



FEDERAL REGISTER

Vol. 88

Thursday

No. 12

January 19, 2023

Pages 3283–3628

OFFICE OF THE FEDERAL REGISTER



The **FEDERAL REGISTER** (ISSN 0097-6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see www.federalregister.gov.

The seal of the National Archives and Records Administration authenticates the **Federal Register** as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at www.govinfo.gov, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, gpocusthelp.com.

The annual subscription price for the **Federal Register** paper edition is \$860 plus postage, or \$929, for a combined **Federal Register**, **Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is \$330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register**, including postage, is based on the number of pages: \$11 for an issue containing less than 200 pages; \$22 for an issue containing 200 to 400 pages; and \$33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for \$3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see bookstore.gpo.gov.

There are no restrictions on the republication of material appearing in the **Federal Register**.

How To Cite This Publication: Use the volume number and the page number. Example: 88 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	202-512-1800
Assistance with public subscriptions	202-512-1806

General online information 202-512-1530; 1-888-293-6498

Single copies/back copies:

Paper or fiche	202-512-1800
Assistance with public single copies	1-866-512-1800 (Toll-Free)

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	FRSubscriptions@nara.gov
Phone	202-741-6000

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: <https://www.gpo.gov/frsubs>.



Contents

Federal Register

Vol. 88, No. 12

Thursday, January 19, 2023

Agricultural Marketing Service

RULES

National Organic Program:
Strengthening Organic Enforcement, 3548–3627

Agriculture Department

See Agricultural Marketing Service
See Animal and Plant Health Inspection Service
See Food and Nutrition Service
See Rural Business-Cooperative Service

Animal and Plant Health Inspection Service

PROPOSED RULES

Use of Electronic Identification Eartags as Official
Identification in Cattle and Bison, 3320–3330

Centers for Disease Control and Prevention

NOTICES

Meetings:

Disease, Disability, and Injury Prevention and Control
Special Emphasis Panel, Panel A, Occupational
Safety and Health Education and Research Centers,
3414

Disease, Disability, and Injury Prevention and Control
Special Emphasis Panel, Panel B, Occupational
Safety and Health Education and Research Centers,
3415

Civil Rights Commission

NOTICES

Meetings:

Mississippi Advisory Committee, 3382

Coast Guard

PROPOSED RULES

Special Local Regulation:
Sector Ohio Valley Annual and Recurring Special Local
Regulations, Update, 3366–3372

Commerce Department

See International Trade Administration
See National Institute of Standards and Technology
See National Oceanic and Atmospheric Administration
See Patent and Trademark Office

Commodity Futures Trading Commission

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Position Limits, 3395–3396

Community Development Financial Institutions Fund

NOTICES

Funding Opportunity:
Capital Magnet Fund; 2023 Funding Round, 3460–3478

Defense Department

See Engineers Corps

Education Department

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Evaluation of Full-Service Community Schools: Early
Implementation Data Collection, 3396–3397
Visual Representations for Proportional Reasoning:
Impacts of a Teacher Professional Development
Program for Multilingual Learners and Other
Students, 3397–3398

Energy Department

See Federal Energy Regulatory Commission

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 3398–3400
Meetings:
Environmental Management Site-Specific Advisory
Board, Idaho Cleanup Project, 3398
Environmental Management Site-Specific Advisory
Board, Nevada, 3399

Engineers Corps

PROPOSED RULES

Danger Zone:

Naval Support Activity Annapolis, Annapolis, MD, in the
Waters of Carr Creek and Whitehall Bay, 3372–3373

Environmental Protection Agency

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Clean Water State Revolving Fund and Drinking Water
State Revolving Fund Programs, 3409–3411
Prevention of Significant Deterioration and
Nonattainment New Source Review, 3404–3405
Survey to Improve Economic Analysis of Surface Water
Quality Changes, 3405–3406
New Approach Methodologies in the Endocrine Disruptor
Screening Program, 3406–3408
Recent Postings of Broadly Applicable Alternative Test
Methods, 3408–3409

Federal Aviation Administration

PROPOSED RULES

Airworthiness Directives:

Airbus Helicopters, 3330–3334

Federal Communications Commission

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 3411–3412

Federal Election Commission

NOTICES

Meetings; Sunshine Act, 3412

Federal Energy Regulatory Commission

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 3400–3401
Application:
Moretown Hydroelectric, LLC, 3403

Northern States Power Co., 3401–3403
 Combined Filings, 3403–3404
 Surrender of Preliminary Permit:
 Lock plus TM Hydro Friends Fund XVIII, LLC, 3401

Federal Maritime Commission

NOTICES

Agreements Filed, 3412–3413
 Meetings; Sunshine Act, 3413

Federal Motor Carrier Safety Administration

NOTICES

Exemption Application:
 Hours of Service of Drivers; Ronnie Brown III, 3458–3459

Federal Trade Commission

PROPOSED RULES

Non-Compete Clause Rule, 3482–3546

NOTICES

Agency Information Collection Activities; Proposals,
 Submissions, and Approvals, 3413–3414

Financial Crimes Enforcement Network

RULES

Civil Monetary Penalty Inflation Adjustment, 3311–3313

Fish and Wildlife Service

NOTICES

Permits; Applications, Issuances, etc.:
 Candidate Conservation Agreement with Assurances for
 the Fisher in Oregon; Enhancement of Survival
 Permit Applications; Hampton and Starker Site
 Plans, 3428–3429

Food and Drug Administration

NOTICES

Agency Information Collection Activities; Proposals,
 Submissions, and Approvals:
 Accreditation Scheme for Conformity Assessment
 Program, 3419–3422
 Adverse Event Program for Medical Devices (Medical
 Product Safety Network), 3417–3419
 Protection of Human Subjects and Institutional Review
 Boards, 3415–3417

Food and Nutrition Service

NOTICES

Summer Food Service Program; 2023 Reimbursement Rates;
 Correction, 3376

Health and Human Services Department

See Centers for Disease Control and Prevention
See Food and Drug Administration
See Health Resources and Services Administration
See National Institutes of Health
See Substance Abuse and Mental Health Services
 Administration

NOTICES

Annual Update of Poverty Guidelines, 3424–3425
 Meetings:
 2025 Dietary Guidelines Advisory Committee, 3423–3424

Health Resources and Services Administration

NOTICES

Meetings:
 Advisory Committee on Heritable Disorders in Newborns
 and Children, 3422–3423

Homeland Security Department

See Coast Guard

Interior Department

See Fish and Wildlife Service
See Land Management Bureau
See Ocean Energy Management Bureau
See Office of Natural Resources Revenue

RULES

Civil Monetary Penalty Inflation Adjustment, 3315–3317

PROPOSED RULES

Natural Resource Damages for Hazardous Substances, 3373–
 3375

Internal Revenue Service

NOTICES

Agency Information Collection Activities; Proposals,
 Submissions, and Approvals, 3479–3480
 Agency Information Collection Activities; Proposals,
 Submissions, and Approvals:
 Extraterritorial Income Exclusion, 3479
 Information Return of Nontaxable Energy Grants or
 Subsidized Energy Financing, 3480
 Superfund Chemical Substance Tax:
 List of Taxable Substances; Filing of Petition for 4,4'-
 Isopropylidenediphenol-Epichlorohydrin Copolymer,
 3478–3479

International Trade Administration

NOTICES

Antidumping or Countervailing Duty Investigations, Orders,
 or Reviews:
 Certain Preserved Mushrooms from France, 3382–3384
 Ripe Olives from Spain, 3384–3385

International Trade Commission

NOTICES

Antidumping or Countervailing Duty Investigations, Orders,
 or Reviews:
 Sodium Nitrite from India, 3438–3439
 Investigations; Determinations, Modifications, and Rulings,
 etc.:
 Certain Casual Footwear and Packaging Thereof, 3437–
 3438
 Certain Video Security Equipment and Systems, Related
 Software, Components Thereof, and Products
 Containing Same, 3435–3437
 Meetings; Sunshine Act, 3435

Justice Department

NOTICES

Proposed Consent Decree:
 Resource Conservation and Recovery Act, 3439

Labor Department

See Workers Compensation Programs Office

NOTICES

Agency Information Collection Activities; Proposals,
 Submissions, and Approvals:
 Reemployment Services and Eligibility Assessments
 Program Implementation Study, Reinstatement,
 3439–3441

Land Management Bureau

NOTICES

Agency Information Collection Activities; Proposals,
 Submissions, and Approvals:
 Recordation of Location Notices and Mining Claims;
 Payment of Fees, 3430

Legal Services Corporation**NOTICES**

Funding Availability:

Calendar Year 2023 Competitive Grant Funds for the
Technology Initiative Grant Program, 3441–3442

Maritime Administration**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:

Requirements for Eligibility of U.S.-Flag Vessels of 100
Feet or Greater in Registered Length to Obtain a
Fishery Endorsement, 3459–3460

National Institute of Standards and Technology**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:

Generic Clearance for Diversity, Equity, Inclusion, and
Accessibility Data Collections, 3386–3387

Meetings:

Advisory Committee on Earthquake Hazards Reduction,
3385–3386
Industrial Advisory Committee, 3387

National Institutes of Health**NOTICES**

Meetings:

National Center for Advancing Translational Sciences,
3425–3426
National Institute of Dental and Craniofacial Research,
3425
National Institute of Environmental Health Sciences,
3426–3427
National Institute on Aging, 3426

National Oceanic and Atmospheric Administration**RULES**

Fisheries of the Exclusive Economic Zone off Alaska:

Pacific Cod by Catcher Vessels less than 60 Feet (18.3
Meters) Length Overall Using Hook-and-Line or Pot
Gear in the Bering Sea and Aleutian Islands
Management Area, 3318–3319

Pacific Cod by Catcher/Processors Using Trawl Gear in
the Bering Sea and Aleutian Islands Management
Area, 3318

Fisheries of the Northeastern United States:

Atlantic Sea Scallop Fishery; Closure of the Closed Area
I Scallop Access Area to General Category Individual
Fishing Quota Scallop Vessels, 3317

PROPOSED RULES

Proposed Lake Ontario National Marine Sanctuary, 3334–
3349

Taking or Importing of Marine Mammals:

Revolution Wind Offshore Wind Farm Project Offshore
Rhode Island, 3375

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:

Fisheries Finance Program Requirements, 3387–3388
International Dolphin Conservation Program, 3393–3394
Reporting Requirements for Sea Otter Interactions with
the Pacific Sardine Fishery; Coastal Pelagic Species
Fishery Management Plan, 3388–3389

Endangered and Threatened Species:

Take of Anadromous Fish, 3390–3392

Meetings:

Evaluation of New York State Coastal Management
Program, 3389

Gulf of Mexico Fishery Management Council; Correction,
3389–3390

Permits; Applications, Issuances, etc.:

Endangered Species; File No: 26645, 3392–3393

Nuclear Regulatory Commission**RULES**

NuScale Small Modular Reactor Design Certification, 3287–
3311

Ocean Energy Management Bureau**NOTICES**

Bid Adequacy Procedures for Offshore Oil and Gas Lease
Sales, 3433–3435

Office of Natural Resources Revenue**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:

Suspensions Pending Appeal and Bonding, 3430–3433

Patent and Trademark Office**NOTICES**

Expanding Admission Criteria for Registration to Practice in
Patent Cases, 3394–3395

Expanding Opportunities to Appear before the Patent Trial
and Appeal Board, 3394

Postal Regulatory Commission**RULES**

Competitive Postal Products, 3313–3315

NOTICES

Income Tax Review, 3442

Presidential Documents**PROCLAMATIONS**

Special Observances:

Martin Luther King, Jr., Federal Holiday (Proc. 10513),
3283–3284

Religious Freedom Day (Proc. 10514), 3285–3286

Rural Business-Cooperative Service**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 3381–3382

Funding Opportunity:

Rural Business Development Grant Program to Provide
Technical Assistance for Rural Transportation
Systems for Fiscal Year 2023, 3376–3381

Securities and Exchange Commission**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:

Investment Company Interactive Data, 3451–3452

Application:

Prospect Capital Management, LP and Prospect Floating
Rate and Alternative Income Fund, Inc., 3452–3453

RBB Fund Trust and Element ETFs, LLC, 3448–3449

Self-Regulatory Organizations; Proposed Rule Changes:

Cboe C2 Exchange, Inc., 3443–3444, 3449–3451

Cboe EDGX Exchange, Inc., 3453–3455

Cboe Exchange, Inc., 3444–3448

Nasdaq PHLX, LLC, 3456–3458

NYSE American, LLC, 3448

**Substance Abuse and Mental Health Services
Administration****NOTICES**

Meetings, 3428

Meetings:

Interdepartmental Serious Mental Illness Coordinating
Committee, 3427–3428**Transportation Department***See* Federal Aviation Administration*See* Federal Motor Carrier Safety Administration*See* Maritime Administration**Treasury Department***See* Community Development Financial Institutions Fund*See* Financial Crimes Enforcement Network*See* Internal Revenue Service**Workers Compensation Programs Office****PROPOSED RULES**

Black Lung Benefits Act:

Authorization of Self-Insurers, 3349–3366

Separate Parts In This Issue**Part II**

Federal Trade Commission, 3482–3546

Part IIIAgriculture Department, Agricultural Marketing Service,
3548–3627

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to <https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR**Proclamations:**

10513.....3283
10514.....3285

7 CFR

205.....3548

9 CFR**Proposed Rules:**

71.....3320
77.....3320
78.....3320
86.....3320

10 CFR

52.....3287

14 CFR**Proposed Rules:**

39.....3330

15 CFR**Proposed Rules:**

922.....3334

16 CFR**Proposed Rules:**

910.....3482

20 CFR**Proposed Rules:**

726.....3349

31 CFR

1010.....3311

33 CFR**Proposed Rules:**

100.....3366
334.....3372

39 CFR

3035.....3313

43 CFR

10.....3315

Proposed Rules:

11.....3373

50 CFR

648.....3317

679 (2 documents)3318

Proposed Rules:

217.....3375

Presidential Documents

Title 3—

Proclamation 10513 of January 13, 2023

The President

Martin Luther King, Jr., Federal Holiday, 2023

By the President of the United States of America

A Proclamation

Today, we honor the Reverend Dr. Martin Luther King, Jr., by continuing his unfinished work to redeem the soul of America.

Dr. King came of age in the South during a time when racial discrimination was the law of the land. Black Americans risked jail time for accessing public accommodations like drinking fountains, parks, restrooms, restaurants, and hotels. Their voting rights were denied by complicated, onerous, and discriminatory rules. Even if they attempted to register to vote, they could be fired from their jobs, be run off of their farms, or face vigilante violence.

Dr. King imagined a different future for America—an America he called the “Beloved Community.” Building the Beloved Community required a key shift in human understanding. It meant looking beyond external differences to see the union of all humankind. It also meant finding a way to deal with our grievances without animosity, in a way that recognized the interconnectedness of all humanity and allowed us to move forward together.

From the pulpit to the podium to the streets, Dr. King devoted his life to the quest for this Beloved Community in our Nation. His activism and moral authority helped usher in the Civil Rights Act of 1964 and the Voting Rights Act of 1965. He gave a voice to the restless spirit of millions yearning for change. He gave us a roadmap to unify, to heal, and to sustain the blessings of the Nation to all of its people.

But the work continues because it remains unfinished. That is why my Administration has called on the Congress to pass the John Lewis Voting Rights Advancement Act and the Freedom to Vote Act to ensure that every citizen has a voice in deciding our future.

In keeping with Dr. King’s campaign for economic justice and the rights of workers, my Administration is striving to make the American Dream a reality for every family. By creating good-paying jobs, investing in the middle class, improving access to affordable housing and quality education, and closing the racial and gender wealth gaps, we can give hardworking families the dignity Dr. King would say they deserve.

Dr. King called for greater fairness in our health care system, and my Administration is pushing to put quality, affordable health care within reach of all people—especially the most vulnerable and marginalized Americans. By lowering costs and improving access, we can make health care a right and not just a privilege.

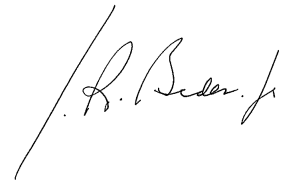
Dr. King preached that “darkness cannot drive out darkness, only light can do that.” In his memory, we strive to challenge violence and bigotry with grace and goodness. We work to embed equity and opportunity into all of the Federal Government’s policies and programs. And we serve to bring together a Nation in our dedication to these ideals.

This Sunday, I will pay my respects and express my gratitude for his life and legacy by speaking at services at his cherished Ebenezer Baptist Church. On this day of commemoration, service, and action, let us hold

up a mirror to America and ask ourselves: What kind of country do we want to be? Will we honor Dr. King's legacy by rising together—buttressed by each other's successes, enriched by each other's differences, and made whole by each other's compassion? I believe we can. It will require constant care for our democracy, stubborn faith in this great experiment, and a commitment to stamping out discrimination in all forms. It will demand honest reflection about how far we have come and how far we have yet to go to be the best version of ourselves. But like Dr. King, I know that there is nothing beyond this Nation's capacity and that we will fulfill the promise of America for all Americans—perfecting the Union we love and must protect.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim Monday, January 16, 2023, as the Martin Luther King, Jr., Federal Holiday. I encourage all Americans to observe this day with appropriate civic, community, and service projects in honor of Dr. King and to visit [MLKDay.gov](https://www.MLKDay.gov) to find Martin Luther King, Jr., Day of Service projects across our country.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of January, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



Presidential Documents

Proclamation 10514 of January 13, 2023

Religious Freedom Day, 2023

By the President of the United States of America

A Proclamation

On Religious Freedom Day, we reflect on our right to practice, pray, and preach our faiths peacefully and openly. Across the country, we practice many different religions. We celebrate many different traditions. And we honor our faiths in many different ways and places—from churches, to mosques, to synagogues, to temples. This religious freedom—this freedom to practice religion fully and freely or to practice no religion at all—is enshrined in our Constitution. And together we must continue to preserve and protect it.

This effort is as important now as it has ever been. In the United States, we are facing a rising tide of antisemitism and renewed attacks against certain religious groups. Across the world, minority communities—including Uyghurs, Rohingya, Ahmadiyya Muslims, Jews, Christians, Bahá'ís, Yazidis, atheists, and humanists—continue to face intimidation, violence, and unequal protection under the law. This hate is harmful to our communities and countries, and it is on all of us to speak out and stop it.

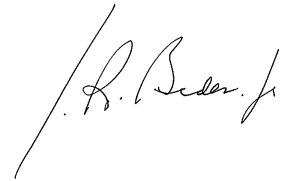
That is exactly what my Administration is doing. We established the Protecting Places of Worship Interagency Policy Committee last January, and implemented the largest-ever increase in funding for the physical security of non-profits—including churches, gurdwaras, mosques, synagogues, temples, and other houses of worship. In my 2023 Budget proposal, I called for another large increase in funding for this key program. In September, we hosted the United We Stand Summit, the first White House summit on combating hate-motivated violence, including violence on the basis of religion. In December, I established a new interagency group to increase and better coordinate the Federal Government's efforts to counter antisemitism, Islamophobia, and other forms of bias and discrimination within the United States. As its first order of business, this group is developing a national strategy to fight antisemitism. To build bridges across beliefs and backgrounds, the White House Office of Faith-Based and Neighborhood Partnerships is collaborating with diverse faith and community leaders on a range of projects—including helping families recover from disasters, distributing COVID-19 vaccines, improving maternal and child health, and resettling refugees across the United States.

The United States is also speaking out and standing up against religious persecution around the world. Last year, my Administration provided \$20 million to help promote religious freedom and protections for members of religious minorities globally, including helping ensure that people everywhere can practice their faiths free from fear. I appointed Rashad Hussain as Ambassador at Large for International Religious Freedom—the first Muslim to hold this post—and Deborah Lipstadt, a Holocaust expert, as the first Ambassador-level Special Envoy to Monitor and Combat Antisemitism. As a founding member of the International Religious Freedom or Belief Alliance, we also have coordinated with partners around the world to promote the rights of religious minority groups and combat persecution. And we are ensuring that United States diplomats continue to receive training on religious freedom and its central importance to our work.

Faith has sustained me throughout my life. For me and for so many others, it serves as a reminder of both our collective purpose and potential in the world. But for far too many people within our borders and beyond, practicing their faith still means facing fear and persecution. Today, let us recommit ourselves to ending this hate. And let us work together to ensure that people of all religions—and no religion—are treated with equal dignity and respect.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim January 16, 2023, as Religious Freedom Day.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of January, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.

A handwritten signature in black ink, appearing to read "J. R. Biden Jr.", with a long, sweeping underline that extends to the left.

Rules and Regulations

Federal Register

Vol. 88, No. 12

Thursday, January 19, 2023

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 52

[NRC–2017–0029]

RIN 3150–AJ98

NuScale Small Modular Reactor Design Certification

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to certify the NuScale standard design for a small modular reactor. Applicants or licensees intending to construct and operate a NuScale standard design may do so by referencing this design certification rule. The applicant for certification of the NuScale standard design is NuScale Power, LLC.

DATES: This final rule is effective on February 21, 2023. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of February 21, 2023.

ADDRESSES: Please refer to Docket ID NRC–2017–0029 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2017–0029. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: Dawn.Forder@nrc.gov. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the

ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the “Availability of Documents” section.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

- *Technical Library:* The Technical Library, which is located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852, is open by appointment only. Interested parties may make appointments to examine documents by contacting the NRC Technical Library by email at Library.Resource@nrc.gov between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Yanely Malave, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–1519, email: Yanely.Malave@nrc.gov, and Carolyn Lauron, Office of Nuclear Reactor Regulation, telephone: 301–415–2736, email: Carolyn.Lauron@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background
- II. Opportunities for Public Participation
- III. Regulatory and Policy Issues
- IV. Technical Issues Associated With the NuScale Design
- V. Discussion
 - A. Introduction (Section I)
 - B. Definitions (Section II)
 - C. Scope and Contents (Section III)
 - D. Additional Requirements and Restrictions (Section IV)
 - E. Applicable Regulations (Section V)
 - F. Issue Resolution (Section VI)
 - G. Duration of This Appendix (Section VII)

- H. Processes for Changes and Departures (Section VIII)
- I. [Reserved] (Section IX)
- J. Records and Reporting (Section X)
- VI. Public Comment Analysis
- VII. Section-by-Section Analysis
- VIII. Regulatory Flexibility Certification
- IX. Regulatory Analysis
- X. Backfitting and Issue Finality
- XI. Plain Writing
- XII. Environmental Assessment and Finding of No Significant Impact
- XIII. Paperwork Reduction Act
- XIV. Congressional Review Act
- XV. Agreement State Compatibility
- XVI. Voluntary Consensus Standards
- XVII. Availability of Documents
- XVIII. Incorporation by Reference—Reasonable Availability to Interested Parties

I. Background

Part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), “Licenses, Certifications, and Approvals for Nuclear Power Plants,” subpart B, “Standard Design Certifications,” presents the process for obtaining standard design certifications. By letter dated December 31, 2016, NuScale Power, LLC, (NuScale Power) filed its application for certification of the NuScale standard design (hereafter referred to as NuScale). The NRC published a notification of receipt of the design certification application (DCA) in the **Federal Register** on February 22, 2017 (82 FR 11372). On March 30, 2017, the NRC published a notification of acceptance for docketing of the application in the **Federal Register** (82 FR 15717) and assigned docket number 52–048. The preapplication information submitted before the NRC formally accepted the application can be found in ADAMS under Docket No. PROJ0769.

NuScale is the first small modular reactor design reviewed by the NRC. NuScale is based on a small light water reactor developed at Oregon State University in the early 2000s. It consists of one or more NuScale power modules (hereafter referred to as power module(s)). A power module is a natural circulation light water reactor composed of a reactor core, a pressurizer, and two helical coil steam generators located in a common reactor pressure vessel that is housed in a compact cylindrical steel containment. The NuScale reactor building is designed to hold up to 12 power modules. Each power module has a rated thermal output of 160 megawatt thermal (MWt) and electrical output of 50 megawatt electric (MWe), yielding a

total capacity of 600 MWe for 12 power modules. All the NuScale power modules are partially submerged in a common safety-related pool, which is also the ultimate heat sink for up to 12 power modules. The pool portion of the reactor building is located below grade. The design utilizes several first-of-a-kind approaches for accomplishing key safety functions, resulting in no need for Class 1E safety-related power (no emergency diesel generators), no need for pumps to inject water into the core for post-accident coolant injection, and reduced need for control room staffing while providing safe operation of the plant during normal and post-accident operation.

II. Opportunities for Public Participation

The proposed rule and environmental assessment were published in the **Federal Register** on July 1, 2021, for a 60-day public comment period (86 FR 34999). The public comment period was scheduled to close on August 30, 2021. The NRC subsequently extended the comment period by 45 days (86 FR 47251; August 24, 2021), providing a total comment period of 105 days. The public comment period closed on October 14, 2021. The public comments informed the development of this final rule.

III. Regulatory and Policy Issues

A. Exemptions for Future Applicants Referencing NuScale

1. Control Room Staffing Requirements

The requirements in §§ 50.54(k) and 50.54(m) identify the minimum number of licensed operators that must be on site, in the control room, and at the controls. The requirements are conditions in every nuclear power reactor operating license issued under 10 CFR part 50, "Domestic Licensing of Production and Utilization Facilities." The requirements also are conditions in every combined license (COL) issued under 10 CFR part 52; however, they are applicable only after the Commission makes the finding under § 52.103(g) that the acceptance criteria in the COL are met.

In a letter to the NRC, dated September 15, 2015, NuScale Power proposed that 6 licensed operators would operate up to 12 power modules from a single control room. The staffing proposal would meet the requirements of § 50.54(k) but would not meet the requirements in § 50.54(m)(2)(i) because the minimum requirements for the onsite staffing table in § 50.54(m)(2)(i) do not address operation of more than two units from a single control room.

The proposal also would not meet § 50.54(m)(2)(iii), which requires a licensed operator at the controls for each fueled unit. Absent alternative staffing requirements, future applicants referencing the NuScale design would need to request an exemption.

In DCA, Part 7, Section 6, NuScale requested that the NRC approve design-specific control room staffing requirements in lieu of the requirements in § 50.54(m). In the DCA Part 7, Section 6.2, "Justification for Rulemaking," NuScale Power provided a technical basis for its proposed alternative control room staffing requirements. NuScale Power's proposed approach is consistent with SECY-11-0098, "Operator Staffing for Small or Multi-Module Nuclear Power Plant Facilities," dated July 22, 2011. For the reasons described in Chapter 18, Section 18.5.4.2, "Evaluation of the Applicant's Technical Basis," of the final safety evaluation report, the NRC found that NuScale Power's proposed staffing level, as described in the DCA Part 7, Section 6, is acceptable. Because Section V, "Applicable Regulations," of this final rule includes the alternative staffing requirement provisions, staffing table, and appropriate table notes, a future applicant or licensee that references appendix G to 10 CFR part 52 will not need to request an exemption from § 50.54(m).

2. Preoperational and Periodic Testing of Primary Reactor Containment

General Design Criterion (GDC) 52, "Capability for Containment Leakage Rate Testing," requires that the containment be designed so that periodic, integrated leakage rate testing can be conducted at containment design pressure; the underlying purpose of which is to provide design capability for testing that assures that containment leakage integrity is maintained and containment vessel leakage does not exceed allowable leakage rate values (see appendix J to 10 CFR part 50). Under 10 CFR 50.54(o), operating licenses and combined licenses for certain water-cooled power reactors must include a condition that the primary containment shall be subject to appendix J to 10 CFR part 50, "Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors." Appendix J to 10 CFR part 50 requires that primary reactor containments meet the containment leakage test requirements to provide for preoperational and periodic verification by tests of the leak-tight integrity of the primary reactor containment (Type A) and systems and components that

penetrate containment (Type B and Type C).

NuScale Power requested an exemption from GDC 52 in order to not design NuScale to include the capability for Type A testing and requested that the design certification rule exempt licensees referencing the NuScale design certification rule from the requirement for Type A testing in appendix J to 10 CFR part 50. NuScale Power's request was based on the NuScale small modular reactor design meeting the underlying purpose of the regulation through means not anticipated when the NRC issued GDC 52 and appendix J to 10 CFR part 50. NuScale Power stated that the NuScale containment has two primary features distinguishing it from containments at existing light water reactors that provide assurance that no unknown leakage pathways will be present. First, the NuScale containment is designed and would be constructed as a pressure vessel, and therefore leakage due to vessel design or fabrication flaws would be identified during a required preservice structural integrity test. In contrast to a Type A test, this test is a hydrostatic leakage test at design pressure, with no visible leakage as its acceptance criterion. Second, the containment is 100-percent inspectable, both inside and outside, whereby aging-related flaws leading to potential leakage could be observed. Containment leakage integrity assurance for NuScale is described in detail in technical report TR-1116-51962-NP, "NuScale Containment Leakage Integrity Assurance," Rev. 1 (May 2019), which this final rule incorporates by reference. NuScale Power stated that the required preservice tests and inservice inspections described in TR-1116-51962-NP, including Type B and Type C testing without Type A testing, ensure that containment leakage rates remain acceptable.

In Chapter 6, Section 6.2.6.4, "Technical Evaluation for Exemption Request No. 7," of the final safety evaluation report, the NRC staff concluded that granting this exemption from Type A testing, and associated design features required by GDC 52 to provide for Type A testing, is acceptable because the NuScale design relies on the preservice pressure test, successful Type B and C testing at each refueling as required in appendix J to 10 CFR part 50, periodic inservice inspections, and direct observation of the entire vessel to identify potential degradation or unknown leakage pathways for the remainder of the service life for the containment.

The NRC received a comment that the exemption from the requirement for Type A testing in appendix J to 10 CFR part 50 should have been listed in the proposed rule. The NRC agrees that the exemption should have been included in the proposed rule. The NRC's conclusion that Type A testing is not necessary for NuScale was noticed for comment as the basis for the exemption from GDC 52. The exemption from Type A testing itself was discussed in detail in the same section of final safety evaluation report that evaluated the exemption from GDC 52. Although the exemption from Type A testing was not included in the proposed rule, the change to this final rule only specifies that future licensees that reference this final rule will not be required to perform Type A testing for which NuScale is not designed or required to be capable of. Therefore, the NRC concludes that the exemption from the Type A test in appendix J to 10 CFR part 50 is a logical outgrowth of the proposed rule. In addition, because the issue of whether Type A testing is necessary for NuScale was noticed in the proposed rule and the NRC received no comments on the matter, the NRC finds that notice and comment on this exemption from Type A testing is unnecessary within the meaning of 5 U.S.C. 553(b).

Thus, Section V, "Applicable Regulations," in this final rule includes an exemption for licensees referencing appendix G to 10 CFR part 52 from the requirement of appendix J to 10 CFR part 50 to conduct Type A testing.

B. Incorporation by Reference

Section III.A, "Incorporation by reference approval," of appendix G to 10 CFR part 52 lists documents that were approved by the Director of the Office of the Federal Register for incorporation by reference into this appendix. Section III.B.2 identifies information that is not within the scope of the design certification and, therefore, is not incorporated by reference into this appendix. This information includes conceptual design information, as defined in § 52.47(a)(24), and the discussion of "first principles" described in the Design Control Document (DCD) Part 2, Tier 2, Section 14.3.2, "Tier 1 Design Description and Inspections, Tests, Analyses, and Acceptance Criteria First Principles."

The final rule has been updated to align with the Office of the Federal Register's latest guidance for incorporation by reference, issued on March 1, 2022, as supplemented by Release 1–2022 to the Incorporation by Reference Handbook.

C. Issues Not Resolved by the Design Certification

The NRC identified three issues as not resolved within the meaning of § 52.63(a)(5). There was insufficient information available for the NRC to resolve issues regarding (1) the shielding wall design in certain areas of the plant, (2) the potential for containment leakage from the combustible gas monitoring system, and (3) the ability of the steam generator tubes to maintain structural and leakage integrity during density wave oscillations in the secondary fluid system, including the method of analysis to predict the thermal-hydraulic conditions of the steam generator secondary fluid system and resulting loads, stresses, and deformations from density wave oscillations from reverse flow.

1. Shielding Wall Design

As discussed in Section 12.3.4.1.2 of the final safety evaluation report, the NRC found that there were insufficient design details available regarding shielding wall design with the presence of large penetrations, such as the main steam lines; main feedwater lines; and power module bay heating, ventilation, and air conditioning lines in the radiation shield wall between the power module bay and the reactor building steam gallery area. Without this shielding design information, the NRC is unable to confirm that the radiological doses to workers will be maintained within the radiation zone limits specified in the application.

This issue is narrowly focused on the shielding walls between the reactor module bays and the reactor building steam gallery areas. The radiation zones and dose calculations, including dose calculations for the dose to workers, members of the public, and environmental qualification, in areas outside of the reactor module bay are calculated assuming a solid wall and currently do not account for penetrations in the shield wall. An applicant is required to demonstrate penetration shielding adequate to address the following issues in the NuScale DCD: the plant radiation zones, environmental qualification dose calculations, and dose estimates for workers and the public. An applicant can provide this information for the NRC to review because this issue involves a localized area of the plant without affecting other aspects of the NRC's review of the NuScale design. Therefore, the NRC has determined that this information can be provided by an applicant that references this appendix

without a demonstrable impact on safety or standardization. Appendix G to 10 CFR part 52, Section VI, "Issue Resolution," clarifies that this issue is not resolved within the meaning of § 52.63(a)(5), and Section IV, "Additional Requirements and Restrictions," states that the COL applicant is responsible for providing the design information to address this issue.

2. Containment Leakage From the Combustible Gas Monitoring System

As documented in Section 12.3.4.1.3 of the final safety evaluation report, there was insufficient information available regarding the NuScale combustible gas monitoring system and the potential for leakage from this system outside containment. Without additional information regarding the potential for leakage from this system, the NRC was unable to determine whether this leakage could impact analyses performed to assess main control room dose consequences, offsite dose consequences to members of the public, and whether this system can be safely re-isolated after monitoring is initiated due to potentially high dose levels at or near the isolation valve location. The isolation valve can only be operated locally, and dose levels at the valve location have not been determined.

This issue is narrowly focused on the radiation dose implications as a result of using the post-accident combustible gas monitoring loop. An applicant is required under §§ 50.34(f)(2) and 52.47(a)(2) to demonstrate either that offsite and main control room dose calculations are not exceeded or that the system can be safely re-isolated, if needed. This issue does not affect normal plant operation or non-core damage accidents. The issue may be resolved by performing radiation dose calculations and demonstrating that doses would remain within applicable dose limits in 10 CFR part 20, "Standards for Protection Against Radiation." More information may be available at the application stage that would allow for more detailed calculations. Any design changes to address this issue would only affect the combustible gas monitoring loop to ensure it can be re-isolated or to ensure that dose limits are not exceeded. Such design changes likely would not have an impact on other systems or equipment, and the NRC would review such changes and any resulting effects on other structures, systems, and components during the application review to determine whether there is reasonable assurance of adequate

protection of public health and safety. Therefore, the NRC has determined that this information can be provided by an applicant that references this appendix without a demonstrable impact on safety or standardization. Appendix G to 10 CFR part 52, Section VI, "Issue Resolution," clarifies that this issue is not resolved within the meaning of § 52.63(a)(5), and Section IV, "Additional Requirements and Restrictions," states that the COL applicant is responsible for providing the design information to address this issue.

3. Steam Generator Stability During Density Wave Oscillations and Associated Method of Analysis

Section 5.4.1.2, "System Design," in Revision 2 of the DCA Part 2, Tier 2 (ADAMS Accession No. ML18310A345), stated that a flow restriction device at the inlet to each steam generator tube "ensures secondary-side flow stability and precludes density wave oscillations." However, the applicant modified this section in Revision 3 of the DCA Part 2, Tier 2 (ADAMS Accession No. ML19241A431), to state that the steam generator inlet flow restrictors provide the necessary secondary-side pressure drop "to reduce flow oscillations to acceptable limits." Revision 4.1 of the DCA (ADAMS Accession No. ML20205L562) revised Section 5.4.1.2 to state that the steam generator inlet flow restrictors are designed "to reduce the potential for density wave oscillations." Revision 5 of this section of the DCA (ADAMS Accession No. ML20225A071) provides only editorial changes to Revision 4.1 and does not change the technical content or conclusions.

Sections 3.9.2, 3.9.5, and 5.4.1 of the final safety evaluation report relied on the applicant's statements in Revision 2 and Revision 3 of the DCA that flow oscillations in the secondary fluid system of the steam generators would either be precluded or minimal. After issuance of the advanced safety evaluation report, the NRC noted inconsistencies and gaps in the information provided in Sections 3.9.1, 3.9.2, and 5.4.1 of Revision 4.1 of the DCA Part 2, Tier 2, regarding the potential for significant density wave oscillations in the steam generator tubes, including both forward and reverse secondary flow. The testing performed by the applicant on various conceptual designs of the steam generator inlet flow restrictors only involved flow in the forward direction without oscillation or reverse flow.

As a result, NuScale Power has not demonstrated that the flow oscillations

that are predicted to occur on the secondary side of the steam generators will not cause failure of the inlet flow restrictors. Structural and leakage integrity of the inlet flow restrictors in the steam generators is necessary to avoid damage to multiple steam generator tubes, caused directly by broken parts or indirectly by unexpected density wave oscillation loads. Damage to multiple steam generator tubes could disrupt natural circulation in the reactor coolant pathway and interfere with the decay heat removal system and the emergency core cooling system, which is relied upon to cool the reactor core in a NuScale power module. The failure of multiple steam generator tubes resulting from failure of an inlet flow restrictor has not been included within the scope of the NuScale accident analyses in DCA Part 2, Tier 2, Chapter 15. Therefore, the NRC concludes that NuScale Power has not demonstrated compliance with 10 CFR 52.47(a)(2)(iv) and appendix A to 10 CFR part 50, GDC 4 and GDC 31, relative to potential impacts on steam generator tube integrity from inlet flow restrictor failure.

As described previously, NuScale Power made a change to the description of inlet flow restrictor performance beginning with DCA Part 2, Tier 2, Revision 3, that indicates that the design no longer precludes density wave oscillations in the secondary side of the steam generators. As a result, the design needs a method of analysis to predict the thermal-hydraulic conditions of the steam generator secondary fluid system and resulting loads, stresses, and deformations from density wave oscillations including reverse flow. However, as described in the next paragraph, NuScale power did not provide verification and validation for its proposed method of analysis to demonstrate it is appropriate for this purpose.

The DCA Part 2, Tier 2, Section 3.9.1.2, "Computer Programs Used in Analyses," lists the computer programs used by NuScale Power in the dynamic and static analyses of mechanical loads, stresses, and deformations, and in the hydraulic transient load analyses of seismic Category I components and supports for the NuScale nuclear power plant. Section 3.9.1.2 states that NRELAP5 is NuScale's proprietary system thermal-hydraulics code for use in safety-related design and analysis calculations and is pre-verified and configuration-managed. The advanced safety evaluation report, Section 3.9.1.4.9, "Computer Programs Used in Analyses," states that the NRELAP5

computer program had received verification and validation. Following preparation of the advanced safety evaluation report, the NRC noted a discrepancy between two statements in the DCA about validation for NRELAP5: DCA Part 2, Tier 2, Section 5.4.1.3, in Revision 4 stated that NRELAP5 was validated for determining density wave oscillation thermal-hydraulic conditions, referring to Section 15.0.2 for more information, but neither Section 15.0.2 nor technical report TR-1016-51669-NP describe validation for determining density wave oscillation thermal-hydraulic conditions.

On June 19, 2020, NuScale submitted Revision 4.1 of the DCA Part 2, Tier 2 (ADAMS Accession No. ML20205L562; subsequently included in Revision 5 of the DCA submitted on July 29, 2020 (ADAMS Accession No. ML20225A071)), to correct the discrepancies and acknowledge the need for a COL applicant to address secondary-side instabilities in the steam generator design. Specifically, the update to Section 3.9.1.2 in Revision 4.1 of DCA Part 2, Tier 2, references DCA Part 2, Tier 2, Section 15.0.2, "Review of Transient and Accident Analysis Methods," for the discussion of the development, use, verification, validation, and code limitations of the NRELAP5 computer program for application to transient and accident analyses. The correction to Section 3.9.1.2 also references technical report TR-1016-51669-NP, "NuScale Power Module Short-Term Transient Analysis," incorporated by reference in DCA Part 2, Tier 2, Table 1.6-2, for application of the NRELAP5 computer program to short-term transient dynamic mechanical loads, such as pipe breaks and valve actuations. In addition, the correction to Section 3.9.1.2 includes a new COL item specifying that a COL applicant that references the NuScale DCD will develop an evaluation methodology for the analysis of secondary-side instabilities in the steam generator design. The COL item states that this methodology would address the identification of potential density wave oscillations in the steam generator tubes and qualification of the applicable portions of the reactor coolant system integral reactor pressure vessel and steam generator given the occurrence of density wave oscillations, including the effects of reverse fluid flows within the tubes. These corrections to the DCA clarify that the evaluation methodology for the analysis of secondary-side instabilities in the steam generator design was not verified and validated as

part of the NuScale DCA but will need to be established by the COL applicant.

This steam generator design issue is narrowly focused on the effects of density wave oscillations in the secondary fluid system on steam generator tubes to maintain structural and leakage integrity, including the method of analysis to predict the thermal-hydraulic conditions of the steam generator secondary fluid system and resulting loads, stresses, and deformations from density wave oscillations including reverse flow. No other reactor safety aspect of the steam generators is impacted by this design issue. As a result, the NRC finds that this is an isolated issue that does not affect other aspects of the NRC's review of the design of the NuScale nuclear power plant. Therefore, the NRC has determined that this information can be provided by an applicant that references this appendix, consistent with the other design information regarding steam generator integrity described in DCA Part 2, Tier 2, Sections 3.9.1, 3.9.2, and 5.4.1, without a demonstrable impact on safety or standardization. Therefore, appendix G to 10 CFR part 52, Section VI, "Issue Resolution," clarifies that this issue is not resolved within the meaning of § 52.63(a)(5), and Section IV, "Additional Requirements and Restrictions," states that the COL applicant is responsible for providing the design information to address this issue.

