing sex-linked, neurotoxic harms from *in utero* chlorpyrifos exposure are available—even if such studies are supposedly not perfectly aligned with (unspecified) international standards. And peer-reviewed cohort studies showing harms to infants' neurological development following their mothers' exposure to chlorpyrifos are available—even if the underlying data is not. The EPA speculates that it might find an error if the unspecified international standards were applied to the animal studies or if the data from the Human Cohort Studies were available. But that is all it is: Speculation. Such speculation ''runs counter to the evidence before the agency,'' so it cannot form the basis for denying the 2007 Petition.'' (*Id.* pgs. 699 and 700 (citations excluded))

Moreover, in its recent framework document concerning the use of epidemiology studies, EPA recognizes that it is quite common and understood that certain information may be unavailable in epidemiology studies or suffer some limitations that may impede their use in quantitative risk assessment. (Ref. 19 at pgs. 10 and 16) That does not mean EPA cannot rely on these studies or use them to inform risk assessment. Often, such studies can ''provide insight into the effects cause by actual chemical exposures in humans and thus can contribute to problem formulation and hazard/risk characterization.'' In addition, epidemiological data ''can guide additional analyses or data generations . . . , identify potentially susceptible populations, identify new health effects, or confirm the existing toxicological observations.'' (*Id.* at pg. 4) Epidemiology studies ''have the potential to help inform multiple components of the risk assessment'', *e.g.,* qualitative comparisons between outcomes in epidemiologic studies to those in *in vitro* and animal studies to evaluate the human relevance of animal findings or assessing the biological plausibility of epidemiologic outcomes. (*Id.* at pg. 16)

Turning to the epidemiology studies themselves, there is extensive evidence in the record to support EPA's scientific decision to include those studies as part of its WOE analysis. Until its statements in the 2019 Denial Order and attendant litigation, which was rejected by the Ninth Circuit, EPA had concluded that the three prospective cohort studies (CCCEH, Mt. Sinai, and CHAMACOS, as described in Unit III.A.1.b.ii. of this document) were ''strong studies which support a conclusion that chlorpyrifos likely played a role in these [neurodevelopmental] outcomes.'' (Ref. 20 at pg. 33) Having considered the strengths and limitations of the studies, EPA concluded that the observed positive associations between *in utero* chlorpyrifos exposures and adverse neurodevelopmental effects were unlikely the result of errors in the design of the study. (*Id.*) While EPA did identify limitations in the studies, overall, EPA found the studies to be sound and worthy of consideration as part of a WOE analysis of available data concerning the potential pre- and postnatal toxicity of chlorpyrifos.

Under EPA's Epidemiologic Framework, ''human health characterizations involve the consideration of all available and relevant data, including but not limited to human studies/epidemiology . . . .'' (Ref. 19 at pg. 12) In evaluating epidemiology studies for use in pesticide risk assessment, EPA considers the ''quality of epidemiologic research, sufficiency of documentation of the study (study design and results), and relevance to risk assessment.'' (*Id.* at pg. 21) EPA will take into consideration various aspects of the study, including, but not limited to, adequacy of the exposure assessment, sample population and statistical power of the study, reliability of identifying affected individuals, adequacy of method for identifying confounding variables, characterization of systematic biases, among others. (*Id.* at pgs. 22 through 36)

For the epidemiology studies incorporated into EPA's WOE analysis, EPA fully evaluated and characterized the strengths and limitations of those studies consistent with its Framework Document. (Ref. 20 at pgs. 32–49) Despite limitations in the studies, EPA found ''considerable strengths in study design, conduct, and analyses demonstrated'' in the three cohort studies, including using prospective birth cohorts as a strong study design; using several methods for measuring pesticide exposure; using well-established, validated analytical tools for ascertaining developmental outcomes; measuring, analyzing, and adjusting for potentially confounding variables. Balancing those strengths against the limitations (one-time measure of exposure to assess prenatal exposure, lack of assessment of influence of mixtures, and small sample size, as well as lack of understanding of a critical window of exposure), EPA concluded that ''these data present an informative body of evidence with some notable consistencies across studies.'' (*Id.* at pg. 34)

Therefore, there is no merit to the Objectors' claim that it was unlawful for EPA to rely on the epidemiological studies in its assessment of chlorpyrifos. There is no requirement for the underlying data to be made available before EPA can rely on these studies,

and EPA had a rational scientific basis for including such data in its review in order to satisfy its statutory obligation to consider all data concerning the special susceptibility of infants and children.

e. Whether There Are ''reliable data'' Supporting a Different FQPA Safety Factor

i. Objection subissue. By objecting to the retention of the 10X FQPA safety factor, the Objectors appear to assert that EPA had ''reliable data'' to support a different margin of safety than the default 10X FQPA safety factor. However, most Objectors (Sugarbeet Associations, Gharda, Minor Crop Farmer Alliance) argue that because the epidemiological data is allegedly unreliable, the data should not be utilized. (Refs. 37, 39, and 49) Thus, removing the epidemiological data from consideration erases ''uncertainties'' and removes the need to retain the default safety factor. As EPA has demonstrated, the epidemiological studies have been evaluated and have been determined to support the conclusion of a potential effect on the developing brain associated with chlorpyrifos exposure.

The Coalition of OP Registrants assert that the toxicological profile of chlorpyrifos and other OPs indicates that the acetylcholinesterase inhibition endpoint is protective of the neurodevelopmental effects and thus the 10X FQPA safety factor was unnecessary to protect infants and children. (Ref. 53) Moreover, although noting that work concerning the New Approach Methodologies (NAMs) is ongoing, the Coalition of OP Registrants and the Agricultural Retailers Association, *et al.,* assert that NAMs would also support the position that the acetylcholinesterase inhibition endpoint would be protective of adverse neurodevelopmental effects. (Refs. 47 and 53)

ii. Denial of objection subissue. As noted previously, the FQPA amended the FFDCA to include an additional tenfold margin of safety to ensure the protection of infants and children. EPA may use a different margin of safety ''only if, on the basis of reliable data, such margin will be safe for infants and children.'' (21 U.S.C. 346a(b)(2)(C)) Thus, the presumption is to retain the 10X FQPA safety factor, unless there are reliable data to support a conclusion that a different safety factor will protect infants and children, taking into consideration potential pre- and postnatal toxicity and any residual uncertainties in the toxicity and exposure databases. Rather than requiring EPA to justify why the default factor is retained, the statute puts the burden on EPA to ensure that there are ''reliable data'' supporting a conclusion that a different safety margin would be protective for infants and children. Contrary to Gharda's implication, the FFDCA provides no flexibility for EPA to consider impacts on registrants or users of a pesticide when determining whether the available data is sufficiently reliable; this determination, much like the ''reasonable certainty of no harm'' standard is a purely risk-only standard, intended to ensure protection of infants and children from the harmful impacts of a pesticide.

As discussed in the FQPA Policy Paper, where there is a high degree of concern for potential pre- and postnatal toxicity, where data raise uncertainties or a high concern for infants or children that cannot be addressed through traditional uncertainty factors or other tools, those residual concerns or uncertainties should be addressed through retention of the default FQPA safety factor. (Ref. 9 at pg. 35) If there are ''reliable data'' that can account for the uncertainty regarding the potential for pre- or postnatal toxicity, a different FQPA safety factor may be appropriate. (*Id.* at pg. 30) As noted previously, ''reliable data'' must ''be sufficiently sound such that OPP could routinely rely on such information in taking regulatory action'' and would lead to a conclusion that the ''hazard or exposure . . . will not be underestimated.'' (*Id.* at pgs. A–5 and A–8)

As noted previously and in the final rule, acetylcholinesterase inhibition remains the most robust quantitative dose-response data in the chlorpyrifos toxicity database and thus, has been and continues to be the critical effect for quantitative risk assessment. Based on its historic experience and confirmation from the 2008 and 2012 SAPs, EPA used acetylcholinesterase inhibition as the endpoint for assessing chlorpyrifos risks. Despite the robustness of that dataset, the Agency's WOE analysis indicates that there is qualitative evidence of an association with potential effects on the developing brain and chlorpyrifos exposure. As EPA noted in the final rule and in the 2020 PID, despite several years of study, the science addressing neurodevelopmental effects remained unresolved. In the face of that uncertainty, and given the potential concerns for neurodevelopmental effects in infants and children, the Agency could not conclude that a different margin of safety would be safe to infants and children. The data considered at the time of the final rule did not resolve the uncertainty about the levels at which these effects may occur.

The purpose of the FQPA safety factor is to ensure the protection of infants and children against special susceptibilities identified in the toxicological database, including the potential for neurodevelopmental effects and effects occurring *in utero.* While the Agency's extensive database on the impacts of chlorpyrifos on acetylcholinesterase is well-established, the additional data—including animal studies, mechanistic studies, as well as epidemiological studies—concerning the special susceptibility of infants and children and the potential for neurodevelopmental effects raised additional questions, and residual uncertainties remain about the levels at which those effects may occur. Those uncertainties could not be ignored. In the face of unresolved uncertainties, EPA cannot determine that a different safety factor would ensure the safety of infants and children with regard to these effects. At the time of the final rule, EPA did not have sufficient ''reliable data'' to identify a different safety factor that would assure protection of infants and children.

At the time of the final rule, EPA acknowledged that ongoing work to develop NAMs may inform the assessment of the developmental neurotoxicity potential for chemicals, including chlorpyrifos and other OPs. EPA noted that it had convened a FIFRA SAP in September 2020 regarding the use of NAMs, and the SAP released its report and recommendations on EPA's proposed use of the NAMs data in December 2020. (Refs. 23 and 24) In the final rule, EPA stated that the advice of the SAP was being taken into consideration and thus ''analysis and implementation of NAMs for risk assessment of chlorpyrifos is in progress and was unable to be completed in time for use in this rulemaking.'' (Ref. 1 at pg. 48325) For purposes of the final rule then, EPA did not consider the NAMs data among the information available to inform its decision on the safety of chlorpyrifos.

As noted previously, the FFDCA permits the use of a different safety factor only if EPA has ''reliable data'' to support a determination that a different factor would be safe for infants and children. (21 U.S.C. 346a(b)(2)(C)) At the time of the final rule, under pressure to finalize a rule by a tight court-ordered deadline from a court that found EPA's delays to be ''egregious'' and a ''total abdication'' of its statutory duty, EPA relied heavily on data already reviewed. EPA did not conduct any new risk assessments for chlorpyrifos or

incorporate any new data after the Court's decision was issued.

Courts have recognized that court-imposed deadlines can become a ''substantive constraint on what an agency can reasonably do.'' (*San Luis & Delta-Mendota Water Authority* v. *Jewell,* 747 F.3d 581, 606 (9th Cir. 2014); *see also Am. Iron and Steel Inst.* v. *EPA,* 115 F.3d 979, 1006–07 (D.C. Cir. 1997) (recognizing that EPA was not required to stop process due to new evidence; ''mentioning the new evidence'' in the guidance and subsequently announcing use of that new evidence satisfied the requirement to deal with the new evidence ''in some reasonable fashion'')) In this case, EPA did recognize the NAMs data and its relevance, but because the Agency's path for incorporating NAMs into risk assessments was not finalized by the Court's deadline, EPA did not consider the NAMs data in the context of chlorpyrifos nor incorporate that data into any of its risk assessments or risk management decisions.

Although the Objectors suggest that the NAMs data may support the conclusion that the AChE endpoint is protective of the potential for neurodevelopmental effects in infants and children and thus obviate the need to retain the 10X FQPA safety factor, at this time, such conclusions are merely speculative. EPA's work on responding to the SAP report and developing a path forward for incorporation of the NAMs data into risk assessment is ongoing; EPA has not yet finalized its approach. When EPA's analysis is complete, EPA will proceed, as appropriate, with its use of the NAMs data in accordance with that evaluation.

f. Conclusion

In summary, EPA's inclusion of the epidemiological studies in its WOE was reasonable and consistent with sound science and its FQPA Policy Paper and Epidemiological Framework. Moreover, given the uncertainties surrounding the potential for neurodevelopmental effects, EPA's retention of the default 10X FQPA safety factor was consistent with the standard to apply the 10X margin of safety unless there is reliable data demonstrating that a different margin would be safe for infants and children. In any event, as EPA explained at the beginning of this section addressing the objection concerning the retention of the 10X FQPA safety factor, the question of what FQPA safety factor to apply is ultimately not outcome determinative in light of aggregate chlorpyrifos exposures resulting from registered uses. Even if EPA were to reduce the FQPA safety factor to 1X, the currently registered uses still result in aggregate risks of concern, and thus would not change the Agency's determination that the tolerances were unsafe and needed to be revoked. Therefore, this objection is denied.

3. Objections Related to EPA's Assessment of Drinking Water Exposures

The Sugarbeet Associations, Gharda, and the Agricultural Retailers Association, *et al.,* submitted objections concerning EPA's assessment of drinking water exposures. (Refs. 37, 39, and 47) Essentially, there were two objections related to drinking water: (1) Whether EPA had a rational basis for relying on the April 14, 2016, Chlorpyrifos Refined Drinking Water Assessment for Registration Review (2016 DWA) (Ref. 29) in the final rule instead of the September 15, 2020 Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review (2020 DWA) (Ref. 30) and (2) whether it was reasonable for EPA to assess exposures to chlorpyrifos-oxon, a metabolite of chlorpyrifos that forms in drinking water, in its drinking water assessment. Both of these objections are denied for the reasons discussed in the following unit.

a. Reliance on 2016 DWA

i. Objection. For the objection concerning reliance on the 2016 DWA, the Objectors claim that because EPA had conducted a more updated and refined drinking water assessment in 2020, the Agency could no longer rely on the 2016 DWA, which the Objectors allege no longer reflected the ''best available science.'' (Ref. 37 at pg. 10) The Objectors identify no substantive problems with the analysis of the 2016 DWA itself but believe that it fails solely because it did not incorporate the following refinements that were used in the 2020 DWA: (a) New surface water modeling scenarios, (b) Presentation of the entire distribution of community water systems percent cropped area (PCA) adjustment factors and integration of state-level crop-treated data using percent crop treated (PCT) factors, and (c) Quantitative use of surface water monitoring data. (Ref. 47 at pg. 7) Gharda further claims that EPA could not rely on the 2016 DWA because EPA has failed to take into consideration comments submitted in response to the 2016 DWA. (Ref. 39 at pgs. 31 and 32) Gharda cites Dow AgroSciences LLC's Comments on the 2016 Notice of Data Availability, Revised Human Health Risk assessment and Refined Drinking Water Assessment for Chlorpyrifos and Dow AgroSciences LLC's Response to Objections to EPA's Denial of Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos (Ref. 39). Again, Gharda points to no specific deficiencies about the 2016 DWA identified in the Dow comments on the 2016 DWA and Dow Response to Objections; rather, Gharda simply summarizes the Dow submissions as commenting that the 2016 DWA is ''an overly conservative, screening-level estimate that far over-estimates real world exposures and ignores science-based refinements submitted by'' Dow (now Corteva) and asserting that the 2016 DWA was ''incomplete and unrefined.'' (*Id.* at pgs. 31 and 32) In addition, Gharda states that there were ''significant limitations'' in the 2016 DWA, although those limitations seem, again, tied to the absence of the refinements in the 2020 DWA. (*Id.* at pg. 32)

ii. Background. As described in Unit II.B.1.c.ii.(d), EPA takes a tiered approach to assessing drinking water. Lower tiered assessments are more conservative based on the defaults or upper-bound assumptions and may compound conservatisms, while higher tiers integrate more available data and provide more realistic estimates of environmental pesticide concentrations. (Ref. 13)

Over the years, EPA has conducted several drinking water assessments for chlorpyrifos and refined those assessments as new information and tools became available. In 2011, EPA completed a preliminary DWA. (Ref. 26) That assessment recommended use of surface water estimated drinking water concentrations (EDWCs) derived from modeling and concluded that a range of agricultural uses could lead to high levels of chlorpyrifos in surface water that could potentially be used by community water systems to supply drinking water. That assessment discussed the effects of drinking water treatment on chlorpyrifos and concluded that during the chlorination disinfection processes, chlorpyrifos can be readily converted to chlorpyrifos-oxon. Therefore, chlorpyrifos and its oxon were considered residues of concern in the preliminary assessment.