D. The Term "Multi-Unit" as Applied to NuScale

In a letter response to NuScale Power dated October 25, 2016, the NRC staff explained how the staff's review of NuScale would apply the definitions for "nuclear power unit" from Appendix A to 10 CFR part 50, "General Design Criteria for Nuclear Power Plants," and "modular design" from § 52.1, "Definitions." As defined in Appendix A to 10 CFR part 50, a nuclear power unit is the combination of a nuclear reactor and the equipment for power generation. As defined in § 52.1, modular design means that the nuclear power station consists of two or more essentially identical nuclear reactors (modules) and that each module is capable of operation independent of the other modules, even if they have some shared systems.

The NuScale modular design combines one or more nuclear reactors (up to 12) with the necessary equipment for power generation, such that each separate nuclear reactor can be operated independent of the stage of completion or operating condition of any other nuclear reactor on the same site.

Therefore, each reactor (*i.e.*, power module) is a separate nuclear power unit. However, NuScale's modular design means that some multi-unit considerations are integral to the design. The NuScale DCD addresses multi-unit considerations other than construction for up to 12 power modules in a single reactor building, but the NuScale DCD does not address multi-unit issues that may arise if a NuScale facility is constructed and operated on the same site as another nuclear facility.

For previously certified or licensed power reactor designs (one nuclear power unit per reactor building), multi-unit site considerations arose when multiple nuclear power units (in separate reactor buildings) on the same site could affect the construction or operation of another unit in a manner not previously reviewed by the NRC. However, because the NuScale design has been reviewed and is certified for multiple units in a single reactor building, issues related to multiple NuScale units in the same reactor building constructed at the same time have been resolved. Future applicants referencing the NuScale design certification will need to address multi-unit construction issues and, if applicable, multi-unit issues for a proposed NuScale facility to be constructed and operated on the same site as another nuclear facility, including adding additional NuScale modules to a previously licensed NuScale reactor building.

The NRC has added a definition of the term "nuclear power unit" to this final rule.

IV. Technical Issues Associated With the NuScale Design

The NRC identified significant technical issues associated with the following design areas that were resolved during the review:

- Comprehensive vibration assessment program;
- Containment safety analysis;
- Emergency core cooling system inadvertent actuation block valve;
- Conformance with GDC 27, "Combined Reactivity Control Systems Capability," of appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR part 50;
- Absence of safety-related Class 1E alternating current (AC) or direct current (DC) electrical power;
- Accident source term methodology;
- Boron redistribution during passive cooling modes.

In addition, the NRC granted 17 exemptions from 10 CFR part 50 to address various aspects of NuScale Power's design.

A. Comprehensive Vibration Assessment Program

The NuScale comprehensive vibration assessment program limits potentially adverse effects from flow, acoustic, and mechanically induced vibrations and resonances on NuScale power module components, including the helical coil steam generators. The NuScale steam generators are different from those of operating pressurized-water reactors in that the primary reactor coolant is on the outside of the steam generator tubes and the steam is on the inside. Because of this design, there is the possibility of density wave oscillation instabilities in the secondary coolant, which could challenge the integrity of the tubes. The NRC's review and findings, including independent analyses and observation of vibration testing, are documented in detail in Chapter 3, "Design of Structures, Systems, Components and Equipment," Section 3.9.2, "Dynamic Testing and Analysis of Systems, Structures, and Components," of the final safety evaluation report. The review focused on assuring that the design of the helical coil steam generator tubes would not result in issues with flow-induced vibration.

As part of the comprehensive vibration assessment, the NRC also reviewed and found acceptable the steam generator tube margin against fluid-elastic instability, steam generator tube margin against vortex shedding, control rod drive shaft margin against vortex shedding, in-core instrument guide tube against vortex shedding, decay heat removal system piping against acoustic resonance, and control rod assembly guide tube against turbulence buffeting. The steam generator tube margins against fluid-elastic instability and vortex shedding will be validated in the TF-3 testing facility as described in DCA Part 2, Tier 1, Section 2.1.1, "Design Description." In addition, the initial startup testing will confirm that flow-induced vibration will not cause adverse effects on the plant system components including the steam generator tubes. With the exception of the steam generator tube and inlet flow restrictor issue discussed in Section III.C.3, the NRC found the comprehensive vibration assessment program adequate to ensure the structural integrity of the NuScale power module components.

B. Containment Safety Analysis

NuScale incorporates novel and unique features that result in transient thermal-hydraulic responses that are different from those of currently licensed reactors.

There are several peak containment pressure analysis technical issues unique to NuScale, including the associated thermal-hydraulic analyses. In support of containment safety analysis, NuScale Power submitted technical report TR-0516-49084-NP, Revision 3, "Containment Response Analysis Methodology," May 2020, which describes the conservative containment pressure and temperature safety analyses for several design-basis events related to the containment design margins. NuScale Power also submitted topical report TR-0516-49422-NP, "Loss-of-Coolant Accident Evaluation Model," Revision 1, dated November 2019. This topical report describes the evaluation model used to analyze the power module response during a design-basis loss-of-coolant accident. The NRC reviewed this topical report as part of the containment safety analysis.

The NRC also observed thermal-hydraulic performance testing at NuScale Power's integrated system test facility, which validates the analytical model. Based on initial testing results and thermal-hydraulic analyses, NuScale Power made design changes to increase the initial reactor building pool level and the in-containment vessel design pressure to account for some uncertainties.

The NRC reviewed the details of the computer thermal-hydraulic evaluation model described in the DCA Part 2, Tier 2, Section 6.2.1.1, to determine whether any uncertainties were properly accounted for and found the containment design margins to be acceptable. The associated safety evaluation report approving topical report TR-0516-49422 was issued on February 18, 2020. The NRC's review and specific findings, including independent analyses and observation of NuScale testing, are documented in Chapter 6, "Engineered Safety Features," Section 6.2.1.1, "Containment Structure," of the safety evaluation report.

C. Emergency Core Cooling System Inadvertent Actuation Block Valve

The NuScale emergency core cooling system relies on natural circulation cooling of the reactor core by releasing the heated reactor coolant steam from the top of the reactor pressure vessel through three reactor vent valves into the containment vessel and returning the cooled condensed reactor coolant water to the reactor pressure vessel through two reactor recirculation valves. Each reactor vent valve and reactor recirculation valve consists of a first-of-a-kind arrangement of a main valve, an inadvertent actuation block (IAB) valve,

a solenoid trip valve, and a solenoid reset valve. The IAB valve for each reactor vent valve and reactor recirculation valve is designed to close rapidly to prevent its corresponding emergency core cooling system main valve from opening when the reactor coolant system is at high pressure conditions. Premature opening of the emergency core cooling system main valves could result in fuel damage. The IAB valve then opens at reduced reactor coolant system pressure to allow the main valve to open and permit natural circulation cooling of the reactor core in response to a plant event. Although the valve assemblies are considered an active component, NuScale Power does not apply the single failure criterion to the IAB valve, including to the IAB valve's function to close. Consistent with Commission safety goals and the practice of risk-informed decisionmaking, the NRC evaluated the NuScale emergency core cooling system valve system without assuming a single active failure of the IAB valve to close.

During design demonstration tests of the first-of-a-kind emergency core cooling system valve system performed under § 50.43(e), NuScale Power implemented design modifications to the main valve and IAB valve to demonstrate that the IAB valve will operate within a specific design pressure range. The DCD specifies that the emergency core cooling system valves (including the IAB valves) will be qualified under American Society of Mechanical Engineers Standard QME-1-2007, "Qualification of Active Mechanical Equipment Used in Nuclear Power Plants," as endorsed by NRC Regulatory Guide 1.100, Revision 3, "Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants," prior to installation in a NuScale nuclear power plant. Additionally, the NRC regulations in § 50.55a require that a NuScale nuclear power plant meet the requirements of the American Society of Mechanical Engineers Operation and Maintenance of Nuclear Power Plants, Division 1, OM Code: Section IST (OM Code) as incorporated by reference in § 50.55a for inservice testing of the emergency core cooling system valves, unless relief is granted or an alternative is authorized by the NRC. The NRC's review and findings related to the IAB valve are documented in safety evaluation report Chapter 3, "Design of Structures, Systems, Components and Equipment," Section 3.9.6, "Functional Design, Qualification, and Inservice Testing

Programs for Pumps, Valves, and Dynamic Restraints." These findings show that the NRC regulatory requirements and DCD Part 2, Tier 2 provisions provide reasonable assurance that the emergency core system valve system will be capable of performing its design-basis functions in light of the safety significance of the required opening and closing pressures for the individual IAB valves.

Further, Chapter 15, "Transient and Accident Analyses," Section 15.0.0.5, "Limiting Single Failures," of the safety evaluation report states that the IAB valve is a first-of-a-kind, safety-significant, active component integral to the NuScale emergency core cooling system. NuScale Power does not apply the single failure criterion to the IAB valve, and, on July 2, 2019, the Commission directed the staff in SRM-SECY-19-0036, "Staff Requirements—SECY-19-0036—Application of the Single Failure Criterion to NuScale Power LLC's Inadvertent Actuation Block Valves," to "review Chapter 15 of the NuScale Design Certification Application without assuming a single active failure of the inadvertent actuation block valve to close." The Commission further stated that "[t]his approach is consistent with the Commission's safety goal policy and associated core damage and large release frequency goals and existing Commission direction on the use of risk-informed decision-making, as articulated in the 1995 Policy Statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities and the White Paper on Risk-Informed and Performance-Based Regulation (in SRM-SECY-98-144, "White Paper on Risk-Informed and Performance-Based Regulation," and Yellow Announcement 99-019)."

Based on the NRC's historic application of the single failure criterion and Commission direction on the subject, as described in SECY-77-439, "Single Failure Criterion"; SRM-SECY-94-084, "Policy and Technical Issues associated with the Regulatory Treatment of Non-Safety Systems and Implementation of Design Certification and Light-Water Reactor Design Issues"; and SRM-SECY-19-0036, the NRC has retained discretion, in fact or application-specific circumstances, to decide when to apply the single failure criterion. The Commission's decision in SRM-SECY-19-0036 provides direction regarding the appropriate application and interpretation of the regulatory requirements in 10 CFR part 50 to the NuScale IAB valve's function to close. This decision is similar to those in

previous Commission documents that addressed the use of the single failure criterion and provided clarification on when to apply the single failure criterion in other specific instances.

D. Conformance With General Design Criterion 27, “Combined Reactivity Control Systems Capability”

NuScale Power determined that, under certain end-of-cycle scenarios with one control rod stuck out, the NuScale reactivity control systems could not prevent re-criticality and return to power. This result does not meet GDC 27 of appendix A to 10 CFR part 50, which covers reactivity control systems to reliably control reactivity changes under postulated accident conditions with margin for stuck control rods. Therefore, NuScale Power submitted an exemption request for GDC 27 (refer to Section 15, “10 CFR 50, Appendix A, Criterion 27, ‘Combined Reactivity Control Systems Capability,’” of DCA Part 7, “Exemptions”).

NuScale Power analyses determined that the specified acceptable fuel design limits would not be exceeded and that core cooling would be maintained during a return to power under these scenarios. The global core power level would be less than 10 percent and within capacity of the safety-related, passive decay heat removal system. The NRC independently verified NuScale Power’s results and found that NuScale achieves the fundamental safety functions for nuclear reactor safety, which are to control heat generation, remove heat, and limit the release of radioactive materials. Chapter 15, Section 15.0.6.4.1, of the safety evaluation report contains details of the evaluation of this exemption request. Additional information is provided in SECY-18-0099, “NuScale Power Exemption Request from 10 CFR part 50, Appendix A, General Design Criterion 27, ‘Combined Reactivity Control Systems Capability,’” dated October 9, 2018. The NRC granted the exemption request.

E. Absence of Safety-Related Class 1E AC or DC Electrical Power

NuScale does not contain safety-related Class 1E AC or DC electrical power systems. The purpose of appendix A to 10 CFR part 50, GDC 17, “Electric Power Systems,” is to ensure that sufficient electric power is available to accomplish plant functions important to safety. NuScale provides passive safety systems and features to accomplish plant safety-related functions without reliance on electrical power.

NuScale incorporates several innovative features that reduce the overall complexity of the design and lower the number of safety-related systems necessary to mitigate postulated accidents. NuScale has no safety-related functions that rely on electrical power. For example, the emergency core cooling system performs its safety function without reliance on safety-related electrical power or external sources of coolant inventory makeup. NuScale Power provided a methodology to substantiate its assertion that the safety-related systems do not rely on Class 1E electrical power in topical report TR-0815-16497, Revision 1, “Safety Classification of Passive Nuclear Power Plant Electrical Systems,” dated February 7, 2017. The NRC reviewed topical report TR-0815-16497 and concluded that NuScale Power demonstrated that the safety-related systems do not rely on Class 1E electrical power. The NRC’s review and conclusions are documented in a safety evaluation report approving topical report TR-0815-16497, issued December 13, 2017, as described in the final safety evaluation report for Chapter 1, “Introduction and General Discussion,” and included in the approved version of the topical report, TR-0815-16497-NP-A.

Because no safety-related functions of NuScale rely on electrical power, NuScale does not need any safety-related electrical power systems. Therefore, NuScale Power requested an exemption from GDC 17, which requires the provision of onsite and offsite power to provide sufficient capacity and capability to assure that (1) specified acceptable fuel design limits and design conditions of the reactor coolant pressure boundary are not exceeded as a result of anticipated operational occurrences and (2) the core is cooled and containment integrity and other vital functions are maintained in the event of postulated accidents. The NRC determined that, subject to limitations and conditions stipulated in its safety evaluation report for TR-0815-16497, the underlying purpose of GDC 17 (to ensure sufficient electric power is available to accomplish the safety functions of the respective systems), is met without reliance on Class 1E electric power. In other words, the onsite and offsite electric power systems are classified as non-Class 1E systems and electric power is not needed (1) to achieve or maintain safe shutdown, (2) to assure specified acceptable fuel design limits and design conditions of the reactor coolant pressure boundary are not exceeded as a result of

anticipated operational occurrences, or (3) to maintain core cooling, containment integrity, and other vital functions during postulated accidents. Further, the onsite and offsite power systems are not needed to permit functioning of structures, systems, and components important to safety. Therefore, NuScale Power was granted an exemption from GDC 17. The NRC’s evaluation of NuScale Power’s exemption request from the requirements of GDC 17 is documented in Section 8.1.5, “Technical Evaluation for Exemptions,” of the final safety evaluation report for Chapter 8, “Electric Power.”

F. Accident Source Term Methodology

The NRC reviewed NuScale Power’s methods for developing accident source terms and performing accident radiological consequence analyses. As defined in § 50.2, “Definitions,” a source term “refers to the magnitude and mix of the radionuclides released from the fuel, expressed as fractions of the fission product inventory in the fuel, as well as their physical and chemical form, and the timing of their release.” NuScale Power developed source terms for deterministic accidents for NuScale that are similar to those that have been used in safety and siting assessments for large light water reactors. The design-basis accidents for NuScale are the main steam line break outside containment, rod ejection accident, fuel handling accident, steam generator tube failure, and the failure of small lines carrying primary coolant outside containment.

To address the source term regulatory requirements, NuScale Power submitted topical report TR-0915-17565, Revision 3, “Accident Source Term Methodology,” dated April 2019. The topical report proposes a methodology to develop a source term based on several severe accident scenarios that result in core damage, taken from the design probabilistic risk assessment. This source term is the surrogate radiological source term for a core damage event.

The topical report also provides methods for determining radiation sources not developed from core damage scenarios for use in the evaluation of environmental qualification of equipment under § 50.49, “Environmental qualification of electric equipment important to safety for nuclear power plants.” Specifically, the report describes an iodine spike source term not involving core damage, which is a surrogate accident that bounds potential accidents with release of the reactor coolant into the containment vessel.

The NRC staff submitted a related information paper to the Commission, SECY-19-0079, “Staff Approach to Evaluate Accident Source Terms for the NuScale Power Design Certification Application,” dated August 16, 2019, describing the regulatory and technical issues raised by unique aspects of NuScale Power’s methodology and the staff’s approach to reviewing topical report TR-0915-17565.

The NRC’s review and findings of topical report TR-0915-17565, Revision 3, are documented in the topical report final safety evaluation report issued on October 24, 2019. The approved version of topical report TR-0915-17565-NP-A, Revision 4, is discussed in the final safety evaluation report Section 12.2, “Radiation Sources,” Section 12.3, “Radiation Protection Design Features,” Section 3.11 “Environmental Qualification of Mechanical and Electrical Equipment,” Section 15.0.2, “Review of Transient and Accident Analysis Methods,” and Section 15.0.3, “Radiological Consequences of Design Basis Accidents.” The NRC found the accident source terms acceptable for the purposes described in each of the above safety evaluation report sections.

G. Boron Redistribution During Passive Cooling Modes

The NRC evaluated the effects of boron volatility and redistribution during long term passive cooling. During this mode of operation, boron-free steam will enter the downcomer and containment, which can potentially challenge reactor core shutdown margin and could lead to a return to power. The NRC reviewed analyses provided by NuScale Power demonstrating that the reactor remains subcritical and that specified acceptable fuel design limits are not exceeded. The NRC evaluated the technical basis for NuScale Power’s approach and conducted confirmatory calculations and independent assessments to determine its acceptability. The staff’s review is primarily documented in Chapter 15, Section 15.0.5, “Long Term Decay Heat and Residual Heat Removal,” and Section 15.6.5, “Loss of Coolant Accidents Resulting from Spectrum of Postulated Piping Breaks within the Reactor Coolant Pressure Boundary,” of the safety evaluation report. Specifically, the staff concluded that the top of active fuel remains covered with acceptably low cladding temperatures and that for beginning-of-cycle and middle-of-cycle conditions, with no operator actions, the core remains subcritical. The potential for an end-of-cycle return to power is discussed in Section IV.D, “Conformance with

General Design Criterion 27, ‘Combined Reactivity Control Systems Capability,’” of this document. In addition, Chapter 19, Section 19.1.4.6.4, “Success Criteria, Accident Sequences, and Systems Analyses,” of the safety evaluation report concludes that an operator error during recovery of the module from an uneven boron distribution scenario is unlikely to lead to core damage and is not a significant risk contributor.

H. Exemptions

NuScale Power submitted a total of 17 requests for exemptions from the following regulations, including those discussed as part of the significant technical issues mentioned previously (see Table 1.14-1, ‘NuScale Design Certification Exemptions,’ in Chapter 1 of the final safety evaluation report):

1. §§ 50.46a and 50.34(f)(2)(vi) (Reactor Coolant System Venting)
2. § 50.44 (Combustible Gas Control)
3. § 50.62(c)(1) (Reduction of Risk from Anticipated Transients Without Scram)
4. Appendix A to 10 CFR part 50, GDC 17, “Electric Power Systems”; GDC 18, “Inspection and Testing of Electric Power Systems”; and related provisions of GDC 34, “Residual Heat removal”; GDC 35, “Emergency Core Cooling”; GDC 38, “Containment Heat Removal”; GDC 41, “Containment Atmosphere Cleanup”; and GDC 44, “Cooling Water” (Electric Power Systems GDCs)
5. Appendix A to 10 CFR part 50, GDC 33, “Reactor Coolant Makeup”
6. § 50.54(m) (Control Room Staffing) (Alternative to meet the regulation)
7. Appendix A to 10 CFR part 50, GDC 52, “Capability for Containment Leakage Rate Testing” and Appendix J to 10 CFR part 50 (Type A testing)
8. Appendix A to 10 CFR part 50, GDC 40, “Testing of Containment Heat Removal System”
9. Appendix A to 10 CFR part 50, GDC 55, “Reactor Coolant Pressure Boundary Penetrating Containment,” GDC 56, “Primary Containment Isolation,” and GDC 57, “Closed Systems Isolation Valves” (Containment Isolation)
10. Appendix K to 10 CFR part 50 (Emergency Core Cooling System Evaluation Models)
11. § 50.34(f)(2)(xx) (Power Supplies for Pressurizer Relief Valves, Block Valves, and Level Indicators)
12. § 50.34(f)(2)(xiii) (Pressurizer Heater Power Supplies)
13. § 50.34(f)(2)(xiv)(E) (Containment Evacuation System Isolation)
14. § 50.46 (Fuel Rod Cladding Material)

15. Appendix A to 10 CFR part 50, GDC 27, “Combined Reactivity Control Systems Capability”
16. § 50.34(f)(2)(viii) (Post-Accident Sampling)
17. Appendix A to 10 CFR part 50, GDC 19, “Control Room”

NRC’s safety evaluation report for Chapter 1, “Introduction and General Discussion,” Section 1.14, “Index of Exemptions,” lists these exemption requests with the corresponding sections of the safety evaluation report where these exemption requests have been evaluated. The NRC granted each exemption request.

I. Differing Professional Opinion Related to Chapter 3 of NuScale

On September 17, 2020, a Differing Professional Opinion (DPO) was submitted that raised concerns related to the seismic margin evaluation of the NuScale reactor building and its structural response during the review level earthquake. An ad-hoc review panel was formed and tasked to review the DPO. The review panel subsequently issued its report to the Director of the Office of Nuclear Reactor Regulation (NRR) on April 19, 2021. On May 19, 2021, the Director of NRR issued a decision to the DPO submitter. For the reasons described in the decision, the Director of NRR agreed with the review panel’s finding that the NuScale reactor building design was complete and acceptable for the purposes of a design certification application. On June 14, 2021, the DPO submitter appealed the DPO decision to the Executive Director for Operations (EDO).

After consideration of the issues raised in the appeal, the EDO issued a decision on the DPO appeal on February 8, 2022. The EDO directed NRR to (1) document its evaluation of the stress averaging approach used in the NuScale design certification application, including, if necessary, updating the Final Safety Evaluation Report and assess whether there are any impacts to the standard design approval, and (2) evaluate and update guidance, or create knowledge management tools, on how to assess applications that use stress averaging for structural building design. On February 14, 2022, the DPO submitter responded to the EDO’s DPO appeal decision. In this response, the submitter thanked the EDO for thoughtful consideration of the concerns raised and provided clarification regarding the applicability of the Probabilistic Risk Assessment-based seismic margin analysis to the reactor building. After reviewing and considering the submitter’s response to

the DPO appeal decision, on March 15, 2022, the EDO directed the NRC staff to review and consider the totality of the information provided by the submitter when addressing the tasks mandated in the DPO appeal decision.

In response to the EDO tasking, on May 13, 2022, the Director of NRR issued a memo to the EDO (“Response to DPO Tasking”) discussing the staff’s review of the items described in the tasking, documenting the staff’s evaluation of the approach used in the NuScale design certification, and detailing the staff’s assessment of existing related structural analysis guidance (ADAMS Accession No. ML22062A007). The Director of NRR concluded that the staff sufficiently assessed the evaluation of the demand (force/moment) averaging approach used in the NuScale DCA; justified the acceptability to conclude that there are no impacts to the NuScale standard design approval issued in September 2020; determined that an update or supplement to the final safety evaluation report for the NuScale DCA is not necessary; and found that the existing review guidance is sufficient to review and evaluate an applicant’s structural analysis/design. Details on the EDO’s decision on the DPO appeal and related correspondence, and the Response to DPO Tasking are found in the information package for DPO–2020–004 (ADAMS Accession No. ML22122A116).

The NRC staff’s assessment of NuScale’s use of the demand (force/moment) averaging approach is documented in the Response to DPO Tasking. The Response to DPO Tasking elaborates on the reasons for, but does not change, the conclusion in the final safety evaluation report. Based on this assessment, the NRC concludes that the use of the demand (force/moment) averaging approach is acceptable, as stated in the final safety evaluation report.

V. Discussion

Final Safety Evaluation Report

NuScale Power submitted the final revision of the NuScale DCA, Revision 5, in July 2020 (ADAMS Accession No. ML20225A071). In August 2020, the NRC issued a final safety evaluation report after the Advisory Committee on Reactor Safeguards (ACRS) performed its final independent review and issued its July 29, 2020, letter to the Commission on its findings and recommendations. The final safety evaluation report is a collection of reports written by the NRC documenting the safety findings from its review of the

standard design application, and it reflects all changes resulting from interactions with the ACRS as well as changes in the final version of the DCA. The final safety evaluation report, as elaborated on by the Response to DPO Tasking, reflects that NuScale Power has resolved all technical and safety issues with the exception of the three issues discussed previously. As noted above, the Response to DPO Tasking elaborates on the reasons for, but does not change, the conclusion in the final safety evaluation report that NuScale’s use of the demand (force/moment) averaging approach is acceptable as a realistic engineering practice.

In addition, the final safety evaluation report describes the portions of the design that are not receiving finality in this rule and, therefore, are not part of the certified design. The final safety evaluation report also includes an index of all NRC requests for additional information, a chronology of all documents related to the NuScale DCA review, and summaries of public meetings and audits.

NuScale Design Certification Final Rule

This section describes the purpose and key aspects of each section of this NuScale design certification final rule. All section and paragraph references are to the provisions being added as appendix G to 10 CFR part 52, unless otherwise noted. The NRC has modeled this NuScale design certification final rule on existing design certification rules, with certain modifications where necessary to account for differences in the design documentation, design features, and environmental assessment (including severe accident mitigation design alternatives). As a result, design certification rules are standardized to the extent practical.

A. Introduction (Section I)

The purpose of Section I of appendix G to 10 CFR part 52 is to identify the standard design that is approved by this design certification final rule and the applicant for certification of the standard design. Identification of the design certification applicant is necessary to implement appendix G to 10 CFR part 52 for two reasons. First, the implementation of § 52.63(c) depends on whether an applicant contracts with the design certification applicant to obtain the generic DCD and supporting design information. If a COL applicant does not use the design certification applicant to provide the design information and instead uses an alternate vendor, then the COL applicant must meet the requirements in § 52.73. Second, paragraph X.A.1

requires that the identified design certification applicant maintain the generic DCD throughout the time that appendix G to 10 CFR part 52 may be referenced.

B. Definitions (Section II)

The purpose of Section II of appendix G to 10 CFR part 52 is to define specific terminology with respect to this design certification final rule. During development of the first two design certification rules, the NRC decided that there would be both generic DCDs maintained by the NRC and the design certification applicant, as well as individual plant-specific DCDs maintained by each applicant or licensee that references a 10 CFR part 52 appendix. This distinction is necessary in order to specify the relevant plant-specific requirements to applicants and licensees referencing appendix G to 10 CFR part 52.

In order to facilitate the maintenance of the generic DCDs, the NRC requires that applicants for a standard design certification update their application to include an electronic copy of the final version of the DCD. The final version incorporates all amendments to the DCA submitted since the original application and any changes directed by the NRC as a result of its review of the original DCA or as a result of public comments. This final version is then incorporated by reference in the design certification rule. Once incorporated by reference, the final version becomes the “generic DCD,” which will be maintained by the design certification applicant and the NRC and updated as needed to include any generic changes made after this design certification rulemaking. These changes would occur as the result of generic rulemaking by the NRC, under the change criteria in Section VIII of appendix G to 10 CFR part 52.

The NRC also requires each applicant and licensee referencing appendix G to 10 CFR part 52 to submit and maintain a plant-specific DCD as part of the COL final safety analysis report. The plant-specific DCD must either include or incorporate by reference the information in the generic DCD. The COL licensee is required to maintain the plant-specific DCD, updating it as necessary to reflect the generic changes to the DCD that the NRC may adopt through rulemaking, plant-specific departures from the generic DCD that the NRC imposes on the licensee by order, and any plant-specific departures that the licensee chooses to make in accordance with the relevant processes in Section VIII of appendix G to 10 CFR part 52. A COL applicant will also have to include considerations for a multi-unit site in

the plant-specific DCD that were not previously evaluated as part of the design certification rule, e.g., construction impacts on operating units. Therefore, the plant-specific DCD functions like an updated final safety analysis report because it would provide the most complete and accurate information on a plant's design basis for that part of the plant that would be within the scope of appendix G to 10 CFR part 52.

The NRC is treating the technical specifications in Part 4, "Technical Specifications," of the DCA as a special category of information and designating them as generic technical specifications in order to facilitate the special treatment of this information under appendix G to 10 CFR part 52. A COL applicant must submit plant-specific technical specifications that consist of the generic technical specifications, which may be modified as specified in paragraph VIII.C, and the remaining site-specific information needed to complete the technical specifications. The final safety analysis report that is required by § 52.79 will consist of the plant-specific DCD, the site-specific final safety analysis report, and the plant-specific technical specifications.

The terms Tier 1, Tier 2, and COL items (license information) are defined in appendix G to 10 CFR part 52 because these concepts were not envisioned when 10 CFR part 52 was developed. The design certification applicants and the NRC use these terms in implementing a two-tiered rule structure (the DCD is divided into Tier 1 and Tier 2 to support the rule structure) that was proposed by representatives of the nuclear industry after publication of 10 CFR part 52. The Commission approved the use of the two-tiered rule structure in its staff requirements memorandum (SRM), dated February 15, 1991, on SRM-SECY-90-377, "Requirements for Design Certification under 10 CFR part 52," dated November 8, 1990.

Tier 1 information means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix. Tier 2 information means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix. The change process for Tier 2 information is similar, but not identical to, the change process set forth in § 50.59. The regulations in § 50.59 describe when a licensee may make changes to a plant as described in its final safety analysis report without a license amendment. Because of some differences in how the change control

requirements are structured in the design certification rules, certain definitions contained in § 50.59 are not applicable to 10 CFR part 52 and are not being included in this final rule. The NRC is including a definition for "Departure from a method of evaluation" in paragraph II.F of appendix G to 10 CFR part 52, so that the eight criteria in paragraph VIII.B.5.b will be implemented for new reactors as intended.

C. Scope and Contents (Section III)

The purpose of Section III of appendix G to 10 CFR part 52 is to describe and define the scope and content of this design certification, explain how to obtain a copy of the generic DCD, identify requirements for incorporation by reference of the design certification rule, and set forth how documentation discrepancies or inconsistencies are to be resolved.

Paragraph III.A is the required statement of the Office of the Federal Register for approval of the incorporation by reference of the NuScale DCD, Revision 5. In addition, this paragraph provides the information on how to obtain a copy of the DCD. Unlike previous design certifications, the documents submitted to the NRC by NuScale Power did not use the title "Design Control Document;" they used the title "Design Certification Application" instead.

Paragraph III.B is the requirement for applicants and licensees referencing appendix G to 10 CFR part 52. The legal effect of incorporation by reference is that the incorporated material has the same legal status as if it were published in the *Code of Federal Regulations*. This material, like any other properly issued regulation, has the force and effect of law. Tier 1 and Tier 2 information (including the technical and topical reports referenced in the DCD Tier 2, Chapter 1) and generic technical specifications have been combined into a single document called the generic DCD in order to effectively control this information and facilitate its incorporation by reference into the rule. In addition, paragraph III.B clarifies that the conceptual design information and NuScale Power's evaluation of severe accident mitigation design alternatives are not considered to be part of appendix G to 10 CFR part 52. As provided by § 52.47(a)(24), these conceptual designs are not part of appendix G to 10 CFR part 52 and, therefore, are not applicable to an application that references appendix G to 10 CFR part 52. Therefore, an applicant would not be required to conform to the conceptual design

information that was provided by the design certification applicant. The conceptual design information, which consists of site-specific design features, was required to facilitate the design certification review. Similarly, the severe accident mitigation design alternatives were required to facilitate the environmental assessment.

Paragraphs III.C and III.D set forth the manner by which potential conflicts are to be resolved and identify the controlling document. Paragraph III.C establishes the Tier 1 description in the DCD as controlling in the event of an inconsistency between the Tier 1 and Tier 2 information in the DCD. Paragraph III.D establishes the generic DCD as the controlling document in the event of an inconsistency between the DCD and the final safety evaluation report for the certified standard design.

Paragraph III.E makes it clear that design activities outside the scope of the design certification may be performed using actual site characteristics. This provision applies to site-specific portions of the plant, such as the administration building.

D. Additional Requirements and Restrictions (Section IV)

Section IV of appendix G to 10 CFR part 52 sets forth additional requirements and restrictions imposed upon an applicant who references appendix G to 10 CFR part 52.

Paragraph IV.A sets forth the information requirements for COL applicants and distinguishes between information and documents that must be *included* in the application or the DCD and those which may be *incorporated by reference*. Any incorporation by reference in the application should be clear and should specify the title, date, edition or version of a document, the page number(s), and table(s) containing the relevant information to be incorporated. The legal effect of such an incorporation by reference into the application is that appendix G to 10 CFR part 52 would be legally binding on the applicant or licensee.

In paragraph IV.B the NRC reserves the right to determine how appendix G to 10 CFR part 52 may be referenced under 10 CFR part 50. This determination may occur in the context of a subsequent rulemaking modifying 10 CFR part 52 or this design certification rule, or on a case-by-case basis in the context of a specific application for a 10 CFR part 50 construction permit or operating license. This provision is necessary because the previous design certification rules were not

implemented in the manner that was originally envisioned at the time that 10 CFR part 52 was issued. The NRC's concern is with the manner by which the inspections, tests, analyses, and acceptance criteria (ITAAC) were developed and the lack of experience with design certifications in a licensing proceeding. Therefore, it is appropriate that the NRC retain some discretion regarding the manner by which appendix G to 10 CFR part 52 could be referenced in a 10 CFR part 50 licensing proceeding.

In paragraph IV.C, the NRC lists design-specific regulations that apply to licenses that reference this appendix.

E. Applicable Regulations (Section V)

The purpose of Section V of appendix G to 10 CFR part 52 is to specify the regulations that were applicable and in effect at the time this design certification was approved. These regulations consist of the technically relevant regulations identified in paragraph V.A, except for the regulations in paragraph V.B that would not be applicable to this certified design.

F. Issue Resolution (Section VI)

The purpose of Section VI of appendix G to 10 CFR part 52 is to identify the scope of issues that are resolved by the NRC through this final rule and, therefore, are "matters resolved" within the meaning and intent of § 52.63(a)(5). The section is divided into five parts: paragraph VI.A identifies the NRC's safety findings in adopting appendix G to 10 CFR part 52, paragraph VI.B identifies the scope and nature of issues that are resolved by this final rule, paragraph VI.C identifies issues that are not resolved by this final rule, and paragraph VI.D identifies the issue finality restrictions applicable to the NRC with respect to appendix G to 10 CFR part 52.

Paragraph VI.A describes the nature of the NRC's findings in general terms and makes the findings required by § 52.54 for the NRC's approval of this design certification final rule.

Paragraph VI.B sets forth the scope of issues that may not be challenged as a matter of right in subsequent proceedings. The introductory phrase of paragraph VI.B clarifies that issue resolution, as described in the remainder of the paragraph, extends to the delineated NRC proceedings referencing appendix G to 10 CFR part 52. The remainder of paragraph VI.B describes the categories of information for which there is issue resolution.

Paragraph VI.C reserves the right of the NRC to impose operational

requirements on applicants that reference appendix G to 10 CFR part 52. This provision reflects the fact that only some operational requirements, including portions of the generic technical specification in Chapter 16 of the DCD, were completely or comprehensively reviewed by the NRC in this design certification final rule proceeding. The NRC notes that operational requirements may be imposed on licensees referencing this design certification through the inclusion of license conditions in the license or inclusion of a description of the operational requirement in the plant-specific final safety analysis report.¹ The NRC's choice of the regulatory vehicle for imposing the operational requirements will depend upon, among other things, (1) whether the development and/or implementation of these requirements must occur prior to either the issuance of the COL or the Commission finding under § 52.103(g), and (2) the nature of the change controls that are appropriate given the regulatory, safety, and security significance of each operational requirement.

Also, paragraph VI.C allows the NRC to impose future operational requirements (distinct from design matters) on applicants who reference this design certification. License conditions for portions of the plant within the scope of this design certification (e.g., startup and power ascension testing) are not restricted by § 52.63. The requirement to perform these testing programs is contained in the Tier 1 information. However, ITAAC cannot be specified for these subjects because the matters to be addressed in these license conditions cannot be verified prior to fuel load and operation when the ITAAC are satisfied. In the absence of detailed design information to evaluate the need for and develop specific post-fuel load verifications for these matters, the NRC is reserving the right to impose, at the time of COL issuance, license conditions addressing post-fuel load verification activities for portions of the plant within the scope of this design certification.

Paragraph VI.D reiterates the restrictions (contained in Section VIII of appendix G to 10 CFR part 52) placed upon the NRC when ordering generic or plant-specific modifications, changes, or additions to structures, systems, and

¹ Certain activities ordinarily conducted following fuel load and, therefore, considered "operational requirements," but which may be relied upon to support a Commission finding under § 52.103(g), may themselves be the subject of ITAAC to ensure their implementation prior to the § 52.103(g) finding.

components, design features, design criteria, and ITAAC within the scope of the certified design.

Paragraph VI.E provides that the NRC will specify at an appropriate time the procedures on how to obtain access to sensitive unclassified and non-safeguards information (SUNSI) and safeguards information (SGI) for the NuScale design certification rule. Access to such information would be for the sole purpose of requesting or participating in certain specified hearings, such as hearings required by § 52.85 or an adjudicatory hearing. For proceedings where the notice of hearing was published before the effective date of the final rule, the Commission's order governing access to SUNSI and SGI shall be used to govern access to such information within the scope of the rulemaking. For proceedings in which the notice of hearing or opportunity for hearing is published after the effective date of the final rule, paragraph VI.E applies and governs access to SUNSI and SGI.

G. Duration of This Appendix (Section VII)

The purpose of Section VII of appendix G to 10 CFR part 52 is, in part, to specify the period during which this design certification may be referenced by an applicant, under § 52.55, and the period it will remain valid when the design certification is referenced. For example, if an application references this design certification during the 15-year period, then the design certification would be effective until the application is withdrawn or the license issued on that application expires. The NRC intends for appendix G to 10 CFR part 52 to remain valid for the life of any license that references the design certification to achieve the benefits of standardization and licensing stability. This means that changes to, or plant-specific departures from, information in the plant-specific DCD must be made under the change processes in Section VIII for the life of the plant.

H. Processes for Changes and Departures (Section VIII)

The purpose of Section VIII of appendix G to 10 CFR part 52 is to set forth the processes for generic changes to, or plant-specific departures (including exemptions) from, the DCD. The NRC adopted this restrictive change process in order to achieve a more stable licensing process for applicants and licensees that reference design certification rules. Section VIII is divided into three paragraphs, which correspond to Tier 1, Tier 2, and operational requirements.

Generic *changes* (called “modifications” in § 52.63(a)(3)) must be accomplished by rulemaking because the intended subject of the change is this design certification rule itself, as is contemplated by § 52.63(a)(1). Consistent with § 52.63(a)(3), any generic rulemaking changes are applicable to all plants, absent circumstances which render the change technically irrelevant. By contrast, plant-specific *departures* could be required by either an order to one or more applicants or licensees; or an applicant or licensee-initiated departure applicable only to that applicant’s or licensee’s plant(s), similar to a § 50.59 departure or an exemption. Because these plant-specific departures will result in a DCD that is unique for that plant, Section X requires an applicant or licensee to maintain a plant-specific DCD. For purposes of brevity, the following discussion refers to the processes for both generic changes and plant-specific departures as “change processes.” Section VIII refers to an exemption from one or more requirements of this appendix and addresses the criteria for granting an exemption. The NRC cautions that when the exemption involves an underlying substantive requirement (*i.e.*, a requirement outside this appendix), then the applicant or licensee requesting the exemption must demonstrate that an exemption from the underlying applicable requirement meets the criteria of §§ 52.7 and 50.12.

For the NuScale review, the staff followed the approach described in SECY-17-0075, “Planned Improvements in Design Certification Tiered Information Designations,” dated July 24, 2017, to evaluate the applicant’s designation of information as Tier 1 or Tier 2 information. Unlike some of the prior DCAs, this application did not contain any Tier 2* information. As described in SECY-17-0075, prior design certification rules in 10 CFR part 52, appendices A through E, information contained in the DCD was divided into three designations: Tier 1, Tier 2, and Tier 2*. Tier 1 information is the portion of design-related information in the generic DCD that the Commission approves in the 10 CFR part 52 design certification rule appendices. To change Tier 1 information, NRC approval by rulemaking or approval of an exemption from the certified design rule is required. Tier 2 information is also approved by the Commission in the 10 CFR part 52 design certification rule appendices, but it is not certified and licensees who reference the design can

change this information using the process outlined in Section VIII of the appendices. This change process is similar to that in § 50.59 and is generally referred to as the “50.59-like” process. If the criteria in Section VIII are met, a licensee can change Tier 2 information without prior NRC approval.

As mentioned in the previous paragraph, the NRC created a third category, Tier 2*, in other design certification rules. This third category was created to address industry requests to minimize the scope of Tier 1 information and provide greater flexibility for making changes. Unlike Tier 2 information, all changes to Tier 2* information require a license amendment, but unlike Tier 1 information, no exemption is required. In those rules, Tier 2* information has the same safety significance as Tier 1 information but is part of the Tier 2 section of the DCD to afford more flexibility for licensees to change this type of information.

The applicant did not designate or categorize any Tier 2* information in the NuScale DCA. The NRC evaluated the Tier 2 information to determine whether any of that information should require NRC approval before it is changed. If the NRC had identified any such information in Tier 2, then the NRC would have requested that the applicant revise the application to categorize that information as Tier 1 or Tier 2*. The NRC did not identify any information in Tier 2 that should be categorized as Tier 2*. Because neither the applicant nor the NRC have designated any information in the DCD as Tier 2*, that designation and related requirements are not being used in this design certification rule.