Taking into consideration public comments on the 2011 preliminary DWA, EPA updated that assessment in a 2014 DWA to include additional analyses focused on clarifying labeled uses, evaluating volatility and spray drift, revising aquatic modeling input values, comparing aquatic modeling and monitoring data, summarizing effects of drinking water treatment, updating model simulations, and proposing a

strategy to refine the assessment using community water system-specific drinking water intake percent cropped area (PCA) adjustment factors. (Ref. 27) This 2014 DWA confirmed the findings of the 2011 preliminary DWA, concluding that there were a number of uses that may result in exposures to chlorpyrifos-oxon in drinking water at unsafe levels, although the 2014 DWA also noted that additional analyses would be needed in order to finish identifying specific geographical areas where exposures may be of concern. (*Id.* at pgs. 8 and 9)

In 2016, EPA conducted a refined drinking water assessment that estimated drinking water concentrations based on modeling of all registered uses, as well as all available surface water monitoring data. That assessment considered several refinement strategies in a two-step process to derive exposure estimates for chlorpyrifos and chlorpyrifos oxon across the country. The first step was an assessment of potential exposure based on the current maximum label rates at a national level. This indicated that the EDWCs could be above the DWLOC. The second step considered model estimates, as well as measured concentrations, at a more localized level and more typical use scenarios. This built on the approach presented in the 2014 DWA for deriving more regionally specific estimated drinking water exposure concentrations for chlorpyrifos and chlorpyrifos-oxon. The results of this second-step analysis also concluded that there were high levels of chlorpyrifos and chlorpyrifos-oxon in drinking water. (Ref. 29)

Following the completion of the 2016 DWA, EPA developed refinement strategies to examine those estimated regional/watershed drinking water concentrations to pinpoint community drinking water systems where exposure to chlorpyrifos oxon as a result of chlorpyrifos applications may pose an exposure concern. At that time, EPA was anticipating that a more refined drinking water assessment might allow EPA to better identify where at-risk watersheds are located throughout the country for the purpose of supporting more targeted risk mitigation through the registration review process. The refinements better account for variability in the use area treated within a watershed that may contribute to a drinking water intake (referred to as PCA or percent use area when considering non-agricultural uses) and incorporate data on the amount of a pesticide that is historically applied based on user surveys within a watershed for agricultural uses (referred to as PCT). These refinement approaches underwent external peer review and were issued for public comment in January 2020. (Ref. 54) In addition, EPA used average application rates, average numbers of annual applications for specific crops, and estimated typical application timing at the state-level based on pesticide usage data derived from Kynetec, a statistically reliable private market survey database; publicly available survey data collected by the USDA; and state-specific scientific literature from crop extension experts.

The recently developed refinements were integrated into the 2020 DWA. (Ref. 30) Because of how high the estimated drinking water concentrations were in the 2016 DWA, it was not expected that the exposures for all uses could be refined to a safe level; therefore, the Agency decided to focus its refinements for the 2020 updated drinking water assessment on a subset of uses in specific regions of the United States. The purpose of the focus on this subset of uses was to determine whether, if these were the only uses permitted on the label, the resulting estimated drinking water concentrations would be below the DWLOC. The subset of uses assessed were selected because they were identified as critical uses by a registrant or high-benefit uses to growers by EPA. That subset of currently registered uses included alfalfa, apple, asparagus, cherry, citrus, cotton, peach, soybean, sugar beet, strawberry, and wheat, confined to specific areas of the country. (*Id.* at Appendix A) The updated assessment applied the new methods for considering the entire distribution of community water systems PCA adjustment factors, integrated state level PCT data, and included quantitative use of surface water monitoring data in addition to considering state level usage rate and data information. The results of this analysis indicated that the EDWCs from this subset of uses limited to certain regions would be below the DWLOC. (*Id.* at pgs. 16 and 17)

It is important to emphasize that the 2020 DWA ''focuse[d] on a subset of currently registered chlorpyrifos uses. . . . The exposure estimates reported in [the 2020 DWA] and associated conclusions drawn are solely for those uses. . . . Adding additional uses would require reassessment and could change estimated drinking water concentrations and thus, exposure conclusions, and ultimately the risk conclusion relative to the drinking water level of comparison(s).'' (*Id.* at cover memo) In other words, EPA recognized that the subset of assessed uses was only one combination of possible subsets that might be safe. Recognizing that in response to the Agency's proposal in the 2020 PID, registrants or growers could have advocated for a different subset of uses or to add different uses or geographic regions, EPA noted that additional analyses would need to be completed to determine the contributions to drinking water in those impacted regions and whether such uses would be safe.

iii. Denial of objection. The Objectors' primary argument is that EPA could not rely on the 2016 DWA (Ref. 29) because the subsequently developed refinements used in the 2020 DWA (Ref. 30) meant that the 2016 DWA, having been conducted without those refinements, did not represent the best available science. As EPA acknowledges in the background discussion, the 2020 DWA incorporated several refinements, including updated surface water scenarios, new methods for considering the entire distribution of community water systems PCA adjustment factors, integrated state-level PCT data, and a quantitative use of surface water monitoring data. (Ref. 30) The 2020 DWA represents one of, if not, the highest tiered, most refined drinking water assessment EPA has conducted to date. Nevertheless, the availability of the more refined 2020 DWA does not make it unlawful for EPA to rely on the 2016 DWA in the final rule, particularly where the 2020 DWA was confined to a scenario that did not exist at the time of the final rule.

In denying this objection, EPA finds the scope of the 2020 DWA to be determinative. As noted previously and in the final rule, the 2020 DWA evaluated only a subset of the currently registered uses. Specifically, the 2020 DWA evaluated only 11 of the over 50 agricultural use sites and non-agricultural use sites currently registered for chlorpyrifos. Moreover, those 11 uses were assessed only in specific geographic regions (not all geographic regions in which the pesticide is currently being used) based on typical use rates rather than maximum labeled application rates. The underlying presumption of the 2020 DWA was that chlorpyrifos would not be labeled for any other uses, including non-food uses, besides that limited subset. As such, it presented a highly refined evaluation of a particular subset of predicted uses only; it was not a complete and full assessment of the approved uses of chlorpyrifos and thus did not provide an accurate picture of aggregate exposures from all currently registered use patterns. Although the Sugarbeet Associations assert that EPA could have relied on the 2020 DWA

since it tracks the proposal in the 2020 PID, that argument fails for all the same reasons why EPA could not rely on the conclusions in the 2020 PID to retain the 11 uses, as explained in Unit VIII.C.1. Since the FFDCA, in requiring consideration of aggregate exposure, required EPA to evaluate food, drinking water, and residential exposures from all registered uses, EPA could not rely on the partial assessment of registered chlorpyrifos uses for estimated drinking water concentrations, unless all other uses were canceled. Doing so would have presented an incomplete picture of potential drinking water contributions from currently registered uses. Thus, the 2016 DWA, which is the most recent EPA assessment of contributions to drinking water from all registered uses of chlorpyrifos—and not the 2020 DWA—represented the most recent, most robust ''best available science'' for use by the Agency for the uses on current labels.

EPA also disagrees with the Objectors' implication that the mere existence of new refinement methodologies somehow impacts the reliability of the 2016 DWA. At the time the 2016 DWA was issued, it represented the most refined drinking water assessment EPA's OPP had conducted. It applied all available refinement techniques available at that time, including, as discussed previously, using modeled estimates and measured concentrations to drill down to drinking water contributions on a regionally specific level. The subsequent development of additional tools to refine drinking water assessments that show risks of concern does not render the 2016 DWA overly conservative or otherwise scientifically invalid and unreliable. The Agency simply has additional tools and methods that can be applied to refine drinking water assessments where appropriate. The Agency's Drinking Water Framework notes that moving to the higher tiers that were used in the 2020 DWA ''requires a large amount of resources and adds a great amount of complexity to the assessment.'' Therefore, rather than moving to the higher tiers automatically, ''advancement to Tier 4 should be done in consultation with the interdivisional chemical team.'' (Ref. 13 at pg. 51)

The question then is whether it was reasonable for EPA not to apply the 2020 refinements to all the uses assessed in the 2016 DWA; EPA concludes that it was. Following the issuance of the 2016 DWA, in which EPA identified EDWCs from registered chlorpyrifos uses that exceeded safe levels, EPA met with representatives of Corteva, a chlorpyrifos registrant, about whether additional information about critical uses to growers could be used to refine the 2016 DWA as part of the ongoing work in registration review to assess uses of chlorpyrifos. (Ref. 51) Given the large number of uses and high estimates across various vulnerable watersheds throughout the country, EPA focused its resources to apply the refinement strategies on assessing whether a subset of uses that were identified by Corteva as critical and considered by EPA to present high benefits to chlorpyrifos users could result in EDWCs lower than the DWLOC.

Once EPA determined the appropriate subset of uses to evaluate, EPA dedicated extensive resources to apply the newly developed methodologies, including gathering PCT data from states in which the specific crops to be retained were grown, to those uses to determine if the resulting uses would result in estimated drinking water concentrations of chlorpyrifos below the Agency's relevant level of concern, *i.e.,* the DWLOC. This approach is consistent with the Agency's standard practice during registration review; for pesticides that pose risks of concern, EPA will typically consider whether any mitigation is available that would allow the pesticide to meet the registration standard, including the FFDCA safety standard. (*See* 40 CFR 155.53 and 155.56) For chlorpyrifos, for which the Agency had identified high levels of risk in 2016, EPA decided to focus on whether there was a mitigation package that would allow some uses of chlorpyrifos to be considered safe.

Starting with a hypothetical ''blank label'' with no registered uses and adding back just the 11 geographically and application rate limited uses, *i.e.,* assuming all other current uses did not exist, EPA assessed the subset of aforementioned uses applying the new refinement techniques. That analysis resulted in estimates of chlorpyrifos concentrations in drinking water below the DWLOC, which provided a basis for EPA to propose that subset of uses for mitigation of risk in the 2020 PID. For some areas, the estimated drinking water concentrations from combinations of those 11 uses were close to the DWLOC, so there was not much room in the risk cup for adding more uses. For example, EPA concluded that use of chlorpyrifos on alfalfa, sugarbeet, and soybean in the Upper Mississippi region (HUC–07) or on alfalfa, sugar beet, soybean, and spring and winter wheat in the Souris-Red-Rainy region (HUC–09), the estimated drinking water concentrations were 3.2 ppb and 3.3 ppb, respectively; for comparison, a concentration of 4.0 ppb or above would exceed safe levels of chlorpyrifos in those areas. (Ref. 31 at pg. 16) Because EPA was trying to evaluate a specific subset of uses for purposes of providing a mitigation option in the proposed registration review decision and because that evaluation indicated that that subset alone would not pose risks of concern, EPA did not engage in further refinements of other uses from the 2016 DWA to determine if other hypothetical uses could be safe. EPA, however, recognized the possibility that additional or different uses might be requested following that proposal and cautioned that, if so, additional assessment would need to be conducted to support risk management decisions for those other uses.

Thus, at the time the 2020 DWA was conducted, it was reasonable that EPA did not expand the application of refinements beyond the 11 uses assessed. It was also reasonable that EPA did not engage in refinements of the rest of the uses in the 2016 DWA in preparation of the final rule. As EPA has indicated throughout this Order, given the time constraints imposed on the Agency by the court-ordered deadline, EPA did not conduct any new risk assessments, including any new drinking water assessments to further refine the 2016 DWA for all registered uses. To apply the refinements to all currently registered uses would have required an extraordinary investment of resources and time, which EPA did not have in light of the Court's deadline. Consequently, EPA relied on the best available science it had available to assess the currently registered uses as required at the time of the final rule—the 2016 DWA. This objection is denied.

b. Assessing Chlorpyrifos-Oxon

In addition to opposing the use of the 2016 DWA in the final rule, the Agricultural Retailers Association, *et al.,* and Gharda assert that EPA's assessment of aggregate exposure should not have considered chlorpyrifos-oxon, a metabolite of chlorpyrifos.

i. Objection regarding lack of exposure. (A) Objection. The Agricultural Retailers Association, *et al.* note that the 2016 DWA stated that there were ''no detections of chlorpyrifos-oxon degradates in any finished drinking water samples that people actually consume.'' (Ref. 47 at pg. 7) Thus, the Agricultural Retailers Association, *et al.* argue that it was arbitrary and capricious for EPA to assess the exposures of chlorpyrifos oxon in drinking water.

(B) Denial of objection. EPA has extensive reliable data supporting its

conclusion that chlorpyrifos-oxon will be present in at least some drinking water. It is well understood that chlorpyrifos rapidly oxidizes to form chlorpyrifos-oxon almost quantitatively (*i.e.,* nearly 100% conversion of chlorpyrifos into equal quantities of chlorpyrifos-oxon) during drinking water treatment with chlorination. While chlorination is the most common drinking water treatment, there are some areas that use different disinfection processes, such as those using chloramines, which are less effective at converting chlorpyrifos to its oxon, so, the resulting drinking water may contain combination of residues of chlorpyrifos and its oxon.