Tier 1 Information

Paragraph A of Section VIII describes the change process for changes to Tier 1 information that are accomplished by rulemakings that amend the generic DCD and are governed by the standards in § 52.63(a)(1). A generic change under § 52.63(a)(1) will not be made to a certified design while it is in effect unless the change: (1) is necessary for compliance with NRC regulations applicable and in effect at the time the certification was issued; (2) is necessary to provide adequate protection of the public health and safety or common defense and security; (3) reduces unnecessary regulatory burden and maintains protection to public health and safety and common defense and security; (4) provides the detailed design information necessary to resolve select design acceptance criteria; (5)

corrects material errors in the certification information; (6) substantially increases overall safety, reliability, or security of a facility and the costs of the change are justified; or (7) contributes to increased standardization of the certification information. The rulemakings must provide for notice and opportunity for public comment on the proposed change under § 52.63(a)(2). The NRC will give consideration as to whether the benefits justify the costs for plants that are already licensed or for which an application for a permit or license is under consideration.

Departures from Tier 1 may occur in two ways: (1) the NRC may order a licensee to depart from Tier 1, as provided in paragraph VIII.A.3; or (2) an applicant or licensee may request an exemption from Tier 1, as addressed in paragraph VIII.A.4. If the NRC seeks to order a licensee to depart from Tier 1, paragraph VIII.A.3 would require that the NRC find both that the departure is necessary for adequate protection or for compliance and that special circumstances are present. Paragraph VIII.A.4 provides that exemptions from Tier 1 requested by an applicant or licensee are governed by the requirements of §§ 52.63(b)(1) and 52.98(f), which provide an opportunity for a hearing. In addition, the NRC would not grant requests for exemptions that will result in a significant decrease in the level of safety otherwise provided by the design.

Tier 2 Information

Paragraph B of Section VIII describes the change processes for the Tier 2 information, which have the same elements as the Tier 1 change process, but some of the standards for plant-specific orders and exemptions would be different. Generic Tier 2 changes would be accomplished by rulemaking that would amend the generic DCD and would be governed by the standards in § 52.63(a)(1). A generic change under § 52.63(a)(1) would not be made to a certified design while it is in effect unless the change: (1) is necessary for compliance with NRC regulations that were applicable and in effect at the time the certification was issued; (2) is necessary to provide adequate protection of the public health and safety or common defense and security; (3) reduces unnecessary regulatory burden and maintains protection to public health and safety and common defense and security; (4) provides the detailed design information necessary to resolve select design acceptance criteria; (5) corrects material errors in the certification information; (6)

substantially increases overall safety, reliability, or security of a facility and the costs of the change are justified; or (7) contributes to increased standardization of the certification information.

Departures from Tier 2 would occur in four ways: (1) the NRC may order a plant-specific departure, as set forth in paragraph VIII.B.3; (2) an applicant or licensee may request an exemption from a Tier 2 requirement as set forth in paragraph VIII.B.4; (3) a licensee may make a departure without prior NRC approval under paragraph VIII.B.5; or (4) the licensee may request NRC approval for proposed departures that do not meet the requirements in paragraph VIII.B.5 as provided in paragraph VIII.B.5.e.

Similar to ordered Tier 1 departures and generic Tier 2 changes, ordered Tier 2 departures could not be imposed except when necessary, either to bring the certification into compliance with the NRC's regulations applicable and in effect at the time of approval of the design certification or to ensure adequate protection of the public health and safety or common defense and security, as set forth in paragraph VIII.B.3. However, unlike Tier 1 departures, the Commission would not have to consider whether the special circumstances for the Tier 2 departures would outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order, as required by § 52.63(a)(4). The NRC has determined that it is not necessary to impose an additional limitation for standardization similar to that imposed on Tier 1 departures by § 52.63(a)(4) and (b)(1) because it would unnecessarily restrict the flexibility of applicants and licensees with respect to Tier 2 information.

An applicant or licensee may request an exemption from Tier 2 information as set forth in paragraph VIII.B.4. The applicant or licensee would have to demonstrate that the exemption complies with one of the special circumstances in regulations governing specific exemptions in § 50.12(a). In addition, the NRC would not grant requests for exemptions that will result in a significant decrease in the level of safety otherwise provided by the design. However, unlike Tier 1 changes, the special circumstances for the exemption do not have to outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. If the exemption is requested by an applicant for a license, the exemption would be subject to litigation in the same manner as other

issues in the licensing hearing, consistent with § 52.63(b)(1). If the exemption is requested by a licensee, then the exemption would be subject to litigation in the same manner as a license amendment.

Paragraph VIII.B.5 allows an applicant or licensee to depart from Tier 2 information, without prior NRC approval, if it does not involve a change to, or departure from, Tier 1 information, technical specification, or does not require a license amendment under paragraphs VIII.B.5.b or c. The technical specifications referred to in VIII.B.5.a of this paragraph are the technical specifications in Chapter 16 of the generic DCD, including bases, for departures made prior to the issuance of the COL. After the issuance of the COL, the plant-specific technical specifications would be controlling under paragraph VIII.B.5. The requirement for a license amendment in paragraph VIII.B.5.b is similar to the requirement in § 50.59 and applies to all of the information in Tier 2 except for the information that resolves the severe accident issues or the information required by § 52.47(a)(28) to address aircraft impacts.

Paragraph VIII.B.5.d addresses information described in the DCD to address aircraft impacts, in accordance with § 52.47(a)(28). Under § 52.47(a)(28), applicants are required to include the information required by § 50.150(b) in their DCD. An applicant or licensee who changes this information is required to consider the effect of the changed design feature or functional capability on the original aircraft impact assessment required by § 50.150(a). The applicant or licensee is also required to describe in the plant-specific DCD how the modified design features and functional capabilities continue to meet the assessment requirements in § 50.150(a)(1). Submittal of this updated information is governed by the reporting requirements in Section X.B.

During an ongoing adjudicatory proceeding (e.g., for issuance of a COL), a party who believes that an applicant or licensee has not complied with paragraph VIII.B.5 when departing from Tier 2 information may petition to admit such a contention into the proceeding under paragraph VIII.B.5.g. As set forth in paragraph VIII.B.5.g, the petition would have to comply with the NRC's hearing requirements at § 2.309 and show that the departure does not comply with paragraph VIII.B.5. If on the basis of the petition and any responses thereto, the presiding officer in the proceeding determines that the required showing has been made, the

matter would be certified to the Commission for its final determination. In the absence of a proceeding, assertions of nonconformance with paragraph VIII.B.5 requirements applicable to Tier 2 departures would be treated as petitions for enforcement action under § 2.206.

Operational Requirements

The change process for technical specifications and other operational requirements that were reviewed and approved in the design certification rule is set forth in Section VIII, paragraph C. The key to using the change processes described in Section VIII is to determine if the proposed change or departure would require a change to a design feature described in the generic DCD. If a design change is required, then the appropriate change process in paragraph VIII.A or VIII.B would apply. However, if a proposed change to the technical specifications or other operational requirements does not require a change to a design feature in the generic DCD, then paragraph VIII.C would apply. This change process has elements similar to the Tier 1 and Tier 2 change processes in paragraphs VIII.A and VIII.B, but with significantly different change standards. Because of the different finality status for technical specifications and other operational requirements, the NRC designated a special category of information, consisting of the technical specifications and other operational requirements, with its own change process in paragraph VIII.C. The language in paragraph VIII.C also distinguishes between generic (Chapter 16 of the DCD) and plant-specific technical specifications to account for the different treatment and finality consistent with technical specifications before and after a license is issued.

The process in paragraph VIII.C.1 for making generic changes to the generic technical specifications or other operational requirements in the generic DCD is accomplished by rulemaking and governed by the backfit standards in § 50.109. The determination of whether the generic technical specifications and other operational requirements were completely reviewed and approved in the design certification rule is based upon the extent to which the NRC reached a safety conclusion in the final safety evaluation report on this matter. If a technical specification or operational requirement was completely reviewed and finalized in the design certification rule, then the requirement of § 50.109 would apply because a position was taken on that safety matter. Generic changes made under paragraph

VIII.C.1 would be applicable to all applicants or licensees (refer to paragraph VIII.C.2), unless the change is irrelevant because of a plant-specific departure.

Some generic technical specifications contain values in brackets []. The brackets are placeholders indicating that the NRC's review is not complete and represent a requirement that an applicant for a COL referencing appendix G to 10 CFR part 52 must replace the values in brackets with final plant-specific values (refer to guidance provided in Regulatory Guide 1.206, Revision 1, "Applications for Nuclear Power Plants," dated October 2018). The values in brackets are neither part of the design certification rule nor are they binding. Therefore, the replacement of bracketed values with final plant-specific values does not require an exemption from the generic technical specifications.

Plant-specific departures may occur by either an order under paragraph VIII.C.3 or an applicant's exemption request under paragraph VIII.C.4. The basis for determining if the technical specification or operational requirement was completely reviewed and approved for these processes would be the same as for paragraph VIII.C.1 previously discussed. If the technical specification or operational requirement was comprehensively reviewed and finalized in the design certification rule, then the NRC must demonstrate that special circumstances are present before ordering a plant-specific departure. If not, there would be no restriction on plant-specific changes to the technical specifications or operational requirements, prior to the issuance of a license, provided a design change is not required. Although the generic technical specifications were reviewed and approved by the NRC in support of the design certification review, the NRC intends to consider the lessons learned from subsequent operating experience during its licensing review of the plant-specific technical specifications. The process for petitioning to intervene on a technical specification or operational requirement contained in paragraph VIII.C.5 is similar to other issues in a licensing hearing, except that the petitioner must also demonstrate why special circumstances are present pursuant to § 2.335.

Paragraph VIII.C.6 states that the generic technical specifications would have no further effect on the plant-specific technical specifications after the issuance of a license that references this appendix and the change process. After a license is issued, the bases for the plant-specific technical specification

would be controlled by the bases change provision set forth in the administrative controls section of the plant-specific technical specifications.

I. [RESERVED] (Section IX)

This section is reserved for future use. The matters discussed in this section of earlier design certification rules—inspections, tests, analyses, and acceptance criteria—are now addressed in the substantive provisions of 10 CFR part 52. Accordingly, there is no need to repeat these regulatory provisions in the NuScale design certification rule. However, this section is being reserved to maintain consistent section numbering with other design certification rules.

J. Records and Reporting (Section X)

The purpose of Section X of appendix G to 10 CFR part 52 is to set forth the requirements that will apply to maintaining records of changes to and departures from the generic DCD, which are to be reflected in the plant-specific DCD. Section X also sets forth the requirements for submitting reports (including updates to the plant-specific DCD) to the NRC. This section of appendix G to 10 CFR part 52 is similar to the requirements for records and reports in 10 CFR part 50, except for minor differences in information collection and reporting requirements.

Paragraph X.A.1 requires that a generic DCD including referenced SUNSI and SGI be maintained by the applicant for this final rule. The generic DCD concept was developed, in part, to meet the requirements for incorporation by reference, including public availability of documents incorporated by reference. However, the SUNSI and SGI could not be included in the generic DCD because they are not publicly available. Nonetheless, the SUNSI and SGI were reviewed by the NRC and, as stated in paragraph VI.B.2, the NRC would consider the information to be resolved within the meaning of § 52.63(a)(5). Because this information, or its equivalent, is not in the generic DCD, it is required to be provided by an applicant for a license referencing appendix G to 10 CFR part 52. Only the generic DCD is identified and incorporated by reference by this final rule. The generic DCD and the NRC approved version of the SUNSI and SGI must be maintained by the applicant (NuScale Power) for the period of time that appendix G to 10 CFR part 52 may be referenced.

Paragraphs X.A.2 and X.A.3 place recordkeeping requirements on the applicant or licensee that reference this design certification so that its plant-

specific DCD accurately reflects both generic changes to the generic DCD and plant-specific departures made under Section VIII. The term "plant-specific" is used in paragraph X.A.2 and other sections of appendix G to 10 CFR part 52 to distinguish between the generic DCD that this final rule incorporates by reference into appendix G to 10 CFR part 52, and the plant-specific DCD that the COL applicant is required to submit under paragraph IV.A. The requirement to maintain changes to the generic DCD is explicitly stated to ensure that these changes are not only reflected in the generic DCD, which will be maintained by the applicant for the design certification, but also in the plant-specific DCD. Therefore, records of generic changes to the DCD will be required to be maintained by both entities to ensure that both entities have up-to-date DCDs.

Paragraph X.A.4.a requires the design certification rule applicant to maintain a copy of the aircraft impact assessment analysis for the term of the certification and any renewal. This provision, which is consistent with § 50.150(c)(3), would facilitate any NRC inspections of the assessment that the NRC decides to conduct. Similarly, paragraph X.A.4.b requires an applicant or licensee who references appendix G to 10 CFR part 52 to maintain a copy of the aircraft impact assessment performed to comply with the requirements of § 50.150(a) throughout the pendency of the application and for the term of the license and any renewal. This provision is consistent with § 50.150(c)(4). For all applicants and licensees, the supporting documentation retained should describe the methodology used in performing the assessment, including the identification of potential design features and functional capabilities to show that the acceptance criteria in § 50.150(a)(1) will be met.

Paragraph X.A does not place recordkeeping requirements on site specific information that is outside the scope of this rule. As discussed in paragraph V.B of this document, the final safety analysis report required by § 52.79 will contain the plant-specific DCD and the site-specific information for a facility that references this rule. The phrase "site specific portion of the final safety analysis report" in paragraph X.B.3.c refers to the information that is contained in the final safety analysis report for a facility (required by § 52.79), but is not part of the plant-specific DCD (required by paragraph IV.A). Therefore, this final rule does not require that duplicate documentation be maintained by an applicant or licensee that references this

rule because the plant-specific DCD is part of the final safety analysis report for the facility.

Paragraph X.B.1 requires applicants or licensees that reference this rule to submit reports that describe departures from the DCD and include a summary of the written evaluations. The requirement for the written evaluations is set forth in paragraph X.A.3. The frequency of the report submittals is set forth in paragraph X.B.3. The requirement for submitting a summary of the evaluations is similar to the requirement in § 50.59(d)(2).

Paragraph X.B.2 requires applicants or licensees that reference this rule to submit updates to the DCD, which include both generic changes and plant-specific departures, as set forth in paragraph X.B.3. The requirements in paragraph X.B.3 for submitting reports will vary according to certain time periods during a facility's lifetime. If a potential applicant for a COL that references this rule decides to depart from the generic DCD prior to submission of the application, then paragraph X.B.3.a will require that the updated DCD be submitted as part of the initial application for a license. Under paragraph X.B.3.b, the applicant may submit any subsequent updates to its plant-specific DCD along with its amendments to the application provided that the submittals are made at least once per year.

Paragraph X.B.3.b also requires semi-annual submission of the reports required by paragraphs X.B.1 and X.B.2 throughout the period of application review and construction. The NRC will use the information in the reports to support planning for the NRC's inspection and oversight during this phase, when the licensee is conducting detailed design, procurement of components and equipment, construction, and preoperational testing. In addition, the NRC will use the information in making its finding on ITAAC under § 52.103(g), as well as any finding on interim operation under Section 189.a(1)(B)(iii) of the Atomic Energy Act of 1954, as amended. Once a facility begins operation (for a COL under 10 CFR part 52, after the Commission has made a finding under § 52.103(g)), the frequency of reporting will be governed by the requirements in paragraph X.B.3.c.

VI. Public Comment Analysis

The NRC prepared a summary and analysis of public comments received on the 2021 proposed rule, as referenced in the "Availability of Documents" section. The NRC received eight comment submissions during the public

comment period that ended on October 14, 2021, and one late-filed comment submission on October 15, 2021, that the NRC was able to include in its consideration for this final rule. A *comment submission* is a communication or document submitted to the NRC by an individual or entity, with one or more individual comments addressing a subject or issue. Private citizens provided four comment submissions, nuclear industry organizations provided two comment submissions, science advocacy groups provided two comment submissions, and a labor union provided one comment submission. Of the nine comments, six were in favor of the design certification rule, one was opposed, and the other two comment submittals posed questions but stated no preference for the outcome of the rule. Six of the nine comment submissions contained questions on technical aspects of the design, corrections to the statement of considerations, and interpretation of requirements.

The public comment submittals are available on the Federal rulemaking website under Docket ID NRC-2017-0029. NRC's response to the public comments, including a summary of how NRC revised the proposed rule in response to public input, can be found in the public comment analysis document.

VII. Section-by-Section Analysis

The following paragraphs describe the specific changes in this final rule: *Section 52.11, Information collection requirements: Office of Management and Budget (OMB) approval.*

In § 52.11, this final rule adds new appendix G to 10 CFR part 52 to the list of information collection requirements in paragraph (b) of this section.

Appendix G to Part 52—Design Certification Rule for the NuScale Standard Design

This final rule adds appendix G to 10 CFR part 52 to incorporate the NuScale standard design into the NRC's regulations. Applicants intending to construct and operate a plant using NuScale may do so by referencing the design certification rule.

VIII. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule does not have a significant economic impact on a substantial number of small entities. This final rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within

the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

IX. Regulatory Analysis

The NRC has not prepared a regulatory analysis for this final rule. The NRC prepares regulatory analyses for rulemakings that establish generic regulatory requirements applicable to all licensees. Design certifications are not generic rulemakings in the sense that design certifications do not establish standards or requirements with which all licensees must comply. Rather, design certifications are NRC approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for combined licenses. Furthermore, design certification rules are requested by an applicant for a design certification, rather than the NRC. Preparation of a regulatory analysis in this circumstance would not be useful because the design to be certified is proposed by the applicant rather than the NRC. For these reasons, the NRC concludes that preparation of a regulatory analysis is neither required nor appropriate.

X. Backfitting and Issue Finality

The NRC has determined that this final rule does not constitute a backfit as defined in the backfit rule (§ 50.109), and that it is not inconsistent with any applicable issue finality provision in 10 CFR part 52.

This initial design certification rule does not constitute backfitting as defined in the backfit rule (§ 50.109) because there are no operating licenses under 10 CFR part 50 referencing this design certification final rule.

This initial design certification rule is not inconsistent with any applicable issue finality provision in 10 CFR part 52 because it does not impose new or changed requirements on existing design certification rules in appendices A through F to 10 CFR part 52, and no combined licenses, construction permits, or manufacturing licenses issued by the NRC at this time reference this design certification final rule.

For these reasons, neither a backfit analysis nor a discussion addressing the issue finality provisions in 10 CFR part 52 was prepared for this final rule.

XI. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, well-organized manner that also follows other best practices appropriate to the subject or field and the intended audience. The NRC has written this

document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, “Plain Language in Government Writing,” published June 10, 1998 (63 FR 31883).

XII. Environmental Assessment and Finding of No Significant Impact

The NRC conducted an environmental assessment and has determined under the National Environmental Policy Act of 1969, as amended (NEPA), and the NRC’s regulations in subpart A of 10 CFR part 51, that this final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The NRC’s generic determination in this regard is reflected in § 51.32(b)(1). The Commission has determined in § 51.32 that there is no significant environmental impact associated with the issuance of a standard design certification or a design certification amendment, as applicable.

The NRC’s generic determination in this regard, as discussed in the 2007 final rule amending 10 CFR parts 51 and 52 (72 FR 49351; August 28, 2007), is based upon consideration that a design certification rule does not authorize the siting, construction, or operation of a facility referencing any particular design; it only codifies the NuScale design in a rule. The NRC will evaluate the environmental impacts and issue an environmental impact statement as appropriate under NEPA as part of the application for the construction and operation of a facility referencing any particular design certification rule.

Consistent with §§ 51.30(d) and 51.32(b), the NRC has prepared an environmental assessment for the NuScale design addressing various design alternatives to prevent and mitigate severe accidents. The environmental assessment is based, in part, upon the NRC’s review of NuScale Power’s evaluation of various design alternatives to prevent and mitigate severe accidents in Revision 5 of the DCA Part 3, “Application Applicant’s Environmental Report—Standard Design Certification.” Based on a review of NuScale Power’s evaluation, the NRC concludes that (1) NuScale Power identified a reasonably complete set of potential design alternatives to prevent and mitigate severe accidents for the NuScale design and (2) none of the potential design alternatives appropriate at the design certification stage are justified on the basis of cost-benefit considerations. These issues are considered resolved for the NuScale design.

Based on its own independent evaluation, the NRC concluded that none of the possible candidate design alternatives appropriate at this design certification stage are potentially cost beneficial for NuScale for accident events. This independent evaluation was based on reasonable treatment of costs, benefits, and sensitivities. The NRC’s conclusion is applicable for sites with site characteristics that fall within the site parameters of the representative site specified in the NuScale environmental report. The NRC concludes that NuScale Power has adequately identified areas appropriate at this design certification stage where risk potentially could be reduced in a cost beneficial manner and that NuScale Power has adequately assessed whether the implementation of the identified potential severe accident mitigation design alternatives (SAMDA) or candidate design alternatives would be cost beneficial for the representative site. As noted in the environmental assessment, SAMDA candidates for multi-unit sites are evaluated in the context of multiple NuScale reactor buildings, each with up to 12 power modules at the same site. Site-specific SAMDAs, multi-unit aspects, procedural and training SAMDAs, and the design element details of the reactor building crane will need to be assessed when an application for a specific site is submitted to construct and operate a NuScale power plant.

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. The environmental assessment is available as indicated under Section XVIII of this document.

XIII. Paperwork Reduction Act

This final rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collections of information were approved by the Office of Management and Budget, approval number 3150–0151.

The burden to the public for the information collections is estimated to average 130 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection.

The information collection is being conducted to fulfill the requirements of a future applicant that references the design certification to maintain records of changes to and departures from the generic DCD, which are to be reflected

in the plant-specific DCD. This information will be used by the NRC to fulfill its responsibilities in the licensing of nuclear power plants. Responses to this collection of information are mandatory. Confidential and proprietary information submitted to the NRC is protected in accordance with NRC regulations at §§ 9.17(a) and 2.39(b).

You may submit comments on any aspect of the information collections, including suggestions for reducing the burden, by the following methods:

- *Federal rulemaking website:* Go to <https://www.regulations.gov> search for Docket ID NRC–2017–0029.
- *Mail comments to:* FOIA, Library, and Information Collections Branch, Office of the Chief Information Officer, Mail Stop: T6–A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 or to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150–0151), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: oir_submission@omb.eop.gov.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XIV. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

XV. Agreement State Compatibility

Under the “Agreement State Program Policy Statement” approved by the Commission on October 2, 2017, and published in the **Federal Register** on October 18, 2017 (82 FR 48535), this rule is classified as compatibility “NRC.” Compatibility is not required for Category “NRC” regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of title 10 of the *Code of Federal Regulations*, and although an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with a particular State’s administrative procedure laws, but does not confer regulatory authority on the State.

XVI. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC certifies the NuScale standard design for

use in nuclear power plant licensing under 10 CFR parts 50 or 52. Design certifications are not generic rulemakings establishing a generally applicable standard with which all 10 CFR parts 50 and 52 nuclear power plant licensees must comply. Design certifications are Commission approvals of specific nuclear power plant designs by rulemaking. Furthermore, design certifications are initiated by an

applicant for rulemaking, rather than by the NRC. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XVII. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

DOCUMENTS RELATED TO NUSCALE DESIGN CERTIFICATION RULE

Document	ADAMS accession No./web link/ Federal Register citation
SECY–22–0062, “Final Rule: NuScale Small Modular Reactor Design Certification (RIN 3150–AJ98; NRC–2017–0029),” July 1, 2022.	ML22004A002
SECY–21–0004, “Proposed Rule: NuScale Small Modular Reactor Design Certification (RIN 3150–AJ98; NRC–2017–0029),” January 14, 2021.	ML19353A003
Staff Requirements Memorandum for SECY–21–0004, “Proposed Rule: NuScale Small Modular Reactor Design Certification (RIN 3150–AJ98; NRC–2017–0029),” May 6, 2021.	ML21126A153
Annotated Comment Submissions on Proposed Rule: NuScale Small Modular Reactor Design Certification (NRC–2017–0029; RIN 3150–AJ98), June 2022.	ML22045A21
Final Rule Comment Response Document for NuScale Small Modular Reactor Design Certification (public comment analysis document), July 2022.	ML22216A015
NuScale Power, LLC, Submittal of the NuScale Standard Plant Design Certification Application, Revision 5, July 2020.	ML20225A071
NuScale Standard Design Certification Application, Part 3, “Applicant’s Environmental Report—Standard Design Certification,” Revision 5, July 2020.	ML20224A512
NuScale Power, LLC, Submittal of the NuScale Standard Plant Design Certification Application, Revision 4.1, June 19, 2020.	ML20205L562
NuScale Power, LLC, Submittal of the NuScale Standard Plant Design Certification Application, Part 2, Tier 2, Revision 3, August 2019.	ML19241A431
NuScale Power, LLC, Submittal of the NuScale Standard Plant Design Certification Application, Part 2, Tier 2, Revision 2, October 2018.	ML18310A345
NuScale Power, LLC, Topical report TR–0915–17565, Revision 3, Accident Source Term Methodology, April 21, 2019.	ML19112A172
Proposed Rule for the NuScale Small Modular Reactor Design Certification, July 1, 2021	86 FR 34999
Extension of Comment Period for the Proposed Rule, August 24, 2021	86 FR 47251
Docketing Notice for the NuScale Power, LLC, Design Certification Application (DCA), March 30, 2017.	82 FR 15717
Notification of Receipt of the NuScale Power, LLC, Design Certification Application (DCA), February 22, 2017.	82 FR 11372
NuScale Power, LLC, Submittal of the NuScale Standard Plant Design Certification Application (NRC Project No. 0769), Revision 0, December 2016.	ML17013A229
NuScale Power, LLC, Submittal of NuScale Preliminary Concept of Operations Summary and Response to NRC Questions on Control Room Activities, September 15, 2015.	ML15258A846
Information on Differing Professional Opinion (DPO) 2020–004, May 13, 2022	ML22122A116
Final Safety Evaluation Report and Supporting Documents	
NuScale DCA Final Safety Evaluation Report, August 2020	ML20023A318
NRC Safety Evaluation for NuScale Power, LLC, Topical Report, TR–0516–49422, “Loss-of-Coolant,” Revision 1, November 2019.	ML20044E199
NRC Safety Evaluation for NuScale Power, LLC, Topical Report, TR–0815–16497, Revision 1, “Safety Classification of Passive Nuclear Power Plant Electrical Systems,” December 13, 2017.	ML17340A524
NRC Safety Evaluation for NuScale Power, LLC, Topical Report, TR–0915–17565, Rev. 3, “Accident Source Term Methodology,” October 24, 2019.	ML19297G520
NRN Response to Taskings in EDO DPO Appeal Decision Concerning DPO–2020–004, May 13, 2022.	ML22062A007
Environmental Reviews	
Final Environmental Assessment by the U.S. Nuclear Regulatory Commission Relating to the Certification of the NuScale Standard Design, July 2022.	ML22216A014
Environmental Assessment by the U.S. Nuclear Regulatory Commission Relating to the Certification of the NuScale Standard Design, January 14, 2021.	ML19303C179
Staff Technical Analysis in Support of the NuScale Design Certification Environmental Assessment, August 4, 2020.	ML19302E819

DOCUMENTS RELATED TO NUSCALE DESIGN CERTIFICATION RULE—Continued

Document	ADAMS accession No./web link/ Federal Register citation
Commission Papers, Staff Requirement Memoranda, and Other Supporting Documents	
SECY-11-0098, "Operator Staffing for Small or Multi-Module Nuclear Power Plant Facilities," July 22, 2011.	ML111870574
SECY-17-0075, "Planned Improvements in Design Certification Tiered Information Designations," dated July 24, 2017.	ML16196A321
SECY-18-0099, "NuScale Power Exemption Request from 10 CFR Part 50, Appendix A, General Design Criterion 27, 'Combined Reactivity Control Systems Capability,'" dated October 9, 2018.	ML18065A431
SECY-19-0079, "Staff Approach to Evaluate Accident Source Terms for the NuScale Power Design Certification Application," August 16, 2019.	ML19107A455
SECY-77-439, "Single Failure Criterion," August 17, 1977	ML060260236
SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs," April 2, 1993.	ML003708021
SRM-SECY-19-0036, "Staff Requirements—SECY-19-0036—Application of the Single Failure Criterion to NuScale Power LLC's Inadvertent Actuation Block Valves," July 2, 2019.	ML19183A408
SRM-SECY-94-084, "Policy and Technical Issues associated with the Regulatory Treatment of Non-Safety Systems and Implementation of Design Certification and Light-Water Reactor Design Issues," June 30, 1994.	ML003708098
SRM-SECY-90-377, "Requirements for Design Certification under 10 CFR part 52," February 15, 1991.	ML003707892
Response to NuScale Power, LLC Key Issue Resolution Letter, Supplemental Response Regarding Multi-Module Questions, October 25, 2016.	ML16229A522
Advisory Committee on Reactor Safeguards (ACRS) Letter, "Report on the Safety Aspects of the NuScale Small Modular Reactor," July 29, 2020.	ML20211M386
American Society of Mechanical Engineers Standard QME-1-2007, "Qualification of Active Mechanical Equipment Used in Nuclear Power Plants," 2007.	https://webstore.ansi.org/standards/asmel/ansiasmeqme2007
NRC Regulatory Guide 1.100, Rev. 3, "Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants," September 2009.	ML091320468
NRC Regulatory Guide 1.206, Rev. 1, "Applications for Nuclear Power Plants," October 2018	ML18131A181
NRC Agreement State Program Policy Statement, October 18, 2017	82 FR 48535
Final Rule for Licenses, Certifications, and Approvals for Nuclear Power Plants (10 CFR parts 51 and 52), August 28, 2007.	72 FR 49351
Office of the Federal Register (OFR) Final Rule for Incorporation by Reference, November 7, 2014	79 FR 66267
Presidential Memorandum, "Plain Language in Government Writing," June 10, 1998	63 FR 31883
Regulatory History of Design Certification, April 2000 ²	ML003761550
NuScale Technical and Topical Reports	
ES-0304-1381-NP, Human-System Interface Style Guide, Rev. 4, December 2019	ML19338E948
RP-0215-10815-NP, Concept of Operations, Rev. 3, May 2019	ML19133A293
RP-0316-17614-NP, Human Factors Engineering Operating Experience Review Results Summary Report, Rev. 0, December 2016 ³ .	ML16364A342
RP-0316-17615-NP, Human Factors Engineering Functional Requirements Analysis and Function Allocation Results Summary Report, Rev. 0, December 2016 ³ .	ML16364A342
RP-0316-17616-NP, Human Factors Engineering Task Analysis Results Summary Report, Rev. 2, April 2019.	ML19119A393
RP-0316-17617-NP, Human Factors Engineering Staffing and Qualifications Results Summary Report, Rev. 0, December 2016 ³ .	ML17004A222
RP-0316-17618-NP, Human Factors Engineering Treatment of Important Human Actions Results Summary Report, Rev. 0, December 2016 ³ .	ML17004A222
RP-0316-17619-NP, Human Factors Engineering Human-System Interface Design Results Summary Report, Rev. 2, April 2019.	ML19119A398
RP-0516-49116-NP, Control Room Staffing Plan Validation Results, Rev. 1, December 2016	ML16364A356
RP-0914-8534-NP, Human Factors Engineering Program Management Plan, Rev. 5, April 2019	ML19119A342
RP-0914-8543-NP, Human Factors Verification and Validation Implementation Plan, Rev. 5, April 2019.	ML19119A372
RP-0914-8544-NP, Human Factors Engineering Design Implementation Plan, Rev. 4, November 2019.	ML19331A910
RP-1018-61289-NP, Human Factors Engineering Verification and Validation Results Summary Report, Rev. 1, July 2019.	ML19212A773
RP-1215-20253-NP, Control Room Staffing Plan Validation Methodology, Rev. 3, December 2016	ML16364A353
TR-0116-20781-NP, Fluence Calculation Methodology and Results, Rev. 1, July 2019	ML19183A485
TR-0116-20825-NP-A, Applicability of AREVA Fuel Methodology for the NuScale Design, Rev. 1, June 2016.	ML18040B306
TR-0116-21012-NP-A, NuScale Power Critical Heat Flux Correlations, Rev. 1, December 2018	ML18360A632
TR-0316-22048-NP, Nuclear Steam Supply System Advanced Sensor Technical Report, Rev. 3, May 2020.	ML20141M764
TR-0515-13952-NP-A, Risk Significance Determination, Rev. 0, October 2016	ML16284A016
TR-0516-49084-NP, Containment Response Analysis Methodology Technical Report, Rev. 3, May 2020.	ML20141L808

DOCUMENTS RELATED TO NUSCALE DESIGN CERTIFICATION RULE—Continued

Document	ADAMS accession No./web link/ Federal Register citation
TR-0516-49416-NP-A, Non-Loss-of-Coolant Accident Analysis Methodology, Rev. 3, July 2020	ML20191A281
TR-0516-49417-NP-A, Evaluation Methodology for Stability Analysis of the NuScale Power Module, Rev. 1, March 2020.	ML20078Q094
TR-0516-49422-NP-A, Loss-of-Coolant Accident Evaluation Model, Rev. 2, July 2020	ML20189A644
TR-0616-48793-NP-A, Nuclear Analysis Codes and Methods Qualification, Rev. 1, November 2018.	ML18348B036
TR-0616-49121-NP, NuScale Instrument Setpoint Methodology Technical Report, Rev. 3, May 2020.	ML20141M114
TR-0716-50350-NP-A, Rod Ejection Accident Methodology, Rev. 1, June 2020	ML20168B203
TR-0716-50351-NP-A, NuScale Applicability of AREVA Method for the Evaluation of Fuel Assembly Structural Response to Externally Applied Forces, Rev. 1, April 2020.	ML20122A248
TR-0716-50424-NP, Combustible Gas Control, Rev. 1, March 2019	ML19091A232
TR-0716-50439-NP, NuScale Comprehensive Vibration Assessment Program Analysis Technical Report, Rev. 2, July 2019.	ML19212A776
TR-0815-16497-NP-A, Safety Classification of Passive Nuclear Power Plant Electrical Systems Topical Report, Rev. 1, January 2018.	ML18054B607
TR-0816-49833-NP, Fuel Storage Rack Analysis, Rev. 1, November 2018	ML18310A154
TR-0816-50796-NP, Loss of Large Areas Due to Explosions and Fires Assessment, Rev. 1, June 2019.	ML19165A294
TR-0816-50797 (NuScale Nonproprietary), Mitigation Strategies for Loss of All AC Power Event, Rev. 3, October 2019.	ML19302H598
TR-0816-51127-NP, NuFuel-HTP2™ Fuel and Control Rod Assembly Designs, Rev. 3, December 2019.	ML19353A719
TR-0818-61384-NP, Pipe Rupture Hazards Analysis, Rev. 2, July 2019	ML19212A682
TR-0915-17564-NP-A, Subchannel Analysis Methodology, Rev. 2, February 2019	ML19067A256
TR-0915-17565-NP-A, Accident Source Term Methodology, Rev. 4, February 2020	ML20057G132
TR-0916-51299-NP, Long-Term Cooling Methodology, Rev. 3, May 2020	ML20141L816
TR-0916-51502-NP, NuScale Power Module Seismic Analysis, Rev. 2, April 2019	ML19093B850
TR-0917-56119-NP, CNV Ultimate Pressure Integrity, Rev. 1, June 2019	ML19158A382
TR-0918-60894-NP, Comprehensive Vibration Assessment Program Measurement and Inspection Plan Technical Report, Rev. 1, August 2019.	ML19214A248
TR-1010-859-NP-A, NuScale Topical Report: Quality Assurance Program Description for the NuScale Power Plant, Rev. 5, May 2020.	ML20176A494
TR-1015-18177-NP, Pressure and Temperature Limits Methodology, Rev. 2, October 2018	ML18298A304
TR-1015-18653-NP-A, Design of the Highly Integrated Protection System Platform Topical Report, Rev. 2, May 2017.	ML17256A892
TR-1016-51669-NP, NuScale Power Module Short-Term Transient Analysis, Rev. 1, July 2019	ML19211D411
TR-1116-51962-NP, NuScale Containment Leakage Integrity Assurance, Rev. 1, May 2019	ML19149A298
TR-1116-52065-NP, Effluent Release (GALE Replacement) Methodology and Results, Rev. 1, November 2018.	ML18317A364

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at <https://www.regulations.gov> under Docket ID NRC-2017-0029. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC-2017-0029); (2) click the “Subscribe” link; and (3) enter an email address and click on the “Subscribe” link.

² The regulatory history of the NRC’s design certification reviews is a package of documents that is available in the NRC’s PDR and NRC Library. This history spans the period during which the NRC simultaneously developed the regulatory standards for reviewing these designs and the form and content of the rules that certified the designs.

³ The duplicate ADAMS Accession Nos. ML16364A342 and ML17004A222 are intentional and indicate when multiple reports are part of a single submittal.

XVIII. Incorporation by Reference—Reasonable Availability to Interested Parties

The NRC is incorporating by reference the NuScale DCA, Revision 5. As described in the “Discussion” sections of this document, the generic DCD includes Tier 1 and Tier 2 information (including the technical and topical reports referenced in Chapter 1) and generic technical specifications in order to effectively control this information and facilitate its incorporation by reference into the rule. NuScale Power submitted Revision 5 of the DCA to the NRC in July 2020.

The NRC is required by law to obtain approval for incorporation by reference from the Office of the Federal Register (OFR). The OFR’s requirements for incorporation by reference are set forth in 1 CFR part 51. On November 7, 2014, the OFR adopted changes to its regulations governing incorporation by reference (79 FR 66267). The OFR

regulations require an agency to discuss, in the preamble of the final rule, the ways that the materials it incorporates by reference are reasonably available to interested parties and how interested parties can obtain the materials. The discussion in this section complies with the requirement for final rules as set forth in 1 CFR 51.5(a)(1).

The NRC considers “interested parties” to include all potential NRC stakeholders, not only the individuals and entities regulated or otherwise subject to the NRC’s regulatory oversight. These NRC stakeholders are not a homogenous group but vary with respect to the considerations for determining reasonable availability. Therefore, the NRC distinguishes between different classes of interested parties for the purposes of determining whether the material is “reasonably available.” The NRC considers the following to be classes of interested parties in NRC rulemakings with regard

to the material to be incorporated by reference:

- Individuals and small entities regulated or otherwise subject to the NRC's regulatory oversight (this class also includes applicants and potential applicants or licenses and other NRC regulatory approvals) and who are subject to the material to be incorporated by reference by rulemaking. In this context, "small entities" has the same meaning as a "small entity" under § 2.810.

- Large entities otherwise subject to the NRC's regulatory oversight (this class also includes applicants and potential applicants for licenses and other NRC regulatory approvals) and who are subject to the material to be incorporated by reference by rulemaking. In this context, "large entities" are those which do not qualify as a "small entity" under § 2.810.

- Non-governmental organizations with institutional interests in the matters regulated by the NRC.

- Other Federal agencies, States, and local governmental bodies (within the meaning of § 2.315(c)).

- Federally-recognized and State-recognized⁴ Indian tribes.

- Members of the general public (*i.e.*, individual, unaffiliated members of the public who are not regulated or otherwise subject to the NRC's regulatory oversight) who may wish to gain access to the materials which the NRC incorporates by reference by rulemaking in order to participate in the rulemaking process.

The NRC makes the materials incorporated by reference available for inspection to all interested parties, by appointment, at the NRC Technical Library, which is located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852; telephone: 301-415-7000; email: Library.Resource@nrc.gov. In addition, as described in Section XVIII of this document, documents related to this final rule are available online in the NRC's ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>.

The NRC concludes that the materials the NRC is incorporating by reference in this final rule are reasonably available to all interested parties because the materials are available in multiple ways and in a manner consistent with their interest in the materials.

⁴ State-recognized Indian tribes are not within the scope of 10 CFR 2.315(c). However, for purposes of the NRC's compliance with 1 CFR 51.5, "interested parties" includes a broad set of stakeholders, including State-recognized Indian tribes.

List of Subjects in 10 CFR Part 52

Administrative practice and procedure, Antitrust, Combined license, Early site permit, Emergency planning, Fees, Incorporation by reference, Inspection, Issue finality, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Penalties, Reporting and recordkeeping requirements, Standard design, Standard design certification.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553, the NRC is amending 10 CFR part 52 as follows:

PART 52—LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS

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

Authority: Atomic Energy Act of 1954, secs. 103, 104, 147, 149, 161, 181, 182, 183, 185, 186, 189, 223, 234 (42 U.S.C. 2133, 2134, 2167, 2169, 2201, 2231, 2232, 2233, 2235, 2236, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

§ 52.11 [Amended]

■ 2. In § 52.11(b), remove the phrase "appendices A, B, C, D, E, F, and N of this part" and add, in its place, the phrase "appendices A, B, C, D, E, F, G, and N of this part".

■ 3. Add appendix G to part 52 to read as follows:

Appendix G to Part 52—Design Certification Rule for NuScale

I. Introduction

Appendix G constitutes the standard design certification for the NuScale design (hereinafter referred to as NuScale), in accordance with 10 CFR part 52, subpart B. The applicant for this standard design certification NuScale is NuScale Power, LLC.

II. Definitions

A. *Generic design control document (generic DCD)* means the documents containing the Tier 1 and Tier 2 information (including the technical and topical reports referenced in Chapter 1) and generic technical specifications that are incorporated by reference into this appendix.

B. *Generic technical specifications (generic TS)* means the information required by 10 CFR 50.36 and 50.36a for the portion of the plant that is within the scope of this appendix.

C. *Plant-specific DCD* means that portion of the combined license (COL) final safety analysis report (FSAR) that sets forth both the

generic DCD information and any plant-specific changes to generic DCD information.

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions;
2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);
4. Significant site parameters; and
5. Significant interface requirements.

E. *Tier 2* means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by Section VIII of this appendix. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1.

Compliance methods differing from Tier 2 must satisfy the change process in Section VIII of this appendix. Regardless of these differences, an applicant or licensee must meet the requirement in paragraph III.B of this appendix to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by § 52.47(a) and (c), with the exception of generic TS and conceptual design information;
2. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and
3. COL action items (COL license information) identify certain matters that must be addressed in the site-specific portion of the FSAR by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

F. *Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses* means:

1. Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or
2. Changing from a method described in the plant-specific DCD to another method unless that method has been approved by the NRC for the intended application.

G. *Nuclear power unit*, as applied to this certified design, means a nuclear power module and associated equipment necessary for electric power generation and includes those structures, systems, and components required to provide reasonable assurance the facility can be operated without undue risk to the health and safety of the public.

H. All other terms in this appendix have the meaning set out in 10 CFR 50.2, 10 CFR

52.1, or Section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

III. Scope and Contents

A. Incorporation by reference.

1. Certain material listed in paragraph III.A.2 of this appendix is incorporated by reference into this appendix G with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material in paragraph III.A.2 of this appendix may be obtained from NuScale Power, LLC, 6650 SW Redwood Lane, Suite 210, Portland, Oregon 97224, telephone: 1-971-371-1592, email: RegulatoryAffairs@nucscalepower.com, and can be inspected as follows:

a. Contact the U.S. Nuclear Regulatory Commission at: U.S. Nuclear Regulatory Commission, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852; telephone: 301-415-7000; email: Library.Resource@nrc.gov; <https://www.nrc.gov/reading-rm/pdr.html>.

b. Access ADAMS and view the material online in the NRC Library at <https://www.nrc.gov/reading-rm/adams.html>. In ADAMS, search under ADAMS Accession No. ML20225A071. The material is available in the ADAMS Public Documents collection.

c. If you do not have access to ADAMS or if you have problems accessing documents located in ADAMS, contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-3747, or by email at PDR.Resource@nrc.gov.

d. For information on the availability of this material at the National Archives and Records Administration, visit www.archives.gov/federal-register/cfr/ibr-locations.html or email: fr.inspection@nara.gov.

2. Material incorporated by reference.

a. NuScale Standard Plant Design Certification Application, Certified Design Descriptions and Inspections, Tests, Analyses, & Acceptance Criteria (ITAAC), Part 2—Tier 1, Revision 5, July 2020.

b. NuScale Standard Plant Design Certification Application, Part 2—Tier 2, Revision 5, July 2020, including:

i. Chapter One, Introduction and General Description of the Plant.

ii. Chapter Two, Site Characteristics and Site Parameters.

iii. Chapter Three, Design of Structures, Systems, Components and Equipment.

iv. Chapter Four, Reactor.

v. Chapter Five, Reactor Coolant System and Connecting Systems.

vi. Chapter Six, Engineered Safety Features.

vii. Chapter Seven, Instrumentation and Controls.

viii. Chapter Eight, Electric Power.

ix. Chapter Nine, Auxiliary Systems.

x. Chapter Ten, Steam and Power Conversion System.

xi. Chapter Eleven, Radioactive Waste Management.

xii. Chapter Twelve, Radiation Protection.

xiii. Chapter Thirteen, Conduct of Operations.

xiv. Chapter Fourteen, Initial Test Program and Inspections, Tests, Analyses, and Acceptance Criteria.

xv. Chapter Fifteen, Transient and Accident Analyses.

xvi. Chapter Sixteen, Technical Specifications.

xvii. Chapter Seventeen, Quality Assurance and Reliability Assurance.

xviii. Chapter Eighteen, Human Factors Engineering.

xix. Chapter Nineteen, Probabilistic Risk Assessment and Severe Accident Evaluation.

xx. Chapter Twenty, Mitigation of Beyond-Design-Basis Events.

xxi. Chapter Twenty-One, Multi-Module Design Considerations.

c. DCA Part 4, Volume 1, Revision 5.0, Generic Technical Specifications, NuScale Nuclear Power Plants, Volume 1: Specifications.

d. DCA Part 4, Volume 2, Revision 5.0, Generic Technical Specifications, NuScale Nuclear Power Plants, Volume 2: Bases.

e. ES-0304-1381-NP, Human-System Interface Style Guide, December 2019, Revision 4.

f. RP-0215-10815-NP, Concept of Operations, May 2019, Revision 3.

g. RP-0316-17614-NP, Human Factors Engineering Operating Experience Review Results Summary Report, December 7, 2016, Revision 0.

h. RP-0316-17615-NP, Human Factors Engineering Functional Requirements Analysis and Function Allocation Results Summary Report, December 2, 2016, Revision 0.

i. RP-0316-17616-NP, Human Factors Engineering Task Analysis Results Summary Report, April 2019, Revision 2.

j. RP-0316-17617-NP, Human Factors Engineering Staffing and Qualifications Results Summary Report, December 2, 2016, Revision 0.

k. RP-0316-17618-NP, Human Factors Engineering Treatment of Important Human Actions Results Summary Report, December 2, 2016, Revision 0.

l. RP-0316-17619-NP, Human Factors Engineering Human-System Interface Design Results Summary Report, April 2019, Revision 2.

m. RP-0516-49116-NP, Control Room Staffing Plan Validation Results, December 2, 2016, Revision 1.

n. RP-0914-8534-NP, Human Factors Engineering Program Management Plan, April 2019, Revision 5.

o. RP-0914-8543-NP, Human Factors Verification and Validation Implementation Plan, April 2019, Revision 5.

p. RP-0914-8544-NP, Human Factors Engineering Design Implementation Plan, November 2019, Revision 4.

q. RP-1018-61289-NP, Human Factors Engineering Verification and Validation Results Summary Report, July 2019, Revision 1.

r. RP-1215-20253-NP, Control Room Staffing Plan Validation Methodology, December 2, 2016, Revision 3.

s. TR-0116-20781-NP, Fluence Calculation Methodology and Results, July 2019, Revision 1.

t. TR-0116-20825-NP-A, Applicability of AREVA Fuel Methodology for the NuScale Design, June 2016, Revision 1.

u. TR-0116-21012-NP-A, NuScale Power Critical Heat Flux Correlations, December 2018, Revision 1.

v. TR-0316-22048-NP, Nuclear Steam Supply System Advanced Sensor Technical Report, May 2020, Revision 3.

w. TR-0515-13952-NP-A, Risk Significance Determination, October 2016, Revision 0.

x. TR-0516-49084-NP, Containment Response Analysis Methodology Technical Report, May 2020, Revision 3.

y. TR-0516-49416-NP-A, Non-Loss-of-Coolant Accident Analysis Methodology, July 2020, Revision 3.

z. TR-0516-49417-NP-A, Evaluation Methodology for Stability Analysis of the NuScale Power Module, March 2020, Revision 1.

aa. TR-0516-49422-NP-A, Loss-of-Coolant Accident Evaluation Model, July 2020, Revision 2.

ab. TR-0616-48793-NP-A, Nuclear Analysis Codes and Methods Qualification, November 2018, Revision 1.

ac. TR-0616-49121-NP, NuScale Instrument Setpoint Methodology Technical Report, May 2020, Revision 3.

ad. TR-0716-50350-NP-A, Rod Ejection Accident Methodology, June 2020, Revision 1.

ae. TR-0716-50351-NP-A, NuScale Applicability of AREVA Method for the Evaluation of Fuel Assembly Structural Response to Externally Applied Forces, April 2020, Revision 1.

af. TR-0716-50424-NP, Combustible Gas Control, March 2019, Revision 1.

ag. TR-0716-50439-NP, NuScale Comprehensive Vibration Assessment Program Analysis Technical Report, July 2019, Revision 2.

ah. TR-0815-16497-NP-A, Safety Classification of Passive Nuclear Power Plant Electrical Systems, January 2018, Revision 1.

ai. TR-0816-49833-NP, Fuel Storage Rack Analysis, November 2018, Revision 1.

aj. TR-0816-50796-NP, Loss of Large Areas Due to Explosions and Fires Assessment, June 2019, Revision 1.

ak. TR-0816-50797, Mitigation Strategies for Loss of All AC Power Event [NuScale Nonproprietary], October 2019, Revision 3.

al. TR-0816-51127-NP, NuFuel-HTP2™ Fuel and Control Rod Assembly Designs, December 2019, Revision 3.

am. TR-0818-61384-NP, Pipe Rupture Hazards Analysis, July 2019, Revision 2.

an. TR-0915-17564-NP-A, Subchannel Analysis Methodology, February 2019, Revision 2.

ao. TR-0915-17565-NP-A, Accident Source Term Methodology, February 2020, Revision 4.

ap. TR-0916-51299-NP, Long-Term Cooling Methodology, May 2020, Revision 3.

aq. TR-0916-51502-NP, NuScale Power Module Seismic Analysis, April 2019, Revision 2.

ar. TR-0917-56119-NP, CNV Ultimate Pressure Integrity, June 2019, Revision 1.

as. TR-0918-60894-NP, NuScale Comprehensive Vibration Assessment Program Measurement and Inspection Plan Technical Report, August 2019, Revision 1.

at. NP-TR-1010-859-NP-A, NuScale Topical Report: Quality Assurance Program

Description for the NuScale Power Plant, May 2020, Revision 5.

au. TR-1015-18177-NP, Pressure and Temperature Limits Methodology, October 2018, Revision 2.

av. TR-1015-18653-NP-A, Design of the Highly Integrated Protection System Platform, May 2017, Revision 2.

aw. TR-1016-51669-NP, NuScale Power Module Short-Term Transient Analysis, July 2019, Revision 1.

ax. TR-1116-51962-NP, NuScale Containment Leakage Integrity Assurance, May 2019, Revision 1.

ay. TR-1116-52065-NP, Effluent Release (GALE Replacement) Methodology and Results, November 2018, Revision 1.

B.1. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix except as otherwise provided in this appendix.

2. Conceptual design information, as set forth in the design certification application Part 2, Tier 2, Section 1.2, and the discussion of “first principles” contained in design certification application Part 2, Tier 2, Section 14.3.2, are not incorporated by reference into this appendix.

C. If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

D. If there is a conflict between the generic DCD and either the application for the design certification of NuScale or the final safety evaluation report related to certification of the NuScale standard design, then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site characteristics, provided the design activities do not affect the DCD or conflict with the interface requirements.

IV. Additional Requirements and Restrictions

A. An applicant for a COL that wishes to reference this appendix shall, in addition to complying with the requirements of §§ 52.77, 52.79, and 52.80, comply with the following requirements:

1. Incorporate by reference, as part of its application, this appendix.

2. Include, as part of its application:

a. A plant-specific DCD containing the same type of information and using the same organization and numbering as the generic DCD for NuScale, either by including or incorporating by reference the generic DCD information, and as modified and supplemented by the applicant’s exemptions and departures;

b. The reports on departures from and updates to the plant-specific DCD required by paragraph X.B of this appendix;

c. Plant-specific TS, consisting of the generic and site-specific TS that are required by 10 CFR 50.36 and 50.36a;

d. Information demonstrating that the site characteristics fall within the site parameters and that the interface requirements have been met;

e. Information that addresses the COL action items;

f. Information required by § 52.47(a) that is not within the scope of this appendix;

g. Information demonstrating that necessary shielding to limit radiological dose consistent with the radiation zones specified in design certification application Part 2, Tier 2, Chapter 12, Figure 12.3-1, “Reactor Building Radiation Zone Map,” is provided to account for penetrations in the radiation shield wall between the power module bay and the reactor building steam gallery area;

h. Information demonstrating that the requirements of 10 CFR 50.34(f)(2)(xxviii) are met with respect to potential radiological releases under accident conditions from the systems used for post-accident hydrogen and oxygen monitoring described in design certification application Part 2, Tier 2, Section 6.2.5; information demonstrating that post-accident leakage from these systems does not result in the total main control room dose exceeding the dose criteria for the surrogate event with significant core damage, which may include use of design features compliant with 10 CFR 50.34(f)(2)(vii), as appropriate; and information demonstrating that post-accident leakage from these systems does not result in the total dose for the surrogate event with significant core damage exceeding the offsite dose criteria, as required by 10 CFR 52.47(a)(2)(iv); and

i. Information demonstrating that the requirements of 10 CFR 52.47(a)(2)(iv) and General Design Criterion (GDC) 4 and GDC 31 of appendix A to 10 CFR part 50 are met with

respect to the structural and leakage integrity of the steam generator tubes that might be compromised by effects from density wave oscillations in the secondary fluid system, including the method of analysis to predict the thermal-hydraulic conditions of the steam generator secondary fluid system and resulting loads, stresses, and deformations from density wave oscillations and reverse flow. This information must be consistent with the other design information regarding steam generator integrity contained in design certification application Part 2, Tier 2, Sections 3.9.2 and 5.4.1.

3. Include, in the plant-specific DCD, the sensitive, unclassified, non-safeguards information (including proprietary information and security-related information) and safeguards information referenced in the NuScale generic DCD.

4. Include, as part of its application, a demonstration that an entity other than NuScale Power, LLC, is qualified to supply the NuScale generic DCD, unless NuScale Power, LLC, supplies the design for the applicant’s use.

B. The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR part 50.

C. A licensee referencing the NuScale design certification is exempt from portions of the following regulation:

1. Paragraph (m) of 10 CFR 50.54—Minimum Staffing. In lieu of these requirements, a licensee that references this appendix must comply with the following:

a. A senior operator licensed pursuant to part 55 of this chapter shall be present at the facility or readily available on call at all times during its operation, and shall be present at the facility during initial startup and approach to power, recovery from an unplanned or unscheduled shutdown or significant reduction in power, and refueling, or as otherwise prescribed in the facility license.

b. Licensees shall meet the following requirements:

i. Each licensee shall meet the minimum licensed operator staffing requirements identified in Table 1:

TABLE 1—MINIMUM REQUIREMENTS PER SHIFT FOR ON-SITE STAFFING OF NUSCALE POWER PLANTS BY OPERATORS AND SENIOR OPERATORS LICENSED UNDER 10 CFR PART 55

Number of units operating (a nuclear power unit is considered to be operating when it is in MODE 1, 2, or 3 as defined by the unit’s technical specifications)	Position	One to twelve units
		One control room
None	Senior operator	1
	Operator	2
One to twelve	Senior operator	3
	Operator	3

Source: Design Certification Application, Part 7, Section 6.1.3, “Requested Action.”

ii. Each facility licensee shall have at its site a person holding a senior operator license for all fueled units at the site who is assigned responsibility for overall plant

operation at all times there is fuel in any unit. At all times any module is fueled, regardless of mode, there must be a licensed

operator or senior operator in the control room.

iii. When a nuclear power unit is in MODE 1, 2, or 3, as defined by the unit’s technical

specifications, each licensee shall have a person holding a senior operator license for the nuclear power unit in the control room at all times. In addition to this senior operator, a second person who is either a licensed operator or licensed senior operator shall be present at the controls at all times. A third person who is either a licensed operator or licensed senior operator shall be in the control room envelope at all times.

iv. Each licensee shall have present, during alteration or movement of the core of a nuclear power unit (including fuel loading, fuel transfer, or movement of a module that contains fuel), a person holding a senior operator license or a senior operator license limited to fuel handling to directly supervise the activity and, during this time, the licensee shall not assign other duties to this person.

2. Appendix J to 10 CFR part 50, Type A testing—Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors.

V. Applicable Regulations

A. Except as indicated in paragraph B of this section, the regulations that apply to NuScale are in 10 CFR parts 20, 50, 52, 73, and 100, codified as of February 21, 2023, that are applicable and technically relevant, as described in the final safety evaluation report.

B. The NuScale design is exempt from portions of the following regulations:

1. Paragraph (f)(2)(vi) of 10 CFR 50.34 and 10 CFR 50.46a—High point venting for the reactor coolant system and reactor pressure vessel head.

2. Paragraph (f)(2)(viii) of 10 CFR 50.34—Post-accident sampling of the reactor coolant system and containment.

3. Paragraph (f)(2)(xiii) of 10 CFR 50.34—Power supplies for pressurizer heaters.

4. Paragraph (f)(2)(xiv)(E) of 10 CFR 50.34—Automatic closing of containment isolation systems on a high radiation signal.

5. Paragraph (f)(2)(xx) of 10 CFR 50.34—Power from vital buses and emergency power sources for pressurizer level indication.

6. Paragraph (c)(2) of 10 CFR 50.44—Combustible gas control.

7. Paragraph (a)(1)(i) of 10 CFR 50.46—Applicability limited to reactor designs that use zircaloy or ZIRLO fuel rod cladding material.

8. Paragraph (c)(1) of 10 CFR 50.62—Diverse equipment to initiate a turbine trip under conditions indicative of an anticipated transient without scram.

9. Appendix A of 10 CFR part 50—Electric Power Systems GDCs:

a. GDC 17—Electric power systems for safety-related functions;

b. GDC 18—Design to permit periodic inspection and testing of electric power systems;

c. GDC 34—Electric power systems for residual heat removal;

d. GDC 35—Electric power systems for emergency core cooling;

e. GDC 38—Electric power systems for containment heat removal;

f. GDC 41—Electric power systems for containment atmosphere cleanup; and

g. GDC 44—Electric power systems for cooling.

10. Appendix A to 10 CFR part 50, GDC 19—Equipment outside the control room with capability for cold shutdown of the reactor.

11. Appendix A to 10 CFR part 50, GDC 27—Demonstration of long-term shutdown under post-accident conditions with an assumed worst rod stuck out.

12. Appendix A to 10 CFR part 50, GDC 33—Reactor coolant makeup for protection against small breaks in the reactor coolant pressure boundary.

13. Appendix A to 10 CFR part 50, GDC 40—Periodic pressure and functional testing of containment heat removal system.

14. Appendix A to 10 CFR part 50, GDC 52—Design to allow periodic containment leakage rate testing.

15. Appendix A of 10 CFR part 50, GDCs 55, 56, and 57—Containment Isolation:

a. GDC 55—Isolation valves for certain reactor coolant pressure boundary lines penetrating containment;

b. GDC 56—Isolation valves for certain primary containment lines; and

c. GDC 57—Isolation valves for certain closed systems lines.

16. Appendix K to 10 CFR part 50—Emergency Core Cooling System Evaluation Models:

a. Section I.A.4—Heat generation rates from radioactive decay of fission products;

b. Section I.A.5—Rate of energy release, hydrogen generation, and cladding oxidation from the metal/water reaction;

c. Section I.B—Predicting cladding swelling and rupture;

d. Section I.C.1.b—Calculation of the discharge rate for all times after the discharging fluid has been calculated to be two-phase;

e. Section I.C.5.a—Post-critical heat flux correlations of heat transfer from the fuel cladding to the surrounding fluid; and

f. Section I.C.7.a—Calculation of cross-flow between the hot and average channel regions of the core during blowdown.

VI. Issue Resolution

A. The Commission has determined that the structures, systems, and components and design features of NuScale comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in Section V of this appendix; and therefore, provide adequate protection to the health and safety of the public. A conclusion that a matter is resolved includes the finding that additional or alternative structures, systems, and components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for NuScale.

B. The Commission considers the following matters resolved within the meaning of § 52.63(a)(5) in subsequent proceedings for issuance of a COL, amendment of a COL, or renewal of a COL, proceedings held under § 52.103, and enforcement proceedings involving plants referencing this appendix:

1. All nuclear safety issues associated with the information in the final safety evaluation report, Tier 1, Tier 2, and the rulemaking record for certification of the NuScale design, with the exception of the following:

a. generic TS and other operational requirements;

b. the adequacy of the design of the shield wall between the NuScale power module and the reactor building steam gallery to limit potential radiological doses consistent with the radiation zones specified in design certification application Part 2, Tier 2, Chapter 12, Figure 12.3–1, “Reactor Building Radiation Zone Map”;

c. the adequacy of the design of the systems used for post-accident hydrogen and oxygen monitoring described in design certification application Part 2, Tier 2, Section 6.2.5 to meet the requirements of 10 CFR 50.34(f)(2)(vii), 10 CFR

50.34(f)(2)(xxviii), and 10 CFR 52.47(a)(2)(iv), with respect to radiological releases caused by leakage from these systems under accident conditions; and

d. the ability of the steam generator tubes to maintain structural and leakage integrity during density wave oscillations in the secondary fluid system, including the method of analysis to predict the thermal-hydraulic conditions of the steam generator secondary fluid system and resulting loads, stresses, and deformations from density wave oscillations and reverse flow, consistent with the other design information regarding steam generator integrity described in DCA Part 2, Tier 2, Sections 3.9.1, 3.9.2, 5.4.1, and 15.6.3, and in accordance with 10 CFR part 50, GDC 4 and 31;

2. All nuclear safety and safeguards issues associated with the referenced information in the non-public documents in Tables 1.6–1 and 1.6–2 of Tier 2 of the DCD, which contain sensitive unclassified non-safeguards information (including proprietary information and security-related information) and safeguards information and which, in context, are intended as requirements in the generic DCD for the NuScale design;

3. All generic changes to the DCD under and in compliance with the change processes in paragraphs VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD under and in compliance with the change processes in paragraphs VIII.A.4 and VIII.B.4 of this appendix, but only for that plant;

5. All departures from the DCD that are approved by license amendment, but only for that plant;

6. Except as provided in paragraph VIII.B.5.g of this appendix, all departures from Tier 2 under and in compliance with the change processes in paragraph VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant; and

7. All environmental issues concerning severe accident mitigation design alternatives associated with the information in the NRC’s environmental assessment for NuScale (ADAMS Accession No. ML22004A006) and DCD Part 3, “Applicant’s Environmental Report—Standard Design Certification,” Revision 5, dated July 2020 (ADAMS Accession No. ML20224A512), for plants referencing this appendix whose site characteristics fall within the site parameters of the representative site specified in the NuScale environmental report.

C. The Commission does not consider operational requirements for an applicant or

licensee who references this appendix to be matters resolved within the meaning of § 52.63(a)(5). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except under the change processes in Section VIII of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

1. Modify structures, systems, and components or design features as described in the generic DCD;
2. Provide additional or alternative structures, systems, and components or design features not discussed in the generic DCD; or
3. Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, and components or design features discussed in the generic DCD.

E. The NRC will specify, at an appropriate time, the procedures to be used by an interested person who wishes to review portions of the design certification or references containing safeguards information or sensitive unclassified non-safeguards information (including proprietary information, such as trade secrets and commercial or financial information obtained from a person that are privileged or confidential (10 CFR 2.390 and 10 CFR part 9), and security-related information), for the purpose of participating in the hearing required by § 52.85, the hearing provided under § 52.103, or in any other proceeding relating to this appendix, in which interested persons have a right to request an adjudicatory hearing.

VII. Duration of This Appendix

This appendix may be referenced for a period of 15 years from February 21, 2023, except as provided for in §§ 52.55(b) and 52.57(b). This appendix remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

VIII. Processes for Changes and Departures

A. Tier 1 Information

1. Generic changes to Tier 1 information are governed by the requirements in § 52.63(a)(1).
2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.
3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in § 52.63(a)(4).
4. Exemptions from Tier 1 information are governed by the requirements in §§ 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

B. Tier 2 Information

1. Generic changes to Tier 2 information are governed by the requirements in § 52.63(a)(1).
2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, or B.5, of this section.
3. The Commission may not require new requirements on Tier 2 information by plant-specific order, while this appendix is in effect under § 52.55 or § 52.61, unless:
 - a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to ensure adequate protection of the public health and safety or the common defense and security; and
 - b. Special circumstances as defined in 10 CFR 50.12(a) are present.
4. An applicant or licensee who references this appendix may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The granting of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The granting of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, or the TS, or requires a license amendment under paragraph B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD or one affecting information required by § 52.47(a)(28) to address aircraft impacts, requires a license amendment if it would:

- (1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;
- (2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component important to safety and previously evaluated in the plant-specific DCD;
- (3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;
- (4) Result in more than a minimal increase in the consequences of a malfunction of a structure, system, or component important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of a structure, system, or component important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design-basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2, affecting resolution of an ex-vessel severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of an ex-vessel severe accident such that a particular ex-vessel severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular ex-vessel severe accident previously reviewed.

d. A proposed departure from Tier 2 information required by § 52.47(a)(28) to address aircraft impacts shall consider the effect of the changed design feature or functional capability on the original aircraft impact assessment required by 10 CFR 50.150(a). The applicant or licensee shall describe, in the plant-specific DCD, how the modified design features and functional capabilities continue to meet the aircraft impact assessment requirements in 10 CFR 50.150(a)(1).

e. If a departure requires a license amendment under paragraph B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

f. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

g. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under § 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition to admit into the proceeding such a contention. In addition to complying with the general requirements of 10 CFR 2.309, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a § 52.103 preoperational hearing, or that the departure bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such

a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

C. Operational Requirements

1. Changes to NuScale design certification generic TS and other operational requirements that were completely reviewed and approved in the design certification rule and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Changes that require a change to a design feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Changes to NuScale design certification generic TS and other operational requirements are applicable to all applicants who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic TS and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special circumstances, as defined in 10 CFR 2.335 are present. The Commission may modify or supplement generic TS and other operational requirements that were not completely reviewed and approved or require additional TS and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic TS or other operational requirements. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 52.7. The granting of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for the issuance, amendment, or renewal of a license, or for operation under § 52.103(a), who believes that an operational requirement approved in the DCD or a TS derived from the generic TS must be changed, may petition to admit such a contention into the proceeding. The petition must comply with the general requirements of § 2.309 of this chapter and must either demonstrate why special circumstances as defined in § 2.335 of this chapter are present or demonstrate that the proposed change is necessary for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in Section V of this appendix. Any other party may file a response to the petition. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. All other issues with respect to the plant-specific TS or other operational requirements are subject to a hearing as part of the licensing proceeding.

6. After issuance of a license, the generic TS have no further effect on the plant-

specific TS. Changes to the plant-specific TS will be treated as license amendments under 10 CFR 50.90.

IX. [Reserved]

X. Records and Reporting

A. Records

1. The applicant for this appendix shall maintain a copy of the generic DCD that includes all generic changes that are made to Tier 1 and Tier 2, and the generic TS and other operational requirements. The applicant shall maintain the sensitive unclassified non-safeguards information (including proprietary information and security-related information) and safeguards information referenced in the generic DCD for the period that this appendix may be referenced, as specified in Section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made under Section VIII of this appendix throughout the period of application and for the term of the license (including any periods of renewal).

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations that provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any periods of renewal).

4.a. The applicant for NuScale shall maintain a copy of the aircraft impact assessment performed to comply with the requirements of 10 CFR 50.150(a) for the term of the certification (including any period of renewal).

b. An applicant or licensee who references this appendix shall maintain a copy of the aircraft impact assessment performed to comply with the requirements of 10 CFR 50.150(a) throughout the pendency of the application and for the term of the license (including any periods of renewal).

B. Reporting

1. An applicant or licensee who references this appendix shall submit a report to the NRC containing a brief description of any plant-specific departures from the DCD, including a summary of the evaluation of each departure. This report must be filed in accordance with the filing requirements applicable to reports in § 52.3.

2. An applicant or licensee who references this appendix shall submit updates to its plant-specific DCD, which reflect the generic changes to and plant-specific departures from the generic DCD made under Section VIII of this appendix. These updates shall be filed under the filing requirements applicable to final safety analysis report updates in 10 CFR 50.71(e) and 52.3.

3. The reports and updates required by paragraphs X.B.1 and X.B.2 of this appendix must be submitted as follows:

a. On the date that an application for a license referencing this appendix is submitted, the application must include the report and any updates to the generic DCD.

b. During the interval from the date of application for a license to the date the Commission makes its finding required by § 52.103(g), the report must be submitted semiannually. Updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. After the Commission makes the finding required by § 52.103(g), the reports and updates to the plant-specific DCD must be submitted, along with updates to the site-specific portion of the final safety analysis report for the facility, at the intervals required by 10 CFR 50.59(d)(2) and 50.71(e)(4), respectively, or at shorter intervals as specified in the license.

Dated: January 11, 2023.

For the Nuclear Regulatory Commission.

Brooke P. Clark,

Secretary of the Commission.

[FR Doc. 2023–00729 Filed 1–18–23; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Part 1010

Financial Crimes Enforcement Network; Inflation Adjustment of Civil Monetary Penalties

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Final rule.

SUMMARY: FinCEN is publishing this final rule to reflect inflation adjustments to its civil monetary penalties as mandated by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended. This rule adjusts certain maximum civil monetary penalties within the jurisdiction of FinCEN to the amounts required by that Act.

DATES: Effective January 19, 2023.

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory Support Section at 1–800–767–2825, or electronically at frc@fincen.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In order to improve the effectiveness of civil monetary penalties (CMPs) and to maintain their deterrent effect, the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended in 2015 by section 701 of Public Law 114–74, codified at 28 U.S.C. 2461 note (the Act), requires Federal agencies to adjust for inflation each CMP provided by law within the jurisdiction of the agency. The Act requires agencies to adjust the level of CMPs with an initial “catch-up” adjustment through an interim final rulemaking. After the initial “catch-up”

adjustment, agencies are required to adjust CMPs annually and to make the adjustments notwithstanding 5 U.S.C. 553, which requires notice-and-comment rulemaking for certain agency actions. The Act provides that any increase in a CMP shall apply to CMPs that are assessed after the date the increase takes effect, regardless of whether the underlying violation predated such increase.¹

II. Method of Calculation

The method of calculating CMP adjustments applied in this final rule is required by the Act. Under the Act and Office of Management and Budget (OMB) guidance, annual inflation adjustments subsequent to the initial catch-up adjustment are to be based on the percent change between the Consumer Price Index for all Urban Consumers (CPI-U) for the October preceding the date of the adjustment and the prior year's October CPI-U. As set forth in OMB Memorandum M-23-05 of December 15, 2022, the adjustment multiplier for 2023 is 1.07745. In order to complete the 2023 annual adjustment, each current CMP (all of which were themselves last adjusted in 2022) is multiplied by the 2023 adjustment multiplier. Under the Act, any increase in CMP must be rounded to the nearest multiple of \$1.²

Procedural Matters

1. Administrative Procedure Act
Section 4(b) of the Act requires agencies, beginning in 2017, to make annual adjustments for inflation to CMPs notwithstanding the notice and comment requirements of 5 U.S.C. 553. Additionally, the methodology used for adjusting CMPs for inflation, effective 2017, is provided by statute, with no discretion provided to agencies regarding the substance of the adjustments for inflation to CMPs. Accordingly, prior public notice and an opportunity for public comment and a delayed effective date are not required for this rule.
2. Regulatory Flexibility Act
Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.
3. Executive Order 12866.
This rule is not a significant regulatory action as defined in section 3(f) of Executive Order 12866.
4. Paperwork Reduction Act
The provisions of the Paperwork Reduction Act of 1995, Public Law 104-13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this rule because

there are no new or revised recordkeeping or reporting requirements.

List of Subjects in 31 CFR Part 1010

Authority delegations (Government agencies), Administrative practice and procedure, Banks, banking, Brokers, Currency, Foreign banking, Foreign currencies, Gambling, Investigations, Penalties, Reporting and recordkeeping requirements, Securities, Terrorism.

Authority and Issuance

For the reasons set forth in the preamble, part 1010 of chapter X of title 31 of the Code of Federal Regulations is amended as follows:

PART 1010—GENERAL PROVISIONS

■ 1. The authority citation for part 1010 continues to read as follows:

Authority: 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5314 and 5316–5336; title III, sec. 314, Pub. L. 107–56, 115 Stat. 307; sec. 2006, Pub. L. 114–41, 129 Stat. 458–459; sec. 701, Pub. L. 114–74, 129 Stat. 599.

■ 2. Amend § 1010.821 by revising table 1 following paragraph (b) to read as follows:

§ 1010.821 Penalty adjustment and table.
* * * * *
(b) * * *

TABLE 1 OF § 1010.821—PENALTY ADJUSTMENT TABLE

U.S. Code citation	Civil monetary penalty description	Penalties as last amended by statute	Maximum penalty amounts or range of minimum and maximum penalty amounts for penalties assessed on or after 1/19/2022
12 U.S.C. 1829b(j)	Relating to Recordkeeping Violations For Funds Transfers	\$10,000	\$24,793
12 U.S.C. 1955	Willful or Grossly Negligent Recordkeeping Violations	10,000	24,793
31 U.S.C. 5318(k)(3)(C)	Failure to Terminate Correspondent Relationship with Foreign Bank.	10,000	16,771
31 U.S.C. 5321(a)(1)	General Civil Penalty Provision for Willful Violations of Bank Secrecy Act Requirements.	25,000–100,000	67,544–270,180
31 U.S.C. 5321(a)(5)(B)(i)	Foreign Financial Agency Transaction—Non-Willful Violation of Transaction.	10,000	15,611
31 U.S.C. 5321(a)(5)(C)(i)(I)	Foreign Financial Agency Transaction—Willful Violation of Transaction.	100,000	156,107
31 U.S.C. 5321(a)(6)(A)	Negligent Violation by Financial Institution or Non-Financial Trade or Business.	500	1,350
31 U.S.C. 5321(a)(6)(B)	Pattern of Negligent Activity by Financial Institution or Non-Financial Trade or Business.	50,000	105,083
31 U.S.C. 5321(a)(7)	Violation of Certain Due Diligence Requirements, Prohibition on Correspondent Accounts for Shell Banks, and Special Measures.	1,000,000	1,677,030
31 U.S.C. 5330(e)	Civil Penalty for Failure to Register as Money Transmitting Business.	5,000	9,966

¹ The increased CMPs, however, apply only with respect to underlying violations occurring after November 2, 2015 the date of enactment of the most recent amendment to the Act.

² FinCEN has previously described that it applied a catch-up adjustment for each penalty subject to

the Act, based on the year and corresponding amount(s) for which the maximum penalty or range of minimum and maximum penalties was established or last adjusted, whichever is later. See Civil Monetary Penalty Adjustment and Table, 81 FR 42503, 42504 (June 30, 2016). Because the year

varies for different penalties, penalties that were originally of the same size when promulgated can have different values today pursuant to the application of the Act.

Himamauli Das,

Acting Director, Financial Crimes
Enforcement Network.

[FR Doc. 2023-00943 Filed 1-18-23; 8:45 am]

BILLING CODE 4810-02-P

POSTAL REGULATORY COMMISSION

39 CFR Part 3035

[Docket Nos. RM2017-1 and RM2022-2;
Order No. 6399]

Competitive Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Final rulemaking.

SUMMARY: The Commission is adopting a final rule concerning the minimum amount that the Postal Service's competitive products as a whole are required to contribute to institutional costs annually. The rule as adopted uses a formula-based approach to annually calculate competitive products' appropriate share of institutional costs. For additional information, Order No. 6399 can be accessed electronically through the Commission's website at <https://www.prc.gov>.

DATES: Effective February 21, 2023.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Relevant Statutory Requirements
- II. Background
- III. Basis and Purpose of Final Rule
- IV. Final Rule

I. Relevant Statutory Requirements

Section 3633(a)(3) of title 39 of the United States Code requires the Commission to "ensure that all competitive products collectively cover what the Commission determines to be an appropriate share of the institutional costs of the Postal Service." 39 U.S.C. 3633(a)(3). Section 3633(b) requires that the Commission revisit the appropriate share regulation at least every 5 years in order to determine if the minimum contribution requirement should be "retained in its current form, modified, or eliminated." 39 U.S.C. 3633(b). In making such a determination, the Commission is required to consider "all relevant circumstances, including the prevailing competitive conditions in the market, and the degree to which any costs are uniquely or disproportionately associated with any competitive products." *Id.*

II. Background

Pursuant to section 3633(b), the Commission initiated Docket No. RM2017-1 for the purpose of conducting its second review of the appropriate share requirement since the enactment of the Postal Accountability and Enhancement Act (PAEA), Public Law 109-435, 120 Stat. 3198 (2006). In its second review of the appropriate share, the Commission found that market conditions have changed since the PAEA's enactment and since the Commission's last review of the appropriate share.¹ As a result, in Order No. 4963, the Commission adopted a final rule implementing a dynamic formula-based approach to setting the appropriate share.²

However, Order No. 4963 was appealed by the United Parcel Service, Inc. and later remanded to the Commission for further consideration by the United States Court of Appeals for the District of Columbia Circuit.³ The court identified two major aspects of Order No. 4963 for the Commission to clarify on remand. The Commission issued Order No. 6043, which was a supplemental notice of proposed rulemaking that addressed the issues identified by the court and provided an opportunity for interested persons to file initial comments and reply comments concerning the Commission's third 5-year review of the appropriate share as required by 39 U.S.C. 3633(b).⁴ In addition, the Commission issued Order No. 6269, which invited public comment relating to the Commission's analysis pursuant to uncodified section 703(d) of the Postal Accountability and Enhancement Act (PAEA).⁵

The Commission received and considered comments with respect to

nearly every aspect of the Commission's findings in Order Nos. 6043 and 6269.

In Section IV., the Commission addresses comments relating to the Commission's statutory interpretation of the appropriate share provisions at 39 U.S.C. 3633(a)(3) and (b). After considering these comments, the Commission has determined not to alter its interpretation as articulated in Order No. 6043, which the Commission continues to conclude is consistent with the PAEA's text and structure, as well as its context and legislative history. *See* Section IV.

In Section V.A., the Commission addresses comments relating to the application of the "uniquely or disproportionately associated" phrase from 39 U.S.C. 3633(b) to the Postal Service's accrued costs. The Commission continues to find that all attributable costs are already included in the 39 U.S.C. 3633(a)(3) price floor and are furthermore implicitly considered as part of the formula. *See* Section V.A.2.b. The price floors set under 39 U.S.C. 3633(a)(1) and (a)(3) fully ameliorate any competitive deficit alleged to be unaddressed by the price floor under 39 U.S.C. 3633(a)(2), and that the use of incremental costs for purposes of the price floors under 39 U.S.C. 3633(a)(1) and (a)(2) is sufficient to prevent subsidization of Competitive products. *See* Section V.A.3.b. Any further attempt to account for attributable costs as part of the appropriate share would constitute double-counting of those costs that would be economically unsound and potentially harmful to the Postal Service. *See* Section V.A.4.b. There is no meaningful relationship between unattributed inframarginal costs and Competitive products; there are no costs uniquely or disproportionately associated with Competitive products within currently-existing institutional costs; and using economically sound measurement is reasonable. *See* Sections V.A.5.b., V.A.6.b., V.A.7.b. The arbitrary allocation of institutional costs to Competitive products would contravene the intent of the PAEA, would be economically unsound, would degrade the existing costing methodology, and could harm the Postal Service and consumers. *See* Section V.A.8.b.

In Section V.B., the Commission addresses comments relating to the prevailing competitive conditions in the market and other relevant circumstances. The Commission confirms that revenue is the appropriate measure of market size, and that the profitability of competitors is relevant to assessing the prevailing competitive

¹ *See* Docket No. RM2017-1, Order Adopting Final Rules Relating to the Institutional Cost Contribution Requirement for Competitive Products, January 3, 2019, at 4-12, 114-170 (Order No. 4963); *see* 84 FR 537 (January 1, 2019).

² Order Adopting Final Rules Relating to the Institutional Cost Contribution Requirement for Competitive Products, January 3, 2019 (Order No. 4963). The Final Rulemaking was published in the **Federal Register** on January 31, 2019. *See* 84 FR 537 (Jan. 31, 2019).

³ *UPS II*, 955 F.3d 1038, No. 19-1026, ECF Document No. 1846181, at 1, (issuing formal mandate), June 8, 2020.

⁴ Supplemental Notice of Proposed Rulemaking and Order Initiating the Third Review of the Institutional Cost Contribution Requirement for Competitive Products, November 18, 2021 (Order No. 6043). The Supplemental Notice of Proposed Rulemaking was published in the **Federal Register** on August 13, 2018. *See* 86 FR 67882 (Nov. 30, 2021).

⁵ Notice and Order Providing an Opportunity to Comment on the Commission's Section 703(d) Analysis, September 7, 2022 (Order No. 6269); Postal Accountability and Enhancement Act (PAEA), Public Law 109-435, Title VII, § 703, 120 Stat. 3198, 3244 (2006).

conditions in the market. *See* Section V.B.2.b. The Commission presents an updated market analysis and continues to find that the state of competition in the market for competitive postal services is healthy. *See id.*

With respect to comments suggesting that the Commission should consider the Postal Service's financial losses, the "non-existence of a level playing field" and "subsidization," the Commission explains why these three potential circumstances are not relevant to this review. *See* Section V.B.3.b. The Commission finds that comparative harm and the balance of risk and actual Competitive product contribution to institutional costs are relevant circumstances which all weigh in favor of readopting the dynamic formula-based approach. *See id.* Finally, the Commission reiterates its dismissal of comments alleging that the formula is arbitrary and capricious. *See* Section V.B.4.b.

In Section VI. the Commission addresses comments regarding the Commission's analysis pursuant to uncodified section 703(d) of the PAEA. *See* PAEA 703(d). In accordance with that provision, the Commission invited additional public comment regarding Commission updates to a quantification by the Federal Trade Commission (FTC) of the net economic effect of federal and state laws that apply differently to the Postal Service than to private competitors in the market for competitive postal services, based on subsequent events that the Commission found affected the ongoing validity of the FTC's findings. *See* Order No. 6269. The Commission concludes that the additional events (beyond those identified by the Commission in Order No. 6269) raised by commenters are outside the scope of the Commission's 703(d) analysis. *See* Section VI.C.

In Section VII., the Commission addresses arguments relating to each specific type of costs alleged by any commenters to be uniquely or disproportionately associated with Competitive products. Upon consideration of each category of costs raised, the Commission concludes that none of these costs raised by commenters are uniquely or disproportionately associated with Competitive products and that it would be inappropriate to alter the formula-based approach to take these cost categories into account. *See* Section VII.

In Section VIII. the Commission addresses comments proposing alternatives to the formula-based approach to setting the appropriate share. The Commission concludes that UPS's four alternative proposals would

each involve the arbitrary allocation of institutional costs to Competitive products, and furthermore all suffer from numerous methodological flaws and inconsistencies with the PAEA. *See* Sections VIII.A.3., VIII.B.3., VIII.C.3., VIII.D.3. With respect to comments that the appropriate share should be eliminated, the Commission reiterates that it has, pursuant to the discretion accorded to it by 39 U.S.C. 3633(b), elected to retain the appropriate share requirement as a margin of safety against any possibility of the Postal Service having an unfair competitive advantage. *See* Section VIII.E.3.

Based on the analysis provided above and its review of comments, the Commission readopts its dynamic formula-based approach to calculating the appropriate share.