Currently, there are no data available on the removal efficiency of chlorpyrifos prior to chlorination or the removal efficiency of chlorpyrifos-oxon after formation. Stability studies indicate that once chlorpyrifos-oxon forms, little transformation is likely to occur between water treatment and consumption of the drinking water; the chlorpyrifos-oxon has been shown to be relatively stable following drinking water treatment (*i.e.,* with a half-life of 12 days). While some drinking water treatment procedures, such as granular activated carbon filtration and water softening, may reduce the amount of chlorpyrifos-oxon in drinking water, it is unlikely that these treatment processes completely remove chlorpyrifos-oxon from drinking water. In addition, these treatment methods are not typical practices across the country for surface water. For these reasons, it is reasonable for EPA to assume that drinking water will contain chlorpyrifos-oxon residues as a result of water treatment systems. (Ref. 26 at pgs. 2, 22 and 23)

The Agricultural Retailers Association, *et al.* point out that the 2016 DWA states that there have been no detections of chlorpyrifos oxon in finished water samples. (Ref. 47 at pg. 7; Ref. 29 at pg. 111) While it is correct that the 2016 DWA contains this statement, the lack of detections in finished water does not mean that chlorpyrifos-oxon is not present in some drinking water. There were several detections in the monitoring data of both chlorpyrifos and oxon in filtered and unfiltered surface water, and in surface water with known particulates (Ref. 29 at pgs. 97 through 113), so it is clear that chlorpyrifos and its oxon are present in at least some drinking water. Chlorpyrifos found in surface water that enters a drinking water treatment plant will be converted in most instances, as indicated previously, into chlorpyrifos-oxon before it leaves the plant and travels to consumers. There are several reasons why chlorpyrifos and chlorpyrifos-oxon may not have been detected in finished drinking water, including sample site location, sampling frequency, as well as drinking water treatment not involving chlorination that may lead to less oxon formation. There is insufficient data available to determine if the community water systems sampled for chlorpyrifos to date are located in watersheds vulnerable to chlorpyrifos contamination. (Ref. 29 at pg. 10) Due to the limitations of monitoring data, EPA cannot conclusively determine that chlorpyrifos-oxon will not be present in some drinking water, in light of the available science demonstrating conversion of chlorpyrifos to its oxon during chlorination, which occurs in the vast majority of major drinking water treatment systems throughout this country.

ii. Objection regarding lack of toxicity. (A) Objection. Gharda objects to EPA's assessment of chlorpyrifos-oxon residues in drinking water because Gharda believes that the ''drinking water risks associated with the oxon are not a risk concern for any agricultural uses of chlorpyrifos and should not be part of the EPA's aggregate risk assessment or serve as a basis for limiting uses of chlorpyrifos.'' (Ref. 39 at pgs. 32 and 33) Gharda bases this conclusion on its interpretation of the Corteva Oxon Study, which Gharda asserts found ''(a) no detectable circulating chlorpyrifos oxon in blood, (b) no statistically significant AChE inhibition in either RBC or brain, and (c) an absence of clinical signs of toxicity or markers of exposure,'' and therefore nullified EPA's assumption in the 2020 DWA ''that chlorpyrifos oxon is more toxic than the parent chlorpyrifos for drinking water exposure purposes.'' (*Id.* at pg. 32) Gharda argues that EPA's failure to consider this study makes EPA's final rule arbitrary and capricious.

(B) Denial of objection. As noted throughout this document, in light of the time constraints imposed on EPA by the Court and the direction to avoid further delay and fact-finding 14 years after the petition to revoke the tolerances had been filed, EPA focused on information already assessed to determine whether the chlorpyrifos tolerances were safe. The Agency did not conduct any additional analyses of other data, including review of the Corteva Oxon Study, due to the time constraints that were imposed on the Agency by the Ninth Circuit's deadline. That study had not been incorporated into any Agency's risk assessments at the time of the final rule, given that this study was submitted to EPA in December 2020, after the Agency's risk assessments on chlorpyrifos had been finalized (in September 2020). Due to the ongoing status of registration review, the Agency has not yet determined whether—and if so, how—to integrate this study into any risk assessment. Therefore, the final rule was not arbitrary and capricious for failure to incorporate this study into the completed risk assessments.

In any event, as EPA indicated in Unit VII.C.2., Gharda has failed to demonstrate how EPA could conclude that the tolerances are safe, even if EPA were able to incorporate this study into its assessment and agreed that the oxon was not relevant for risk assessment purposes. Also as discussed in Unit VII.C.2., EPA has concluded that even assuming that chlorpyrifos-oxon is not more toxic than chlorpyrifos and thus should not be the residue of concern for evaluating exposures in drinking water, the concentrations of the parent compound, chlorpyrifos, in drinking water would still result in exposures that were unsafe. Based on a comparison of 2016 DWA estimates of chlorpyrifos residues in drinking water to the chlorpyrifos DWLOC, registered uses of chlorpyrifos result in levels of chlorpyrifos in drinking water that would exceed safe levels of chlorpyrifos exposure. Therefore, this objection is denied for failure to demonstrate that using the Corteva Oxon Study would have a material impact on the Agency's safety finding.

4. Procedural Considerations

A number of objections were filed raising a variety of process claims: Failure to consider public comments on the Agency's 2015 proposal to revoke chlorpyrifos tolerances in response to the 2007 Petition and on the 2020 PID; delayed opening of the portal for submission of objections; and failure to comply with requirements for interagency coordination under Executive Order 12866. These objections are denied for the reasons discussed in this unit.

a. Prior Comments

i. Objection. The Sugarbeet Associations and CLA/RISE assert that the failure to consider and respond to the more than 90,000 comments on the 2015 proposed rule and the comments submitted in response to the 2020 PID is inconsistent with the principles of due process and transparency. (Refs. 37 and 50)

ii. Denial of objection. EPA denies this objection for lack of specificity and

relevance. EPA's regulations require that an objection ''[s]pecify with particularity the provision(s) of the . . . regulation . . . objected to, the basis for the objection(s), and the relief sought.'' (40 CFR 178.25(a)(2)) The objection claiming that EPA must consider the 90,000 comments on a prior proposed rule fails to meet this test. Other than objecting to EPA's not having considered those prior comments, the objections do not specify a particular aspect of the final rule that is problematic. Neither do the objectors point to anything specifically raised in the comments on the 2015 proposed rule that would support a particular objection they have to the rule. Without something specific to address, these comments as a general matter are not relevant to the Agency's final rule, for the reasons articulated directly following this discussion in this document. For this reason, this objection is denied as not conforming to the required form of objections. (40 CFR 178.30(a)(1))

Moreover, EPA does not believe that responses to the comments submitted on the 2015 proposed rule are required before proceeding with this final action, due to the unique regulatory structure provided under the FFDCA. The FFDCA sets up three options for EPA in responding to a petition seeking revocation of tolerances: (1) To issue a final rule establishing, modifying or revoking a tolerance; (2) to issue a proposed rule subject to public comment and thereafter issue a final rule; or (3) to issue an Order denying the petition. (21 U.S.C. 346a(d)(4)(A)(i), (ii), (iii)) The 2015 proposed rule was issued in response to the 2007 Petition under the second option provided in the statute. (21 U.S.C. 346a(d)(4)(A)(ii)) Based on comments submitted in response to that proposed rule, EPA conducted additional risk assessments, which were also released for public comment. (*See* Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment (81 FR 81049, November 17, 2016) (FRL–9954–65)) No formal responses to those comments were ever finalized, as soon thereafter, EPA abandoned the proposed rule and issued the 2017 Order Denying Petition under the third option provided in the statute. (21 U.S.C. 346a(d)(4)(A)(iii)) EPA's final rule was issued under the first option provided by the statute—to issue a final rule establishing, modifying, or revoking a tolerance without public comment. In sum, the statute provides EPA with choices on how to act and does not constrain EPA's ability to follow any of the statutory paths.

After EPA denied objections to the 2017 Order Denying Petition in 2019, a lawsuit was filed, and the Ninth Circuit vacated the 2017 and 2019 Orders and directed EPA to ''publish a legally sufficient final response to the 2007 Petition within 60 days of the issuance of the mandate.'' (*LULAC,* 996 F.3d at pg. 703) Notably, the court also specifically ordered EPA to issue a final rule either revoking or modifying chlorpyrifos tolerances under the first option provided in the statute, which provides for the issuance of a final rule ''without further notice and without further period for public comment.'' (21 U.S.C. 346a(d)(4)(A)(i)) Since the Court directed EPA to proceed with a final rule without directing EPA to finalize the 2015 proposed rule, EPA interpreted the Court's mandate as requiring an independent final rule based on available information, not a finalization of the prior rule. The Court's strict deadline for finalizing the rule further suggests that the Court did not expect EPA to formalize responses to a large number of potentially stale comments. As such, EPA is not obligated to respond to comments on a rule that was never finalized.

With regard to the comments submitted in response to the 2020 PID, those comments were submitted in response to the separate registration review action. As a separate action, EPA is also not obligated to respond to those comments as part of its final rule. That registration review process for chlorpyrifos is ongoing, and EPA is still reviewing the comments received in connection with that process and was not in a position at the time of the final rule to have finalized its responses to those comments. It is also worth noting that, as alluded to earlier in Unit VIII.C.1.a. of this document, the scope of the registration review differs from that of the final rule, *i.e.,* registration review under FIFRA also includes consideration of environmental risks and benefits information that are not relevant to the Agency's final rule decision. As a result, several of the comments are not likely to be relevant to the final rule.

Finally, to the extent any objector believes that a comment on the 2015 proposed rule or the 2020 PID raises specific substantive challenges that should have been considered in the final rule, the FFDCA affords the exact due process they seek. Under the special administrative procedures provided in FFDCA section 408(g), ''any *person* may file objections thereto with the *Administrator,* specifying with particularity the provisions of the regulation or Order deemed objectionable and stating reasonable grounds therefor.'' (21 U.S.C. 346a(g)(1)) Any objector can take advantage of the due process allowed by the FFDCA and submit any specific comments for Agency consideration as an objection to the final rule. Because of the opportunity to provide such objections directly to EPA as part of the objections process, there is no due process violation for not responding to comments on a proposed rule that was never finalized or to comments submitted on a separate regulatory action that remains ongoing.

b. Objections Portal

i. Objection. The American Soybean Association argues that the final rule failed to provide adequate procedural due process as a result of technical delays in opening the Federal eRulemaking Portal for submission of objections. (Ref. 36 at pgs. 3 and 4) The American Soybean Association states that on October 12, 2021, its staff discovered that the docket for the final rule was not open to accepting comments. The American Soybean Association speculates that having the objections portal disabled for any portion of the objections period could have prevented individual growers from being able to submit objections, thus denying them the right to object to the final rule.

ii. Denial of objection. EPA denies this objection. EPA's regulations require that objections be filed with the Hearing Clerk no later than 60 days following publication of the final rule in the **Federal Register** in accordance with EPA's regulations in 40 CFR part 178. (*See* 40 CFR 178.25(a)(6) and (7)) This mandatory requirement, including the direction to submit filings through the Office of Administrative Law Judges' electronic filing system, was clearly laid out in EPA's final rule, as the American Soybean Association notes. In addition to the mandatory filing of objections with the Hearing Clerk, EPA also requests that objectors submit their filed objections online (redacting any Confidential Business Information (CBI)) ''for inclusion in the public docket''. This additional step allows submitters to ensure the protection of any sensitive information in what is uploaded as part of the public docket for the action. This additional request does not include a deadline for submissions. The American Soybean Association objects only to the delayed opening of this latter online public docket.

While EPA concedes that there were technical issues with the opening of the

Federal eRulemaking Portal, this appears to be a harmless error as there is no legal consequence from the delay, and there is no indication that anyone was deprived of the opportunity to submit objections. Promptly upon receiving notice that the docket for the final rule was not open to accepting comments, and well before the close of the objection period on October 15, 2021, this issue was resolved by EPA. The American Soybean Association and over 100 other Objectors were able to submit their objections, hearing requests, and requests for stay without issue. While the American Soybean Association speculates that individual growers seeking to object might not have had the opportunity to do so, EPA did not receive any information suggesting that might be the case. On the contrary, EPA received dozens of submissions to the Federal eRulemaking Portal from individual growers, which were filed as both standalone objections (see the objections filed by individual growers Chris Hill, Willard Jack, Steve Kelley, Andrew Lance, Alan Meadows, and Joel Schreuers, Ref. 1) and included in a transmittal of 93 independent comment letters submitted by the Sugarbeet Associations (Ref. 37, Attachment 4).

c. Interagency Review Process

i. Objection. The Sugarbeet Associations, Gharda, and the Agricultural Retailers Association argue that EPA failed to comply with Executive Order 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993), and thus deprived other federal agencies an opportunity to provide feedback on the final rule. (Refs. 37, 39, and 47) The Objectors argue that the final rule is a ''significant regulatory action'' as defined in the Executive order, noting that EPA estimated a high-end annual economic benefit of chlorpyrifos of $130 million, based on higher-cost alternatives and pest damage. (Ref. 56 at pg. 39) The Agricultural Retailers Association, *et al.* and Gharda both argue in the alternative that the final rule meets the definition of a significant regulatory action in that it is ''likely to adversely affect the entire agricultural economy, jobs, productivity, and our environment.'' (Ref. 39 at pgs. 47 and 48; Ref. 47 at pg. 4) In addition, Gharda and the Sugarbeet Associations assert that tolerance revocations are not covered by Office of Management and Budget's (OMB) guidance on Executive Order 12866, which excepts tolerance actions from OMB review, because that guidance excludes from the exemption only ''those [tolerance actions] that make an existing tolerance more stringent.'' (Ref. 39 at pg. 47; Ref. 47 at pg. 12)

ii. Background. Executive Order 12866 provides that ''significant regulatory actions'' must be submitted for review to the Office of Information and Regulatory Affairs in OMB. A significant regulatory action is generally any regulatory action that is likely to result in a rule that might, among other things, have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. After the issuance of Executive Order 12866, OMB issued *Guidance for Implementing E.O. 12866,* which exempted tolerance actions under the FFDCA from Executive Order 12866 review, ''except those that make an existing tolerance more stringent.'' (Ref. 55)

iii. Denial of Objection. As an initial matter, EPA notes that Executive Order 12866—like most, if not all, executive orders—explicitly says that it ''does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.'' (58 FR 51744) Thus, not submitting the final rule to OMB cannot constitute a violation of any law, such that a reviewing court could reasonably be expected to find that EPA's action was ''not in accordance with law'' under 5 U.S.C. 706(2)(A) or ''without observance of procedure required by law'' under 5 U.S.C. 706(2)(D). Therefore, this is not a judicially reviewable issue. Moreover, EPA notes that resolution of this particular objection has no bearing on any substantive issues with the final rule that are raised separately in other objections. Thus, this objection is denied.