III. Basis and Purpose of the Final Rule

The purpose of the Commission's formula-based approach is to provide an objective basis on which to quantify the statutory considerations of section 3633(b) in order to determine the year-to-year change in competitive products' joint minimal capacity to generate profit that can be contributed to the coverage of institutional costs. Order No. 6399 at 114.

The formula seeks to determine the Postal Service's overall market power by measuring its absolute and relative market power. *Id.* at 115–117. In order to assess the Postal Service's absolute market power and its market position, the formula utilizes two distinct components. *Id.* The first component is the Competitive Contribution Margin, which measures the Postal Service's absolute market power. *Id.* at 115. Specifically, the Competitive Contribution Margin is calculated by subtracting the total attributable costs of producing the Postal Service's competitive products collectively from the total amount of revenue the Postal Service is able to realize from those competitive products collectively in a given fiscal year, and then dividing this result by the total competitive product revenue. *Id.* The formula assesses the year-over-year percent change in the Competitive Contribution Margin to determine how much, if any, the Postal Service's absolute market power has changed. *Id.*

The second component of the formula is the Competitive Growth Differential, which measures the Postal Service's market position. *Id.* at 116–117. Specifically, the Competitive Growth Differential is calculated by subtracting the year-over-year percent change in the combined revenue for the Postal Service's competitors from the year-

over-year percent change in the Postal Service's competitive product revenue. *Id.* at 116. This relative growth is then weighted by the Postal Service's market share. *Id.*

Using the above-described components, the Commission's formula is represented by the following equation:

$$AS_{t+1} = AS_t * (1 + \% \Delta CCM_{t-1} + CGD_{t-1})$$

If $t = 0 = FY 2007$, $AS = 5.5\%$

Where,

AS = Appropriate Share

CCM = Competitive Contribution Margin

CGD = Competitive Growth Differential

t = Fiscal Year

Id. at 117.

In order to calculate an upcoming fiscal year's appropriate share percentage (AS_{t+1}), the formula multiplies the sum of the prior fiscal year's Competitive Growth Differential and percentage change in the Competitive Contribution Margin ($1 + \% \Delta CCM_{t-1} + CGD_{t-1}$) by the current fiscal year's appropriate share (AS_t). *Id.* at 118. Both components of the formula are given equal weight. *Id.* The formula is recursive in order to incorporate all changes in the parcel delivery market since the PAEA was enacted and the appropriate share was initially set. *Id.* at 103. The formula's calculation thus begins in FY 2007 with a beginning appropriate share of 5.5 percent. *Id.* The upcoming fiscal year's appropriate share will be updated by the Commission each year as part of the Commission's Annual Compliance Determination, which is performed pursuant to 39 U.S.C. 3653. *Id.*

IV. Final Rule

In order to implement the Commission's formula, existing § 3035.107(c) is revised. Final § 3035.1077(c)(1) establishes the formula which is to be used in calculating the appropriate share and defines each of the formula's terms. Final § 3035.107(c) states that the appropriate share of institutional costs to be covered by competitive products set forth in that rule is a minimum contribution level. Final § 3035.107(c)(2) establishes the process by which the Commission shall update the appropriate share for each fiscal year. The Commission will annually use the formula to calculate the minimum appropriate share for the upcoming fiscal year and report the new appropriate share level for the upcoming fiscal year as part of its Annual Compliance Determination.

List of Subjects for 39 CFR Part 3035

Administrative practice and procedure.

For the reasons stated in the preamble, the Commission amends chapter III of title 39 of the Code of Federal Regulations as follows:

PART 3035—REGULATION OF RATES FOR COMPETITIVE PRODUCTS

■ 1. The authority citation for part 3035 continues to read as follows:

Authority: 39 U.S.C. 503; 3633.

■ 2. Amend § 3035.107 by revising paragraph (c) to read as follows:

§ 3035.107 Standards for Compliance.

* * * * *

(c)(1) Annually, on a fiscal year basis, the appropriate share of institutional costs to be recovered from competitive products collectively, at a minimum, will be calculated using the following formula:

$$AS_{t+1} = AS_t * (1 + \% \Delta CCM_{t-1} + CGD_{t-1})$$

Where,

AS = Appropriate Share, expressed as a percentage and rounded to one decimal place

CCM = Competitive Contribution Margin

CGD = Competitive Growth Differential

t = Fiscal Year

If t = 0 = FY 2007, AS = 5.5 percent

(2) The Commission shall, as part of each Annual Compliance Determination, calculate and report competitive products' appropriate share for the upcoming fiscal year using the formula set forth in paragraph (c)(1) of this section.

By the Commission.

Erica A. Barker,
Secretary.

[FR Doc. 2023-00944 Filed 1-18-23; 8:45 am]

BILLING CODE 7710-FW-P

DEPARTMENT OF THE INTERIOR

Office of the Secretary of the Interior

43 CFR Part 10

[NPS-WASO-NAGPRA-33240;
PPWOVPADU0/PPMPRLE1Y.Y00000]

RIN 1024-AE78

Civil Penalties Inflation Adjustments

AGENCY: Office of the Secretary, Interior.

ACTION: Final rule.

SUMMARY: This rule revises U.S. Department of the Interior regulations implementing the Native American Graves Protection and Repatriation Act to provide for annual adjustments of civil penalties to account for inflation under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget guidance. The purpose of these adjustments is to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statute.

DATES: This rule is effective on January 19, 2023.

FOR FURTHER INFORMATION CONTACT: Melanie O'Brien, Manager, National NAGPRA Program, (202) 354-2204, National Park Service, 1849 C Street NW, Washington, DC 20240.

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (sec. 701 of Pub. L. 114-74) ("the Act"). The Act requires Federal agencies to adjust the level of civil monetary penalties annually for inflation no later than January 15 of each year.

II. Calculation of Annual Adjustments

The Office of Management and Budget (OMB) recently issued guidance to assist

Federal agencies in implementing the annual adjustments required by the Act which agencies must complete by January 15, 2023. See December 15, 2022, Memorandum for the Heads of Executive Departments and Agencies, from Shalanda D. Young, Director, Office of Management and Budget, re: *Implementation of Penalty Inflation Adjustments for 2023, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (M-23-05). The guidance states that the cost-of-living adjustment multiplier for 2023, based on the Consumer Price Index (CPI-U) for the month of October 2022, not seasonally adjusted, is 1.07745.

Annual inflation adjustments are based on the percent change between each published October's CPI-U. In this case, October 2022 CPI-U (298.012)/ October 2021 CPI-U (276.589) = 1.07745.) The guidance instructs agencies to complete the 2023 annual adjustment by multiplying each applicable penalty by the multiplier, 1.07745, and rounding to the nearest dollar.

The annual adjustment applies to all civil monetary penalties with a dollar amount that are subject to the Act. A civil monetary penalty is any assessment with a dollar amount that is levied for a violation of a Federal civil statute or regulation, and is assessed or enforceable through a civil action in Federal court or an administrative proceeding. A civil monetary penalty does not include a penalty levied for violation of a criminal statute, or fees for services, licenses, permits, or other regulatory review. This final rule adjusts the following civil monetary penalties contained in the Department regulations implementing the Native American Graves Protection and Repatriation Act (NAGPRA) for 2023 by multiplying 1.07745 by each penalty amount as updated by the adjustment made in 2022:

CFR citation	Description of the penalty	Current penalty including catch-up adjustment	Annual adjustment (multiplier)	Adjusted penalty
43 CFR 10.12(g)(2)	Failure of Museum to Comply	\$7,475	1.07745	\$8,054
43 CFR 10.12(g)(3)	Continued Failure to Comply Per Day	1,496	1.07745	1,612

Consistent with the Act, the adjusted penalty levels for 2023 will take effect immediately upon the effective date of the adjustment. The adjusted penalty levels for 2023 will apply to penalties assessed after that date including, if

consistent with agency policy, assessments associated with violations that occurred on or after November 2, 2015. The Act does not, however, change previously assessed penalties that the Department is collecting or has

collected. Nor does the Act change an agency's existing statutory authorities to adjust penalties.

III. Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs 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.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. See 5 U.S.C. 603(a) and 604(a). The RFA does not apply to this final rule because the Office of the Secretary is not required to publish a proposed rule for the reasons explained below in Section III.L.

C. Congressional Review Act (CRA)

This rule is not a major rule under 5 U.S.C. 804(2), the CRA. This rule:

(a) Does not have an annual effect on the economy of \$100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

D. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or

tribal governments, or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

E. Takings (E.O. 12630)

This rule does not effect a taking of private property or otherwise have taking implications under Executive Order 12630. A takings implication assessment is not required.

F. Federalism (E.O. 13132)

Under the criteria in section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. A federalism summary impact statement is not required.

G. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. Consultation With Indian Tribes (E.O. 13175 and Departmental Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. The Department has evaluated this rule under its consultation policy and under the criteria in Executive Order 13175 and has determined that the rule has no substantial direct effects on federally recognized Indian tribes and that consultation under the Department's tribal consultation policy is not required.

I. Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act (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.

J. National Environmental Policy Act (NEPA)

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the NEPA is not required because the rule is covered by a categorical exclusion. This rule is excluded from the requirement to prepare a detailed statement because it is a regulation of an administrative nature. (For further information see 43 CFR 46.210(i).) We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

K. Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in Executive Order 13211; the rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy, and the rule has not otherwise been designated by the Administrator of Office of Information and Regulatory Affairs as a significant energy action. A Statement of Energy Effects is not required.

L. Administrative Procedure Act

The Act requires agencies to publish annual inflation adjustments by no later than January 15 of each year, notwithstanding section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). OMB has interpreted this direction to mean that the usual procedure for rulemaking under the APA—which includes public notice of a proposed rule, an opportunity for public comment, and a delay in the effective date of a final rule—is not required when agencies issue regulations to implement the annual adjustments to civil penalties that the Act requires. Accordingly, we are issuing the 2023 annual adjustments as a final rule without prior notice or an opportunity for comment and with an effective date immediately upon publication in the **Federal Register**.

List of Subjects in 43 CFR Part 10

Administrative practice and procedure, Hawaiian Natives, Historic preservation, Indians—claims, Indians—lands, Museums, Penalties, Public lands, Reporting and recordkeeping requirements.

For the reasons given in the preamble, the Office of the Secretary amends 43 CFR part 10 as follows:

PART 10—NATIVE AMERICAN GRAVES PROTECTION AND REPATRIATION REGULATIONS

■ 1. The authority citation for part 10 continues to read as follows:

Authority: 16 U.S.C. 470dd; 25 U.S.C. 9, 3001 *et seq.*

§ 10.12 [Amended]

■ 2. In § 10.12:

■ a. In paragraph (g)(2) introductory text, remove “\$7,475” and add in its place “\$8,054”.

■ b. In paragraph (g)(3), remove “\$1,496” and add in its place “\$1,612”.

Signing Authority

Shannon Estenoz, Assistant Secretary for Fish and Wildlife and Parks, approved this action on January 9, 2023, for publication. On January 13, 2023, Shannon Estenoz authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of the Interior.

Maureen D. Foster,

Chief of Staff, Office of the Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2023-00982 Filed 1-18-23; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 220325-0078; RTID 0648-XC494]

Fisheries of the Northeastern United States; Atlantic Sea Scallop Fishery; Closure of the Closed Area I Scallop Access Area to General Category Individual Fishing Quota Scallop Vessels

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces that the Closed Area I Scallop Access Area is closed to Limited Access General Category Individual Fishing Quota scallop vessels for the remainder of the 2022 fishing year. Regulations require

this action once it is projected that 100 percent of trips allocated to the Limited Access General Category Individual Fishing Quota scallop vessels for the Closed Area I Scallop Access Area will be taken. This action is intended to prevent the number of trips in the Closed Area I Scallop Access Area from exceeding what is allowed under the Atlantic Sea Scallop Fishery Management Plan.

DATES: Effective 0001 hr local time, January 14, 2023, through March 31, 2023.

FOR FURTHER INFORMATION CONTACT: Louis Forristall, Fishery Management Specialist, (978) 281-9321.

SUPPLEMENTARY INFORMATION:

Regulations governing fishing activity in the Sea Scallop Access Areas can be found in 50 CFR 648.59 and 648.60. These regulations authorize vessels issued a valid Limited Access General Category (LAGC) Individual Fishing Quota (IFQ) scallop permit to fish in the Closed Area I Scallop Access Area under specific conditions, including a total of 714 trips that may be taken during the 2022 fishing year. Section 648.59(g)(3)(iii) requires NMFS to close the Closed Area I Scallop Access Area to LAGC IFQ permitted vessels for the remainder of the fishing year once it determines that the allocated number of trips for the fishing year are projected to be taken.

Based on trip declarations by LAGC IFQ scallop vessels fishing in the Closed Area I Scallop Access Area, analysis of fishing effort, and other information, NMFS projects that 714 trips will be taken as of January 14, 2023. Therefore, in accordance with § 648.59(g)(3)(iii), NMFS is closing the Closed Area I Scallop Access Area to all LAGC IFQ scallop vessels as of January 14, 2023. No vessel issued an LAGC IFQ permit may fish for, possess, or land scallops in or from the Closed Area I Scallop Access Area after 0001 hr local time, January 14, 2023. Any LAGC IFQ vessel that has declared into the Closed Area I Access Area scallop fishery, complied with all trip notification and observer requirements, and crossed the Vessel Monitoring System demarcation line on the way to the area before 0001 hr, January 14, 2023, may complete its trip without being subject to this closure. This closure is in effect for the remainder of the 2022 scallop fishing year, through March 31, 2023.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Fishery Conservation and Management Act. This action is required by 50 CFR part 648, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest. The Closed Area I Scallop Access Area opened for the 2022 fishing year on April 1, 2022. The regulations at § 648.59(g)(3)(iii) require this closure to ensure that LAGC IFQ scallop vessels do not take more than their allocated number of trips in the area. The projected date on which the LAGC IFQ fleet will have taken all of its allocated trips in an Access Area becomes apparent only as trips into the area occur on a real-time basis and as activity trends begin to appear. As a result, NMFS can only make an accurate projection very close in time to when the fleet has taken all of its trips. To allow LAGC IFQ scallop vessels to continue to take trips in the Closed Area I Scallop Access Area during the period necessary to publish and receive comments on a proposed rule would likely result in the vessels taking much more than the allowed number of trips in the Closed Area I Scallop Access Area. Excessive trips and harvest from the Closed Area I Scallop Access Area would result in excessive fishing effort in the area, where effort controls are critical, thereby undermining conservation objectives of the Atlantic Sea Scallop Fishery Management Plan and requiring more restrictive future management measures. Also, the public had prior notice and full opportunity to comment on this closure process when it was enacted, as well as during the public comment period on the action to set specifications for the 2022 fishing year. For these same reasons, NMFS further finds, under 5 U.S.C 553(d)(3), good cause to waive the 30-day delayed effectiveness period.

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

Dated: January 13, 2023.

Jennifer M. Wallace,

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

[FR Doc. 2023-00979 Filed 1-13-23; 4:15 pm]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 679**

[Docket No. 220223-0054; RTID 0648-XC687]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher/Processors Using Trawl Gear in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by American Fisheries Act (AFA) trawl catcher/processors in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the annual 2023 Pacific cod total allowable catch (TAC) allocated to AFA trawl catcher/processors in the BSAI.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), January 20, 2023, through 1200 hours, A.l.t., November 1, 2023.

FOR FURTHER INFORMATION CONTACT: Krista Milani, 907-581-2062.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The annual apportionment of the 2023 Pacific cod TAC allocated to AFA trawl catcher/processors in the BSAI is 2,790 metric tons (mt) as established by the final 2022 and 2023 harvest specifications for groundfish in the BSAI (87 FR 11626, March 2, 2022) and inseason adjustment (87 FR 80090, December 29, 2022).

In accordance with §§ 679.20(d)(1)(i) and 679.20(d)(1)(ii)(B), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the annual 2023 Pacific cod TAC allocated to AFA trawl catcher/processors in the BSAI is necessary to account for the incidental

catch in other anticipated fisheries. Therefore, the Regional Administrator is establishing a directed fishing allowance of 0 mt and is setting aside the remaining 2,790 mt as incidental catch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by AFA trawl catcher/processors in the BSAI.

While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion, and would delay the closure of Pacific cod by AFA trawl catcher/processors in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of January 12, 2023.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

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

Dated: January 13, 2023.

Jennifer M. Wallace,

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

[FR Doc. 2023-00965 Filed 1-18-23; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 679**

[Docket No. 220223-0054; RTID 0648-XC676]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Less Than 60 Feet (18.3 Meters) Length Overall Using Hook-and-Line or Pot Gear in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 meters (m)) length overall (LOA) using hook-and-line or pot gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2023 Pacific cod total allowable catch (TAC) allocated to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), January 16, 2023, through 2400 hours, A.l.t., December 31, 2023.

FOR FURTHER INFORMATION CONTACT: Krista Milani, 907-581-2062.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2023 Pacific cod TAC allocated to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI is 3,363 metric tons as established by the final 2022 and 2023 harvest specifications for groundfish in the BSAI (87 FR 11626, March 2, 2022), inseason adjustment (87 FR 80090, December 29, 2022), correction (88 FR 789, January 5, 2023), and reallocation (88 FR 2271, January 13, 2023).

In accordance with § 679.20(d)(1)(iii), the Administrator, Alaska Region, NMFS (Regional Administrator), has

determined that the 2023 Pacific cod TAC allocated as a directed fishing allowance to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI will soon be reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI.

While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens

Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of Pacific cod by catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most

recent, relevant data only became available as of January 12, 2023.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

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

Dated: January 13, 2023.

Jennifer M. Wallace,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023-00978 Filed 1-13-23; 4:15 pm]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 88, No. 12

Thursday, January 19, 2023

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 AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 71, 77, 78, and 86

[Docket No. APHIS–2021–0020]

RIN 0579–AE64

Use of Electronic Identification Eartags as Official Identification in Cattle and Bison

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the animal disease traceability regulations to require that eartags applied on or after a date 6 months (180 days) after publication in the **Federal Register** of a final rule following this proposed rule be both visually and electronically readable in order to be recognized for use as official eartags for interstate movement of cattle and bison covered under the regulations. We are also proposing to clarify certain record retention and record access requirements and revise some requirements pertaining to slaughter cattle. These proposed changes would enhance the ability of Tribal, State and Federal officials, private veterinarians, and livestock producers to quickly respond to high-impact diseases currently existing in the United States, as well as foreign animal diseases that threaten the viability of the U.S. cattle and bison industries.

DATES: We will consider all comments that we receive on or before March 20, 2023.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov. Enter APHIS–2021–0020 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No.

APHIS–2021–0020, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at www.regulations.gov or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Aaron Scott, Director, National Animal Disease Traceability and Veterinary Accreditation Center, Strategy & Policy, Veterinary Services, APHIS, 2150 Centre Ave, Fort Collins, CO 80526; traceability@usda.gov; (970) 494–7249.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service's (APHIS') Animal Disease Traceability (ADT) framework was established to improve the ability to trace animals back from slaughter and forward from premises where the animals are officially identified, in addition to tracing animals' interstate movements. Knowing where diseased and exposed animals are, as well as where they have been and when, is indispensable to emergency response and ongoing disease control and eradication programs. The ability to trace animals accurately and rapidly does not prevent disease epidemics, but does allow Tribal, State, and Federal veterinarians to contain potentially devastating disease outbreaks before they can do substantial damage to the U.S. cattle and bison industries. A comprehensive animal disease traceability system is the best protection against a devastating disease outbreak.

Tracing of animals has multiple components, including identification of the animal, tracking its movements, discovering other exposed animals, and finding the associated records quickly enough to implement mitigations to the impact of the disease. Time to find records is critical for diseases, such as foot and mouth disease (FMD), that may transmit from animal to animal in as little as 24 to 48 hours. For other diseases that can have prolonged

latency periods and may result in a significant number of exposed animals, such as bovine tuberculosis and brucellosis, accuracy of data collection and data retrieval is important. In either case, consequences of late or inaccurate records may result in large financial losses.

Foreign animal diseases such as FMD have been largely excluded from the United States; however, exclusion of every high impact disease through every pathway of introduction is likely an unachievable task. Costs of incursions vary, but even a small outbreak of FMD would have multi-billion dollar impacts on U.S. livestock producers' access to export markets with additional losses to production, reproduction, and animal population. Other diseases, such as bovine tuberculosis, move slowly but may infect many herds before detection. The financial consequences of this insidious and incurable disease, which can also affect other animals and people, as well as intangible impacts related to consequences or loss of a family farm, can be high.

Jurisdiction and responsibility for controlling diseases that can cause significant damage to the livestock industry is divided among State, Tribal, and U.S. Department of Agriculture (USDA) animal health officials. Interstate movement of cattle and bison falls under the responsibility of USDA, APHIS, while movements within the State and Tribal boundaries fall under their respective governments. There are approximately 100 million cattle and bison in the United States, and they are likely to make multiple movements through their lifetimes. Rapid and accurate recordkeeping for this volume of animals and movement is not achievable without electronic systems.

Eartags are an essential component for animal health officials to identify and track the movement of animals that are diseased or exposed to disease. Official eartags are approved by APHIS to identify certain classes of animals that move interstate or are part of Federal disease control and eradication programs. USDA records show that approximately 11 million official visually readable only, *i.e.*, non-electronic identification (EID) eartags were used per year in fiscal years 2017 through 2021, which corresponds to 11 percent of the national population of cattle and bison.

Official identification tags may be placed on the animal by the animal owner but are more frequently placed at livestock markets or by veterinarians who create the movement documents required for the interstate travel of the animals. In either case, EID eartags offer a number of advantages over non-EID eartags. With non-EID eartags, the animal must be physically restrained to allow the eartag number to safely be read and transcribed. Often, the eartag must be cleaned before the number can accurately be read. Visual eartag numbers may be recorded on paper, or manually entered in a database. Errors can occur while reading, transcribing, or entering the eartag number into a database. Costs to the producers may include that of the tags as well as the time for restraining the animals and reading the numbers. Alternatively, for EID tags, the numbers may be read visually, similarly to the non-EID tags, or may be read without restraint as the animal goes past an electronic reader. Once the reader scans the tag, the electronically collected tag number can be rapidly and accurately transmitted from the reader to a connected electronic database. Since the eartag number does not need to be manually read, transcribed, or entered in a database, the risk of errors at these steps is eliminated. Electronic identification numbers are stored in electronic data systems, whereas visual identification numbers may be stored in electronic data systems after entry or filed as paper records. Disease investigations that involve tracing an animal with electronic records take only minutes to hours, while searching paper records for a visual eartag number can take days to weeks or longer. Shorter disease investigations minimize the impact on individual producers, herds, businesses, and communities.

Currently, the livestock industry uses APHIS-approved EID tags as well as other EID tags intended for production management. Official EID eartag numbers are read on the same radio frequency as other electronic eartags and are quality-tested to last the lifetime of an animal. Hence, they serve a dual purpose whether official identification is needed or when integrated into production systems.

APHIS has primary regulatory responsibility to control and eradicate communicable diseases of livestock and to prevent the introduction and dissemination of any pest or disease of livestock into the United States. The animal disease traceability regulations,

which were set forth in a final rule¹ published on January 9, 2013 (78 FR 2040–2075, Docket No. APHIS–2009–0091), provide the requirements for identification and documentation for certain classes of cattle and bison to move interstate. These regulations establish minimum national official identification and documentation requirements for the traceability of livestock moving interstate. The species covered in the regulations include cattle and bison, sheep and goats, swine, horses and other equids, captive cervids (e.g., deer and elk), and poultry.

Since the enactment of these regulations, APHIS has worked with stakeholders to enhance its traceability capacity within the ADT program. In January 2017, APHIS staff officers met with State officials and APHIS Veterinary Services field officers to gather input on what was working well in the traceability program and what gaps remained. A report of our findings was published in April 2017 (<https://www.aphis.usda.gov/traceability/downloads/adt-assessment.pdf>). Among other findings, the report discussed gaps in tracing animals due to the challenges of reading and recording numbers from non-EID eartags. A similar gap identified was the need for greater efficiency in collecting AINs or other official identification numbers of individual animals at slaughter and removing those identification numbers from future tracing efforts. Eliminating this gap was determined not to be feasible with visual-only eartags, but could be achieved at a future time with EID eartags.

On April 4, 2017, we published in the **Federal Register** (82 FR 16336, Docket No. APHIS–2017–0016) a notice² announcing a series of public meetings aimed at soliciting comment on the animal disease traceability program. A total of nine public meetings were hosted by APHIS between April and July of that year, and an additional meeting was hosted by the Kansas Department of Agriculture. As discussed in the April 2017 notice, the purpose of the meetings paralleled the prior discussion with State officials and APHIS field officers: To “hear from the public about the successes and challenges of the current ADT framework.” We specifically solicited attendance from cattle and bison

¹ To view the final rule, the proposed rule, and the comments we received on the proposed rule, go to www.regulations.gov and enter APHIS–2009–0091 in the Search field.

² To view the notice, go to www.regulations.gov and enter APHIS–2017–0016 in the Search field.

industry members, as well as impacted States and Tribes.

The notice and meetings generated 462 written public comments. A working group formed in March of 2017 to plan and attend the public meetings was further tasked with listening to the discussions and preparing a final report summarizing input from the meetings and proposing directions to address gaps in the traceability system. The report was presented at the National Institute for Agriculture fall public forum in September of 2017 and published in April of 2018 (https://www.aphis.usda.gov/publications/animal_health/adt-summary-program-review.pdf).

During the remainder of 2017, 2018, and 2019, APHIS personnel frequently met with stakeholders to discuss questions and topics that arose during the 2017 outreach meetings. In addition to individual and industry organization meetings, APHIS officers met with State officials as well as industry stakeholders at national public forums including the United States Animal Health Association and the National Institute for Animal Agriculture forum.

During this period, cattle and bison organizations provided significant and ongoing input on the animal disease traceability program. Although not everyone agreed, many stakeholders commented that electronic records and electronic identification were of significant value and were needed to protect the industry from diseases with potential for high economic impacts.

Under the regulations, official identification devices or methods are determined by the APHIS Administrator. An *official identification device or method* is defined in 9 CFR 86.1 of the regulations as “[a] means approved by the Administrator of applying an official identification number to an animal of a specific species or associating an official identification number with an animal or group of animals of a specific species or otherwise officially identifying an animal or group of animals.”

One of the approved identification methods for cattle and bison covered by part 86 is an official eartag. An *official eartag* is defined in § 86.1 of the regulations as “[a]n identification tag approved by APHIS that bears an official identification number for individual animals. Beginning March 11, 2014, all official eartags manufactured must bear an official eartag shield. Beginning March 11, 2015, all official eartags applied to animals must bear an official eartag shield. The design, size, shape, color, and other characteristics of the official

ear tag will depend on the needs of the users, subject to the approval of the Administrator. The official ear tag must be tamper-resistant and have a high retention rate in the animal.” The other methods of official identification of cattle and bison include “brands registered with a recognized brand inspection authority and accompanied by an official brand inspection certificate, when agreed to by the shipping and receiving State or Tribal animal health authorities; or tattoos and other identification methods acceptable to a breed association for registration purposes, accompanied by a breed registration certificate, when agreed to by the shipping and receiving State or Tribal animal health authorities; or Group/lot identification when a group/lot identification number (GIN) may be used.” (See 9 CFR 86.4(a)).

Historically, APHIS has used non-EID (metal) tags for animal identification in disease programs for many decades and has approved both non-EID and radio frequency identification (RFID) tags for use as official ear tags in cattle and bison since 2008.

While APHIS focuses on interstate movements of livestock, States and Tribal Nations remain responsible for the traceability of livestock within their jurisdictions. APHIS partners with State veterinary officials each year to test the performance of States’ animal disease traceability systems. (Tribes are free to request such test exercises on a voluntary basis and APHIS will report to the Tribes the results of any such exercise.) Results of these test exercises, which can be viewed on APHIS’s traceability web page,³ indicate that when State veterinary officials are provided an identification number from an animal that has been identified with an official identification ear tag, whether non-EID (*e.g.*, metal or plastic) or electronic, and the number has been entered accurately into a data system, States can trace animals to any one of these four locations in less than 1 hour: The State where an animal was officially identified, the location in-State where an animal was officially identified, the State from which an animal was shipped out of, and the location in-State that an animal was shipped out-of-State from. However, lengthy times or failed traces in the test exercises resulted when numbers from non-EID tags were transcribed inaccurately, movement records were not readily available, or information was

only retrievable from labor-intensive paper filing systems. Electronic tags and electronic record systems provide a significant advantage over non-EID tags by enabling rapid and accurate reading and recording of tag numbers and retrieval of traceability information.

In support of greater efficiency in traceability and in furtherance of the above-listed program goals, on July 6, 2020, we published in the **Federal Register** (85 FR 40184–40185, Docket No. APHIS–2020–0022) a notice⁴ in which we announced our proposal to approve only RFID tags as the official ear tag for use in interstate movement of cattle and bison that are covered under the regulations. Specifically, the notice proposed that:

- Beginning January 1, 2022, USDA would no longer approve vendors to use the official USDA shield in production of visual ear tags or other ear tags that do not have RFID components.
- On January 1, 2023, RFID tags would become the only identification devices approved as an official ear tag for cattle and bison pursuant to § 86.4(a)(1)(i).
- For cattle and bison that have official USDA visual (metal) tags in place before January 1, 2023, APHIS would recognize the visual (metal) tag as an official identification device for the life of the animal.

The notice further clarified that we were proposing no changes to the regulations pertaining to, nor proposing to restrict the use of, other official identification methods authorized by those regulations (such as the use of tattoos and brands when accepted by State Officials in the sending and receiving states).

We solicited comments on the notice for 90 days ending on October 5, 2020. We received 935 comments by that date from industry groups, producers, veterinarians, State departments of agriculture, and individuals.

Many of the commenters representing industry organizations and State department of agriculture regulatory officials were supportive of the transition and agreed with APHIS that RFID allowed for greater efficiency than non-electronic means of identification and furthered the goals of the ADT program with regard to animal traceability. We also received many comments expressing opposition to the proposal, however.

Many of the commenters opposed to the proposal were concerned with the perceived costs imposed on producers

and livestock markets of having to purchase electronic reading equipment and computer systems. We do not agree with the commenters regarding the magnitude of costs to the domestic cattle and bison industry. Many of these commenters were not aware that the official RFID tags are easily read visually and therefore could be used as they are currently using non-EID tags without the added expense of purchasing reading equipment. Also, large categories of cattle, such as feeder cattle or cull cattle going to slaughter, are not subject to the official identification requirements and would not require official ear tags. We address the costs in greater detail in the regulatory impact analysis accompanying this proposed rule.

Other commenters expressed concern about the retention time on the animals of RFID ear tags, claiming that non-EID ear tags were superior in that regard. These commenters, however, did not differentiate between USDA-approved official tags that must meet quality standards for long-term retention and other RFID tags intended for unofficial uses. Prior to approval by APHIS, official RFID tag manufacturers are required to provide data that supports high long-term retention in cattle including laboratory testing, field trials, and/or sales data from approvals in other countries. Reports of tag retention failures of official tags are followed up and may result in removal of the company’s approval for the tag. From the period between 2013 and 2022, only one company has had approval removed due to tag failure. Tags that are not USDA-approved for use as official ear tags are often intended for feedlot cattle and do not require long-term retention. Livestock producers that place the short-term tags in cattle other than feeders can expect high loss of tags.

Other commenters who opposed the transition to RFID ear tags questioned our legal authority under the Administrative Procedure Act (5 U.S.C. 500 *et seq.*) to change the ear tag requirements using a notice-based procedure rather than rulemaking. Some of these commenters suggested that implementing the proposed RFID requirement would effectively change the regulations in part 86, as well as the domestic animal disease-program regulations in other parts of the Code of Federal Regulations, none of which specify that RFID ear tags are the only ear tags that we recognize as official for interstate movement of cattle and bison. Some commenters expressed opposition to mandatory animal identification and government regulations in general.

³ See ADT Trace Performance Metric Report 2013–2022. <https://www.aphis.usda.gov/traceability/downloads/adt-trace-perf-report-2013-2022.pdf>.

⁴ To view the notice, the assessment, and the comments we received, go to www.regulations.gov and enter APHIS–2020–0022 in the Search field.

Our proposal to implement the transition through a notice-based process was informed by our view that we did not need to amend the regulations. As noted above, we define, in § 86.1 and elsewhere in the regulations, an *official eartag* as “an identification tag approved by APHIS that bears an official identification number for individual animals.” The definition also states that the “design, size, shape, color, and other characteristics of the official eartag will depend on the needs of the users, subject to the approval of the Administrator.” In our view at the time, that definition provided sufficient flexibility to enable us to require the use of RFID eartags when moving cattle and bison interstate.

After reviewing the comments on the July 2020 notice, however, we determined that withdrawing our recognition of visual-only (non-EID) eartags as official eartags for cattle and bison moving interstate would constitute a change in the application of our regulatory requirements of sufficient magnitude to merit rulemaking rather than the notice-based process we originally envisioned. We also determined that the goal of maximizing transparency and public participation would also best be served through rulemaking in this instance. Therefore, on March 23, 2021, we issued a stakeholder announcement indicating that we would not finalize the notice, and that we “would use the rulemaking process for further action related to the proposal.”⁵ Should we propose another change of similar magnitude and scope to our requirements for official eartags for cattle and bison that move interstate at some future date, we would likewise use rulemaking for that proposal.

This proposed rule supersedes the July 2020 notice. In the notice’s stead, we are proposing to amend the regulations to recognize as official eartags for cattle and bison that currently require them for interstate movement only those eartags that are readable both visually and electronically. To allow adequate time for producers to comply with the proposed requirements, the new proposed effective date would be a date 6 months (180 days) after the publication date in the **Federal Register** of a final rule following this proposed rule. As we stated in the notice, non-EID (metal) tags applied to cattle and bison before that date would continue to be recognized as official identification for

the life of the animals. We believe that allowing 6 months (180 days) after publication of a final rule for implementation is appropriate for the following reasons: The primary change proposed is the use of EID eartags rather than non-EID tags for official use. Because all EID tags are readable visually, however, no modifications are necessary to facilities or equipment currently in use. We would also note that animals that would not be impacted by the transition to EID constitute about 89 percent of the national herd of approximately 100 million cattle and bison. Animals not impacted would include animals that do not cross State lines or those already tagged with official EID, as well as animals exempted under the rule such as beef cattle and bison under the age of 18 months and animals going to slaughter or through an APHIS-approved market and then to slaughter.

There are a few aspects of this proposed rule that differ from the July 2020 notice, however. In this proposed rule, as opposed to the July 2020 notice and the existing regulations in part 86, we refer to electronic identification (EID) tags rather than to RFID tags. Currently, the only official electronically readable identification tags are RFID tags; however, at some future time there may be other electronically readable technology. APHIS’ goal is to rapidly and accurately collect the tag numbers and be able to adapt to technological developments, not to codify RFID technology as the only technology option for traceability.

We are also proposing several other changes to part 86 aimed at clarifying the regulations. These include revising the definition of dairy cattle and amending certain provisions pertaining to recordkeeping, and the disposition of slaughter cattle. The specific changes we are proposing are discussed in detail below.

Definitions

The current definition of an *approved tagging site* is: “A premises, authorized by APHIS, State, or Tribal animal health officials, where livestock may be officially identified on behalf of their owner or the person in possession, care, or control of the animals when they are brought to the premises.” We would revise the definition of *approved tagging site* to read as follows: “A premises, authorized by APHIS, State, or Tribal animal health officials, where livestock without official identification may be transferred to have official identification applied on behalf of their owner or the person in possession, care, or control of the animals when they are brought to

the premises.” This proposed definition, while very similar to the existing one, offers greater clarity regarding the nature of an approved tagging site, specifying that such sites are where official identification tags are physically applied to animals.

The current definition of dairy cattle is: “All cattle, regardless of age or sex or current use, that are of a breed(s) used to produce milk or other dairy products for human consumption, including, but not limited to, Ayrshire, Brown Swiss, Holstein, Jersey, Guernsey, Milking Shorthorn, and Red and Whites.” We are proposing to revise the definition of dairy cattle to read as follows: “All cattle, regardless of age or sex, breed, or current use, that are born on a dairy farm or are of a breed(s) used to produce milk or other dairy products for human consumption, or cross bred calves of any breed that are born to dairy cattle including, but not limited to, Ayrshire, Brown Swiss, Holstein, Jersey, Guernsey, Milking Shorthorn, and Red and Whites. This proposed definition differs from the existing one in that it includes not only certain breeds that are reared specifically to produce milk or other dairy products but also other cattle that are reared under the same management practices as purebred dairy cattle. Under part 86, dairy cattle have different requirements for official identification and movement documentation from beef cattle because of the increased risks that dairy animals have for contracting diseases early in life. Dairy farm management practices result in higher risk of disease transmission and include practices such as pooling colostrum from multiple cows for many calves, commingling calves at different locations during their lifetimes, and movement to many destinations. Because the increased disease risk is due to the management of the cattle rather than their genetic makeup as a dairy breed, it is necessary to change the definition accordingly. We welcome comments from the public on this issue.

We are proposing some editorial and formatting changes to the definition of *interstate certificate of veterinary inspection (ICVI)*. The existing definition contains requirements pertaining only to paper ICVIs, but electronic ICVIs are now commonly used and accepted across the United States for animal movement. Our proposed editorial changes would account for electronic ICVIs as well as paper ones. The proposed formatting changes would make the definition clearer and easier for users to understand. Substantively, however, the

⁵ See https://www.aphis.usda.gov/aphis/newsroom/news/sa_by_date/sa-2021/rfid-traceability-rulemaking.

revised definition would not otherwise change the definition.

We are proposing to add to § 86.1 a definition of *Official Animal Identification Device Standards (OAIDS)*. The proposed definition would state that the OAIDS is a document providing further information regarding official identification device recordkeeping requirements contained in the regulations. The definition would also indicate that when APHIS updates or modifies the standards, an announcement will be made to the public by means of a notice published in the **Federal Register**. The notice-based process would provide the regulatory flexibility needed to account for rapid advances in EID technology. The OAIDS replaces the old title for the document, the Animal Disease Traceability General Standards document. In our view, the new title more accurately reflects the content of the document, which focuses on official identification devices. There would also be some substantive changes to the document, as discussed below.

In broad terms, the proposed OAIDS, like the existing Standards document, would provide guidelines, technical standards, and specifications for tag manufacturers requesting APHIS approval of new official identification devices. The requirements contained in both documents reflect our recognition of the importance of quality in tag design, safety, and retention. We have determined, however, that some of our current requirements may be burdensome and inhibit manufacturers seeking APHIS approval of new official identification devices. Therefore, the proposed OAIDS would streamline the process for approval of new EID tags and reduce the burden for development of new tags. Specific changes would include the following:

- Accepting EID device testing equivalent to International Committee for Animal Recording (ICAR) testing and allowing APHIS to consider requests, on a case-by-case basis, for approval of alternative field trials or eartags with previously generated verifiable data if equivalency to the standards is demonstrated;
- Modifying the field trial requirements by reducing timelines for the three approval statuses (trial, preliminary, and conditional), reducing the number of required field trial locations, and reducing the number of cattle and bison required for field trials; and
- Reducing the timeframe before allowing unlimited sales of devices from a minimum of 24 months to a minimum

of 12 months if devices meet the required performance standards.

In addition, the OAIDS would be updated to correspond with the changes in this proposed rule. These updates would include removing some language that no longer applies pertaining to National Uniform Eartagging Standards (NUES) metal tags, which are non-EID tags, and adding a new section on USDA backtags. There would be additional, nonsubstantive edits made to clarify wording and to format tables consistently.

We are proposing to revise the definition of *official eartag* to read as “An identification tag approved by APHIS that bears an official identification number for individual animals. The design, size, shape, color, and other characteristics of the official eartag will depend on the needs of the users, subject to the approval of the Administrator. The official eartag must be tamper-resistant and have a high retention rate in the animal.” This proposed definition is largely the same as the existing one, except for the removal of the following language: “Beginning March 11, 2014, all official eartags manufactured must bear an official eartag shield. Beginning March 11, 2015, all official eartags applied to animals must bear an official eartag shield.” Those dates are no longer relevant. There are still many eartags in use that were grandfathered in under the January 2013 final rule because they were applied to animals prior to then; however, all eartags that have been applied to cattle and bison since the implementation dates provided in the current regulations meet the above requirements. A list of currently approved eartags is available at https://www.aphis.usda.gov/traceability/downloads/ADT_device_ain.pdf.

Recordkeeping

The existing recordkeeping requirements in § 86.3 do not address such issues as record accuracy, quality, completeness, availability, and accessibility. In the case of a fast-moving disease, records that are not readily available to enable the tracing of diseased or exposed animals in adequate time to contain the outbreak provide little value. We are therefore proposing to revise § 86.3 to address these deficiencies. The proposed changes are discussed in detail below.

Current § 86.3(a) states that any State, Tribe, accredited veterinarian, or other person or entity who distributes official identification devices must maintain for 5 years a record of the names and addresses of anyone to whom the devices were distributed. To address the

issues of availability and accessibility, we are proposing to add a requirement to that paragraph that official identification device distribution records must be entered by the person distributing the devices into the Tribal, State, or Federal databases designated by each government entity to meet their tag tracing requirements. States and Tribal governments and accredited veterinarians may also use APHIS’ tag manager database at no cost. The revised paragraph would also include a statement indicating that OAIDS would contain more specific details on how to meet the requirements of § 86.3 and which parties would be responsible for meeting them.

The requirements contained in current paragraph (b), pertaining to record retention requirements for ICVIs or alternate documentation, would appear under paragraph (c) in this proposed rule. We are proposing to add a new paragraph (b), which would state that records of official identification devices applied by a federally accredited veterinarian to a client animal must be recorded in a readily accessible record system. This may be the veterinarian’s medical records system or comparable means of record management. Alternately, the veterinarian may use APHIS’ tag management database at no cost to record tag distributions. This proposed requirement would help to ensure that such records are available to APHIS when needed for traceback investigations.

Finally, we would add a new paragraph (d) to § 86.3 stating that records required under paragraphs (a) through (c) of the section would have to be maintained by the responsible person or entity and be of sufficient accuracy, quality, and completeness to demonstrate compliance with all conditions and requirements under part 86. The paragraph would further state that, during normal business hours, APHIS must be allowed access to all records, to include visual inspection and reproduction (e.g., photocopying, digital reproduction). Because disease tracing may involve multiple movements of animals among many locations and persons, prolonged retrieval of tracing information can create significant delays in the containment of serious threats to the livestock industry. For this reason, the responsible person or entity must submit to APHIS all reports and notices containing the information specified within 48 hours of receipt. We welcome comments from the public on this proposed timeline.

Official Identification

We are proposing to revise § 86.4(a) introductory text by adding a sentence stating that additional information on official identification devices, methods, and the approval process can be found in the OAIMS.

We are proposing to revise § 86.4(a)(1)(i) to add the requirement, discussed above, that beginning 6 months (180 days) after the publication date of a final rule following this proposed rule, all official eartags sold for or applied to cattle and bison must be readable both visually and electronically. This requirement would enhance our traceback investigation capabilities because, as discussed in greater detail above, EID eartags and electronic recordkeeping allow for greater efficiency and accuracy than do non-EID eartags and paper records. EID tags enable producers or officials to capture accurately animal identification numbers almost instantly, without the need for animal restraint, and to transmit those numbers to a connected electronic database. The use of such tags, therefore, facilitates electronic recordkeeping, which, however, would not be required under this proposed rule.

The existing regulations in § 86.4(b)(1)(ii) allow cattle to move interstate to an approved livestock market and then to slaughter or directly to slaughter without official identification. Current § 86.4(b)(1)(ii)(C) stipulates that the cattle or bison must be identified if held for more than 3 days. The existing regulations are silent on identification requirements for slaughter cattle or bison that are not held at slaughter or held at slaughter for 3 or fewer days and then move to a new location. As noted earlier, difficulties in tracking animals leaving slaughter channels have been identified by State officials as a major gap in traceability, because cattle and bison may move to slaughter without official identification or ICVIs. If they leave the slaughter channel, they may become untraceable.

We are therefore proposing to add paragraph (b)(1)(ii)(D) to § 86.4. The paragraph would read as follows:

- Cattle and bison leaving a slaughter establishment may only be moved to another recognized slaughter establishment or approved feedlot and can only be sold/re-sold as slaughter cattle and must be accompanied by an owner-shipper statement in accordance with § 86.5(c)(1). Information listed on the owner-shipper statement must include the name and address of the slaughter establishment from which the animals left, the official identification

numbers, as defined in § 86.1, correlated with the USDA backtag number (if available), the name of the destination slaughter establishment, or approved feedlot (as defined in 9 CFR 77.5) to which the animals are being shipped.

These proposed requirements clarify that the animals must stay within the intended terminal slaughter channels but may be moved to an additional slaughter plant or approved feedlot with appropriate documentation and identification.

Current § 86.4(b)(1)(iii) lists the following categories of cattle and bison as covered by the official identification requirements for interstate movement:

- All sexually intact cattle and bison 18 months of age or over;
- All female dairy cattle of any age and all dairy males born after March 11, 2013;
- Cattle and bison of any age used for rodeo or recreational events; and
- Cattle and bison of any age used for shows or exhibitions.

Because, as described earlier, we are proposing to amend the definition of *dairy cattle* to reflect the management practices of the premises on which the animals are raised, we would revise paragraph (b)(1)(iii)(B) so that the official identification requirements would apply to all dairy cattle, including offspring of dairy cattle, rather than all females and all males born after March 11, 2013. There exists the possibility that as a result of these proposed changes, more animals may be subject to the official identification requirements for interstate movement than are currently. As we note in the economic analysis accompanying this proposed rule, we are seeking public comment on this issue.

Currently, paragraph (c)(3) of § 86.4 allows the application of either a non-EID or an RFID eartag with an animal identification number (AIN) having an 840 prefix to animals already tagged with National Uniform Eartagging System (NUES) tags and/or brucellosis vaccination eartags. We are proposing to revise that paragraph to state that a visually and electronically readable official eartag may be applied to animals currently identified with non-EID official eartags or vaccination tags. Our proposed revision would codify the EID eartag requirement and provide the regulatory flexibility to allow us to account for the development of new EID technologies. In order to allow for the possibility that different numbering systems may be developed and used in the future on EID eartags, the revised paragraph would not specify that the visually and electronically readable eartag would have to have an AIN with

an 840 prefix and would not refer specifically to NUES eartags.

We are proposing to remove § 86.4(c)(4), which states that a brucellosis vaccination visual eartag with a NUES number may be applied in accordance with the regulations in 9 CFR part 78 to an animal that is already officially identified with one or more official eartags under this part. As a result of this rulemaking, the visual, *i.e.*, non-EID, brucellosis NUES tag would no longer be allowed as official identification under part 86, which eliminates the need for the paragraph.

Throughout current § 86.4(e), there are references to RFID devices. For reasons discussed above, proposed § 86.4(e) would refer to EID devices instead.

Documentation

Current § 86.5(c)(7)(ii) states that, with certain exceptions, the official identification numbers of cattle or bison moving interstate must be recorded on the ICVI or alternate documentation unless the cattle and bison that are sexually intact and under 18 months of age or are steers or spayed heifers. One of those exceptions covers sexually intact dairy cattle, *i.e.*, recording of official identification numbers is required when such cattle are moved interstate. We are proposing to amend that paragraph by removing the qualifier “sexually intact.” This proposed change accords with the change we are proposing to the definition of *dairy cattle*, as discussed earlier, and our view of the risks associated with such cattle.

We are not proposing to make any other substantive changes to § 86.5, but we would reorganize the section such that the documentation requirements, which are listed by species, would be ordered in a manner consistent with other sections of part 86. We are also proposing to update the terminology in this section, as discussed under the heading Miscellaneous below.

Changes to Other Parts of the Regulations

In 9 CFR parts 71, 77, and 78, respectively, we are proposing to revise definitions of *official eartag* and *interstate certificate of veterinary inspection (ICVI)* to correspond with the changes to the definitions that we are proposing for part 86.

Miscellaneous

Sections 86.3, 86.4, and 86.5 contain numerous references to “equines.” To make our terminology consistent with current usage, we propose to substitute “equids” or “equine species,” as appropriate, in each of those instances.

Executive Orders 12866, 13563, and Regulatory Flexibility Act

This proposed rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which 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, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides an initial regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the *Regulations.gov* website (see **ADDRESSES** above for instructions for accessing *Regulations.gov*).

We are proposing to amend the animal disease traceability regulations to recognize only eartags that are both visually and electronically readable as official eartags for use for interstate movement of cattle and bison that are covered under the regulations. We are also proposing to clarify certain record retention and record access requirements. These proposed changes would enhance the ability of State, Federal, and private veterinarians, and livestock producers to quickly respond to high-impact diseases currently existing in the United States, as well as foreign animal diseases that threaten the viability of the U.S. cattle and bison industries. The benefits of animal disease traceability include: Enhancing the ability of the United States to regionalize and compartmentalize animal health issues, minimizing the costs of disease outbreaks, and enabling the reestablishment of foreign and domestic market access with minimum delay following an animal disease event.

APHIS conducted a benefit-cost analysis to determine how the transition to electronic identification (EID) tags would affect the cattle and bison industries. Our analysis suggests that approximately 11 million cattle are

currently tagged with official non-EID eartags per year. The proposed rule would not change the number of cattle tagged, but it would increase the costs associated with tagging. The estimated total average annual cost of purchasing approximately 11 million EID tags, instead of the non-EID tags, is approximately \$26.1 million dollars per year, or \$30.45 per cattle or bison operation.

RFID technology, a type of electronic identification, has been available in the livestock industry for many years. APHIS has evaluated the cost structure of different RFID technologies, commonly known as FDX and HDX. Both technologies work well and have similar qualities. This report describes the cost structure of these EID eartags. We provide 10 years of historic population levels for cattle and bison in order to provide the reader with a range of cost estimates based upon a fluctuating cattle and bison population.

EID technology is a vital component to efficient and accurate traceability of cattle and bison. It benefits stakeholders by significantly reducing the numbers of animals and response time involved in a disease investigation.

One of the most significant benefits of the proposed rule would be the enhanced ability of the United States to regionalize and compartmentalize animal disease outbreaks more quickly. Regionalization is the concept of separating subpopulations of animals in order to maintain a specific health status in one or more disease-free regions or zones. This risk-based process can help to mitigate the adverse economic effects of a disease outbreak. Traceability of animals is necessary to form these zones that facilitate reestablishment of foreign and domestic market access with minimum delay in the wake of an animal disease event. Having an EID system in place would, therefore, minimize not only the spread of disease but also the trade impacts an outbreak may have.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no

retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of 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 policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

APHIS has determined that this proposed rule, if finalized, may have substantial direct effects on one or more Tribes, and that affording Tribes an opportunity for consultation is therefore warranted. Accordingly, APHIS provided a webinar to Tribal nations on October 27, 2021, to notify Tribes of this rulemaking and solicit consultation. The Tribal leaders welcomed the presentation and requested a follow up webinar, which was presented June 23, 2022. APHIS met in person with representatives of the Indian Nation Conservation Alliance (INCA) in October 2022, to give additional updates. INCA is an alliance of Tribal conservation districts covering most of the western half of the United States. APHIS will work with the Office of Tribal Relations to ensure that additional outreach occurs in 202.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the reporting, recordkeeping, and third-party disclosure requirements described in this proposed rule are currently approved by the Office of Management and Budget (OMB) under OMB control number 0579-0327.

The trace/test exercises referenced on earlier in this document are conducted as part of APHIS' ADT cooperative agreements with State, territorial, and Tribal governments. The existing collection referenced above (0579-0327) covers the cooperative agreements, including associated recordkeeping. Under the cooperative agreements, State, territorial, and Tribal governments must, each quarter, report successful completion of the goals and

objectives outlined in the agreements. This includes evaluating performance, acknowledge current tracing capabilities, and identifying traceability risks within the State, Tribe, or territory; governments must conduct test exercises to evaluate performance and identify risks. Governmental entities must also submit cooperative agreement “road maps” that outline at least four animal disease traceability performance measures. APHIS tracks governmental entity recordkeeping for cooperative agreement paperwork as part of 0579–0327.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Mr. Joseph Moxey, APHIS’ Paperwork Reduction Act Coordinator, at (301) 851–2483.

Lists of Subjects

9 CFR Part 71

Animal diseases, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 77

Animal diseases, Bison, Cattle, Reporting and recordkeeping requirements, Transportation, Tuberculosis.

9 CFR Part 78

Animal diseases, Bison, Cattle, Quarantine, Reporting and recordkeeping requirements, Swine, Transportation.

9 CFR Part 86

Animal diseases, Bison, Cattle, Livestock, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR parts 71, 77, 78, and 86 as follows:

PART 71—GENERAL PROVISIONS

- 1. The authority citation for part 71 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

- 2. Amend § 71.1 by revising the definition of “Official eartag” to read as follows:

§ 71.1 Definitions.

* * * * *

Official eartag. An identification tag approved by APHIS that bears an official identification number for individual animals. The design, size, shape, color, and other characteristics of the official eartag will depend on the needs of the users, subject to the approval of the Administrator. The official eartag must be tamper-resistant and have a high retention rate in the animal.

* * * * *

PART 77—TUBERCULOSIS

- 3. The authority citation for part 77 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

- 4. Amend § 77.2, by revising the definitions of “Interstate certificate of veterinary inspection (ICVI)” and “Official eartag” to read as follows:

§ 77.2 Definitions.

* * * * *

Interstate certificate of veterinary inspection (ICVI). An official document issued by a Federal, State, Tribal, or accredited veterinarian certifying the inspection of animals in preparation for interstate movement.

(1) The ICVI must show:

- (i) The species of animals covered by the ICVI;
- (ii) The number of animals covered by the ICVI;
- (iii) The purpose for which the animals are to be moved;
- (iv) The address at which the animals were loaded for interstate movement;
- (v) The address to which the animals are destined; and
- (vi) The names of the consignor and the consignee and their addresses if different from the address at which the animals were loaded or the address to which the animals are destined.

(vii) Additionally, unless the species-specific requirements for ICVIs provide an exception, the ICVI must list the official identification number of each animal, except as provided in paragraph (2) of this definition, or group of animals moved that is required to be officially identified, or, if an alternative form of identification has been agreed upon by the sending and receiving States, the ICVI must include a record of that identification. If animals moving under a GIN also have individual official identification, only the GIN must be listed on the ICVI. An ICVI may not be issued for any animal that is not officially identified if official identification is required. If the animals are not required by the regulations to be

officially identified, the ICVI must state the exemption that applies (e.g., the cattle and bison do not belong to one of the classes of cattle and bison to which the official identification requirements of this part apply). If the animals are required to be officially identified but the identification number does not have to be recorded on the ICVI, the ICVI must state that all animals to be moved under the ICVI are officially identified.

(2) As an alternative to recording individual animal identification on an ICVI, if agreed to by the receiving State or Tribe, another document may be attached to provide this information, but only under the following conditions:

(i) The document must be a State form or APHIS form that requires individual identification of animals or a printout of official identification numbers generated by computer or other means;

(ii) A legible copy of the document must be attached to the original and each copy of the ICVI;

(iii) Each copy of the document must identify each animal to be moved with the ICVI. The document must not contain any information pertaining to other animals; and

(iv) The following information must be included in the identification column on the original and each copy of the ICVI:

(A) The name of the document; and

(B) Either the unique serial number on the document or both the name of the person who prepared the document and the date the document was signed.

* * * * *

Official eartag. An identification tag approved by APHIS that bears an official identification number for individual animals. The design, size, shape, color, and other characteristics of the official eartag will depend on the needs of the users, subject to the approval of the Administrator. The official eartag must be tamper-resistant and have a high retention rate in the animal.

* * * * *

PART 78—BRUCELLOSIS

- 5. The authority citation for part 78 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

- 6. Amend § 78.1 by revising the definitions of “Interstate certificate of veterinary inspection (ICVI)” and “Official eartag” to read as follows:

§ 78.1 Definitions.

* * * * *

Interstate certificate of veterinary inspection (ICVI). An official document

issued by a Federal, State, Tribal, or accredited veterinarian certifying the inspection of animals in preparation for interstate movement.

(1) The ICVI must show:

- (i) The species of animals covered by the ICVI;
- (ii) The number of animals covered by the ICVI;
- (iii) The purpose for which the animals are to be moved;
- (iv) The address at which the animals were loaded for interstate movement;
- (v) The address to which the animals are destined; and
- (vi) The names of the consignor and the consignee and their addresses if different from the address at which the animals were loaded or the address to which the animals are destined.

(vii) Additionally, unless the species-specific requirements for ICVIs provide an exception, the ICVI must list the official identification number of each animal, except as provided in paragraph (2) of this definition, or group of animals moved that is required to be officially identified, or, if an alternative form of identification has been agreed upon by the sending and receiving States, the ICVI must include a record of that identification. If animals moving under a GIN also have individual official identification, only the GIN must be listed on the ICVI. An ICVI may not be issued for any animal that is not officially identified if official identification is required. If the animals are not required by the regulations to be officially identified, the ICVI must state the exemption that applies (e.g., the cattle and bison do not belong to one of the classes of cattle and bison to which the official identification requirements of this part apply). If the animals are required to be officially identified but the identification number does not have to be recorded on the ICVI, the ICVI must state that all animals to be moved under the ICVI are officially identified.

(2) As an alternative to recording individual animal identification on an ICVI, if agreed to by the receiving State or Tribe, another document may be attached to provide this information, but only under the following conditions:

- (i) The document must be a Tribal or State form or APHIS form that requires individual identification of animals or a printout of official identification numbers generated by computer or other means;
- (ii) A legible copy of the document must be attached to the original and each copy of the ICVI;
- (iii) Each copy of the document must identify each animal to be moved with the ICVI. The document must not

contain any information pertaining to other animals; and

(iv) The following information must be included in the identification column on the original and each copy of the ICVI:

- (A) The name of the document; and
- (B) Either the unique serial number on the document or both the name of the person who prepared the document and the date the document was signed.

* * * * *

Official eartag. An identification tag approved by APHIS that bears an official identification number for individual animals. The design, size, shape, color, and other characteristics of the official eartag will depend on the needs of the users, subject to the approval of the Administrator. The official eartag must be tamper-resistant and have a high retention rate in the animal.

* * * * *

PART 86—ANIMAL DISEASE TRACEABILITY

■ 7. The authority citation for part 86 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

- 8. Amend § 86.1 by:
 - a. Revising the definitions of “Approved tagging site”, “Dairy cattle”, and “Interstate certificate of veterinary inspection (ICVI)”;
 - b. Adding in alphabetical order the definition for “Official Animal Identification Device Standards (OAIDS)”;
 - c. Revising the definition of “Official eartag”.

The revisions and addition read as follows:

§ 86.1 Definitions.

* * * * *

Approved tagging site. A premises, authorized by APHIS, State, or Tribal animal health officials, where livestock without official identification may be transferred to have official identification applied on behalf of their owner or the person in possession, care, or control of the animals when they are brought to the premises.

* * * * *

Dairy cattle. All cattle, regardless of age or sex, breed, or current use, that are born on a dairy farm or of a breed(s) used to produce milk or other dairy products for human consumption, or cross bred calves of any breed that are born to dairy cattle including, but not limited to, Ayrshire, Brown Swiss, Holstein, Jersey, Guernsey, Milking Shorthorn, and Red and Whites.

* * * * *

Interstate certificate of veterinary inspection (ICVI). An official document issued by a Federal, State, or Tribal government, or an accredited veterinarian, certifying the inspection of animals in preparation for interstate movement.

- (1) The ICVI must show:
 - (i) The species of animals covered by the ICVI;
 - (ii) The number of animals covered by the ICVI;
 - (iii) The purpose for which the animals are to be moved;
 - (iv) The address at which the animals were loaded for interstate movement;
 - (v) The address to which the animals are destined; and
 - (vi) The names of the consignor and the consignee and their addresses if different from the address at which the animals were loaded or the address to which the animals are destined.

(vii) Additionally, unless the species-specific requirements for ICVIs provide an exception, the ICVI must list the official identification number of each animal, except as provided in paragraph (2) of this definition, or group of animals moved that is required to be officially identified, or, if an alternative form of identification has been agreed upon by the sending and receiving States, the ICVI must include a record of that identification. If animals moving under a GIN also have individual official identification, only the GIN must be listed on the ICVI. An ICVI may not be issued for any animal that is not officially identified if official identification is required. If the animals are not required by the regulations to be officially identified, the ICVI must state the exemption that applies (e.g., the cattle and bison do not belong to one of the classes of cattle and bison to which the official identification requirements of this part apply). If the animals are required to be officially identified but the identification number does not have to be recorded on the ICVI, the ICVI must state that all animals to be moved under the ICVI are officially identified.

(2) As an alternative to recording individual animal identification on an ICVI, if agreed to by the receiving State or Tribe, another document may be attached to provide this information, but only under the following conditions:

- (i) The document must be a State form or APHIS form that requires individual identification of animals or a printout of official identification numbers generated by computer or other means;
- (ii) A legible copy of the document must be attached to the original and each copy of the ICVI;
- (iii) Each copy of the document must identify each animal to be moved with

the ICVI. The document must not contain any information pertaining to other animals; and

(iv) The following information must be included in the identification column on the original and each copy of the ICVI:

- (A) The name of the document; and
- (B) Either the unique serial number on the document or both the name of the person who prepared the document and the date the document was signed.

* * * * *

Official Animal Identification Device Standards (OAIDS). A document providing further information regarding the official identification device recordkeeping requirements of this part, and technical descriptions, specifications, and details under which APHIS would approve identification devices for official use. Updates or modifications to the Standards document will be announced to the public by means of a notice published in the **Federal Register**.

Official eartag. An identification tag approved by APHIS that bears an official identification number for individual animals. The design, size, shape, color, and other characteristics of the official eartag will depend on the needs of the users, subject to the approval of the Administrator. The official eartag must be tamper-resistant and have a high retention rate in the animal.

* * * * *

■ 9. Revise § 86.3 to read as follows:

§ 86.3 Recordkeeping requirements.

(a) Any State, Tribe, accredited veterinarian, or other person or entity who distributes official identification devices must maintain for 5 years a record of the names and addresses of anyone to whom the devices were distributed. Official identification device distribution records must be entered by the person distributing the devices into the State or Federal database designated by APHIS. Additional guidance on meeting these recordkeeping requirements is found in the OAIDS.

(b) Records of official identification devices applied by a federally accredited veterinarian to a client animal must be kept in a readily accessible record system.

(c) Approved livestock facilities must keep any ICVIs or alternate documentation that is required by this part for the interstate movement of covered livestock that enter the facility on or after March 11, 2013. For poultry and swine, such documents must be kept for at least 2 years, and for cattle

and bison, sheep and goats, cervids, and equids, 5 years.

(d) Records required under paragraphs (a) through (c) of this section must be maintained by the responsible person or entity and must be of sufficient accuracy, quality, and completeness to demonstrate compliance with all conditions and requirements under this part. During normal business hours, APHIS must be allowed access to all records, to include visual inspection and reproduction (e.g., photocopying, digital reproduction). The responsible person or entity must submit to APHIS all reports and notices containing the information specified within 48 hours of receipt of request or earlier if warranted by an emergency disease response.

■ 10. Amend § 86.4 by:

- a. Revising paragraphs (a) introductory text and (a)(1)(i);
- b. Removing in paragraphs (a)(2)(i) and (iv) the word “equine” each time it appears and adding in its place the word “equid”;
- c. Removing in paragraph (a)(2)(iii) the words “to the equine” and adding in their place the words “into the equid”;
- d. Removing in paragraph (a)(2)(v) the word “equines” and adding in their place the word “equids”;
- e. Adding paragraph (b)(1)(ii)(D);
- f. Revising paragraphs (b)(1)(iii)(B), (b)(4) introductory text, and (c)(3);
- g. Removing paragraph (c)(4);
- h. Revising paragraphs (e)(1)(iii) and (iv); and
- i. Adding in paragraph (e)(2)(iv), by adding the words “or other EID” between the words “RFID” and “eartag”.

The addition and revisions read as follows:

§ 86.4 Official identification.

(a) *Official identification devices and methods.* The Administrator has approved the following official identification devices or methods for the species listed. The Administrator may authorize the use of additional devices or methods for a specific species if he or she determines that such additional devices or methods will provide for adequate traceability. Additional guidance on official identification devices, methods, and the approval process is found in the Official Animal Identification Device Standards (OAIDS) document.

(1) * * *

(i) For an official eartag, beginning [Date 180 days after the date of publication of a final rule in the **Federal Register**], all official eartags sold for or applied to cattle and bison must be

readable both visually and electronically (EID);

* * * * *

- (b) * * *
- (1) * * *
- (ii) * * *

(D) Cattle and bison leaving a slaughter establishment may only be moved to another recognized slaughter establishment or approved feedlot and can only be sold/re-sold as slaughter cattle, and must be accompanied by an owner-shipper statement in accordance with § 86.5(c)(1). Information listed on the document must include the name and address of the slaughter establishment from which the animals left, the official identification numbers, as defined in § 86.1, correlated with the USDA backtag number (if available), the name of the destination slaughter establishment, or approved feedlot (as defined in § 77.5 of this subchapter) to which the animals are being shipped.

(iii) * * *

(B) All dairy cattle;

* * * * *

(4) *Horses and other equids.* Horses and other equids moving interstate must be officially identified prior to the interstate movement, using an official identification device or method listed in paragraph (a)(2) of this section unless:

* * * * *

(c) * * *

(3) A visually and electronically readable eartag may be applied to an animal that is already officially identified with one or more non-EID official eartags and/or a non-EID official vaccination eartag used for brucellosis. The person applying the new visually and electronically readable eartag must record the date the eartag is applied to the animal and the official identification numbers of both official eartags and must maintain those records for 5 years.

* * * * *

(e) * * *

(1) * * *

(iii) Malfunction of the electronic component of an electronically readable (EID) device; or

(iv) Incompatibility or inoperability of the electronic component of an EID device with the management system or unacceptable functionality of the management system due to use of an EID device.

* * * * *

■ 11. Revise § 86.5 to read as follows:

§ 86.5 Documentation requirements for interstate movement of covered livestock.

(a) *Responsible persons and required documentation.* The persons responsible for animals leaving a premises for interstate movement must

ensure that the animals are accompanied by an interstate certificate of veterinary inspection (ICVI) or other document required by this part for the interstate movement of animals.

(b) *Forwarding of documents.* (1) The APHIS representative, State or Tribal representative, or accredited veterinarian issuing an ICVI or other document required for the interstate movement of animals under this part must forward a copy of the ICVI or other document to the State or Tribal animal health official of the State or Tribe of origin within 7 calendar days from the date on which the ICVI or other document is issued. The State or Tribal animal health official in the State or Tribe of origin must forward a copy of the ICVI or other document to the State or Tribal animal health official the State or Tribe of destination within 7 calendar days from date on which the ICVI or other document is received.

(2) The animal health official or accredited veterinarian issuing or receiving an ICVI or other interstate movement document in accordance with paragraph (b)(1) of this section must keep a copy of the ICVI or alternate documentation. For poultry and swine, such documents must be kept for at least 2 years, and for cattle and bison, sheep and goats, cervids, and equine species, 5 years.

(c) *Cattle and bison.* Cattle and bison moved interstate must be accompanied by an ICVI unless:

(1) They are moved directly to a recognized slaughtering establishment, or directly to an approved livestock facility and then directly to a recognized slaughtering establishment, and they are accompanied by an owner-shipper statement.

(2) They are moved directly to an approved livestock facility with an owner-shipper statement and do not move interstate from the facility unless accompanied by an ICVI.

(3) They are moved from the farm of origin for veterinary medical examination or treatment and returned to the farm of origin without change in ownership.

(4) They are moved directly from one State through another State and back to the original State.

(5) They are moved as a commuter herd with a copy of the commuter herd agreement or other document as agreed to by the States or Tribes involved in the movement.

(6) Additionally, cattle and bison may be moved between shipping and receiving States or Tribes with documentation other than an ICVI, *e.g.*, a brand inspection certificate, as agreed

upon by animal health officials in the shipping and receiving States or Tribes.

(7) The official identification number of cattle or bison must be recorded on the ICVI or alternate documentation unless:

(i) The cattle or bison are moved from an approved livestock facility directly to a recognized slaughtering establishment; or

(ii) The cattle and bison are sexually intact cattle or bison under 18 months of age or steers or spayed heifers; *Except that:* This exception does not apply to dairy cattle of any age or to cattle or bison used for rodeo, exhibition, or recreational purposes.

(d) *Horses and other equine species.* Horses and other equine species moved interstate must be accompanied by an ICVI unless:

(1) They are used as the mode of transportation (horseback, horse and buggy) for travel to another location and then return direct to the original location; or

(2) They are moved from the farm or stable for veterinary medical examination or treatment and returned to the same location without change in ownership; or

(3) They are moved directly from a location in one State through another State to a second location in the original State.

(4) Additionally, equids may be moved between shipping and receiving States or Tribes with documentation other than an ICVI, *e.g.*, an equine infectious anemia test chart, as agreed to by the shipping and receiving States or Tribes involved in the movement.

(5) Equids moving commercially to slaughter must be accompanied by documentation in accordance with part 88 of this subchapter. Equine infectious anemia reactors moving interstate must be accompanied by documentation as required by part 75 of this subchapter.

(e) *Poultry.* Poultry moved interstate must be accompanied by an ICVI unless:

(1) They are from a flock participating in the National Poultry Improvement Plan (NPIP) and are accompanied by the documentation required under the NPIP regulations (parts 145 through 147 of this chapter) for participation in that program; or

(2) They are moved directly to a recognized slaughtering or rendering establishment; or

(3) They are moved from the farm of origin for veterinary medical examination, treatment, or diagnostic purposes and either returned to the farm of origin without change in ownership or euthanized and disposed of at the veterinary facility; or

(4) They are moved directly from one State through another State and back to the original State; or

(5) They are moved between shipping and receiving States or Tribes with a VS Form 9–3 or documentation other than an ICVI, as agreed upon by animal health officials in the shipping and receiving States or Tribes; or

(6) They are moved under permit in accordance with part 82 of this subchapter.

(f) *Sheep and goats.* Sheep and goats moved interstate must be accompanied by documentation as required by part 79 of this subchapter.

(g) *Swine.* Swine moved interstate must be accompanied by documentation in accordance with § 71.19 of this subchapter or, if applicable, with part 85 of this subchapter.

(h) *Captive cervids.* Captive cervids moved interstate must be accompanied by documentation as required by part 77 of this subchapter.

Done in Washington, DC, this 5th day of January 2023.

Jennifer Moffitt,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2023–00505 Filed 1–18–23; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0016; Project Identifier MCAI–2022–00416–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus Helicopters Model EC120B, EC130B4, and EC130T2 helicopters. This proposed AD was prompted by a report of corrosion detected on certain part-numbered landing gear assemblies. This proposed AD would require, for helicopters with certain part-numbered landing gear assemblies installed, visually inspecting for cracks and corrosion; borescope inspecting; and if required, removing corrosion, measuring thickness, interpreting results of the measurements, applying chemical conversion coating and primer, and removing affected parts

(landing gear assembly) and affected part sub-assemblies (front or rear crossbeam or left-hand or right-hand skid assembly) from service and replacing with airworthy parts. This proposed AD would allow an affected part or affected part sub-assembly to be installed on a helicopter if certain actions in this proposed AD are accomplished. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by March 6, 2023.

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

- *Federal eRulemaking Portal:* Go to [regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- *Fax:* (202) 493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2023-0016; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For service information identified in this NPRM, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at www.airbus.com/helicopters/services/technical-support.html.

- You may view this material 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. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2023-0016.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include “Docket No.

FAA-2023-0016; Project Identifier MCAI-2022-00416-R” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Stephanie Sunderbruch, Aerospace Engineer, Safety Risk Management Section, Systems Policy Branch, Policy & Innovation Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-4659; email Stephanie.L.Sunderbruch@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022-0053, dated March 23, 2022 (EASA AD 2022-0053), to correct an unsafe condition for Airbus Helicopters Model EC 120 B, EC 130 B4, and EC 130 T2 helicopters, all serial numbers. EASA advises an occurrence was reported of corrosion found on a landing gear assembly of a Model EC 130

helicopter. EASA further advises that other helicopter models are affected by the same unsafe condition due to design similarity. This condition, if not addressed, could result in the landing gear collapsing, damage to the helicopter, and injury to occupants.

Accordingly, EASA AD 2022-0053 requires, for helicopters with certain part-numbered landing gear assemblies installed, a one-time visual inspection of the external areas of the landing gear tubes for corrosion and cracks, and a borescope inspection of the internal sides of the landing gear tubes for corrosion (including, but not limited to, leafing and exfoliant corrosion) and cracks. EASA AD 2022-0053 also requires contacting Airbus Helicopters for approved corrective action if any crack, or leafing or exfoliant corrosion, is found or if the remaining thickness of affected part sub-assemblies do not meet specified acceptability criteria during any of the inspections. EASA AD 2022-0053 allows replacing the affected part sub-assembly in lieu of contacting Airbus Helicopters for approved corrective action. EASA AD 2022-0053 also requires reporting inspection results to Airbus Helicopters within 30 days after the inspection or within 30 days after the effective date of EASA AD 2022-0053, whichever occurs later.

Additionally, EASA AD 2022-0053 allows credit for certain inspections and corrective actions if those actions were done before the effective date of EASA AD 2022-0053, and allows an affected part or affected part sub-assembly to be installed on a helicopter if certain requirements of EASA AD 2022-0053 are met. EASA considers its AD an interim action and states that further AD action may follow.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of these same type designs.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Airbus Helicopters Alert Service Bulletin (ASB) No. EC120-32A014 (EC120-32A014 Rev 1), for Model EC120B helicopters and Airbus Helicopters ASB No. EC130-32A013 (EC130-32A013 Rev 1), for Model

EC130B4 and EC130T2 helicopters, both Revision 1, and both dated October 17, 2022. This service information includes Detail A Figure 3 (EC120–32A014 Rev 1) and Detail A Figure 4 (EC130–32A013 Rev 1), which identify the areas and zones to be inspected for cracks and corrosion (including, but not limited to leafing and exfoliant corrosion). This service information also includes Table 3, which identifies the minimum material thickness permitted after corrosion is removed. Additionally, this service information specifies procedures for visually inspecting the external areas and borescope inspecting the internal areas of the landing gear tubes, removing corrosion, measuring thickness, interpreting results of the measurements, and applying a chemical conversion coating and primer.

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.

Proposed AD Requirements in This NPRM

This proposed AD would require, for helicopters with certain part-numbered landing gear assemblies installed, removing and cleaning certain parts and visually inspecting the external areas of the landing gear tubes for cracks and corrosion (including, but not limited to, leafing and exfoliant corrosion). If any crack, leafing corrosion, or exfoliant corrosion is detected, this proposed AD would require removing certain parts from service and replacing with airworthy parts. If any corrosion other than leafing or exfoliant corrosion is detected, this proposed AD would require removing the corrosion.

This proposed AD would also require borescope inspecting the internal side of the landing gear tubes for cracks and corrosion (including, but not limited to, leafing and exfoliant corrosion). If any crack, leafing corrosion, or exfoliant corrosion is detected, this proposed AD would require removing any affected part from service and replacing it with an airworthy part. If any corrosion other than leafing or exfoliant corrosion is detected, this proposed AD would require removing the corrosion.

If any corrosion other than leafing or exfoliant corrosion is detected during any of the inspections required by this proposed AD, this proposed AD would require removing all corrosion and measuring the remaining thickness of the landing gear tubes. This proposed AD would require interpreting the results of the measurements and if the remaining thickness does not meet the permitted criteria as specified, this

proposed AD would require removing each affected sub-assembly from service and replacing it with an airworthy part. If the remaining thickness meets the permitted criteria as specified, this proposed AD would require applying a chemical conversion coating and a double layer of primer.

Additionally, this proposed AD would allow an affected part or affected part sub-assembly to be installed on a helicopter, if certain requirements of this proposed AD have been accomplished.

Differences Between This Proposed AD and EASA AD 2022–0053

EASA AD 2022–0053 requires, for certain helicopters, the initial inspections to be completed within certain compliance times specified in Table 1 of EASA AD 2022–0053, whereas this proposed AD would require the initial inspections to be completed within 13 months after the effective date of this proposed AD. EASA AD 2022–0053 requires contacting Airbus Helicopters for repair instructions if any cracks, leafing corrosion, or exfoliant corrosion are found, or if the residual thickness of an affected part sub-assembly does not meet certain criteria, whereas this proposed AD would require removing the affected part or part sub-assembly from service instead. EASA AD 2022–0053 allows credit for certain inspections and corrective actions if these requirements were accomplished in accordance with previously issued service information, whereas this proposed AD would not allow credit for the inspections and corrective actions if previously issued service information was used. EASA AD 2022–0053 requires reporting the inspection results to Airbus Helicopters, whereas this proposed AD would not require reporting.

Interim Action

The FAA considers this proposed AD would be an interim action. Once final action has been identified, the FAA might consider further rulemaking.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 353 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 proposed AD.

Removing and cleaning parts, and visually inspecting the external surface of each landing gear tube for cracks and corrosion would take about 2 work-hours for an estimated cost of \$170 per

inspection, up to \$680 per helicopter (4 landing gear tubes per helicopter), and up to \$240,040 for the U.S. fleet.

Borecope inspecting the internal side of each landing gear tube for cracks and corrosion (including, but not limited to, leafing and exfoliant corrosion) would take about 1 work-hour for an estimated cost of \$85 per inspection, up to \$340 per helicopter (4 landing gear tubes per helicopter), and up to \$120,020 for the U.S. fleet.

If required, applying a chemical conversion coating and a double layer of primer would take about 2 work-hours and parts would cost a minimal amount for an estimated cost of \$170 per helicopter and up to \$60,010 for the U.S. fleet.

If required, disassembling certain zones and removing corrosion would take about 1 work hour for an estimated cost of \$85 per helicopter.

If required, measuring the thickness of the internal side of each landing gear tube and interpreting the results would take up to 1 work-hour for an estimated cost of \$85 per helicopter.

If required, replacing a landing gear assembly would take about 2 work-hours and parts would cost up to \$106,612 for an estimated cost of up to \$106,782 per replacement.

If required, replacing a front crossbeam would take about 1 work-hour and parts would cost up to \$9,081 for an estimated cost of up to \$9,166 per replacement.

If required, replacing a rear crossbeam would take about 1 work-hour and parts would cost up to \$11,639 for an estimated cost of up to \$11,724 per replacement.

If required, replacing a right-hand or left-hand skid assembly would take about 1 work-hour and parts would cost up to \$21,447 for an estimated cost of up to \$21,532 per skid assembly replacement.

Authority for This Rulemaking

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

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce.

This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

For the reasons discussed, I certify this proposed regulation:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Would not affect intrastate aviation in Alaska, and
- (3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

Airbus Helicopters: Docket No. FAA–2023–0016; Project Identifier MCAI–2022–00416–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by March 6, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus Helicopters Model EC120B, EC130B4, and EC130T2 helicopters certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 3213, Main Landing Gear Strut, Axle, Truck.

(e) Unsafe Condition

This AD was prompted by a report of corrosion detected on certain part-numbered landing gear assemblies. The FAA is issuing this AD to detect corrosion and cracks on the landing gear tubes. The unsafe condition, if not addressed, could result in the landing gear collapsing, damage to the helicopter, and injury to occupants.

(f) Compliance

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

(g) Required Actions

(1) Within 13 months after the effective date of this AD, for Model EC120B helicopters with landing gear assembly part number (P/N) C321A2106102, P/N C321A2501101, P/N C321A2501102, P/N C321A2601051AA, P/N C321A2601051CA, or P/N C321A2601052 installed, and for Model EC130B4 and EC130T2 helicopters with landing gear assembly P/N 350A41–0077–0201, P/N 350A41–0080–1102, P/N 350A41–0080–1103, P/N 350A41–0081–0201, P/N 350A41–0082–0101, or P/N 350A41–0082–0102 installed, except those having a date of first installation on a helicopter of February 16, 2022 or later; and for helicopters with a landing gear assembly having a P/N specified in this paragraph, with an unknown installation date, do the following:

(i) Remove the landing gear fairing from the rear crossbeam and clean the external areas of each of the landing gear tubes item a, item c, item d, and item e, including Zones B1, B2, C1, C2, D, E, F, and M as depicted in Detail A, Figure 3, and Details B and C, Figure 4 of Airbus Helicopters Alert Service Bulletin (ASB) No. EC120–32A014 (ASB EC120–32A014 Rev 1), or as depicted in Detail A, Figure 4, and Details B and C, Figure 5 of Airbus Helicopters ASB No. EC130–32A013 (ASB EC130–32A013 Rev 1), both Revision 1, and both dated October 17, 2022, as applicable to your model helicopter.

(ii) Visually inspect the external areas of each of the landing gear tubes item a, item c, item d, and item e, including Zones B1, B2, C1, C2, D, E, F, and M for corrosion (including, but not limited to leafing and exfoliant corrosion) and cracks.

(A) If any crack or leafing or exfoliant corrosion is detected, before further flight, remove the affected part from service and replace it with an airworthy part.

(B) If any corrosion is detected in Zone C1, C2, or E, other than leafing or exfoliant corrosion, before further flight, disassemble the landing gear and using a non-metal abrasive pad, remove all corrosion from all zones.

(C) If any corrosion is detected in only Zone B1, B2, D, F, or M, other than leafing or exfoliant corrosion, before further flight, using a non-metal abrasive pad, remove all corrosion from all zones.

(iii) Borescope inspect the internal side of each of the landing gear tubes item a, item c, item d, and item e, including Zones B1, B2, C1, C2, D, E, F, and M for corrosion (including, but not limited to leafing and exfoliant corrosion) and cracks.

(A) If any crack, leafing corrosion, or exfoliant corrosion is detected, before further flight, remove the affected part from service and replace it with an airworthy part. (B) If any corrosion is detected in Zone C1, C2, or E, other than leafing or exfoliant corrosion before further flight, disassemble the landing gear and using a non-metal abrasive pad, remove all corrosion from all zones.

(C) If any corrosion is detected in only Zone B1, B2, D, F, or M, other than leafing or exfoliant corrosion, before further flight, using a non-metal abrasive pad, remove all corrosion from all zones.

(iv) Before further flight after performing the inspections required by paragraphs (g)(1)(ii) and (iii) of this AD, if any corrosion was detected during any inspection required by paragraphs (g)(1)(ii) and (iii) of this AD other than leafing or exfoliant corrosion, using an ultrasonic thickness gauge, measure the remaining thickness of the landing gear tubes in the zones where any corrosion was removed. Interpret the results of the measurement using the criteria specified in Table 3 of ASB EC120–32A014 Rev 1 or Table 3 of EC130–32A013 Rev 1, as applicable to your model helicopter. If the remaining thickness does not meet the permitted criteria as specified, before further flight, remove each affected sub-assembly from service and replace it with an airworthy part. If the remaining thickness meets the permitted criteria as specified, before further flight, accomplish the actions required by paragraph (g)(1)(v) of this AD.

(v) Apply a chemical conversion coating (Alodine 1200) or equivalent, and a double layer of chromate Primer P05 and Primer P20, or equivalent, below the collar in Zones F and M and to any reworked zone.