In any event, EPA disagrees that the final rule revoking chlorpyrifos tolerances triggers the Executive Order 12866 interagency review requirements. EPA believes the OMB guidance regarding Executive Order 12866 and its application to pesticide tolerance actions can be interpreted to mean that a pesticide tolerance is made ''more stringent,'' and thus subject to Executive Order 12866 requirements, when EPA does not make accommodations for affected parties to adjust to the impacts of the rule. With respect to the revocation of tolerances for chlorpyrifos, however, the final rule provided a meaningful period of time for affected parties to adjust to the rule's impact, in light of the identified safety concerns. Specifically, EPA provided six months between the publication of the final rule and its effective date, which far exceeds the 30-day effective date requirement contained in the Administrative Procedure Act. In addition, this approach is both consistent with the Agency's obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures and, in the Agency's view, generous in light of the Agency's conclusion that chlorpyrifos tolerances were not safe. Finally, this approach is consistent with the Agency's approach for other pesticide tolerance revocations that EPA determined were not subject to Executive Order 12866; *see, e.g.,* EPA's revocations of tolerances for carbofuran in 2009 (74 FR 23045), butylate, clethodim, dichlorvos, dicofol, and isopropyl carbanilate, et al. in 2012 (77 FR 59120), and tebufenozide in 2017 (82 FR 53423).

For all the foregoing reasons, the objection regarding Executive Order 12866 and interagency review is denied.

5. Objections That, As a Matter of Law, Do Not Provide a Basis for Leaving Tolerances in Place

Many Objectors suggested that EPA's final rule was inappropriate on grounds that are immaterial to the question of whether tolerances can be maintained under the FFDCA. The FFDCA and EPA's regulations require that objections identify a particular aspect of the final rule deemed objectionable and specify with particularity the provision of the regulation objected to and the relief sought. (21 U.S.C. 346a(g)(2), 40 CFR 178.25(a)(2)) In addition, the objection must seek relief that is consistent with the FFDCA. (40 CFR 178.30(a)(2)) Objections that do not meet these conditions will be denied. The objections discussed in this sub-unit provide no reliable information pertaining to the FFDCA safety standard in section 408(b)(2) that could support leaving the tolerances in place. Because these complaints are meritless on their face, these objections are denied. EPA provides further discussion in this unit.

a. Economic and Environmental Impacts

i. Objection. A majority of Objectors, including the Agricultural Retailers Association, *et al.,* the Sugarbeet Associations, American Soybean Association, Cherry Marketing Institute, and 93 sugarbeet growers as part of a mass mailer, allege that the revocation of chlorpyrifos tolerances will have detrimental impacts on their crops due to increased pest pressure, force growers

to use more expensive and less efficacious alternatives, and result in harmful effects on the environment. (Ref. 1)

ii. Denial of objection. EPA appreciates that the revocation of chlorpyrifos tolerances will have an impact on growers who use the pesticide and the agricultural industry. Chlorpyrifos is a widely used pesticide that has been registered for many uses since 1965. As part of the registration review process under FIFRA, the Agency did evaluate the benefits of chlorpyrifos to growers by crop. (Ref. 56) EPA is aware that IPM and resistance management are critical pest management benefits of many pesticides, and where benefits considerations are permitted by law, the Agency takes these aspects into serious consideration. However, consideration of information on pesticidal benefits to growers or impacts on the environment from loss of a pesticide, while relevant considerations under FIFRA (*see* 7 U.S.C. 136(bb)), are not factors for consideration under the FFDCA, with one exception not applicable here. (*See* 21 U.S.C. 346a(b)(2)(B))

The safety standard under the FFDCA is strictly a human-health risk-based standard, which does not permit consideration of benefits or environmental information, in determining whether a tolerance is safe. Invariably, FFDCA section 408 directs EPA to consider factors relevant to the safety of the pesticide residue in food (aggregated with other sources of exposure to the pesticide residue), placing particular emphasis on human dietary risk. (*See, e.g.,* 21 U.S.C. 346a(b)(2)(B) (addressing an exception to the safety standard for pesticide residues as to which EPA ''is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health''); 21 U.S.C. 346a(b)(2)(C) (requiring special safety findings as to ''infants and children'' regarding their ''disproportionately high consumption of foods'' and their ''special susceptibility * * * to pesticide chemical residues''); 21 U.S.C. 346a(b)(2)(D)(iii) (requiring consideration of the relationship between toxic effects found in pesticide studies and human risk); 21 U.S.C. 346a(b)(2)(D)(iv), (vi), and (vii) (requiring consideration of available information on ''dietary consumption patterns of consumers,'' ''aggregate exposure levels of consumers,'' and the ''variability of the sensitivities of major identifiable subgroups of consumers''); 21 U.S.C. 346a(b)(2)(D)(vi) (requiring consideration of ''non-occupational'' sources of exposure); 21 U.S.C. 346a(b)(2)(D)(viii) (requiring consideration of information bearing on whether a pesticide ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects''); 21 U.S.C. 346a(l)(2) and (3) (requiring revocation or suspension of tolerances where associated FIFRA registration is canceled or suspended ''due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food'')) Thus, under section 408, EPA has no discretion to insert economic or environmental considerations into its decisions on the chlorpyrifos tolerances.

Therefore, objections that EPA should have taken economic and environmental impacts into consideration in issuing the final rule are denied, as EPA has no authority to do so as part of its safety evaluation under the FFDCA.

b. Consideration of Occupational Exposure by EPA

i. Objection. Gharda and the Sugarbeet Associations assert that EPA unlawfully considered occupational exposures as a reason for revoking the tolerances. In support of this objection, they point to an EPA press release regarding the final rule dated August 18, 2021, which mentioned that the tolerance revocation will result in protections for farmworkers. (Ref. 37 at 13; Ref. 39 at 33)

ii. Denial of Objection. The August 18, 2021 press release announcing the publication of the final rule included statements that EPA was stopping the use of chlorpyrifos on food ''to better protect human health, particularly that of children and farmworkers,'' and that ending the use of chlorpyrifos on food ''will help to ensure children, farmworkers, and all people are protected'' from potentially dangerous consequences of chlorpyrifos. (Ref. 57) Based on these statements alone, the Objectors argue that these references to farmworkers suggest that EPA impermissibly considered occupational exposures in its decision to revoke chlorpyrifos tolerances. However, the Objectors' arguments are not supported by the final rule itself, which specifically affirms that the FFDCA standard does not include occupational exposures to workers and which explicitly and repeatedly emphasizes that EPA's review included food, drinking water, and all non-occupational exposures (*e.g.,* in residential settings), but did not include occupational exposures to workers. (*See, e.g.,* Ref. 1 at pgs. 48318, 48332 through 48333) The fact that the press release cited by the Sugarbeet Associations discusses the potential for incidental benefits to farmworkers from the final rule does not mean that such potential benefits were considered by EPA in the final rule. The Objectors' claim is meritless and is denied.

c. Compliance With Relevant International Standards

i. Objection. The Republic of Colombia objects to the final rule on the basis that the final rule's revocation of chlorpyrifos tolerances deviates from the Codex Alimentarius (Codex) international standard of 0.05 mg/kg for chlorpyrifos. (Ref. 58) Colombia requests that EPA reconsider the final rule's revocation of chlorpyrifos tolerances in light of the Codex MRL for chlorpyrifos, which it alleges is based on conclusive scientific evidence, although Columbia does not provide that scientific evidence with its objection for EPA to consider. In addition, Colombia requests that EPA consider, in its assessment of chlorpyrifos tolerances, the factors identified for consideration under Article 5, paragraphs 2 and 3 of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Those paragraphs require Members to the SPS Agreement to ''take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest—or disease—free areas; relevant ecological and environmental conditions; and quarantine or other treatment'' and ''relevant economic factors.'' (Ref. 59 at art. 5, paragraphs 2, 3)

ii. Denial of objection. The Codex is a collection of internationally adopted food standards and related texts published by the Codex Alimentarius Commission, an international organization formed to promote the coordination of international food standards. (*See https://www.fao.org/fao-who-codexalimentarius/en/*) The Codex Committee on Pesticide Residues, a committee within the Codex Alimentarius Commission, establishes Codex Maximum Residue Limits (MRLs) for pesticide products, which are similar to tolerances in that they set the limit for allowable pesticide residues in food. Although the Objector seems to be referring to a single universal Codex MRL of 0.05 mg/kg for chlorpyrifos residues, in actuality, Codex has promulgated several MRLs ranging from 0.01 mg/kg to 20 mg/kg for chlorpyrifos

residues on a variety of commodities. (Ref. 60) It is unclear why Colombia is pointing the Agency to a generic MRL of 0.05 mg/kg.

The FFDCA requires consideration of Codex MRLs when EPA is making a decision to *establish* a tolerance. (21 U.S.C. 346a(b)(4)) Notably, the statute does not require the same consideration in revoking tolerances. That is because revocation is required when a tolerance is unsafe, (21 U.S.C. 346a(b)(2)(A)(i)), regardless of whether another international body, including Codex, is maintaining the same determination. In the final rule, EPA determined that current tolerances for chlorpyrifos are not safe under FFDCA and must therefore be revoked. Columbia has not provided any reliable information to support a reconsideration of that conclusion.

As far as the request to consider the factors under Article 5, paragraph 2 of the SPS Agreement is concerned, EPA reiterates its earlier arguments, that it is bound by its domestic statute, which requires that unsafe tolerances be revoked (21 U.S.C. 346a(b)(2)(A)(i)) and which does not permit consideration of environmental or economic factors. (See Unit VIII.C.5.a.) EPA does not have discretion to retain tolerances, based on consideration of the factors listed in SPS Agreement, where the Agency has determined those tolerances do not meet the FFDCA safety standard. For these reasons, the Republic of Colombia's objection with respect to the Codex MRLs and the SPS Agreement is denied.

d. Implementation Timeframe

i. Objection. While EPA received many requests for an extension of the phase-out period, this section address the single objection asserting that the Agency's six-month expiration date for the tolerances was unlawful. The requests EPA received for extensions of the tolerance expiration date are addressed in Unit IX, along with other requests seeking a stay of the final rule.

Seeking a ''gradual, multi-year phase-out of crop uses'' to mitigate economic injury to itself and growers, Gharda argues that EPA's selection of a six-month grace period was arbitrary and capricious because it did not provide for use in another growing season nor sufficient time for Gharda, distributors, or growers to phase out their inventories and exhaust existing stocks of chlorpyrifos. (Ref. 39 at 40) Nor, Gharda alleges, does the SPS Agreement requirement for a ''reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force'' mandate that EPA select six months as the reasonable interval. (*Id.* at 38)

ii. Denial of objection. Section 408(g)(1) of the FFDCA states that a rule issued under section 408(d)(4) of the FFDCA, which the final rule revoking chlorpyrifos tolerances was, ''shall take effect upon publication'', unless otherwise specified in the rule. (21 U.S.C. 346a(g)(1)) The Agency's authority to specify a different effective date or to set an expiration date for the tolerances is entirely discretionary. Moreover, there is no requirement in the FFDCA for EPA to accommodate, through delays in the effective date or any other way, economic hardships and transitions away from a pesticide that the Agency has found to be unsafe and for which tolerances must be revoked. Indeed, the FFDCA is entirely focused on whether the tolerance is safe, and so it would subvert the intent of the statute to allow all tolerances the Agency has deemed unsafe to remain effective for significant periods of time.

As stated in the final rule, EPA set a six-month expiration date for the chlorpyrifos tolerances, rather than requiring revocation immediately, to accommodate the SPS Agreement requirement to ''allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force.'' (Ref. 59 at Annex B, paragraph 2) The World Trade Organization (WTO) has interpreted the phrase ''reasonable interval'' to mean normally a period of not less than six months, although shorter durations could be justified under ''urgent circumstances.'' (Ref. 61 at paragraph 3.2) In the SPS Agreement, there are some procedural exceptions allow for urgent health concerns. (Ref. 59 at Annex B, paragraph 5; *see also* Appellate Body Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes,* WTO Doc, WT/DS406/AB/R (April 4, 2012) (finding that deviations from the TBT Agreement requirement to provide ''reasonable interval'' may be justified in cases of urgent safety or health concerns))

In light of EPA's inability to conclude that chlorpyrifos tolerances meet the FFDCA safety standard, the Agency determined that a six-month expiration date for the chlorpyrifos tolerances would provide a reasonable interval for importers and growers to adapt to the change in regulation. EPA also notes that the Ninth Circuit's decision directed EPA to act ''immediately,'' and chastised EPA for its ''egregious delay'' in publishing a sufficient response to the 2007 Petition, which ''exposed a generation of American children to unsafe levels of chlorpyrifos.'' (*LULAC,* 996 F.3d. at 703) It simply was not tenuous to leave tolerances in place to allow for additional growing season(s), given the Agency's lack of a safety finding for the chlorpyrifos tolerances in light of the Ninth Circuit's expressed impatience with EPA's delay in acting on the 2007 Petition and the accelerated timeframe provided by the Ninth Circuit for the issuance of the final rule. Consequently, EPA determined that six months was a reasonable period to accommodate growers and importers while minimizing any continued harm.

For these reasons, Gharda's objection with respect to the implementation timeframe of the final rule is denied.

e. Existing Stocks

i. Objection. The following Objectors argue that the final rule should have addressed the treatment of existing stocks of chlorpyrifos products and seek additional clarification on how existing stocks will be addressed: The Sugarbeet Associations, Gharda, the Agricultural Retailers Association, *et al.,* CLA/RISE, and the Michigan Vegetable Council. (Refs. 37, 39, 47, 50, and 62) These Objectors allege that the revocation of the tolerances is likely to leave millions of gallons of chlorpyrifos in the hands of growers or in storage in the United States and that the lack of clarity from EPA regarding the use and/or disposal of these existing stocks of chlorpyrifos places a financial and logistical burden on users and retailers and could inadvertently lead to inappropriate disposal of chlorpyrifos products. Several Objectors argue that guidance published by EPA on its website after publication of the final rule titled ''Frequent Questions about the Chlorpyrifos 2021 Final Rule'' (Ref. 63), fails to clarify this issue, and that the legal status of products with labels and registrations that contain both food and non-food uses remains unclear.

Gharda also argues that EPA, in issuing the final rule without concurrently addressing existing stocks in the final rule or issuing an existing stocks order pursuant to FIFRA section 6(a)(1) (7 U.S.C. 136d(a)(1)), has abdicated its responsibility under FIFRA to ensure the safe, lawful, and orderly phase-out and disposal of chlorpyrifos products. (Refs. 39 at 41 through 45) Gharda asserts that an existing stocks order is necessary to allow end users and others wishing to return existing stocks to the manufacturers or pursue other safe disposal options to avoid violating FIFRA. Gharda also asserts that because the practical effect of the final rule is to render previously registered products unregistered, EPA would have no

enforcement authority over misuse of those pesticides.

ii. Denial of objection. As an initial matter, EPA notes that while the Objectors use the term ''existing stocks,'' existing stocks is a FIFRA term that applies to products that have been released for shipment upon cancellation of a registered pesticide. (*See* Existing Stocks of Pesticide Products; Statement of Policy, 56 FR 29362, June 26, 1991 (FRL–3846–4)) Since the final rule does not cancel any pesticide registrations, it has not created any ''existing stocks'' under FIFRA.

Nevertheless, EPA reads the majority of objections on this particular issue to be seeking clarity and guidance for users of chlorpyrifos on what to do with chlorpyrifos products that have been purchased but cannot be used on food crops following the expiration of the tolerances. As such, these objections are more akin to comments and requests concerning implementation of the final rule, than objections to the final rule itself; thus, they are denied as objections for failure to raise particular concerns with the final rule that can be resolved under the FFDCA. Nevertheless, EPA recognizes the confusion among the agricultural industry as a result of the final rule and the fact that tolerances will be revoked before any registrations for chlorpyrifos products are cancelled under FIFRA. Consequently, EPA will continue to update the FAQ page to provide guidance to assist growers and the agricultural industry with the implementation of this final rule.

Turning to Gharda's objection next, EPA denies that it has somehow abdicated its responsibilities under FIFRA by taking action to revoke unsafe tolerances under the FFDCA. EPA finds that Gharda is essentially making the same argument that EPA rejected in Unit VIII.C.1.b. Gharda's argument boils down to an assertion that EPA was required to take action concurrent with the final rule to cancel chlorpyrifos registrations under FIFRA, to provide for the use and disposition of existing stocks in that cancellation order, and then to revoke tolerances consistent with the existing stocks provisions of that cancellation order; thus, for the same reasons articulated in that previous Unit, Gharda's objection is denied. As noted previously, nothing in the FFDCA compels EPA to take action under FIFRA to cancel pesticide registrations and provide for existing stocks concurrently with or prior to revoking tolerances for that same chemical. Moreover, there is no requirement in the FFDCA, when revoking a tolerance, to resolve questions regarding existing stocks in the final rule itself.

Gharda appears to conflate the EPA's issuance of a rule revoking tolerances under the FFDCA with EPA's cancellation of registered pesticides under FIFRA. Gharda argues that because EPA's revocation of the tolerances under the FFDCA essentially renders the product unregistered, EPA was obligated to address the issue of existing stocks under FIFRA. However, Gharda misstates the effect of the final rule. The revocation of tolerances does not have the effect of rendering the chlorpyrifos products unregistered. Registered products only become unregistered once they are cancelled under FIFRA section 6. (7 U.S.C. 136d) EPA has no authority to issue a cancellation order under the FFDCA, only under FIFRA, and as discussed in Unit VIII.C.1.b., EPA is not required to cancel pesticides under FIFRA prior to taking action to revoke tolerances under the FFDCA. Because the actual remedy Gharda is seeking with this objection—a cancellation order with instructions on how to handle existing stocks—is only available under FIFRA, this is not a proper objection to the final rule.

f. Channels of Trade

i. Objection. The American Soybean Association and Willard Jack (an individual grower) submitted objections arguing that the final rule fails to provide adequate guidance for food or feed treated with chlorpyrifos that is or will be in the channels of trade when the tolerances are set to expire on February 28, 2022. (Refs. 36 and 64) The Objectors express concern that growers will be adversely impacted by this rule due to a lack of guidance and the potential of having adulterated food seized by the FDA.

ii. Denial of objection. To the extent this objection asserts that lack of guidance is a fatal flaw with the final rule, this objection is denied. This issue does not provide a basis for reversing the Agency's position on the safety of chlorpyrifos and changing the final rule. Nevertheless, EPA recognizes the need for guidance for farmers and food processors following the revocation of the chlorpyrifos tolerances. As EPA indicated in the final rule, section 408(l)(5) of the FFDCA governs commodities treated with pesticides and in the channels of trade following the tolerance revocations. Under that provision, chlorpyrifos residues in or on food in the absence of a tolerance will not render that food adulterated, as long as it is shown to the satisfaction of the U.S. Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and

2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance that was in effect at the time of the application. (21 U.S.C. 346a(l)(5))

The FDA, which is responsible for enforcing tolerances and implementing this provision, has developed guidance for growers and food processors for foods treated with chlorpyrifos. (Ref. 65) That guidance, which covers residues of chlorpyrifos in human food commodities, clarifies the FDA's planned enforcement concerning those foods containing chlorpyrifos residues after the tolerances expire. Animal feed items, which are regulated by FDA's Center for Veterinary Medicine, and various livestock commodities, which are regulated by USDA, are not covered by this guidance. EPA intends to work with those other agencies to assist with questions of compliance as they arise.

g. Substantive Due Process Concerns

i. Objection. Gharda argues that it and other registrants have a fundamental property right in their chlorpyrifos registrations, which is protected by the substantive due process doctrine provided for under the U.S. Constitution. (Ref. 39 at 36 through 37) Gharda claims that the economic value of its chlorpyrifos registration for food use crops is dependent on having tolerances for chlorpyrifos in place. Gharda argues that because the Agency revoked those tolerances ''without a reasoned explanation or valid scientific basis, and in disregard of scientific data,'' the Agency improperly deprived Gharda of economic value of its registration and violated its substantive due process rights.

ii. Denial of objection. Whether Gharda has a substantive due process right to its registrations and the revocation of tolerances somehow infringes that right is immaterial to the question EPA must answer when leaving a tolerance in place—whether the tolerance is safe. The FFDCA is clear: When a tolerance is not safe, it must be modified or revoked. Whether the revocation of that rule has implications for registrants of products or growers of crops is outside the scope of considerations in the FFDCA. Since nothing about this objection provides information bearing on the safety of chlorpyrifos, this objection is denied.

In any event, EPA disagrees with Gharda's claim that the final rule has infringed substantive due process rights.

''To state a substantive due process claim, a plaintiff must allege: (1) That it had property or a property interest; (2) the government deprived it of that property interest; and (3) the government's actions fall so far beyond the outer limits of legitimate governmental action that no process could cure the deficiency. . . . [S]ubstantive due process concerns governmental action which is so arbitrary and irrational, so unjustified by any circumstance or governmental interest, as to be literally incapable of avoidance by any pre-deprivation procedural protections or of adequate rectification by any post-deprivation . . . remedies. . . . Thus, a substantive due process claim is warranted only where *no process* could cure the deficiencies in the governmental action.'' (*Syngenta Crop Protection, Inc.* v. *EPA,* 444 F.Supp.2d 435, 447 (M.D.N.C. 2006) (internal citations and quotations omitted)) EPA disagrees that Gharda has a property interest in the food uses here since ''there is no property interest in using property in a manner that is harmful to the general public.'' (*American Vanguard Corp.* v. *United States,* 142 Fed. Cl. 320, 328 (Jan. 28, 2019) (citing *Mitchell Arms, Inc.* v. *United States,* 7 F.3d 212 (Fed. Cir. 1993))) Moreover, Gharda has failed to allege any activity by EPA that would implicate the ''outer limits of legitimate governmental action'' or that is ''so arbitrary and irrational, so unjustified by any circumstance or governmental interest,'' as to be incapable of remedy. Gharda alleges no activity that is ''so arbitrary or irrational'' other than a general claim that the final rule is ''without a reasoned explanation or valid scientific basis, and in disregard of scientific data.''

EPA notes that the final rule includes significant explanation for its finding that EPA is unable to determine that there is a reasonable certainty that no harm will result from aggregate exposures to chlorpyrifos residues for which there is reliable information. For example, the final rule includes, among other key information, an overview of the numerous human health risk assessments EPA has conducted and FIFRA SAPs that were convened to discuss chlorpyrifos, a detailed summary of EPA's risk assessment for chlorpyrifos, EPA's hazard assessment of chlorpyrifos, EPA's exposure assessment for chlorpyrifos, and EPA's process for assessing aggregate risk based on the aforementioned assessments. To the extent that this assertion is intended to refer to or incorporate Gharda's other objections—such as Gharda's argument that EPA's explanation for not retaining the eleven uses proposed for retention in the 2020 PID or fails to consider the Corteva oxon study—EPA has already provided responses to those more detailed objections elsewhere in this Order.

In any event, it cannot be said that EPA taking action to revoke an unsafe tolerance under its statutory mandate to ensure that pesticide residues in food are safe for public consumption is outside the bounds of a legitimate governmental action. Congress tasked EPA specifically with the responsibility to ensure that tolerances are only left in place if they are safe and to revoke or modify tolerances if they are not. (*See* 21 U.S.C. 346a(b)(2)(A)) Upon concluding that aggregate exposures were not safe, EPA revoked the tolerances in accordance with the statutory mandate, which is clearly within the bounds of a legitimate government action to ensure that residues of pesticides in or on food are safe for consumption. It is necessarily the case that when EPA revokes a tolerance on the basis of dietary risks for pesticides that are registered under FIFRA, there are going to be impacts to the registrants of those pesticides. Leaving tolerances in place to avoid impacts to pesticide registrants would be inconsistent with the FFDCA. Finally, Gharda is not without process for curing any deficiencies in EPA's actions, including procedures afforded by FIFRA, the APA, and judicial review. Therefore, Gharda's claim that its substantive due process rights have been infringed by EPA's final rule fails.

D. Summary of Reasons for Denying Objections

EPA is denying the objections submitted by the Objectors for several reasons. EPA is denying the objections of the Colombia Ministry of Trade, Industry and Tourism; Drexel Chemical Company; the International Pepper Community; Oregonians for Food and Shelter; and the Republic of Ecuador, because these parties did not submit their objections to the Office of the Hearing Clerk, as required by 40 CFR 178.25(b). As discussed in Unit VIII.A. of this document, EPA grouped the other Objectors' objections into five different substantive categories and addressed each in turn.

Regarding the first category—objections to the scope of the final rule—EPA is denying the objections asserting that revoking all chlorpyrifos tolerances was unlawful and unnecessary in light of the proposal in the 2020 PID for limiting uses to 11 high-benefit crops, because the FFDCA requires that EPA assess aggregate exposure based on all currently registered uses of chlorpyrifos, not on a hypothetical subset of those uses. EPA also denies the objections arguing that the revocation of tolerances should not have been undertaken without coordination of use cancellations under FIFRA, because FFDCA 408(l)(1) does not require that actions under FIFRA precede or occur concurrently with actions under the FFDCA, and because in any event it was not practicable for EPA to first modify of cancel any registrations in light of the Ninth Circuit's deadline for issuing a final rule. Lastly, EPA denies the objections arguing that EPA should retain import tolerances for chlorpyrifos commodities, because EPA is unable to make the safety finding for leaving in place tolerances for imports until enough uses are canceled to reduce aggregate exposures to acceptable levels.

Regarding the second category—objections to the retention of the 10X FQPA safety factor—EPA is denying the objections that EPA's final rule was arbitrary and capricious for retaining the 10X FQPA safety factor. As an initial matter, EPA has determined that whether the Agency retains the 10X FQPA safety factor or uses a different margin of safety does not ultimately have a determinative impact on the Agency's conclusions regarding the safety of chlorpyrifos in the final rule; therefore, this objection is denied for lack of materiality. Nonetheless, EPA concludes that its consideration of the epidemiological studies was reasonable and consistent with EPA's policy for consideration of all available data. EPA notes there is no requirement that the underlying data must be made available before EPA can rely on these studies, and EPA had a rational scientific basis for including such data in its review in order to satisfy its statutory obligation to consider all data concerning the special susceptibility of infants and children. Furthermore, given the uncertainties surrounding the potential for neurodevelopmental effects at the time of the final rule, EPA's retention of the default 10X FQPA safety factor was consistent with the statutory standard to apply the 10X margin of safety unless there is reliable data demonstrating that a different margin would be safe for infants and children.

Regarding the third category—objections relating to EPA's assessment of drinking water exposures—EPA is denying the objections that EPA did not have a rational basis for relying on the 2016 DWA, because, unlike the 2020

DWA, the 2016 DWA considered contributions from all registered uses of chlorpyrifos, and so represented the most recent and robust ''best available science'' for use by the Agency in its final rule. EPA is also denying the objections that it was unreasonable for EPA to assess exposures to chlorpyrifos-oxon in its drinking water assessment, because EPA has reliable data that chlorpyrifos-oxon will be present in at least some drinking water, and because EPA concluded that even assuming chlorpyrifos-oxon is not more toxic and should not be the residue of concern for evaluating exposures in drinking water, the concentrations of the parent compound, chlorpyrifos, in drinking water would still result in exposures that were unsafe.

Regarding the fourth category—objections relating to procedural matters—EPA is denying the objections that EPA acted inconsistently with the principles of due process and transparency in failing to consider and respond to comments previously submitted on the 2015 proposed rule and in response to the 2020 PID. EPA notes that these objections do not identify a specific element of the final rule that is problematic, and so do not conform to the required form of an objection per 40 CFR 178.30(a)(1). EPA also notes that EPA is not obligated to respond to comments on a rule that was never finalized (*i.e.,* the 2015 proposed rule), or on separate albeit parallel regulatory activities (*i.e.,* the 2020 PID). EPA is also denying the American Soybean Association's objection that the final rule failed to provide adequate procedural due process due to technical delays in opening the Federal eRulemaking Portal, because EPA's regulations only require that objections be filed with the Hearing Clerk, with the Portal serving as an additional means of protecting any CBI, and because the delayed opening of the Portal is harmless error. Lastly, EPA is denying the objections that EPA failed to comply with Executive Order 12866, because this is not a judicially reviewable issue and resolution of these objections has no bearing on any substantive issues with the final rule that could be raised separately.

Regarding the fifth and final category—objections that, as a matter of law, do not provide a basis for leaving tolerances in place—EPA is denying these assorted objections because they provide no reliable information pertaining to the FFDCA safety standard that could support leaving chlorpyrifos tolerances in place.