(2) For Model EC120B helicopters, as of the effective date of this AD, do not install landing gear assembly P/N C321A2106102, P/N C321A2501101, P/N C321A2501102, P/N C321A2601051AA, P/N C321A2601051CA, or P/N C321A2601052, previously installed with an unknown installation date or a date of first installation on a helicopter before February 16, 2022; and do not install a front crossbeam, rear crossbeam, left-hand (LH) skid assembly, or right-hand (RH) skid assembly having a P/N identified in Table 2 of ASB EC120–32A014 Rev 1, previously installed with an unknown installation date, or a date of first installation on a helicopter before February 16, 2022, on any helicopter; unless the actions required by paragraphs (g)(1)(i) through (v) of this AD, as applicable, have been accomplished on the part.

(3) For Model EC130B4 and EC130T2 helicopters, as of the effective date of this AD, do not install landing gear assembly P/N 350A41–0077–0201, P/N 350A41–0080–1102, P/N 350A41–0080–1103, P/N 350A41–0081–0201, P/N 350A41–0082–0101, or P/N 350A41–0082–0102, previously installed with an unknown installation date or a date of first installation on a helicopter before February 16, 2022, and do not install a front crossbeam, rear crossbeam, LH skid assembly, or RH skid assembly, having a P/N identified in Table 2 of ASB EC130–32A013 Rev 1 previously installed with an unknown installation date, or a date of first installation on a helicopter before February

16, 2022, on any helicopter, unless the actions required by paragraphs (g)(1)(i) through (v) of this AD, as applicable, have been accomplished on the part.

(h) 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 (i)(2) 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.

(i) Additional Information

(1) Refer to European Union Aviation Safety Agency (EASA) AD 2022-0053, dated March 23, 2022, for related information. This EASA AD may be found in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2023-0016.

(2) For more information about this AD, contact Stephanie Sunderbruch, Aerospace Engineer, Safety Risk Management Section, Systems Policy Branch, Policy & Innovation Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-4659; email Stephanie.L.Sunderbruch@faa.gov.

(j) Material Incorporated by Reference

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

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

(i) Airbus Helicopters Alert Service Bulletin (ASB) No. EC120-32A014, Revision 1, dated October 17, 2022.

(ii) Airbus Helicopters ASB No. EC130-32A013, Revision 1, dated October 17, 2022.

(3) For service information identified in this AD, contact Airbus Helicopters, Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at www.airbus.com/helicopters/services/technical-support.html.

(4) 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.

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

Issued on January 12, 2023.

Gaetano A. Sciortino,

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

[FR Doc. 2023-00886 Filed 1-18-23; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

[Docket No. 221216-0275]

RIN 0648-BJ62

Proposed Lake Ontario National Marine Sanctuary; Notice of Proposed Rulemaking

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Proposed rule.

SUMMARY: NOAA proposes to designate the Lake Ontario National Marine Sanctuary (LONMS) in eastern Lake Ontario to recognize the national significance of the area's historical, archaeological, and cultural resources and to manage this special place as part of the National Marine Sanctuary System. The proposed sanctuary boundary would encompass 1,302 nmi² (1,724 mi²) of eastern Lake Ontario waters and would border Wayne, Cayuga, Oswego, and Jefferson counties. NOAA would co-manage LONMS with New York State. NOAA also proposes regulations to implement the national marine sanctuary designation and establish its terms of designation. This proposed rule follows NOAA's publication of a draft environmental impact statement (DEIS) and draft management plan (DMP) in July 2021. NOAA is soliciting public comment on the proposed rule, as well as possible names for the sanctuary.

DATES:

Comments: Send comments by March 20, 2023.

Public Meetings: NOAA will host four public meetings: three in-person meetings and one virtual meeting. The in-person scoping meetings will occur at the following dates and times:

- Oswego, NY, Date: February 28, 2023, Location: Lake Ontario Event and Conference Center, Address: 26 E 1st St., Oswego, NY 13126, Time: 6:30 p.m.–8 p.m. Eastern Time
- Wolcott, NY, Date: March 1, 2023, Location: Wolcott Elks Lodge No.

1763, Address: 6161 W Port Bay Rd., Wolcott, NY 14590, Time: 6:30 p.m.–8 p.m. Eastern Time

- Watertown, NY, Date: March 2, 2023, Location: Jefferson Community College, Address: 1220 Coffeen St., Sturtz Theater, Room 4-111, Watertown, NY 13601, Time: 6:30 p.m.–8 p.m. Eastern Time

The virtual public scoping meeting will occur at the following dates and time:

- Wednesday, March 8, 2023, 6:30 p.m. to 8 p.m. Eastern Time

Please check <https://sanctuaries.noaa.gov/lake-ontario> for meeting links and the most up-to-date information, should plans for these public meetings change. NOAA may end a virtual or in-person meeting before the time noted above if all participants have concluded their oral comments.

ADDRESSES: You may submit comments on this document, identified by NOAA-NOS-2021-0050, by any of the following methods:

- **Federal e-Rulemaking Portal:** <https://www.regulations.gov> and search for "NOAA-NOS-2021-0050". Follow the instructions for sending comments.
- **Mail:** Send any hard copy public comments by mail to Ellen Brody, Great Lakes Regional Coordinator, 4840 South State Road, Ann Arbor, MI 48108-9719.
- **Public Meetings:** Provide oral comments during public meetings, as described under **DATES**. Webinar registration details and additional information about how to participate in these public scoping meetings is available at: <https://sanctuaries.noaa.gov/lake-ontario>.

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 by NOAA. 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), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NOAA will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous). Comments that are not responsive or contain profanity, vulgarity, threats, or other inappropriate language will not be considered.

FOR FURTHER INFORMATION CONTACT:

Ellen Brody, 734-741-2270, ellen.brody@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

The National Marine Sanctuaries Act (NMSA; 16 U.S.C. 1431 *et seq.*) authorizes the Secretary of Commerce (Secretary) to designate and protect as national marine sanctuaries areas of the marine environment that are of special national significance due to their conservation, recreational, ecological, historical, scientific, cultural, archaeological, educational, or esthetic qualities. Day-to-day management of national marine sanctuaries has been delegated by the Secretary to NOAA's Office of National Marine Sanctuaries (ONMS). The primary objective of the NMSA is to protect the resources of the National Marine Sanctuary System.

NOAA proposes to designate the Lake Ontario National Marine Sanctuary (LONMS) in eastern Lake Ontario to recognize the national significance of the area's historical, archaeological, and cultural resources and to manage this special place as part of the National Marine Sanctuary System. To designate a national marine sanctuary, NOAA would set a boundary to delineate the borders of the sanctuary; run the site as a part of the national marine sanctuary system under the National Marine Sanctuaries Act; establish site-specific regulations to protect underwater cultural and historical resources; and implement a management plan that provides a comprehensive, long-term plan to manage the sanctuary and interpret the significance of the resources and surrounding area to the public. The proposed sanctuary boundary would encompass 1,302 nmi² (1,724 mi²) of eastern Lake Ontario waters and would border Wayne, Cayuga, Oswego, and Jefferson counties. NOAA would co-manage LONMS with New York State.

Eastern Lake Ontario represents a diverse array of important events in our Nation's history including military conflicts, maritime innovation, and American expansion to the west. The eastern corridor is one of the most historically significant regions in the Great Lakes and the country. This area has been critical to maritime trade and transportation for centuries, beginning with the canoes and boats of early Indigenous peoples. Approximately 1,000 years ago, the distinct cultural groups living along the lake shoreline had unified as the Haudenosaunee Confederacy. Portions of the original homelands of the Onondaga Nation, Cayuga Nation, Seneca Nation, and Oneida Nation lie within the proposed boundaries of the sanctuary. During the colonial period, Lake Ontario was a

strategic theater of conflict among European powers and the young American republic. Military actions occurred in the region during the French and Indian War, Revolutionary War, and the War of 1812. Later, this region was critical to the development of the American West and the Nation's industrial core. One of the more tangible and identifiable assets of this history were the vessels that plied Lake Ontario's waters. Carrying goods, people, and the community histories of the Great Lakes region, some of these vessels encountered treacherous conditions and sank. The cold, fresh water of the Great Lakes has preserved a number of these shipwrecks along with their historical and cultural context, making them a cornerstone for the protection, study, and interpretation offered by national marine sanctuaries.

LONMS would contain 43 known shipwrecks and one known submerged aircraft, including one shipwreck (*St. Peter*) listed on the National Register of Historic Places and another listed as a New York State Submerged Cultural Preserve and Dive Site (*David Mills*). This area may also include approximately 20 additional potential shipwreck sites (shipwrecks which likely exist, but additional research is needed to verify and describe them); three aircraft; and several other underwater archaeological sites, such as remnants of piers, aids to navigation, and historic properties that may be of religious and cultural significance to Indigenous Nations and Tribes. At this time, NOAA is unaware of any foreign sovereign shipwrecks located within the proposed boundary.

The exceptional archaeological, historical, and recreational value of these assets spans centuries, as indicated by the commercial schooner *Lady Washington* that was built in 1797, and U.S. Coast Guard Cable Boat 56022, which was lost under tow in 1977. The sanctuary would also include early American commercial vessels, submerged battlefields from the Seven Years War and War of 1812 (at Oswego and Sackets Harbor, respectively), and stellar examples of innovative technologies in shipbuilding from the last two centuries.

B. Need for Action

The National Marine Sanctuaries Act (NMSA; 16 U.S.C. 1431 *et seq.*) authorizes the Secretary of Commerce (Secretary) to designate new national marine sanctuaries to meet the purposes and policies of the NMSA, including:

- “to identify and designate as national marine sanctuaries areas of the marine environment which are of

special national significance and to manage these areas as the National Marine Sanctuary System” (16 U.S.C. 1431(b)(1));

- “to provide authority for comprehensive and coordinated conservation and management of these marine areas, and activities affecting them, in a manner which complements existing regulatory authorities” (16 U.S.C. 1431(b)(2)); and

- “to facilitate to the extent compatible with the primary objective of resource protection, all public and private uses of the resources of these marine areas not prohibited pursuant to other authorities” (16 U.S.C. 1431(b)(6)).

The nationally significant underwater cultural and historical resources within the proposed sanctuary require long-term protection and management to reduce threats that would adversely affect their historical, cultural, archaeological, recreational, and educational value. For example, many of the shipwrecks in the sanctuary, which have a high level of structural integrity as a result of the preservative properties of the cold, fresh water of Lake Ontario and the great depth at which several of them lie, are threatened by both natural processes and human activities. These threats include wind, waves, currents, storms, and ice; invasive species such as zebra and quagga mussels, which currently cover many shipwrecks; anchors and grappling hooks from dive boats; poorly attached mooring lines; artifact removal; artifacts being moved within a shipwreck site; and entanglement from remotely operated vehicle tethers and fishing gear.

Accordingly, NOAA is proposing to designate this area as a national marine sanctuary to: (1) manage and protect nationally significant underwater cultural and historical resources through a regulatory and nonregulatory framework; (2) document, further locate, and monitor these resources; (3) provide interpretation of their cultural, historical, and educational value to the public; (4) promote public stewardship and responsible use of these resources for their recreational value.

Establishing a national marine sanctuary in eastern Lake Ontario would: (a) allow NOAA to complement and supplement existing state and Federal efforts to protect underwater cultural and historical resources and actively manage, study, and interpret them for the public; (b) through outreach and communication, recognize and promote this area's nationally significant historical and cultural properties; (c) provide access to NOAA's extended network of scientific expertise

and technological resources, enhance ongoing research, and provide an umbrella for the coordination of these activities; (d) create and build upon existing educational initiatives and provide programming and technology for students, teachers, and the general public across the country; (e) enhance and facilitate public stewardship of underwater cultural and historical resources; and (f) bolster broader lake conservation efforts and stimulate maritime heritage-related tourism in the many communities that have embraced their centuries-long relationship with Lake Ontario, the St. Lawrence River, the Great Lakes region, and the Nation.

C. Designation Process

1. Notice of Intent To Designate a National Marine Sanctuary

On January 17, 2017, leaders of four New York counties (Oswego, Jefferson, Cayuga, and Wayne) and the City of Oswego, with support from the Governor of New York, submitted a nomination to NOAA through the Sanctuary Nomination Process (SNP) (79 FR 33851) asking NOAA to consider designating a national marine sanctuary in eastern Lake Ontario waters to protect, and increase awareness of, a nationally significant collection of submerged maritime heritage resources; build new partnerships for research and education; and promote tourism and economic development opportunities. NOAA completed its review of the nomination and, on March 21, 2017, added the area to the inventory of nominations eligible for designation. All nominations submitted to NOAA can be found at: <http://www.nominate.noaa.gov/nominations>. NOAA's decision to initiate a designation is based on a number of factors, including the need for resource protection, community and stakeholder support, and agency capacity. The Lake Ontario nomination encapsulates the essence of our maritime culture from the early years of our nation. The proposed Lake Ontario National Marine Sanctuary includes unique and significant submerged cultural resources within a corridor that is one of the most historically significant regions in the Great Lakes and the North American continent. NOAA chose to move forward with designating LONMS because it represented the goals of the National Marine Sanctuaries Act and met the needs of diversity of sites by capturing historical and cultural resources not represented elsewhere in the national marine sanctuary system. NOAA also considered the excellent

condition of the resources located within the nominated area.

On April 17, 2019, NOAA began the sanctuary designation process for the proposed Lake Ontario National Marine Sanctuary by publishing of a notice of intent (84 FR 16004, April 17, 2019) to prepare a draft environmental impact statement (DEIS) and to initiate the public scoping process as required by the National Marine Sanctuaries Act (NMSA) and the National Environmental Policy Act (NEPA). The notice of intent also announced NOAA's intent to fulfill its responsibilities under the requirements of the National Historic Preservation Act (NHPA).

NOAA also established a Sanctuary Advisory Council in 2020 to bring members of the local community together to provide advice to NOAA, to serve as a liaison with the nominating community, and to assist in guiding NOAA through the designation process. The council consists of 15 members in the following seats: citizens-at-large, divers/dive clubs/shipwreck explorers, maritime history, education, tourism, economic development, recreational fishing, and shoreline property owners. In addition, representatives of the four counties, the city of Oswego, the U.S. Coast Guard, the Port of Oswego Authority, New York Sea Grant, and the state of New York are non-voting members.

2. Draft Environmental Impact Statement and Public Comment

In accordance with NEPA (42 U.S.C. 4321 *et seq.*) and the NMSA (16 U.S.C. 1434), NOAA published a DEIS for the proposed national marine sanctuary designation on July 7, 2021 (86 FR 35757). The DEIS (<https://nmssanctuaries.blob.core.windows.net/sanctuaries-prod/media/docs/20210701-proposed-lake-ontario-national-marine-sanctuary-draft-environmental-impact-statement.pdf>) described the purpose and need for the proposed action, identified a range of alternatives, evaluated the environmental consequences of the proposed designation of a national marine sanctuary, and provided an assessment of resources and uses in the area. NOAA included three alternatives in the DEIS: (1) a "no action" alternative where the area would not become a national marine sanctuary; (2) an alternative which would include 1,349 nm² (1,786 mi²) in eastern Lake Ontario and the Thousand Islands region of the St. Lawrence River; and (3) an alternative that would include 1,302 nmi² (1,724 mi²) in eastern Lake Ontario without the St. Lawrence River. The DEIS also described proposed regulatory

concepts and a draft management plan to identify the tools employed by NOAA to manage the sanctuary, such as research and monitoring, education and outreach, tourism and economic development, sanctuary resource protection, and sanctuary operations. NOAA did not select a preferred alternative in the DEIS.

In the DEIS, NOAA evaluated the impacts of each alternative on underwater cultural resources, human uses and socioeconomic resources, physical resources, and biological resources. The various levels of impact used in the DEIS were: negligible, which means the impact on a resource can barely be detected (whether beneficial or adverse) and are therefore discountable; moderate, which means that minor impacts do not rise to the level of significance as defined in significant; and significant, which means that an impact results in an alteration in the state of a resource. Long-term or permanent impacts or impacts with a high intensity or frequency of alteration to a resource, whether beneficial or adverse, would be considered significant. Beneficial impacts are impacts that promote favorable conditions for the resource. Adverse impacts are impacts that are contrary to the goals, objectives, management policies, and practices of NOAA and the public interest or welfare, as well as those that are likely to be damaging, harmful, or unfavorable to one or more of the resources. NOAA's analysis under NEPA concluded that there would be no significant adverse impacts to biological and physical resources, cultural and historic resources, marine area use, recreation, or socioeconomic under any alternative. NOAA anticipates significant long-term beneficial impacts if the proposed action to designate a national marine sanctuary is implemented. For more information about these impacts and terminology definitions, please refer to the DEIS on pgs. 93 and 94.

During the public comment period on the DEIS, NOAA received 87 separate comments either through www.regulations.gov, by mail, or during virtual public meetings.¹ In general, comments were strongly supportive of sanctuary designation. Commenters cited several reasons for this support, including: long-term protection for nationally significant shipwrecks; increased accessibility to these wrecks;

¹ Public comments are available for review at <https://www.regulations.gov/docket/NOAA-NOS-2021-0050>. The comment period on the DEIS started on July 7, 2021 and ended on September 10, 2021.

potential for national recognition of the area to support local tourism and economies; Federal resources to support research on shipwrecks; establishing a mooring program; and, potential educational opportunities for students to study cultural and biological resources in the lake. Local, state, and governments and organizations also expressed strong support of the proposed sanctuary, offering opportunities to partner for education, research, outreach, and other activities. New York state agencies expressed commitment to be key partners in co-management and implementation of the proposed national marine sanctuary. The Lake Ontario Sanctuary Advisory Council unanimously passed a resolution with comments on the DEIS, including a preference for including the Thousand Islands Region of the St. Lawrence River, as long as it would not adversely impact commercial shipping.

Several commenters were supportive of designating LONMS but expressed concern about potential safety issues and navigational challenges in the St. Lawrence Seaway shipping channel if designation led to an increase in the number of divers and other recreational users. Some commenters also noted that installing surface mooring buoys in navigation channels would create a navigation hazard for vessels and asked NOAA to consider excluding navigation structures and dredge disposal sites from the proposed sanctuary. Other commenters expressed concern that there is not enough public interest in local shipwrecks; the shipwrecks are already adequately protected by other laws; most of the wrecks have already been found by private explorers (and, thus, NOAA research was not needed); and that the level of economic development would not be high enough to justify the creation of a national marine sanctuary in the area.

NOAA received a few comments specific to the LONMS boundary proposals. The majority of these comments supported the larger boundary option that includes the Thousand Island region of the St. Lawrence River. A few commenters supported the boundary option that only includes eastern Lake Ontario.

NOAA will use the public comments it receives to shape the final management plan, final rule, and final EIS. NOAA will respond to all public comments on the DEIS, draft management plan, and proposed rulemaking in the final EIS and in the final rulemaking.

3. Development of Proposed Regulations and Terms of Designation

NOAA developed this proposed rulemaking and the sanctuary terms of designation based on input from public comments submitted on the DEIS, interagency coordination, and internal staff analysis and expertise.

The DEIS described possible regulatory concepts for the proposed sanctuary and invited the public to comment on them. Based on internal staff expertise and comments received on the DEIS, NOAA is now proposing specific regulatory text for the sanctuary, including boundary coordinates, definitions, prohibitions, and permitting procedures in this rulemaking. The proposed regulations are generally the same as the regulatory concepts, with some modifications and additions to improve clarity, update terminology, and to provide further detail on administrative processes, such as issuing permits.

As mentioned, NOAA received comments supporting inclusion of the St. Lawrence River in the sanctuary's boundary, including from the LONMS Sanctuary Advisory Council. In addition, NOAA received comments from other Federal agencies in the region speculating that sanctuary designation could potentially lead to an increased number of divers and other recreational users in the St. Lawrence Seaway shipping channel, which they believed could present navigational challenges. After evaluating the comments received, NOAA is not including the St. Lawrence River segment within the proposed sanctuary boundary.

Summary of Proposed Regulations

A. Adding New Subpart U

NOAA is proposing to amend 15 CFR part 922 by adding a new subpart (subpart U) that contains site-specific regulations for the proposed sanctuary. This subpart would include the proposed boundary, contain definitions of common terms used in the new subpart, provide a framework for co-management of the sanctuary, identify prohibited activities and exceptions, and establish procedures for certification of existing uses, permitting otherwise prohibited activities, and emergency regulation procedures.

B. Proposed Sanctuary Boundary

As described above, the proposed sanctuary boundary would encompass 1,302 nmi² (1,724 mi²) of eastern Lake Ontario waters. The sanctuary would border Wayne, Cayuga, Oswego, and Jefferson counties. For the Lake Ontario

shoreline, NOAA would set the shoreline sanctuary boundary at the Low Water Datum (LWD). The LWD is determined by the U.S. Army Corps of Engineers and is the chart datum to which soundings are referenced for NOAA charts in the Great Lakes. The LWD is also well understood internationally because it is a fixed datum for each lake relative to the International Great Lakes Datum 1985. The state of New York uses the LWD as the line that delineates public land ownership. NOAA would set the northern boundary approximately along the U.S. and Canadian border in both Lake Ontario and the entrance to the St. Lawrence River. The western sanctuary boundary would be set approximately along the western border of Wayne County, and the eastern boundary would be a line from approximately the international border between the United States and Canada near Point Alexandria, ON to the shoreline at the low water datum in Cape Vincent, New York near the entrance to the Saint Lawrence River. The remainder of the eastern sanctuary boundary as well as the southern boundary would follow the shoreline around eastern Lake Ontario. The detailed legal sanctuary boundary description for the proposed sanctuary is included in section 922.220 and the coordinates are located in appendix A to subpart U of 922.

To ensure compatible use with commercial shipping and other activities, NOAA would exclude the ports and harbors of Oswego, Pultneyville, Little Sodus, Great Sodus, and Port Ontario from the proposed sanctuary boundary. NOAA would include Sackets Harbor in the sanctuary because of the possible presence of underwater cultural and historical resources there. As the proposed eastern boundary of the sanctuary ends at the intersection of Water St. in the Town of Cape Vincent, Cape Vincent marina is not included in the sanctuary. NOAA would exclude Federal navigation channel approaches to harbors, and Federal anchorage areas from the proposed sanctuary to avoid unintended effects on port operations that are critical to the local, regional, and national economies. NOAA would also exclude privately owned bottomlands from the sanctuary.

C. Definitions

NOAA proposes to include a site-specific definition of "sanctuary resource" for LONMS, to include only the historical resources found in this area in accordance with the purpose of this designation. The definition does not include biological and ecological

resources of the area. Creating this site-specific definition requires NOAA to modify the national definition of “sanctuary resource” in the national regulations at section 922.3 to add an additional sentence that defines the site-specific definition for the proposed sanctuary at section 922.221. This is similar to the approach taken for other national marine sanctuaries, such as Thunder Bay National Marine Sanctuary, that do not make use of the full national “sanctuary resource” definition. NOAA proposes to define “sanctuary resource” for the proposed sanctuary in Lake Ontario to mean all historical resources as defined at 15 CFR 922.3, which includes any pre-contact and historic sites, structures, districts, objects, and shipwreck sites within sanctuary boundaries.

NOAA proposes to further define “shipwreck site” to mean all archaeological and material remains associated with sunken watercraft or aircraft that are historical resources, including associated components, cargo, contents, artifacts, or debris fields that may be exposed or buried within the lake bed.

NOAA also proposes to define “tethered underwater mobile system” to mean remotely operated vehicles and other systems with onboard propulsion systems that utilize a tether connected to a station-holding (e.g. by anchor, dynamic positioning, or manual vessel operation) surface support vessel.

D. Co-Management of the Sanctuary

To enhance opportunities and build on existing protections, NOAA and the State of New York would collaboratively manage the sanctuary. NOAA would establish the framework for co-management at section 922.222 and would develop a Memorandum of Agreement (MOA) with the State to establish further details of co-management. NOAA and the State may develop additional agreements as necessary that would provide details on the execution of sanctuary management, such as activities, programs, and permitting programs that can also be updated to adapt to changing conditions or threats to the sanctuary resources. Any proposed changes to sanctuary regulations or boundaries would be jointly coordinated with the state and subject to public review as mandated by the NMSA and other Federal statutes.

Additionally, NOAA recognizes that designation of a national marine sanctuary would lead to subsequent activities that may be subject to review under section 106 of the National Historic Preservation Act. Therefore, NOAA is pursuing execution of a

Programmatic Agreement (PA) pursuant to 36 CFR 800.14(b). The PA would provide a framework for consideration of future undertakings resulting from management of the sanctuary, if the sanctuary is designated. NOAA is developing this agreement in consultation with the New York State Historic Preservation Officer, the Advisory Council on Historic Preservation, federally-recognized Nations and Tribes, and other consulting parties.

E. Prohibited and Regulated Activities

NOAA is proposing to supplement and complement existing management of this area by proposing the following regulations in section 922.223 to protect sanctuary resources.

1. Prohibition on Damaging or Altering Sanctuary Resources

As a complement to existing protections under state laws and Federal laws, NOAA is proposing to prohibit moving, removing, recovering, altering, destroying, possessing or otherwise injuring, or attempting to move, remove, recover, alter, destroy, possess or otherwise injure a sanctuary resource. This prohibition aims to reduce the risk of direct harm to sanctuary resources. “Moving” and “altering” would include any changes to the position or state of sanctuary resources, as well as covering, uncovering, moving, or taking artifacts, even if the artifacts are not located on or near a shipwreck. This sanctuary prohibition would supplement section 233 of the New York State Education Law which makes it unlawful for any person to “investigate, excavate, remove, injure, appropriate or destroy any object of archaeological, historical, cultural, social, scientific or paleontological interest situated on, in or under lands owned by the state of New York without written permission of the commissioner of education.” NY Educ L § 233.4. This state regulation currently applies in U.S. waters of Lake Ontario and would continue to apply to resources in these waters if the sanctuary is designated.

2. Prohibition on Possessing, Selling, Offering for Sale, Purchasing, Importing, Exporting, Exchanging, Delivering, Carrying, Transporting, or Shipping by Any Means Any Sanctuary Resource Within or Outside of the Sanctuary

This prohibition is intended to deter looting of sanctuary resources and to further the policy of in situ preservation of these resources. As noted, the listed activities would be prohibited both within and outside of the sanctuary. This prohibition is not intended to

apply to artifacts or other sanctuary resources collected before the effective date of sanctuary designation.

3. Prohibition on Grappling Into or Anchoring on Shipwreck Sites

NOAA proposes to prohibit the use of grappling hooks and anchoring devices into or on shipwreck sites, to protect fragile shipwrecks and aircraft within the sanctuary from damage. To help vessels avoid anchoring on known shipwrecks sites, NOAA intends to publish known shipwreck site coordinates on the LONMS website (<https://sanctuaries.noaa.gov/lake-ontario>). However, in accordance with section 304 of the National Historic Preservation Act, NOAA would withhold from public disclosure information about the location, character, or ownership of a historic property if NOAA, in consultation with the Secretary of the Interior, determined that disclosure may risk harm to the historic property. NOAA would also coordinate with the New York State Historic Preservation Officer in making such a determination. Shipwreck sites for which NOAA does not publish coordinates would still be sanctuary resources and the prohibition on anchoring and grappling would still apply. The proposed management plan includes surveying the sanctuary area to identify additional shipwreck sites. As appropriate, and in consideration of resource management conflicts, NOAA intends to update its website as new shipwreck sites are found by the sanctuary or other public or private groups and individuals. As NOAA seeks to promote public access while also ensuring sound resource protection, an initial focus of the sanctuary management plan would be the installation of mooring systems at sanctuary shipwreck sites. The moorings would provide a secure and convenient anchoring point for users, which would eliminate the need for grappling into a wreck. NOAA would also publish guidelines on best practices for anchoring near shipwreck sites to avoid injuring sanctuary resources. Designated Federal anchorage areas would be excluded from the sanctuary.

4. Prohibition on Use of Tethered Underwater Mobile Systems at Shipwreck Sites

Tethered underwater mobile instruments, such as remotely operated vehicles (ROVs), are widely used in underwater survey and site exploration activities, as they enable access to underwater cultural resources at depths beyond recreational and technical diving limits. As tethered instrument

use has continued to increase in the scientific, commercial, and recreational user communities, there is a heightened threat of damage to submerged cultural resources by these systems. Tethered systems present three distinct threats to shipwreck sites: intentional site disturbance, unintentional or incidental site disturbance, and site pollution. Intentional disturbance is characterized by the intentional recovery of artifacts from a wreck site, which may include minor alterations or large-scale recovery. Unintentional disturbance occurs when a tethered system makes contact with the wreck or the instrument tether gets entangled on protruding portions of a wreck, such as the mast. Under these circumstances, disentanglement or attempted disentanglement of snagged instruments can inadvertently displace or damage the wreck. The impact from such activities can result in severe damage to artifact assemblages and the structural integrity of a site. This risk is particularly concerning in the proposed sanctuary area, as a large number of wrecks have intact masts and high site integrity. Finally, if the instrument cannot be disentangled, cutting the tether line leads to pollution of the site with abandoned equipment.

Therefore, NOAA proposes to prohibit deploying a tethered underwater mobile system at shipwreck sites. The proposed provision would complement New York State's prohibition on damaging cultural resources by proactively deterring damage, disturbance, and pollution of these nationally significant sites from tethered systems. Because New York State does not proactively manage or protect shipwrecks in Lake Ontario, it also does not regulate the use of tethered systems at shipwreck sites, which, as described above, pose a threat to these resources. New York State's existing prohibition focuses on permitting for terrestrial resources, rather than underwater cultural resources. As a result, New York State has limited staff expertise regarding maritime archaeology that could inform whether an application for the permitted use of a tethered system is consistent with the preservation of these underwater cultural and historical resources.

The prohibition on operating tethered systems at shipwreck sites would not apply to any activity conducted in accordance with the scope, purpose, terms, and conditions of a permit issued by NOAA, including special use permits pursuant to section 310 of the NMSA. NOAA proposes to allow users to apply for a permit to operate tethered underwater mobile systems at

shipwreck sites within the sanctuary. NOAA would review project proposals against the permit criteria outlined in part 922, subpart D and the proposed permit conditions specific to LONMS to ensure that operators would be adequately prepared to access sanctuary resources in a responsible manner.

Permits issued by New York State relative to the state prohibition are intended to serve the purposes of the New York State Museum by ensuring the appropriate acquisition of cultural and historical objects for the state museum's archiving purposes. Permits issued by NOAA would serve a distinct, yet complementary, purpose of ensuring the permitted activity is consistent and compatible with the purposes for which the sanctuary is designated. Furthermore, because NOAA's proposed prohibition makes it unlawful for any person to deploy a tethered underwater mobile system at a shipwreck site without a NOAA permit, NOAA could target and investigate the unauthorized use of such systems at shipwreck sites before harm occurs. By contrast, the existing New York prohibition is ambiguous in its application prior to direct injury to cultural resources, and this ambiguity would complicate and potentially compromise similar proactive enforcement measures relying, on this provision of New York state law. For more information about NOAA permits please see section 8 below.

NOAA does not intend for these regulations to apply to autonomous underwater vehicles or towed systems, such as side-scan sonar, magnetometers, survey trawls, or other survey instruments that are pulled behind a vessel via a tow cable. Towed systems are typically operated high above the lakebed in order to avoid snagging on objects, so they do not present the same level of entanglement threat to shipwrecks as tethered underwater mobile instruments.

5. Prohibition on Interfering With Investigations

NOAA proposes a regulation to prohibit interfering with sanctuary enforcement activities. This regulation will assist in NOAA's enforcement of the sanctuary regulations and strengthen sanctuary management.

6. Exemption for Emergencies and Law Enforcement

The proposed prohibitions for the sanctuary would not apply to any activity necessary to respond to emergencies that threaten lives, property, or the environment, or activities that are necessary for law enforcement purposes.

F. Emergency Regulations

As part of the designation, NOAA would have the authority to issue emergency regulations in LONMS. Emergency regulations are used in limited cases and under specific conditions when there is an imminent risk to sanctuary resources and a temporary prohibition would prevent the destruction or loss of those resources. An emergency regulation would not take effect without the approval of the Governor of New York or her/his designee or designated agency. NOAA would only issue emergency regulations that address an imminent risk for a fixed amount of time with a maximum of 6 months that can be extended one time for no more than 6 months. NOAA must go through a full rulemaking process to consider making an emergency regulation a permanent regulation, which would include a public comment period.

NOAA would add the proposed sanctuary to a list of sanctuaries that have site-specific regulations related to emergency regulations at 922.44, as well as including detailed site-specific emergency regulations to the regulations at section 922.224.

G. Treaty Rights

The exercise of treaty rights, reserved rights, or similar rights for federally-recognized Tribes and Nations, including the Six Nations of the Haudenosaunee Confederacy, and their citizens is not modified, altered, or in any way affected by the regulations proposed by NOAA in this rulemaking. The Director shall consult with the governing body of each Tribe or Nation protected by the 1794 Treaty of Canandaigua regarding any matter which might affect the ability of their citizens to participate in activities protected by this treaty in the Sanctuary. Please see section III.E "Executive Order 13175" of this document for information about how NOAA has engaged with Tribes and Nations through the sanctuary designation process to date.

H. General Permits, Certifications, Authorizations, and Special Use Permits

1. General Permits

NOAA would have the authority to issue permits to allow certain activities that would otherwise violate the prohibitions in the proposed sanctuary's regulations.² Similar to other national

² A NOAA permit does not relieve an applicant or permittee of responsibility to comply with all other federal, state and local laws and regulations, and the permit is not valid until all other necessary

marine sanctuaries, NOAA is proposing to consider these general permits for the purposes of education, research, or management. In order for an activity to be considered for a general permit, it must also further the goals of the national marine sanctuary and meet regulatory permit review criteria. The Director may subject a general permit to specific terms and conditions as they deem appropriate. For example, a research institution may request to conduct limited archaeological testing at a shipwreck site that involves taking a sample for the purpose of dating the site. This activity would violate the prohibition on damaging or altering a sanctuary resource and would therefore require the issuance of a general permit to allow the activity for the purposes of education, research, or management. NOAA would evaluate the request and would consider the inclusion of permit terms and conditions to ensure the activities are conducted by qualified professionals and to proper archaeological standards, as well as to further ensure that the activity is meeting the appropriate purpose of education, research, or management of the resource.

To address the above additions to the NOAA general permit authority for the proposed sanctuary in Lake Ontario, NOAA would amend the regulatory text in the program-wide regulations in part 922, subpart D, to add references to subpart U, as appropriate.

2. Certifications

Pre-existing activities conducted pursuant to a valid lease, permit, license, or right of subsistence use or of access might be occurring within the LONMS area on the date of sanctuary designation that would otherwise be prohibited by sanctuary regulations. Therefore, NOAA would add a new section, 922.226, to the LONMS regulations that would describe the process by which it would be able to certify a valid lease, permit, license, or right of subsistence use or of access within the proposed sanctuary boundaries. In compliance with the NMSA, the regulations at section 922.226 would state that certification is the process by which permitted activities existing prior to the designation of the sanctuary that violate sanctuary prohibitions may be allowed to continue. NOAA may, however, further regulate the exercise of those permitted activities consistent with the goals of the sanctuary through applying

permits, authorizations, and approvals are obtained. As co-managers, NOAA would coordinate the issuance of permits with New York State.

additional terms and conditions of the certification. Requests for certifying permitted existing uses would have to be received by NOAA within 90 days of the effective date of the designation.

3. Authorizations

NOAA would have the authority to consider allowing an activity otherwise prohibited by section 922.223 if such activity is specifically authorized by any valid Federal, state, or local lease, permit, license, approval, or other authorization issued after the effective date of sanctuary designation. NOAA would also have the authority to add terms and conditions to authorizations to ensure that activities conducted within the sanctuary are carried out in a manner that is consistent with the purposes for which the Sanctuary was designated. As such, NOAA proposes to amend the regulatory text at section 922.36 to add reference to subpart U.

4. Special Use Permits

NOAA has the authority under the NMSA to issue special use permits (SUPs) at national marine sanctuaries, as established by section 310 of the NMSA. SUPs can be used to authorize specific activities in a sanctuary if such authorization is necessary to establish conditions of access to, and use of, any sanctuary resource or to promote public use and understanding of a sanctuary resource. The NMSA requires SUPs to contain four specific conditions (16 U.S.C. 1441(c)): (1) activities must be compatible with the purposes for which the sanctuary is designated and with protection of sanctuary resources; (2) activities carried out under the permit must be conducted in a manner that does not destroy, cause the loss of, or injure sanctuary resources; (3) permittees are required to purchase and maintain comprehensive general liability insurance, or post an equivalent bond, against claims arising out of activities conducted under the permit and to agree to hold the United States harmless against such claims; and (4) SUPs shall not authorize the conduct of any activity for a period of more than 5 years unless renewed by the Secretary. As is the case with general permits, NOAA can place additional conditions on SUPs specific to the activity being permitted. The activities that qualify for a SUP are set forth in the **Federal Register** (78 FR 25957 (May 3, 2013); 82 FR 42298 (Sept. 7, 2017)). Categories of SUPs may be changed or added to through public notice and comment.

NOAA proposes to create a new SUP category for “the operation of tethered underwater mobile systems at shipwreck sites in Lake Ontario

National Marine Sanctuary” to apply when the proposed activity does not qualify for a general permit or authorization, as described above.³ NOAA determined that after appropriate environmental review and application of terms and conditions, operating tethered underwater mobile systems at shipwreck sites can occur without injuring sanctuary resources. NOAA will coordinate with the New York State Historic Preservation Officer to consider terms and conditions that prevent harm to sanctuary resources. Such terms and conditions will generally address potential impacts such as tether management and entanglement mitigation, as well as avoidance of site pollution. While the NMSA allows NOAA to assess and collect fees for the conduct of any activity under an SUP, it also allows NOAA to waive or reduce fees for activities that do not derive profit from the access or use of sanctuary resources. NOAA proposes to waive the associated fee for issuing an SUP for operating tethered underwater mobile systems at shipwreck sites within LONMS when non-commercial operators do not derive profits from their use of the sanctuary or when the operators further the sanctuary’s objectives (e.g. educating the public about the sanctuary or contributing to the sanctuary’s research goals).

I. Other Conforming Amendments

The general regulations in part 922, subpart A, for general information and part 922, subpart E, for regulations of general applicability would also have to be amended so that the regulations are accurate and up-to-date. The modified sections to conform to adding a new sanctuary are:

- Section 922.1 Purposes and applicability of the regulations
- Section 922.4 Boundaries
- Section 922.5 Allowed activities
- Section 922.6 Prohibited or otherwise regulated activities
- Section 922.7 Emergency regulations
- Section 922.11 Definitions
- Section 922.30 National Marine Sanctuary general permits
- Section 922.36 National Marine Sanctuary authorizations

J. Terms of Designation

Section 304(a)(4) of the National Marine Sanctuaries Act (NMSA)

³ A NOAA permit does not relieve an applicant or permittee of responsibility to comply with all other federal, state and local laws and regulations, and the permit is not valid until all other necessary permits, authorizations, and approvals are obtained. As co-managers, NOAA would coordinate the issuance of permits with New York State.

requires that the terms of designation include the geographic area included within the sanctuary; the characteristics of the area that give it conservation, recreational, ecological, historical, research, educational, or aesthetic value; and the types of activities that will be subject to regulation by the Secretary of Commerce to protect these characteristics. Section 304(a)(4) also specifies that the terms of designation may be modified only by the same procedures by which the original designation was made. Thus, the terms of designation serve as a constitution for the Sanctuary.

NOAA is proposing to establish terms of designation that describe the geographic area, resources, and activities as described in details above. NOAA would add the terms of designation language as appendix B to the regulations at 15 CFR part 922, subpart U.

II. Request for Comments

NOAA requests general comments on this proposed rule and in particular, comments on the proposed Special Use Permit category for operating tethered underwater mobile systems at shipwreck sites; the proposed terms of designation; the cost estimates in the Regulatory Flexibility Analysis (section III.F “Regulatory Flexibility Act”); and potential names for the sanctuary.

A comprehensive summary of all public comments on the DEIS and proposed rule, along with responses to comments, will be included in the final environmental impact statement (FEIS). NOAA will publish the FEIS following public review and comment on this proposed rule.

III. Classification

A. National Marine Sanctuaries Act

NOAA has determined that the designation of the Lake Ontario National Marine Sanctuary will not have a negative impact on the national marine sanctuary system and that sufficient resources exist to effectively implement sanctuary management plans and to update site characterizations. The finding for NMSA section 304(f) is published on the ONMS website for the Lake Ontario designation at <https://sanctuaries.noaa.gov/lake-ontario>.

B. National Environmental Policy Act

As described in section I of this rulemaking, NOAA prepared a DEIS to evaluate the impacts of this proposed action, which considered three alternatives for the proposed designation of a national marine sanctuary in eastern Lake Ontario and

the Thousand Islands region of the St. Lawrence River. NOAA is now issuing proposed regulations for the sanctuary as the next phase of this designation process. This proposed rule includes some modifications to components of the proposed action presented in the DEIS (see section I.C.3. “Development of Proposed Regulations and Terms of Designation” of this document for further detail). NOAA evaluated the sufficiency of the DEIS for this proposed rule using the Council on Environmental Quality regulations criteria for supplementation, as well as guidance in the NOAA NEPA Companion Manual. NOAA has determined that a supplemental NEPA analysis is not required at this time for the reasons outlined below.

In evaluating the first criteria for preparing a supplemental EIS, NOAA finds that the changes to the proposed action reflected in this proposed rule are not substantial changes relevant to environmental concerns. NOAA expects that the technical changes made to clarify terminology and the addition of regulations outlining the administrative procedures for sanctuary management would not change the intent or requirements of the proposed regulatory concepts in the DEIS. With respect to sanctuary boundaries, NOAA is proposing the same sanctuary boundary as described in Alternative 2 in the DEIS with one technical change of including, rather than excluding, dredge disposal areas from the sanctuary. Any impacts of these minor changes and this proposed sanctuary boundary would be within the range of potential effects described in the DEIS.

In evaluating the second criteria for preparing a supplemental EIS, NOAA finds new information available since publication of the DEIS, such as comments related to diver safety, commercial shipping interactions, and climate or wetland impacts, does not reflect significant new circumstances or information that is relevant to environmental concerns. In addition, NOAA does not expect that this new information would result in any change in the type or significance of potential impacts of the proposed action from those analyzed in the DEIS.