VIII. Response to Requests for Stay

A. The Standard for Granting a Stay

FFDCA section 408 provides that a regulation issued under subsection 408(d)(4) shall take effect upon publication in the **Federal Register** unless the regulation specifies otherwise. (21 U.S.C. 346(g)(1)) The effective date of the final rule was October 29, 2021, and tolerances for residues of chlorpyrifos on all commodities expire on February 28, 2022. However, section 408 also grants the Administrator the discretion to stay the effectiveness of a regulation if objections are filed. (21 U.S.C. 346a(g)(1))

The statute is silent on the standard to apply in granting a stay. The FFDCA gives EPA unlimited discretion to determine when it might be appropriate to issue a stay, requiring only that objections be filed before EPA may exercise that authority. EPA believes the discretionary nature of this authority gives EPA flexibility in any given case to determine whether and how to stay a rule or order issued under FFDCA section 408(d). EPA has indicated that it will consider the criteria set out in FDA's regulations regarding stays of administrative proceedings at 21 CFR 10.35, in determining whether to grant a stay. (*See, e.g.,* Carbofuran; Final Tolerance Revocations, 74 FR 23045, May 15, 2009; *cf.* Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay, 76 FR 3422, Jan. 19, 2011 (evaluating stay request based on an amalgam of the 21 CFR 10.35 factors and a judicial stay factors)) Under 21 CFR 10.35, a stay shall be granted if all of the following apply: (1) The petitioner will otherwise suffer irreparable injury; (2) the petitioner's case is not frivolous and is being pursued in good faith; (3) the petitioner has demonstrated sound public policy grounds supporting the stay; and (4) the delay resulting from the stay is not outweighed by public health or other public interests. (21 CFR 10.35(e))

B. Requests for Stay and EPA Responses

1. Summary of Requests for Stay

EPA received written requests for EPA to either stay the effective date of the final rule or allow for a longer phase-out period from the following objectors: Amalgamated Sugar Company, American Crystal Sugar Company, the American Soybean Association, the Sugarbeet Associations, the California Citrus Quality Council, the Cherry Marketing Institute, CLA/RISE, Gharda, the Minor Crop Farmer Alliance, the Agricultural Retailers Association, *et al.,* the Republic of Colombia, and several independent sugarbeet growers. (These written requests are available in the final rule docket at *https://www.regulations.gov* in docket ID number EPA–HQ–OPP–2021–0523.)

The requests for stay of the final rule can be sorted into three groups based on the form of the requests and the duration of the stay requested. The first group consists of the requests submitted by the Sugarbeet Associations and Gharda, both of which apply the criteria set out in 21 CFR 10.35 to argue that EPA is required to stay the effectiveness of the final rule. Specifically, these Objectors argue that they will suffer irreparable injury absent a stay, that their objections are not frivolous and are undertaken in good faith, that the public interest favors a stay, and the delay caused by a stay is not outweighed by the public health or public interest. The Sugarbeet Associations and Gharda also request a stay ''until a final resolution, including potential judicial review, is reached on all of the . . . issues raised in [our] objections.'' (Refs. 66 and 67) The second group consists solely of the Republic of Colombia. Colombia requests a period of at least 12 months before chlorpyrifos tolerances expire so that it can ''make the necessary adjustments in the production of [its] crops to ensure compliance.'' (Ref. 58) While Colombia does not explicitly frame its request as a request for a stay of the final rule, and does not reference the criteria at 21 CFR 10.35, EPA's interpretation is that this is best understood and assessed by EPA as a request for stay. Finally, the third group consists of the remaining stay requests. These Objectors do not specifically address the regulatory criteria set forth at 21 CFR 10.35; they simply request that EPA stay the final rule until EPA can address the issues raised in their various objections.

2. Denial of Requests for Stay

As noted previously, only the Sugarbeet Associations and Gharda frame their requests for stay by reference to the regulatory criteria at 21 CFR 10.35, and until ''a final resolution'' can be obtained with respect to the issues raised in their objections. The other stay requests do not reference the regulatory criteria. The sole rationale provided by Colombia for its request for an additional 12-month period before tolerances expire is to enable unspecified parties to ''make the necessary adjustments'' to ensure compliance. Colombia does not include any information regarding any potential injury (irreparable or otherwise) that

might otherwise be suffered, showing that their case is not frivolous and is being made in good faith, demonstrating sound public policy supporting a 12-month delay, or arguing that their desired 12-month delay is not outweighed by public health or other interests. EPA declines to speculate as to the bases for Colombia's request and denies Colombia's stay request due to the lack of supporting information. The other stay requests simply ask EPA to stay the effectiveness of the final rule until EPA can address the issues raised in their various objections. These Objectors appear to contemplate a scenario in which EPA delays addressing their objections until well after the February 28, 2022, expiration date for chlorpyrifos tolerances specified in the final rule. Because EPA has addressed these objections via this Order, by the plain meaning of these stay requests, there is no longer any need to stay the final rule. As a result, EPA denies those requests for stay submitted by Objectors other than the Sugarbeet Associations and Gharda.

With respect to the requests for stay submitted by the Sugarbeet Associations and Gharda, EPA examines these parties' arguments in light of the four factors set forth in at 21 CFR 10.35.

a. Will the Sugarbeet Associations and Gharda suffer irreparable injury without the stay?

i. Summary of arguments concerning injury. The Sugarbeet Associations and Gharda each argue that they will suffer irreparable injury in the form of economic losses and reputational impacts due to the final rule, and Gharda also argues that the deprivation of its chlorpyrifos registration under FIFRA is a due process violation that constitutes irreparable harm. (Refs. 66 and 67) With respect to economic losses, the Sugarbeet Associations argue that due to the lack of similarly effective alternatives to chlorpyrifos, reduced crop yields could cause the sugarbeet industry significant economic harm. (Ref. 66 at pgs. 2 through 4) Similarly, Gharda claims that it could face significant economic losses if, due to the final rule, it is unable to formulate, distribute, and sell the significant volume of raw materials and U.S.-labeled product it has in inventory. (Ref. 67 at pgs. 6 and 7) With respect to reputational impacts, the Sugarbeet Associations argue that the sugarbeet industry is likely to suffer reputational harm as a result of the final rule and the August 18, 2021, press release announcing the final rule, including the potential for ill will against the sugarbeet industry from customers and the public that could affect the industry's ability to sell its products. (Ref. 66 at pgs. 4 and 5) Similarly, Gharda argues that it has suffered and will continue to suffer reputational harm, and that the final rule has strained and will continue to strain Gharda's relationships with its customers, who might not use Gharda products moving forward. (Ref. 67 at pgs. 6 through 8)

As described in more detail in this unit, EPA disagrees that any injuries to the Sugarbeet Associations and/or Gharda are in fact irreparable.

ii. Response to the Sugarbeet Associations' and Gharda's economic injury arguments. EPA disagrees that the Sugarbeet Associations and Gharda have established that they—or, in the case of the Sugarbeet Associations, the farmer-owners and beet sugar manufacturers they represent—will be irreparably harmed without a stay. As Gharda correctly notes, to establish irreparable harm, ''injury must be both certain and great; it must be actual and not theoretical and of such imminence that there is clear and present need for equitable relief.'' (*Olu-Cole* v. *E.L. Haynes Pub. Charter Sch.,* 930 F.3d 519, 529 (D.C. Cir. 2019) (internal quotation marks and citations omitted)) However, this already high ''barrier to proving irreparable injury is higher still'' for the economic losses asserted by the Sugarbeet Associations and Gharda, ''for it is well settled that economic loss does not, in and of itself, constitute irreparable harm.'' (*Mexichem Specialty Resins, Inc.* v. *EPA,* 787 F.3d 544, 555 (D.C. Cir. 2015)) ''Mere injuries, however substantial, in terms of money, time, and energy necessarily expended in the absence of a stay are not enough.'' (*Wisconsin Gas Co.* v. *FERC,* 758 F.2d 669, 674 (D.C. Cir. 1985)) Instead, ''recoverable monetary loss may constitute irreparable harm only where the loss threatens the very existence'' of a company. (*Id.*)

The Sugarbeet Associations and Gharda include identical statements arguing that ''[l]osses for which an aggrieved party has no recourse, such as those caused by a governmental entity immune from suit for monetary relief, are 'irreparable *per se.*'" (Ref. 66 at pg. 3 and Ref. 67 at pgs. 5 and 6, respectively (each citing *Feinerman* v. *Bernardi,* 558 F. Supp. 2d 36, 51 (D.D.C. 2008))) However, the Sugarbeet Associations and Gharda fail to note that subsequent caselaw expressly disagrees with that principle. In *ConverDyn* v. *Moniz,* the District Court for the District of Columbia acknowledges that while in *Feinerman* it ''characterized economic damages that are unrecoverable due to sovereign immunity as 'irreparable *per se*' . . . that characterization goes too far and the inability to recover economic losses can more accurately be considered as a factor in determining whether the movant has shown irreparable harm.'' (68 F. Supp. 3d 34, 49 (D.D.C. 2014) (internal citations omitted)) The Court observed that ''[o]therwise, a litigant seeking injunctive relief against the government would always satisfy the irreparable injury prong, nullifying that requirement in such cases.'' (*Id.; see also N. Air Cargo* v. *U.S. Postal Serv.,* 756 F. Supp. 2d 116, 125 (D.D.C. 2010) (''this Court is of the opinion that a party asserting such a loss is not relieved of its obligation to demonstrate that its harm will be great . . . [otherwise] prospective injunctive relief would often cease to be an extraordinary remedy in cases involving government defendants'') (internal quotation marks and citations omitted))

EPA finds that neither the Sugarbeet Associations nor Gharda have demonstrated that they or their member entities will suffer irreparable economic harm in the absence of a stay of the final rule. The Sugarbeet Associations provide a handful of statistics regarding the estimated financial impacts that they allege will result from the revocation of chlorpyrifos tolerances, and argue that because EPA estimated in the 2020 PID that the benefits of chlorpyrifos for sugarbeets in North Dakota and Minnesota *could* be up to $500 per acre, and there are over 140,000 acres of sugarbeets at risk from sugarbeet root maggots, the sugarbeet industry ''would face tens of millions of dollars in irreparable damages annually'' absent a stay. (Ref. 66 at pg. 4) EPA notes, however, that the Sugarbeet Associations omit key details, and that their conclusion is highly speculative.

The Agency included sugarbeets in its detailed economic analysis of agricultural uses of chlorpyrifos, which was conducted in 2020 to support the preliminary interim registration review decision. The analysis utilized proprietary pesticide usage surveys as well as publicly available pest management recommendations from extension crop experts. (Ref. 56) This analysis indicated that for most sugarbeet pests targeted with chlorpyrifos, several effective alternatives are available. The Agency found that for regions in the upper Midwest where populations of sugarbeet root maggot are very high, yield losses of up to 45% could occur without chlorpyrifos. The impacts of such yield losses are estimated at $498 per acre in

North Dakota and Minnesota, where an average of 61,200 acres were estimated to be affected. While EPA acknowledges that growers in these areas will be impacted, these areas represent about 20% of the sugarbeet acreage in Minnesota and 10% of the acreage in North Dakota. For purposes of comparison, the total national harvested sugarbeet acreage is approximately 1.1 million acres. Furthermore, effective alternatives to chlorpyrifos are available in other areas of the country. Thus, while there are likely to be impacts to some growers, EPA does not agree that the loss of chlorpyrifos will cause an irreparable injury to the sugarbeet industry overall.

EPA also notes that the Sugarbeet Associations fail to provide any context for the economic injuries they claim that they and their members will incur as a result of the final rule. As discussed previously, EPA acknowledges that sugarbeet yields in certain production areas could be reduced, and that some sugarbeet growers and/or beet sugar manufacturers may lose some portion of their revenue due to the final rule. However, even assuming that the figures provided by the Sugarbeet Associations are accurate, it is not clear to EPA what the specific implications of these figures might be for the Sugarbeet Associations or the growers and/or manufacturers they represent, and nowhere in their stay request do the Sugarbeet Associations assert that the failure to stay the final rule will threaten their or their member entities' very existence.

Finally, EPA notes that for many crops—including sugarbeets, as the Sugarbeet Associations acknowledge in their request for stay—alternatives to pesticides are readily available. While these alternatives may be more expensive than chlorpyrifos, or perhaps less effective than chlorpyrifos, the availability of alternatives to chlorpyrifos indicates that it is unlikely that sugarbeets will be left completely unprotected. This in turn suggests that any injury is likely to be temporary and reparable.

EPA also disagrees with Gharda's arguments regarding irreparable economic injury. Although EPA acknowledges that the revocation of tolerances will necessarily impact any registrant of chlorpyrifos products, EPA is not convinced that the economic injuries alleged by Gharda are in fact irreparable. Gharda argues that it will suffer certain economic losses due to the inability to formulate, distribute, and sell chlorpyrifos products, including a loss of future sales of chlorpyrifos products, and that Gharda and its customers will face a loss of their investments in chlorpyrifos. EPA finds that Gharda's claims regarding the loss of future sales of chlorpyrifos products are too speculative to satisfy the requirement that injury ''must be actual and not theoretical.'' (*Olu-Cole,* 930 F.3d at 529) Gharda does not provide any basis for its assumptions regarding future revenues from chlorpyrifos other than a declaration from its president that contains an identical assertion as in the stay request and offers no further evidence. To provide but a few examples, these assumptions regarding future revenues could be undercut by changes in customer preferences, supply chain complications, and/or price fluctuations. Crucially, and in any event, Gharda does not claim that a failure to stay the final rule will threaten either its or its customers' very existences.

EPA notes that the 2020 PID proposed a subset of chlorpyrifos uses that might result in exposures below the Agency's level of concern if significant changes to the labels were made, including use cancellations and geographic limitations, among others. EPA also notes that the final rule does not foreclose Gharda's ability to sell or distribute its products outside of the United States for food applications in other jurisdictions, provided any such treated products are not imported into the United States in a manner inconsistent with FDA's channels of trade guidance. These possibilities undermine Gharda's assertion that any and all economic harms it has suffered or might suffer are irreparable.

EPA also notes that any potential economic injury suffered by Gharda has been significantly exacerbated by Gharda's independent business decisions. Gharda notes that in 2021 it increased production to meet demand for chlorpyrifos after Corteva exited the market, and that it now stands to incur certain losses due to its inability to formulate, distribute, and sell chlorpyrifos products. However, Gharda should have recognized that there was some risk to expanding production in light of the Agency's proposed findings in the 2020 PID (which indicated that some changes to existing registered products would likely be required, including some potentially significant changes), and following the issuance of the Ninth Circuit's decision in April of 2021.

More generally, pursuant to the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* EPA conducted a small business analysis to assess the economic impact of the final rule on small entities. (Ref. 68) That analysis was prepared consistent with other analyses that are prepared for rules subject to notice and comment pursuant to the RFA, which requires an agency to consider the economic impacts that rules subject to notice and comment rulemaking will have on small entities. Since the final rule was not subject to notice and comment, the analysis was not required, but it was prepared to present information on the potential impact to small farms and possible job losses for industry as a result of the revocation of chlorpyrifos tolerances. Based on the analysis in the 2021 SBA memo, EPA concluded that there was not likely to be a significant impact on a substantial number of small entities and that there are unlikely to be significant job losses as a result of the revocation of the rule. Of the approximately 2 million farms currently in the United States, only an estimated 43,430 farms are using chlorpyrifos each year. For about 25,100 affected farms, the impacts of tolerance revocation are less than 1% of gross revenue. Up to 10,500 small farms could see impacts of between 1 and 3% of gross revenue per acre for affected crops. This is less than 1% of all small crop farms. An estimated 1,900 farms would see per-acre impacts of greater than 3%, about 0.13% of small farms producing crops. (Ref. 68 at pg. 2)

iii. Response to the Sugarbeet Associations' and Gharda's reputational arguments. EPA also disagrees with the Sugarbeet Associations' and Gharda's arguments regarding irreparable reputational injury. With respect to Gharda's arguments, EPA notes as a preliminary matter that Gharda claims that it ''has suffered'' reputational harm as a result of the final rule, and that EPA's revocation of the chlorpyrifos tolerances ''has . . . strain[ed]'' Gharda's customer relationships. (Ref. 67 at pg. 7) Even if EPA were to concede that Gharda has incurred such reputational injuries, staying the final rule would not resolve injuries that have allegedly already occurred. As a result, EPA will not further evaluate any reputational injuries Gharda alleges that it has already incurred for purposes of this first factor.

EPA will take the Sugarbeet Associations' and Gharda's remaining reputational arguments in turn. First, Gharda argues that by revoking chlorpyrifos tolerances, ''EPA has directly attacked the safety of chlorpyrifos . . . and the credibility of Gharda in selling and distributing chlorpyrifos products.'' (*Id.*) While EPA has determined that aggregate exposures to chlorpyrifos from currently registered uses are not safe, EPA categorically rejects Gharda's claim that EPA directly

attacked Gharda's credibility. EPA finds it noteworthy that Gharda is unable to cite to a single source for this claim, other than a declaration from its president that simply contains a verbatim assertion as in the stay request and offers no further evidence. EPA also notes that the final rule did not single out Gharda's registered chlorpyrifos products. The final rule itself did not address any specific chlorpyrifos registered products or registrants; rather, the final rule revoked chlorpyrifos tolerances due to safety concerns with the chemical, not concerns with any specific registered product or individual company. Therefore, EPA finds no basis whatsoever for Gharda's claim that EPA attacked its credibility and thereby injured Gharda's reputation.

Second, Gharda asserts that because the final rule disregarded written commitments by Gharda prior to the final rule to modify Gharda's label consistent with EPA's proposal in the 2020 PID, and because ''Gharda assured its customers that it was working cooperatively with EPA to reach agreement that would allow for many continued agricultural uses,'' Gharda suffered reputational injury and a loss of customer goodwill. (*Id.* at pgs. 7 and 8) As already discussed in Unit VII.C.1.b.ii. of this Order, EPA entered into such discussions with Gharda in a good-faith effort to determine if the safety issues identified in EPA's record on chlorpyrifos by the Ninth Circuit could be resolved in a sufficient and timely manner to allow for the modification of tolerances by the Court's imposed timeline. However, it simply was not practicable for EPA to complete any modifications or voluntary cancelations in time to inform the final rule and meet the Ninth Circuit's deadline. Furthermore, at no point during its discussions with Gharda did EPA make a binding commitment to modify chlorpyrifos tolerances instead of revoking them altogether. To the extent that Gharda informed its customers that EPA would modify chlorpyrifos tolerances instead of revoking them, that was an independent business decision made entirely by Gharda, and EPA cannot be held accountable for any consequences of that decision. Any reputational injuries suffered by Gharda as a result of assurances they provided their customers that EPA would modify chlorpyrifos tolerances are wholly attributable to Gharda.

Third, Gharda argues that in light of the scientific record for chlorpyrifos, neither Gharda nor its customers expected EPA to revoke all tolerances, and that EPA's decision to do so ''has cast doubt on Gharda's credibility and resulted in a loss of customer goodwill.'' (*Id.*) EPA's review of the scientific record is already extensively detailed in the final rule and elsewhere in this Order, and EPA has made clear that based on its review of that record, it is unable to conclude that chlorpyrifos tolerances are safe due to the extent of currently registered uses. EPA also notes that chlorpyrifos has been subject to regulatory scrutiny since at least the 2007 Petition, and that on October 28, 2015 ((80 FR 69080, November 6, 2015) (FRL–9954–65)), EPA issued a proposed rule to revoke all tolerances for chlorpyrifos. EPA also reiterates that the 2020 PID made clear that while chlorpyrifos applications could potentially be limited to 11 specific uses in specific geographic areas to reduce aggregate exposures to safe levels, all other existing uses of chlorpyrifos would need to be cancelled under that proposed scenario. Finally, EPA notes that the Ninth Circuit rejected EPA's previous attempt to leave tolerances in place based on an argument that the petitioners had failed to provide sufficient data to support revoking the tolerances and found that the burden was on EPA to demonstrate that the tolerances were safe in order to leave them in place. The Court ordered EPA to act on the 2007 Petition by granting it and issuing a final rule concerning chlorpyrifos tolerances, and therefore, a realistic potential outcome of this order was that EPA might revoke some or all of the chlorpyrifos tolerances. As a result, Gharda had fair warning that EPA might revoke tolerances for chlorpyrifos via the final rule. Also, as noted in the preceding paragraph, any injury arising from Gharda's speculative discussions with its customers is an injury of Gharda's own making and not EPA's rule.

Fourth, Gharda argues that the final rule could result in long-term harm to Gharda due to ''the stigma attached to the unfounded public statements by EPA that its action was taken 'to ensure children, farmworkers, and all people are protected from the potentially dangerous consequences of [chlorpyrifos],' and 'follow[s] the science and put[s] health and safety first.' '' (*Id.* at pg. 8, citing Ref. 57) The Sugarbeet Associations make a similar argument, claiming that because the final rule revoked chlorpyrifos tolerances despite the proposal in the 2020 PID concerning the 11 uses of chlorpyrifos identified by EPA, the sugarbeet industry is likely to suffer reputational harm in the form of ''ill-will . . . from customers and the public.'' It is not clear to EPA why that would be the case. The final rule makes no mention of Gharda or the Sugarbeet Associations at all and includes only a single reference to sugarbeets in its discussion of the 2020 DWA. (See Ref. 1 at pg. 48331) Nowhere in the final rule does EPA disparage sugarbeets, or single out chlorpyrifos applications on sugarbeets as presenting a unique risk to the public. Quite the opposite: EPA revoked *all* chlorpyrifos tolerances due to its inability to conclude that aggregate exposures from all chlorpyrifos uses would be safe. Additionally, while it is not established that Gharda's, the Sugarbeet Associations' or the sugarbeet industry's reputations will suffer as a result of the final rule, EPA's view is that a stay might in fact lead to the reputational harm the Sugarbeet Associations and Gharda are seeking to avoid. As described in the final rule and reiterated throughout this Order, EPA is unable to conclude that chlorpyrifos tolerances are safe for purposes of the FFDCA, and as of February 28, 2022, those tolerances will no longer be in effect. Assuming the Sugarbeet Associations and their member entities and Gharda comply with the revocation and abide by the guidance issued by the FDA and USDA, EPA sees no reason why customers or the public should have any ill will toward these entities for simply complying with the FFDCA. On the other hand, if EPA were to stay the final rule after concluding that tolerances are unsafe, customers and the public might have concerns about the safety of chlorpyrifos residues on food products, and Gharda's and the Sugarbeet Associations' members' roles in making these products available to the public. Therefore, EPA disagrees with Gharda and the Sugarbeet Associations that they and/or the sugarbeet industry will suffer irreparable reputational injury due to the final rule.

iv. Response to Gharda's due process argument. Finally, EPA disagrees with Gharda that EPA has infringed its due process rights via the final rule. As a preliminary matter, EPA notes that Gharda's stay request omits a key element of the due process analysis. Gharda's request characterizes ''the deprivation of a legally protectable property rig*ht (i.e., pestic*ide registration)'' as a due process violation. However, as Gharda itself makes clear in its Objections to the final rule, any such deprivation must also be ''unreasonable, arbitrary or capricious.'' (Ref. 67 at pg. 37 (*citing Nebbia* v. *New York,* 291 U.S. 502, 525 (1934))) As EPA explains in more detail in Unit VII.C.5.g. of this

Order, Gharda has failed to provide information sufficient to establish that the final rule unfairly or arbitrarily revoked chlorpyrifos tolerances. EPA also notes that as a legal matter, the final rule does not in fact effectuate a cancellation of Gharda's registrations. Instead, the final rule simply revokes chlorpyrifos tolerances. As a result, it cannot be said that the final rule infringed Gharda's substantive due process rights and thereby caused Gharda irreparable harm.

b. Were the Sugarbeet Associations' and Gharda's cases for a stay frivolous, and not pursued in good faith?

EPA generally believes that the Sugarbeet Associations' and Gharda's requests for a stay were made in good faith and reflect their concern about the potential implications of the final rule for their and their represented entities' business interests and/or ability to produce food (as the case may be). Chlorpyrifos has been an available insecticide for decades, and EPA recognizes that many growers have come to rely on it as a tool for controlling insect pests. Nor is there any indication in their requests for stay that the Sugarbeet Associations or Gharda are making frivolous arguments; EPA's impression is that the Sugarbeet Associations' and Gharda's requests for stay appear to reflect their good-faith interpretation of 21 CFR 10.35. As discussed in Unit VIII.B.2.a.iii., EPA note that chlorpyrifos has been subject to regulatory scrutiny since at least the 2007 Petition, and that in 2015 EPA issued a proposed rule to revoke all tolerances for chlorpyrifos. The 2020 PID also made clear that while chlorpyrifos applications could potentially be limited to 11 specific uses in specific geographic areas to reduce aggregate exposures to safe levels, all other existing uses of chlorpyrifos would need to be cancelled. Finally, the Ninth Circuit ordered EPA to act on the 2007 Petition by granting it and issuing a final rule concerning chlorpyrifos tolerances, and that a realistic potential outcome of this order was that EPA might revoke some or all of the chlorpyrifos tolerances. As a result, the Sugarbeet Associations and Gharda had fair warning that EPA might revoke tolerances for chlorpyrifos via the final rule. Notwithstanding this fair warning, however, EPA generally agrees with these Objectors that their cases for a stay are not frivolous and are being pursued in good faith.

c. Have the Sugarbeet Associations and Gharda demonstrated sound public policy grounds supporting a stay?

The Sugarbeet Associations and Gharda each argue that public policy grounds support their stay requests, though EPA notes that the Sugarbeet Associations combined this factor and the fourth factor into a single discussion. Both of these Objectors' arguments on this point incorporate several of the arguments raised in their objections, which were submitted under separate cover: That good public policy does not support regulatory decisions that are at odds with EPA's ''best available science'' and the 2020 PID; that EPA issued the final rule in a process that was fundamentally unfair and marked by bad faith; that EPA disregarded cancelation procedures, prior public comments, and interagency review processes, and abdicated its responsibility to oversee a lawful and orderly phase-out of chlorpyrifos products; and that the final rule will result in economic harms to U.S. growers and environmental harms from increased application of chlorpyrifos alternatives. Gharda also argues that the timeframe imposed by the final rule ''will result [in] the needless waste of safe and wholesome food,'' (Ref. 67 at pg. 11) and the Sugarbeet Associations include a general assertion that chlorpyrifos ''is used only when and only as much as necessary.'' (Ref. 66 at pg. 9)

EPA finds that the Sugarbeet Associations and Gharda have failed to demonstrate sound public policy grounds supporting a stay of the final rule. First, EPA notes that most of the arguments marshaled by the Sugarbeet Associations and Gharda on this point are simply restatements of their objections to the final rule, and that these Objectors frequently fail to explain how exactly any particular public policy is furthered by these objections. For example, the Sugarbeet Associations argue that EPA's alleged failure to consider relevant scientific information, as indicated by its decision to revoke chlorpyrifos despite the 2020 PID, is itself a reason that the public interest supports a stay. However, the Sugarbeet Associations do not elaborate on how or why that alleged failure relates to sound public policy or furthers the public interest or in this particular case, supports a conclusion that EPA erred in concluding that chlorpyrifos tolerances were unsafe. Similarly, Gharda argues that the final rule will cause significant hardship to U.S. growers who might need to rely on more expensive and/or less effective alternatives to chlorpyrifos but does not explain in its stay request why that is a matter of public interest, rather than an issue of concern particular to those growers.

Second, EPA notes by requesting a stay ''until a final resolution, including potential judicial review, is reached on all of the . . . issues raised in [our] objections,'' while failing to define what exactly constitutes a ''final resolution,'' the Sugarbeet Associations and Gharda are essentially asking for the final rule to be stayed indefinitely. Even if EPA interprets ''final resolution'' as being limited to the conclusion of judicial review of the final rule—which EPA notes is a much narrower interpretation than the plain language of these Objectors' request—it is extremely unlikely that this matter would be fully and finally resolved by the courts for at least two or three years. FFDCA section 408(h)(1) provides that any person who will be adversely affected by the final rule may obtain judicial review in the relevant U.S. Court of Appeals. Review in the Court of Appeals may, by itself, take several years; for example, over a year and a half elapsed between the LULAC Petitioners' and States' August 7, 2019, petition in the Ninth Circuit for review of the Denial Order and Final Order and the Ninth Circuit's decision on April 29, 2021. However, the process could take still longer, since FFDCA section 408(h)(4) provides that the judgment of the court affirming or setting aside the final rule is subject to review by the Supreme Court of the United States. Even if the Supreme Court denies certiorari, significant time will have elapsed before it could reasonably be said that there has been a ''final resolution'' in terms of judicial review of the final rule. Furthermore, EPA is confident in its legal and scientific analyses, and sees no compelling policy rationale for staying the final rule and leaving chlorpyrifos tolerances in place pending judicial review. Doing so would only perpetuate the public's exposure to the unsafe levels of chlorpyrifos that the Agency identified based on its review of the science and the aggregation of relevant exposures from all currently registered uses, all to mitigate the potential for impacts to Gharda and/or the sugarbeet industry. EPA's position is that there are no sound public policy grounds supporting such a course of action.

It is also clear to EPA that the Sugarbeet Associations' and Gharda's ultimate goal with respect to their stay requests is the rescission or revocation of the final rule. This is evident from the fact that the Sugarbeet Associations and Gharda incorporate many of the arguments made in their objections,

which request that the final rule be immediately or summarily reversed, and from Gharda's stay request, which discusses the economic losses Gharda will allegedly face if the final rule is not ''reversed or rescinded.'' To the extent the Sugarbeet Associations and Gharda are seeking to utilize the stay process to rescind the final rule, EPA notes that there is no need for EPA to stay the final rule simply to give the Sugarbeet Associations and Gharda more time to file litigation seeking rescission. EPA has outlined the relevant judicial review process in the preceding paragraph, and notes that there is no barrier to the Sugarbeet Associations and Gharda deciding to pursue judicial review of the final rule through a challenge to this Order. Nor does EPA believe that any public policy interest is furthered by such a course of action.

In light of the foregoing, EPA has significant concerns that the Sugarbeet Associations and Gharda are seeking to use the stay process to compel the consideration of factors not permitted by the FFDCA, thereby keeping chlorpyrifos tolerances in place despite EPA's inability to make the safety finding required by the FFDCA and the Ninth Circuit. By arguing that public policy grounds favor an effectively indefinite stay of the final rule due to the potential for economic harm, the Sugarbeet Associations and Gharda are asking EPA to keep chlorpyrifos tolerances in place despite EPA's inability to make a statutorily required safety finding for these tolerances and despite the fact that the FFDCA safety standard does not permit consideration of economic costs or benefits. This is a significant request, and EPA expects any party making such a request to demonstrate in detail how it furthers the public interest. However, as noted in the preceding paragraph, the Sugarbeet Associations and Gharda fail to sufficiently explain how the stay request is in the public interest at all, much less how any such public interest warrants deviating from the plain language of the FFDCA. EPA's position is that there are in fact overwhelming public policy grounds supporting EPA's reliance on the plain language of the FFDCA, particularly given the public health concerns underlying that statute.

Specifically, there is a significant public policy argument in favor of the Agency fulfilling its statutory obligation to follow the law as it was enacted by Congress. As enacted by Congress, section 408 of the FFDCA is clear that in order to leave tolerances in place, EPA must determine that there is a reasonable certainty that no harm will result from aggregate exposures to chlorpyrifos, including all anticipated dietary exposures and all other exposures for which there is reliable information. If the tolerances are not safe, EPA must modify or revoke them; any tolerances so modified, however, must also be safe. As discussed throughout this document, the FFDCA does not permit consideration of economic factors in the Agency's determination of safety. There is a compelling public policy argument that EPA must act in accordance with Congress' intent, as evidenced by the plain language of the statute. As a result, EPA's analysis in the final rule was necessarily limited to an assessment of aggregate exposures, including dietary, residential, and drinking water exposures, as instructed by the statute. Because EPA could not determine that such aggregate exposures were safe, EPA revoked tolerances for chlorpyrifos. Furthermore, EPA notes that to disregard the clear statutory language would also entail turning a blind eye to EPA's inability to find that chlorpyrifos tolerances are safe. That is, EPA taking action in direct contravention of the FFDCA is not only poor public policy from an administrative law standpoint, but also from a public health perspective. EPA considers the protection of public health to be a matter of overwhelming importance and is not inclined to so readily disregard its own inability to conclude that chlorpyrifos tolerances are safe.

Notwithstanding, EPA is not saying that it is precluded from ever delaying an effective date of a tolerance revocation rule. In a proposed order granting objections to revoke sulfuryl fluoride tolerances, EPA proposed to phase-out tolerances over varying periods of time due to lack of alternatives and the relatively low contribution of harm coming directly from the use of the pesticide itself as opposed to naturally occurring fluoride. (*See* Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay (76 FR 3422, January 19, 2011 (FRL–8867–9))) But that is not the case here: For chlorpyrifos, the use of the pesticide itself is directly contributing to harmful aggregate exposures, there are some alternatives, and EPA has already delayed the expiration of the revoked tolerances. Therefore, EPA concludes that there are not compelling public policy grounds to further delay in light of the Agency's finding that the chlorpyrifos tolerances are not safe.

With respect to Gharda's argument that the final rule will ''result [in] the needless waste of safe and wholesome food,'' EPA notes that Gharda is incorrect. FFDCA section 408(l)(5) provides for the continued distribution of food treated with chlorpyrifos as long as the conditions in that provision are met. Moreover, FDA has developed guidance describing how FDA intends to monitor any foods containing chlorpyrifos residues and detailing intentions concerning enforcement. (Ref. 65) As a general matter, implementation of the FDA guidance will not result in the ''needless waste'' of food since foods treated with chlorpyrifos prior to the expiration of the tolerances on February 28, 2022, will continue to move through the channels of trade for the next few years consistent with the terms of section 408(l)(5) and the guidance. Therefore, as implemented, EPA does not anticipate that the final rule will result in the disposal of massive amounts of foods treated with chlorpyrifos, or in any ''needless waste.''

Finally, while the Sugarbeet Associations include a general assertion that chlorpyrifos ''is used only when and only as much as necessary,'' EPA again notes that the Sugarbeet Associations fail to demonstrate how that assertion supports a determination that sound public policy grounds support a stay of the final rule. EPA has provided significant detail in the final rule and in this Order describing the analysis supporting its revocation of revoking chlorpyrifos tolerances, which analysis included consideration of estimated exposures from all approved uses of chlorpyrifos.

d. Is the delay resulting from the stay outweighed by public health concerns or other public interests?

The Sugarbeet Associations and Gharda each argue that the delay resulting from a stay is not outweighed by public health concerns or other public interests, though as noted the Sugarbeet Associations combined this factor and the third factor into a single discussion. Gharda's arguments in support of this factor are brief and conclusory. Gharda argues that ''[t]here are no public health or other public interests that will be adversely impacted by granting a stay,'' referencing back to its arguments that the final rule is at odds with the 2020 PID, that EPA incorrectly applied the 10X FQPA safety factor, and that the final rule will result in economic and environmental harms. (Ref. 67 at pg. 11) Similarly, the Sugarbeet Associations state that the ''weighing of the public interest supports a stay'' based on the potential economic harm to growers if no stay is granted, as well as ''the corresponding lack of public health or public interest

counseling against a stay.'' (Ref. 66 at pg. 9)

EPA disagrees with the Sugarbeet Associations and Gharda and finds that the delay resulting from an effectively indefinite stay of the final rule is outweighed by public health concerns and other public interests. First, EPA strongly disagrees with the Sugarbeet Associations and Gharda that there are no public health concerns or other public interests counseling against a stay. Most obviously, EPA is unable to conclude that chlorpyrifos tolerances are safe for purposes of the FFDCA. Continued use of chlorpyrifos on food in accordance with the current labels will continue to cause aggregate exposures that are not safe. While FFDCA section 408(l)(5) and the FDA's Channels of Trade guidance will continue to allow some foods treated with chlorpyrifos to move through the channels of trade, the revocation and expiration of the tolerances will ensure that no chlorpyrifos is used on food after the expiration, thus, limiting the ultimate universe of foods that may contain chlorpyrifos residues to less than what would be available if EPA stayed the rule. Moreover, the final rule's revocation of chlorpyrifos tolerances, which precludes continued application to food crops, would also prevent additional contributions of chlorpyrifos from ending up in drinking water due to its use on food. EPA does not take lightly the FFDCA's clear mandate that tolerances may only be left in place if they are safe and views the safety of pesticide chemical residues on food as a significant public health concern and a matter of overwhelming public interest.

Nor have the Sugarbeet Associations or Gharda presented any persuasive evidence in support of this position. The Sugarbeet Associations simply state that there is a ''lack of public health or public interest counseling against a stay,'' and provide no support whatsoever for this proposition. Gharda makes a similar assertion, and then includes a few sentences briefly referencing arguments made in its objections. However, Gharda does not identify how these points, which appear to be made almost in passing, support their argument that there is a complete absence of public health or other public interests that will be adversely impacted by granting a stay.

Second, EPA is unsettled by the open-ended nature of the Sugarbeet Associations' and Gharda's stay requests, which ask EPA to stay the final rule ''until a final resolution, including potential judicial review, is reached on all of the . . . issues raised in [our] objections.'' EPA notes that neither Objector defines or otherwise limits what exactly might constitute such a ''final resolution,'' particularly since their requests include, but are not limited to, potential judicial review. As a result, EPA views Objectors' request as at best an indefinite stay of the final rule, and at worst as an attempt to effectively rescind the final rule via the stay process—all in direct contravention of a statutory mandate that requires EPA to determine that tolerances are safe in order to leave them in place. While EPA does not necessarily require requests for stays to include a specific timeframe for the duration of the requested stay, EPA does not believe that the public interest is served by granting a stay with such ill-defined parameters. This is particularly true where, as is the case here, the subject matter bears directly on public health concerns. If EPA were to indulge Objectors' requests and stay the final rule on this basis, and after several years Objectors exhaust their judicial avenues for challenging the final rule, Objectors could nonetheless continue to assert that any or all of the specific issues raised in their objections have not been fully resolved and that the stay should continue. As a result, EPA would necessarily have to agree to a definable endpoint for the stay. EPA cannot agree to this indefinite postponement, particularly in light of its inability to conclude that chlorpyrifos tolerances are safe.

Finally, EPA recognizes that the Sugarbeet Associations' and Gharda's requests ask EPA to continue relying on the precise approach for which EPA was so recently and explicitly chastised by the Ninth Circuit. That is, EPA is asked to set aside the final rule in order to engage in ''further factfinding after thirteen years of interminable delay,'' which the Ninth Circuit stated, ''would make a mockery, not just of this Court's prior rulings and determinations, but of the rule of law itself.'' (*LULAC,* 996 F.3d at pg. 702) In light of the Ninth Circuit's clear frustration with EPA for its long delay, EPA is unwilling to return to an approach that would result in further delay for more study of chlorpyrifos tolerances, all in pursuit of an amorphous ''final resolution'' of the Sugarbeet Associations' and Gharda's various concerns. As reiterated several times herein, EPA is unable to conclude that chlorpyrifos tolerances are safe. The statute does not permit EPA to leave tolerances in place when it cannot conclude that they are safe. As a result, EPA refuses to further delay revoking chlorpyrifos tolerances.

e. Denial of the Sugarbeet Associations' and Gharda's Stay Requests

As stated in the regulation, the Agency shall grant a stay if all four of the criteria in 21 CFR 10.35(e) are satisfied. As explained previously, EPA find that the Sugarbeet Associations and Gharda have failed to satisfy three of the four criteria in 21 CFR 10.35(e). Consequently, EPA denies the Sugarbeet Associations' and Gharda's requests for a stay of the final rule.

IX. Earthjustice Feedback and Comments

A. Overview

On October 28, 2021, prior to the close of the objections period, Earthjustice submitted a document titled *LULAC Petitioners' Feedback on the Environmental Protection Agency's Chlorpyrifos Tolerance Revocation Rule and Comments on Growers' Objections* on behalf of the following 12 public interest groups: League of United Latin American Citizens, NRDC, PANNA, California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, GreenLatinos, Labor Council for Latin American Advancement, Learning Disabilities Association of America, National Hispanic Medical Association, Pineros y Campesinos Unidos del Noroeste, and United Farm Workers. (Ref. 69) Earthjustice previously submitted objections to the 2017 Order Denying Petition on behalf of these same 12 public interest groups in June 2017. Earthjustice also represented these 12 public interest groups in their lawsuit challenging the 2017 Order Denying Petition and the 2019 Order Denying Objections to Petition Denial before the Ninth Circuit Court of Appeals, in which they sought to have the chlorpyrifos tolerances revoked.

Notably, Earthjustice does not object to the final rule's revocation of tolerances for chlorpyrifos. On the contrary Earthjustice's submission says that ''[t]he LULAC petitioners . . . celebrate EPA's action.'' (*Id.* at pg. 1) Rather, these comments are primarily focused on arguments that Earthjustice (on behalf of the advocacy groups) believes the Agency must consider and address in the event that chlorpyrifos tolerances would be retained or reinstated at a future time. For the most part, Earthjustice reiterates arguments that it has made previously in its objections to the 2017 Order Denying Petition, including that use of 10% cholinesterase inhibition as the regulatory endpoint, which EPA used in the final rule, is underprotective, even with the retention of the 10X FQPA

safety factor, and should not be used as precedent in future registration review actions for non-food uses of chlorpyrifos or for other organophosphate pesticides.

Earthjustice asserts that, as a scientific and legal matter, EPA is unable to make a finding of reasonable certainty of no harm using 10% cholinesterase inhibition as the regulatory endpoint. Earthjustice alleges that not only does the science support the conclusion that neurodevelopmental harms occur below levels of this regulatory endpoint, but the record and the Ninth Circuit's decision in *LULAC* foreclosed EPA from making such a finding. Earthjustice also takes issues with certain EPA statements in the final rule, which Earthjustice argues are intended to ''disparage'' the causal link between chlorpyrifos exposure and neurodevelopmental harm to children. Earthjustice believes that these statements are at odds with the record and unsupported. Finally, Earthjustice reiterates arguments made previously in response to EPA's 2017 Order Denying Petition that the final rule's retention of the 10X FQPA safety factor is not sufficient to ensure reasonable certainty of no harm to children.

B. Response to Earthjustice's Feedback and Comments

Because EPA is leaving the final rule in place as promulgated in August 2021 and not leaving any tolerances in place, EPA does not believe the Earthjustice comments necessitate a response at this time. While the comments might be relevant in the event that tolerances were retained or in any future action in which EPA considers petitions to establish chlorpyrifos tolerances, they are not relevant to a final rule that revokes tolerances. EPA does not need to address any of these comments as part of this Order, as they are not ripe for consideration at this time.

X. Conclusion

For all of the reasons specified in Unit VI., VII., and VIII. of this document, EPA denies, in full, the objections and requests for hearing on those objections and requests for stay, respectively.

XI. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's order denying objections filed under the FFDCA section 408. As such, this action is an adjudication and not a rule. The regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

XII. Congressional Review Act (CRA)

The CRA, 5 U.S.C. 801 *et seq.,* does not apply to this Order because this action is not a rule for purposes of 5 U.S.C. 804(3).

XIII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022–04139 Filed 2–25–22; 8:45 am]

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