NEPA regulations and NOAA guidance recommend that agencies consider whether the purposes of NEPA would be furthered by preparing a supplemental NEPA analysis, and if the public has sufficient opportunity to meaningfully consider the action based on the alternatives that were presented in the DEIS. In this designation process, NOAA separated the DEIS and rulemaking processes to allow increased

opportunity for public and agency input to inform the development of the proposed rule. Based on the extensive opportunities for input during this designation process and the minimal changes in the proposed action and its potential impacts, NOAA does not believe that the purposes of NEPA would be furthered by the preparation of a supplemental EIS at this time.

After reviewing this proposed rulemaking, comments received on the DEIS, and changes made to certain components of the proposed action, NOAA determined that supplemental analysis is not required for this proposed rule because the DEIS presented the public with a comprehensive analysis of the spectrum of environmental impacts among several alternative scenarios from which this proposed rule was developed. Any changes reflected in the proposed action are insubstantial in that they do not differ from the impacts already analyzed in the DEIS and will not have any synergistic or cumulative impacts not already analyzed in the DEIS. If the proposed action is further revised in response to comments on the proposed rule, NOAA would reexamine the sufficiency of the existing NEPA documents and the need for any supplemental analysis.

C. Executive Order 12866: Regulatory Impact

OMB has determined this rule is significant as that term is defined under Executive Order 12866. NOAA anticipates the associated costs with this proposed rule will be *de minimis*, as explained more fully in the Regulatory Flexibility Analysis in section F “Regulatory Flexibility Act” below.

D. Executive Order 13132: Federalism Assessment

NOAA has concluded that this regulatory action does not have federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 13132 because NOAA supplements and complements state and local laws under the NMSA rather than supersedes or conflicts with them.

E. E.O. 13175 Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13175 of November 6, 2000, Federal departments and agencies are charged with engaging in regular and meaningful consultation and collaboration with officials of federally-recognized Nations and Tribes on the development of Federal policies that have implications for Indigenous

peoples and are responsible for strengthening the government-to-government relationship between the United States and Indian Nations and Tribes. NOAA has concluded that this regulatory action does have Tribal implications under Executive Order 13175.

NOAA invited the following federally recognized Nations and Tribes to engage in government-to-government consultation on the proposed sanctuary designation: Cayuga Nation, Oneida Nation, Onondaga Nation, Seneca Nation, Saint Regis Mohawk Tribe, Tonawanda Seneca Nation, and Tuscarora Nation. NOAA sent initial letters inviting the seven Nations and Tribes to participate in government-to-government consultation prior to publication of the Notice of Intent (December 14, 2018). NOAA later sent notice of the draft Environmental Impact Statement publication to the same Nations and Tribes (July 8, 2021). The Onondaga Nation elected to engage in government-to-consultation with NOAA, and the initial government-to-government consultation meeting with the Onondaga Nation was held on July 30, 2020. To date, the Seneca Nation has chosen to informally engage with NOAA throughout the designation process instead of participating in formal government-to-government consultation. The seven federally recognized Nations and Tribes have the opportunity at any point to participate in the designation process, including a request to initiate formal government-to-government consultation with NOAA. NOAA has also invited the seven federally recognized Nations and Tribes to participate in the development of a Programmatic Agreement to fulfill NOAA's obligations under section 106 of the National Historic Preservation Act. NOAA will continue to engage, and as appropriate consult, with Nations and Tribes throughout the sanctuary designation process.

Upon designation, NOAA will offer consultation to federally recognized Nations and Tribes on sanctuary action that may have Tribal implications as described in E.O. 13175, including those actions that might affect the ability of Nation or Tribal citizens to participate in activities protected by the 1794 Treaty of Canandaigua.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as amended and codified at 5 U.S.C. 601 *et seq.*, requires an agency to prepare a regulatory flexibility analysis of any rule subject to the notice and comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C.

553) or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

This analysis evaluates the potential effects of the proposed rulemaking on small businesses. There are three primary industries considered in this section as small businesses: commercial fishing, recreational for-hire fishing, and dive/snorkeling for-hire operations. Small entities are defined by the Small Business Administration (SBA). The definitions of relevant small businesses presented here are sourced from the most recent size standards published by the SBA in 2019. Size standards are based upon the average annual receipts (all revenue) or the average employment of a firm. The commercial size standards are \$22.0 million for finfish fishing (NAICS code—114111), \$6.0 million for shellfish fishing (NAICS code—114112), and \$8.0 million for other marine fishing (NAICS code—114119). For-hire recreational fishing operations and dive/snorkeling for-hire operations (NAICS code—713990) have size standards of \$8.0 million.⁴ According to these limits, each of the businesses potentially affected by this proposed rule would most likely be small businesses. However, as further discussed below, these regulations will not have a significant economic impact on the affected small entities, and the Chief Counsel for Regulation for the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have significant economic impacts on a substantial number of small entities. Thus, NOAA is not required to prepare and has not prepared an initial regulatory flexibility analysis. The following analysis supports NOAA's decision to certify that there will not be a significant economic impact on a substantial number of entities.

1. Commercial Fishing

i. Description and Estimate of the Number of Small Entities to Which the Proposed Action Would Apply

The data presented here are from the New York Department of Environmental Conservation (NYSDEC). Commercial fishing activity in the New York waters off Lake Ontario is limited to the embayments and nearshore open waters of the eastern basin. In 2018 and 2019, gillnets were the only gears actively employed. Since 2014, there were only

⁴ U.S. Small Business Administration. (2019). Table of Size Standards. available at: <https://www.sba.gov/document/support-table-size-standards>.

two active commercial fishers in eastern Lake Ontario. The proposed rule does not directly limit the number of fishermen or catch. From 2004 through 2013, there were three active fishers (with the exception of 2010, which had two active fishers). From 2015 to 2019, the average number of pounds of fish landed was 54,971, with yellow perch comprising 97.9% of total average annual landings in the New York waters of Eastern Lake Ontario. In 2018, the value of yellow perch landings (38,987 pounds) was \$71,134, and in 2019 the value of the yellow perch landings (54,533 pounds) was \$132,143 in the New York waters of Eastern Lake Ontario.⁵ Although data is not available on the fishers' total catch (outside of eastern Lake Ontario), it is assumed that both of these fishers are small businesses.

ii. Description of the Projected Reporting, Record-Keeping and Other Compliance Requirements of the Proposed Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary for the Preparation of the Report or Records

The proposed regulatory action would not establish any new reporting or record-keeping requirements.

iii. Identification of All Relevant Federal Rules, Which May Duplicate, Overlap or Conflict With the Proposed Rule

No duplicative, overlapping, or conflicting Federal rules have been identified.

iv. Significance of Economic Effects on Small Entities

Substantial Number Criterion

The proposed regulations do not regulate fishing but do prohibit damage to sanctuary resources. A similar provision prohibiting injury to cultural resources is already in existing state law, and therefore, the proposed regulations are not expected to have an effect on businesses.

In 2018 and 2019, there were two active fishing licenses within eastern Lake Ontario. Although it is assumed

⁵ New York Department of Environmental Conservation. (2019). 2018 annual report: Bureau of Fisheries Lake Ontario Unit and St. Lawrence River Unit to the Great Lakes Fishery Commission's Lake Ontario Committee. Available at: https://www.dec.ny.gov/docs/fish_marine_pdf/lourpt18.pdf; New York Department of Environmental Conservation. (2020). 2019 Annual report: Bureau of Fisheries Lake Ontario Unit and St. Lawrence River Unit to the Great Lakes Fishery Commission's Lake Ontario Committee. Available at: https://www.dec.ny.gov/docs/fish_marine_pdf/2019lakeontannualrep.pdf.

that both fishers are small businesses, it is also assumed that the fishers actively avoid using their gillnets on or close to shipwrecks to avoid entangling or damaging their gear and to comply with existing state law. Therefore, the proposed rule will not affect a substantial number of small businesses.

Significant Economic Impacts

The outcome of “significant economic impact” can be ascertained by examining profitability. *Profitability*: Do the regulations significantly reduce profits for a substantial number of small entities?

As mentioned above, it is assumed that fishers in the sanctuary are complying with the existing state law and that they actively avoid known shipwrecks when using gear that could become entangled or damaged by shipwrecks. Therefore, a significant reduction in profits for a substantial number of small entities is not expected to result from the proposed regulatory action.

v. Description of Significant Alternatives to the Proposed Action and Discussion of How the Alternatives Attempt To Minimize Economic Impacts on Small Entities

This proposed regulatory action, if implemented, is not expected to significantly reduce profits for a substantial number of small entities directly regulated by this action. As a result, the issue of significant alternatives is not relevant.

2. Recreational For-Hire Fishing

i. Description and Estimate of the Number of Small Entities to Which the Proposed Action Would Apply

For hire-recreational fishing includes both charter and party boats. Charter boats, generally, are fishing vessels that are hired by a single person to take up to six anglers on a fishing trip. The charge is on a per-trip basis. Party or head boats usually operate on a schedule and may provide several trips in a single day, taking many different fishing parties at a time. The charge is on a per-person basis. Head boats are usually larger and able to accommodate more anglers than a party boat.

Sixty charters operate in Lake Ontario.⁶ Nine charters are identified as fishing inshore, twenty-one as fishing nearshore, twelve as river fishing, and forty-four as lake fishing. (The numbers sum to more than sixty since charters

⁶ Fishing Booker. (2021). Lake Ontario. available at: https://fishingbooker.com/charters/search/us/lake-ontario?&booking_days=1&booking_persons=

may service multiple areas). NOAA does not have data on how many of these charters visit the proposed sanctuary waters. In the absence of cost and earnings data and based upon communications with SAC members, all of the for-hire fishing businesses are believed to be small entities. Therefore, it is assumed that this proposed rule would affect a substantial number of small entities.

ii. Description of the Projected Reporting, Record-Keeping and Other Compliance Requirements of the Proposed Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary for the Preparation of the Report or Records

The proposed regulatory action would not establish any new reporting or record-keeping requirements.

iii. Identification of All Relevant Federal Rules, Which May Duplicate, Overlap or Conflict With the Proposed Rule

No duplicative, overlapping, or conflicting Federal rules have been identified.

iv. Significance of Economic Effects on Small Entities

Substantial Number Criterion

The proposed regulations do not regulate fishing but do prohibit the damage of sanctuary resources. A similar provision prohibiting injury to cultural resources is already in existing state law, and therefore, the proposed regulations are not expected to have an effect on businesses.

To further reduce the likelihood of damage to sanctuary resources, NOAA is proposing to prohibit grappling or anchoring on shipwreck sites. As an initial focus of the sanctuary management plan, NOAA is proposing to implement a mooring program that would provide continued access to these shipwrecks to recreational operations and would reduce the likelihood of damage to the sites. It is not expected that the level of access and use of these shipwrecks would be altered by the regulations. Consequently, the proposed rule will not affect a substantial number of small businesses.

Significant Economic Impacts

Profitability: Do the regulations significantly reduce profits for a substantial number of small entities?

It is assumed that for-hire operations in the sanctuary are already in compliance with the existing state law

and that the level of access and use of these shipwrecks would not be altered by the regulations. The mooring program may actually increase access by providing safe and secure locations to enjoy sanctuary resources. As a result, a significant reduction in profits for a substantial number of small entities is not expected as a result of the proposed regulatory action.

v. Description of Significant Alternatives to the Proposed Action and Discussion of how the Alternatives Attempt To Minimize Economic Impacts on Small Entities

This proposed regulatory action, if implemented, is not expected to reduce the profits of any small businesses directly regulated by this action. As a result, the issue of significant alternatives is not relevant.

3. Non-Consumptive Recreation Industry

This section considers the number of small businesses operating within the non-consumptive recreation industry and the potential effects on those businesses. Small businesses considered within this industry include dive and snorkeling for-hire operations, rental equipment operations, wildlife viewing operations, and other businesses that either utilize or whose customers utilize sanctuary resources.

i. Description and Estimate of the Number of Small Entities to Which the Proposed Action Would Apply

Eighteen dive shops are located within feasible traveling distance to eastern Lake Ontario.⁷ All of these non-consumptive businesses are believed to be small entities.

ii. Description of the Projected Reporting, Record-Keeping and Other Compliance Requirements of the Proposed Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary for the Preparation of the Report or Records

The proposed regulatory action would not establish any new reporting or record-keeping requirements.

⁷ Shea, R., Schwarzmann, D. (2021). Proposed Lake Ontario National Marine Sanctuary study area profile. National Marine Sanctuaries Conservation Series ONMS-21-04. U.S. Department of Commerce, National Oceanic and Atmospheric Administration, Office of National Marine Sanctuaries, Silver Spring, MD. Available at: <https://sanctuaries.noaa.gov/lake-ontario/>.

iii. Identification of All Relevant Federal Rules, Which May Duplicate, Overlap or Conflict With the Proposed Rule

No duplicative, overlapping, or conflicting Federal rules have been identified.

iv. Significance of Economic Effects on Small Entities

Substantial Number Criterion

Since all these non-consumptive businesses are believed to be small entities, it is assumed that this proposed rule would affect a substantial number of small entities.

Significant Economic Impacts

Profitability: Do the regulations significantly reduce profits for a substantial number of small entities?

Estimates of revenues, costs, and profitability of scuba diving and snorkeling for-hire businesses are not available. The proposed regulations are designed to conserve and sustain resources to ensure protection and conservation of shipwrecks without restricting access to the sites. As part of the proposed action, NOAA would set up a mooring program in the sanctuary to provide moorings at popular wreck sites for the public to use to secure their vessels when accessing the wrecks. Moorings eliminate the need for anchoring directly into a shipwreck site, which decreases the likelihood of damage from grappling or anchoring; provide secure and convenient anchoring points for scuba diving and snorkeling for-hire businesses; and facilitate public access and safer diving by providing a sturdy means of descent and ascent for divers. NOAA plans to engage the Sanctuary Advisory Councils and dive charters to determine how many buoys are needed and where to install them. Therefore, this proposed action will support small businesses by providing continued access to these dive and snorkeling sites. Given the information above, a significant reduction in profits for a substantial number of small entities is not expected to result from the proposed regulatory action.

v. Description of Significant Alternatives to the Proposed Action and Discussion of How the Alternatives Attempt To Minimize Economic Impacts on Small Entities

This proposed regulatory action, if implemented, is not expected to reduce the profits of any small businesses directly regulated by this proposed rule. As a result, the issue of significant alternatives is not relevant.

G. Paperwork Reduction Act

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 Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, unless that collection of information displays a currently valid Office of Management and Budget (OMB) control number.

NOAA has a valid Office of Management and Budget (OMB) control number (0648–0141) for the collection of public information related to the processing of permits across the National Marine Sanctuary System. NOAA's proposal to create a national marine sanctuary in Lake Ontario would likely result in a minimal increase in the number of requests for general permits, special use permits, certifications, and authorizations because this action proposes to add those approval types for this proposed sanctuary. A large increase in the number of permit requests would require a change to the reporting burden certified for OMB control number 0648–0141. While not expected, if such permit requests do increase, a revision to this control number for the processing of permits would be requested.

In the most recent Information Collection Request revision and approval for national marine sanctuary permits (dated November 30, 2021), NOAA reported approximately 424 national marine sanctuary permitting actions each year, including applications for all types of permits, requests for permit amendments, and the conduct of administrative appeals. Of this amount, LONMS is expected to add 4 to 5 permit requests per year. The public reporting burden for national marine sanctuaries general permits is estimated to average three responses with an average of 1.5 hours per response, to include application submission, a cruise or flight log (or some other form of activity report), and a final summary report after the activity is complete.

Please send any comments regarding the burden estimate for this data collection requirement or any other aspect of this data collection, including suggestions for reducing the burden, to NOAA (see **ADDRESSES** above) and to OMB by email to *OIRA_submission@omb.eop.gov* or fax to (202) 395–7285. Before an agency submits a collection of information to OMB for approval, the agency shall provide 60-day notice in the **Federal Register**, and otherwise consult with members of the public and

affected agencies concerning each proposed collection of information, to solicit comments to:

- 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.

H. National Historic Preservation Act

Section 106 of the National Historic Preservation Act (NHPA, 54 U.S.C. 306108) requires Federal agencies to consider the effects of their undertakings on historic properties and afford the Advisory Council on Historic Preservation (ACHP) an opportunity to comment. "Historic property" means any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places maintained by the Secretary of the Interior. This term includes artifacts, records, and material remains that are related to and located within such properties, including properties of traditional religious and cultural importance to an Indigenous nation or Tribe or Native Hawaiian organization. The regulations implementing section 106 of the NHPA (36 CFR 800) guide Federal agencies in meeting this responsibility through a process to identify historic properties potentially affected by the undertaking, assess its effects, and seek ways to avoid, minimize, or mitigate any adverse effects on historic properties, all of which occur in consultation with interested parties.

NOAA has determined that although designation of a national marine sanctuary and related rulemaking for sanctuary-specific regulations meet the definition of an undertaking as defined at 800.16(y), these activities are not of the type that have the potential to cause effects on historic properties, and therefore NOAA has no further obligations under section 106, per 800.3(a)(1). NOAA, however, recognizes

that designation of a national marine sanctuary will lead to subsequent activities that may constitute undertakings subject to section 106 review under the NHPA and therefore NOAA is pursuing execution of a Programmatic Agreement (PA) pursuant to 36 CFR 800.14(b). The PA will provide a framework and process for consideration of future undertakings resulting from management of the sanctuary, associated field operations, and other activities, if the sanctuary were designated. NOAA will develop this agreement in consultation with the New York State Historic Preservation Officer (SHPO), the ACHP, and other consulting parties.

I. Sunken Military Craft Act

The Sunken Military Craft Act of 2004 (SMCA; Pub. L. 108–375, Title XIV, sections 1401 to 1408; 10 U.S.C. 113 note) preserves and protects from unauthorized disturbance all sunken military craft that are owned by the United States government, as well as foreign sunken military craft that lie within United States waters, as defined in the SMCA, and other vessels owned or operated by a government on military noncommercial service when it sank. Thousands of U.S. sunken military craft lie in waters around the world, many accessible to looters, treasure hunters, and others who may cause damage to them. These craft, and their associated contents, represent a collection of non-renewable and significant historical resources that often serve as war graves, carry unexploded ordnance, and contain oil and other hazardous materials. By protecting sunken military craft, the SMCA helps reduce the potential for irreversible harm to these nationally important historical and cultural resources.

The proposed Lake Ontario National Marine Sanctuary may include sunken military craft that have yet to be discovered, such as U.S. military training aircraft believed to have been lost in the area. Sunken military craft fall under the jurisdiction of a number of Federal agencies such as the U.S. Navy and the U.S. Coast Guard. NOAA would coordinate with the U.S. Navy and any other applicable Federal agency regarding activities directed at sunken military craft discovered within the sanctuary.

J. Coastal Zone Management Act (CZMA)

Section 307 of the Coastal Zone Management Act (CZMA; 16 U.S.C. 1456) requires Federal agencies to consult with a state's coastal program on potential federal regulations having an

effect on state waters. Because the proposed sanctuary in Lake Ontario would lie in New York State waters, NOAA intends to submit a copy of this proposed rule and supporting documents to the State of New York's Coastal Management Program for evaluation of Federal consistency under the CZMA. NOAA will publish the final rule and designation only after completion of the Federal consistency process under the CZMA.

K. Executive Order 12898: Environmental Justice

Executive Order 12898 directs that the programs of Federal agencies identify and avoid disproportionately high and adverse effects on human health and the environment of minority or low-income populations. The designation of national marine sanctuaries by NOAA helps to ensure the enhancement of environmental quality for all populations in the United States. The alternatives described in this document would not result in disproportionate negative impacts on any minority or low-income population. In addition, many of the potential impacts from designating the proposed sanctuary would result in long-term or permanent beneficial impacts by protecting underwater cultural resources, which may have a positive impact on communities by providing employment and educational opportunities, and potentially result in improved ecosystem services.

List of Subjects in 15 CFR Part 922

Administrative practice and procedure, Coastal zone, Cultural resources, Historic preservation, Marine protected areas, Marine resources, National marine sanctuaries, Recreation and recreation areas, Reporting and recordkeeping requirements, Shipwrecks.

Nicole R. LeBoeuf,

Assistant Administrator for Ocean Services and Coastal Zone Management, National Ocean Service, National Oceanic and Atmospheric Administration.

For the reasons set forth above, NOAA is amending part 922, title 15 of the Code of Federal Regulations as follows:

PART 922—NATIONAL MARINE SANCTUARY PROGRAM REGULATIONS

■ 1. The authority citation for part 922 continues to read as follows:

Authority: 16 U.S.C. 1431 *et seq.*

■ 2. Amend § 922.1 by revising paragraph (a)(2) to read as follows:

§ 922.1 Purposes and applicability of the regulations.

(a) * * *

(2) To implement the designations of the national marine sanctuaries, for which site specific regulations appear in subparts F through U, by regulating activities affecting them, consistent with their respective terms of designation, in order to protect, restore, preserve, manage, and thereby ensure the health, integrity and continued availability of the conservation, recreational, ecological, historical, scientific, educational, cultural, archaeological and aesthetic resources and qualities of these areas.

* * * * *

■ 3. Amend § 922.4 by revising the section to read as follows:

§ 922.4 Boundaries.

The boundaries for each of the sixteen National Marine Sanctuaries covered by this part are described in subparts F through U, respectively.

■ 4. Amend § 922.5 by revising the paragraph to read as follows:

§ 922.5 Allowed activities.

All activities (*e.g.*, fishing, boating, diving, research, education) may be conducted unless prohibited or otherwise regulated in Subparts F through U, subject to any emergency regulations promulgated pursuant to §§ 922.7, 922.112(b), 922.165, 922.185, 922.196, 922.204, 922.214, or 922.224 subject to all prohibitions, regulations, restrictions, and conditions validly imposed by any Federal, State, Tribal, or local authority of competent jurisdiction, including, but not limited to, Federal, Tribal, and State fishery management authorities, and subject to the provisions of section 312 of the NMSA. The Director may only directly regulate fishing activities pursuant to the procedure set forth in section 304(a)(5) of the NMSA.

■ 5. Amend § 922.6 by revising the sentence to read as follows:

§ 922.6 Prohibited or otherwise regulated activities.

Subparts F through U set forth site-specific regulations applicable to the activities specified therein.

■ 6. In § 922.7 add paragraph (b)(7) to read as follows:

§ 922.7 Emergency regulations.

* * * * *

(b) * * *

(7) Lake Ontario National Marine Sanctuary, § 922.224.

■ 7. Amend § 922.11 by revising the definition of “sanctuary resource” to read as follows:

§ 922.11 Definitions.

* * * * *

Sanctuary resource means any living or non-living resource of a national marine sanctuary, or the parts or products thereof, that contributes to the conservation, recreational, ecological, historical, educational, cultural, archaeological, scientific, or aesthetic value of the national marine sanctuary, including, but not limited to, waters of the sanctuary, the seabed or submerged lands of the sanctuary, other submerged features and the surrounding seabed, carbonate rock, corals and other bottom formations, coralline algae and other marine plants and algae, marine invertebrates, brine-seep biota, phytoplankton, zooplankton, fish, birds, sea turtles and other marine reptiles, marine mammals, and maritime heritage, cultural, archaeological, and historical resources. For Thunder Bay National Marine Sanctuary and Underwater Preserve, Sanctuary resource is defined at § 922.191. For Hawaiian Islands Humpback Whale, Sanctuary resource is defined at § 922.182. For Mallows Bay-Potomac River National Marine Sanctuary, Sanctuary resource is defined at § 922.201(a). For Wisconsin Shipwreck Coast National Marine Sanctuary, sanctuary resource is defined at § 922.211. For Lake Ontario National Marine Sanctuary, sanctuary resource is defined at § 922.221.

* * * * *

■ 8. Amend § 922.30 by revising paragraph (a)(2) to read as follows:

§ 922.30 National Marine Sanctuary general permits.

(a) * * *

(2) The permit procedures and criteria for all national marine sanctuaries in which the proposed activity is to take place in accordance with relevant site-specific regulations appearing in subparts F through U.

* * * * *

■ 9. Amend 922.36 by revising paragraphs (a) and (b)(1)(ii) to read as follows:

§ 922.36 National Marine Sanctuary authorizations.

(a) *Authority to issue authorizations.* The Director may authorize a person to conduct an activity otherwise prohibited by subparts L through P or subparts R through U of this part, if such activity is specifically allowed by any valid Federal, State, or local lease, permit, license, approval, or other authorization (hereafter called “agency approval”) issued after the effective date of sanctuary designation or expansion, provided the applicant complies with

the provisions of this section. Such an authorization by ONMS is hereafter referred to as an “ONMS authorization.”

(b) * * *

(ii) Notification must be sent to the Director, Office of National Marine Sanctuaries, to the attention of the relevant Sanctuary Superintendent(s) at the address specified in subparts L through P, or subpart R through U, as appropriate.

* * * * *

■ 10. Add subpart U to read as follows:

Subpart U—Lake Ontario National Marine Sanctuary

Sec.

922.220 Boundary.

922.221 Definitions.

922.222 Co-management.

922.223 Prohibited or otherwise regulated activities.

922.224 Emergency regulations.

922.225 Permit procedures and review criteria.

922.226 Certification of preexisting leases, licenses, permits, approvals, other authorizations, or rights to conduct a prohibited activity.

922.227 Effect on affected federally-recognized Indian Tribes.

Appendix A to Subpart U of Part 922—Lake Ontario National Marine Sanctuary Boundary Description and Coordinates of the Excluded Areas

Appendix B to Subpart U of Part 922—Lake Ontario National Marine Sanctuary Terms of Designation

§ 922.220 Boundary.

Lake Ontario National Marine Sanctuary consists of an area of approximately 1,302 square nautical miles (1,724 square miles) of Lake Ontario waters within the State of New York and the submerged lands thereunder; over, around, and under the submerged underwater cultural resources in Lake Ontario. The precise boundary coordinates are listed in Appendix A to this subpart. The western boundary of the sanctuary begins at approximately the border between Wayne County and Monroe County where the shoreline (defined here and throughout the remainder of this boundary description as the low water datum) intersects the line segment formed between Point 1 and Point 2. From this intersection, the boundary continues north into Lake Ontario to Point 2 and then to each successive point in numerical order to Point 7. The sanctuary boundary continues east from Point 7 to each successive point in numerical order to Point 10. The boundary continues roughly to the northeast from Point 10 to Point 11 and then to Point 12, just east of Alexandria, ON, Canada.

From Point 12, the boundary continues roughly southeast towards Point 13 until it intersects the shoreline at the low water datum near the lakeward end of Market Street in Cape Vincent, New York. The boundary follows the shoreline from this intersection roughly to the southwest around Tibbetts Point and then continues roughly to the southeast around Wilson Point and Dablon Point until it intersects the line segment formed between Point 14 and Point 15 at the Rt. 6 bridge at the upper end of Mud Bay. From this intersection, the boundary continues towards Point 15 until it intersects the shoreline at approximately the mouth of Kents Creek. The boundary follows the shoreline from this intersection to the southwest around Baird Point continuing roughly southeast cutting off the mouths of creeks and streams around Point Peninsula and along western Chaumont Bay until it intersects the line segment formed between Point 16 and Point 17. From this intersection, the boundary continues across the Chaumont River towards Point 17 until it intersects the shoreline near the eastern side of the West Main Street bridge. From this intersection, the boundary follows the shoreline around eastern Chaumont Bay, Point Salubrious, and Guffin Bay and then around Pillar Point and Everleigh Point and up the western side of Black River Bay, until it intersects the line segment formed between Point 18 and Point 19 at approximately the mouth of Black River. The boundary continues from this intersection across the Black River towards Point 19 until it intersects the shoreline.

From this intersection, the boundary follows the shoreline roughly southwest along the eastern side of Black River Bay and Henderson Bay continuing around Stony Point and then roughly south cutting off the mouths of rivers, streams, creeks, and ponds as it continues around Mexico Bay until it intersects the line segment formed between Point 20 and Point 21 just east of Oswego Harbor. From this intersection, the boundary continues towards Point 21 until it intersects the shoreline at the eastern breakwater of Oswego Harbor. From this intersection, the boundary follows the lakeward shoreline northwest until it intersects the line segment formed between Point 22 and Point 23. From this intersection, the boundary continues across the mouth of Oswego Harbor towards Point 22 until it intersects the shoreline at the end of the western breakwater of Oswego Harbor. From this intersection, the

boundary follows the lakeward shoreline roughly to the southwest cutting off the mouths of rivers, streams, creeks, and ponds until it intersects the line segment formed between Point 24 and Point 25 at the end of the eastern breakwater of Little Sodus Bay. From this intersection, the boundary continues across the mouth of Little Sodus Bay towards Point 25 until it intersects the shoreline at the end of the western breakwater of Little Sodus Bay. From this intersection, the boundary follows the lakeward shoreline roughly west until it intersects the line segment formed between Point 26 and Point 27 at the mouth of Blind Sodus Bay. From this intersection, the boundary continues across the mouth of Blind Sodus Bay towards Point 27 until it intersects the shoreline. From this intersection, the boundary follows the shoreline roughly southwest cutting across the mouths of rivers, streams, creeks, and ponds until it intersects the line segment formed between Point 28 and Point 29 at the mouth of Port Bay. From this intersection, the boundary continues across the mouth of Port Bay towards Point 29 until it intersects the shoreline. From this intersection, the boundary follows the shoreline roughly west until it intersects the line segment formed between Point 30 and Point 31 at the mouth of East Bay. From this intersection, the boundary continues across the mouth of East Bay towards Point 31 until it intersects the shoreline.

From this intersection, the boundary follows the shoreline roughly west until it intersects the line segment formed between Point 32 and Point 33 at the eastern breakwater of Sodus Bay. From this intersection, the boundary continues across the mouth of Sodus Bay towards Point 33 until it intersects the shoreline at the western breakwater of Sodus Bay. From this intersection, the boundary follows the shoreline roughly west cutting off the mouths of rivers, streams, creeks, and ponds until it intersects the line segment formed between Point 34 and Point 35 where it ends.

The inner landward sanctuary boundary is defined by and follows the shoreline as defined by the low water datum where not already specified in the boundary description above.

The Tibbetts Point Anchorage Area is excluded from the sanctuary area described above, and its boundary begins at Point TPAA1 and continues to each successive point in numerical order until ending at Point TPAA7.

§ 922.221 Definitions.

(a) The following terms are defined for purposes of Subpart U:

Sanctuary resource means all historical resources as defined at 15 CFR 922.3, which includes any pre-contact and historic sites, structures, districts, objects, and shipwreck sites within sanctuary boundaries.

Shipwreck site means all archaeological and material remains associated with sunken watercraft or aircraft that are historical resources, including associated components, cargo, contents, artifacts, or debris fields that may be exposed or buried within the lake bed.

Tethered underwater mobile system means remotely operated vehicles and other systems with onboard propulsion systems that utilize a tether connected to a station-holding (e.g. by anchor, dynamic positioning, or manual vessel operation) surface support vessel.

§ 922.222 Co-management.

NOAA has primary responsibility for the management of the Sanctuary pursuant to the Act. However, as the Sanctuary is in state waters, NOAA will co-manage Lake Ontario National Marine Sanctuary in collaboration with the State of New York. The Director may enter into a Memorandum of Agreement regarding this collaboration that may address, but not be limited to, such aspects as areas of mutual concern, including sanctuary resource protection, programs, permitting, activities, development, and threats to sanctuary resources.

§ 922.223 Prohibited or otherwise regulated activities.

(a) Except as specified in paragraph (b) of this section, the following activities are prohibited and thus are unlawful for any person to conduct or to cause to be conducted:

(1) Moving, removing, recovering, altering, destroying, possessing or otherwise injuring, or attempting to move, remove, recover, alter, destroy, possess or otherwise injure a sanctuary resource.

(2) Possessing, selling, offering for sale, purchasing, importing, exporting, exchanging, delivering, carrying, transporting, or shipping by any means any sanctuary resource within or outside of the sanctuary.

(3) Grappling into or anchoring on shipwreck sites.

(4) Deploying a tethered underwater mobile system at shipwreck sites.

(5) Interfering with, obstructing, delaying or preventing an investigation, search, seizure or disposition of seized property in connection with enforcement of the Act or any regulation or any permit issued under the Act.

(b) The prohibitions in paragraphs (a)(1) through (5) of this section do not

apply to any activity necessary to respond to an emergency threatening life, property, or the environment; or to activities necessary for valid law enforcement purposes.

§ 922.224 Emergency regulations.

(a) Where necessary to prevent or minimize the destruction of, loss of, or injury to a sanctuary resource, or to minimize the imminent risk of such destruction, loss, or injury, any and all activities are subject to immediate temporary regulation, including prohibition. An emergency regulation shall not take effect without the approval of the Governor of New York or her/his designee or designated agency.

(b) Emergency regulations remain in effect until a date fixed in the rule or six months after the effective date, whichever is earlier. The rule may be extended once for not more than six months.

§ 922.225 Permit procedures and review criteria.

(a) A person may conduct an activity otherwise prohibited by §§ 922.223 (a)(1) through (4) if conducted under and in accordance with the scope, purpose, terms and conditions of a permit issued under this section and subpart D of this part.

(b) Applications for such permits should be addressed to the Director, Office of National Marine Sanctuaries; ATTN: Superintendent, Lake Ontario National Marine Sanctuary, 1305 East-West Highway, Silver Spring, MD 20910.

§ 922.226 Certification of preexisting leases, licenses, permits, approvals, other authorizations, or right to conduct a prohibited activity.

(a) A person may conduct an activity prohibited by §§ 922.223 (a)(1) through (4) within the sanctuary if such activity is specifically authorized by a valid Federal, state, or local lease, permit, license, or right of subsistence use or of access that is in existence on the effective date of sanctuary designation, provided that the holder of the lease, permit, license, or right of subsistence use or of access complies with § 922.10 and provided that:

(1) The holder of such authorization or right notifies the Director, in writing, within 90 days of the effective date of the sanctuary designation of the existence and location of such authorization or right and requests certification of such authorization or right; and

(2) The holder complies with any terms and conditions on the exercise of such authorization or right imposed as

a condition of certification, by the Director, to achieve the purposes for which the sanctuary was designated.

(b) Requests for certifications shall be addressed to the Director, Office of National Marine Sanctuaries; ATTN: Sanctuary Superintendent, Lake Ontario National Marine Sanctuary, 1305 East-West Hwy., 11th Floor, Silver Spring, MD 20910 or sent by electronic means as defined in the instructions for the ONMS permit application. A copy of the lease, permit, license, or right of subsistence use or of access must accompany the request.

(c) A certification requester with an authorization or right described in paragraph (a) of this section authorizing an activity prohibited by § 922.223 (a)(1) through (4) may continue to conduct the activity without being in violation of applicable provisions of § 922.223 (a)(1) through (4), pending the Director's review of and decision regarding his or her certification request.

(d) The Director may request additional information from the certification requester as the Director deems reasonably necessary to condition appropriately the exercise of the certified authorization or right to achieve the purposes for which the sanctuary was designated. The Director must receive the information requested within 45 days of the date of the Director's request for information. Failure to provide the requested information within this time frame may be grounds for denial by the Director of the certification request.

(e) In considering whether to issue a certification, the Director may seek and consider the views of any other person or entity, within or outside the Federal government, and may hold a public hearing as deemed appropriate by the Director.

(f) Upon completion of review of the authorization or right and information received with respect thereto, the Director shall communicate, in writing, any decision on a certification request or any action taken with respect to any certification made under this section, in writing, to both the holder of the certified lease, permit, license, approval, other authorization, or right, and the issuing agency, and shall set forth the reason(s) for the decision or action taken.

(g) The Director may amend, suspend, or revoke any certification issued under this section whenever continued operation would otherwise be inconsistent with any terms or conditions of the certification. Any such action shall be forwarded in writing to both the certification holder and the agency that issued the underlying lease,

permit, license, or right of subsistence use or of access, and shall set forth reason(s) for the action taken.

(h) The Director may amend any certification issued under this section whenever additional information becomes available that he or she determines justifies such an amendment.

(i) The certification holder may appeal any action conditioning, amending, suspending, or revoking any certification in accordance with the procedures set forth at § 922.37.

(j) Any time limit prescribed in or established under this section may be extended by the Director for good cause.

(k) It is unlawful for any person to violate any terms and conditions in a certification issued under this section.

§ 922.227 Effect on affected federally-recognized Indian tribes.

The exercise of treaty rights for federally-recognized Indian Tribes and their citizens is not modified, altered, or in any way affected by the regulations promulgated in this subpart. The Director shall consult with the governing body of each federally-recognized Indian Tribe protected by the 1794 Treaty of Canandaigua regarding any matter which might affect the ability of the Tribe's citizens to participate in activities protected by that treaty in the Sanctuary.

Appendix A to Subpart U of Part 922—Lake Ontario National Marine Sanctuary Boundary Description and Coordinates of the Excluded Areas

[Coordinates listed in this appendix are unprojected (Geographic) and based on the North American Datum of 1983]

Point ID	Longitude	Latitude
1 *	-77.37605	43.27611
2	-77.37595	43.28695
3	-77.37586	43.29671
4	-77.37621	43.34516
5	-77.37720	43.37579
6	-77.38799	43.63154
7	-77.38811	43.63443
8	-77.27009	43.63406
9	-77.03338	43.63283
10	-76.79668	43.63112
11	-76.43893	44.09406
12	-76.35283	44.13432
13 *	-76.33917	44.12954
14 *	-76.31232	44.08230
15 *	-76.31207	44.08198
16 *	-76.14042	44.07041
17 *	-76.13852	44.06959
18 *	-76.06446	43.99626
19 *	-76.06179	43.99401
20 *	-76.50692	43.46890
21 *	-76.50783	43.46975
22 *	-76.51393	43.47389
23 *	-76.51675	43.47341
24 *	-76.70792	43.35032
25 *	-76.70895	43.35029

Point ID	Longitude	Latitude
26 *	-76.72097	43.34356
27 *	-76.72141	43.34356
28 *	-76.83719	43.30480
29 *	-76.83817	43.30492
30 *	-76.89154	43.29490
31 *	-76.89215	43.29513
32 *	-76.97229	43.27682
33 *	-76.97398	43.27738
34 *	-77.37605	43.27611
35	-77.37595	43.28695
TPAA1	-76.39049	44.08896
TPAA2	-76.37805	44.08940
TPAA3	-76.38611	44.07613
TPAA4	-76.39271	44.06881
TPAA5	-76.41217	44.07577
TPAA6	-76.39897	44.09566
TPAA7	-76.39049	44.08896

Note: The coordinates in the table above marked with an asterisk (*) are not a part of the sanctuary boundary. These coordinates are landward reference points used to draw a line segment that intersects with the shoreline at the low water datum.

Appendix B to Subpart U of Part 922—Lake Ontario National Marine Sanctuary Terms of Designation

Under the authority of the National Marine Sanctuaries Act, as amended (the "Act" or "NMSA"), 16 U.S.C. 1431 *et seq.*, 1,302 nmi² (1,724 mi²) of Lake Ontario off the coast of New York's coastal counties of Wayne, Cayuga, Oswego, and Jefferson are hereby designated as a National Marine Sanctuary for the purpose of providing long-term protection and management of the cultural and historical resources and the recreational, research, educational, and aesthetic qualities of the area.

Article I: Effect of Designation

The NMSA authorizes the issuance of such regulations as are necessary and reasonable to implement the designation, including managing and protecting the cultural and historical resources and the recreational, research, and educational qualities of Lake Ontario National Marine Sanctuary (the "Sanctuary"). Section 1 of Article IV of this Designation Document lists those activities that may have to be regulated on the effective date of designation, or at some later date, in order to protect Sanctuary resources and qualities. Listing an activity does not necessarily mean that it will be regulated. However, if an activity is not listed it may not be regulated, except on an emergency basis, unless Section 1 of Article IV is amended by the same procedures by which the original Sanctuary designation was made.

Article II: Description of the Area

Lake Ontario National Marine Sanctuary covers approximately 1,302 nmi² (1,724 mi²) in eastern Lake Ontario. The boundary coordinates are defined by regulation (15 CFR 922.220).

Article III: Special Characteristics of the Area

Over 1,000 years ago, the Mohawk, Oneida, Onondaga, Cayuga and Seneca Nations were united into the Haudenosaunee Confederacy, under the Gayanashagowa, the Great Law of

Peace. Portions of the original homelands of the Onondaga Nation, Cayuga Nation, Seneca Nation, and Oneida Nation lie within the proposed boundaries of the sanctuary. This area was their homeland and they developed a deep understanding of, and had a strong connection to, the land and to the water.

Eastern Lake Ontario represents a diverse array of important events in our Nation's history, including military conflicts, maritime innovation, and American expansion to the west. This area has been a critical nexus of maritime trade and transportation for centuries, beginning with canoes and boats of early Indigenous peoples. During the colonial period, Lake Ontario was a strategic theater of conflict among European powers and the young American republic. Military actions occurred in the region during the French and Indian War, Revolutionary War, and the War of 1812. Later, this region was critical to the development of the American West and the Nation's industrial core.

Well-preserved by cold, fresh water, the shipwrecks and other underwater cultural resources in the proposed sanctuary possess exceptional historical, archaeological and recreational value. Vessels that historically plied Lake Ontario's waters often met with treacherous conditions, which resulted in numerous wrecking events. The area contains a total of 43 known shipwrecks and one aircraft, including one shipwreck (*St. Peter*) that is listed on the National Register of Historic Places and one wreck (*David Mills*) that is a New York State Submerged Cultural Preserve and Dive Site. This area may also include approximately 20 potential shipwreck sites (shipwrecks which may exist, but additional research is needed to locate and describe these shipwrecks), three aircraft, and 13 other underwater archaeological sites. Represented in the collection are commercial and military vessels from colonial wars and the War of 1812, as well as submerged battlefields at Oswego and Sackets Harbor. Other shipwrecks represent the earliest maritime commerce on the Great Lakes, including the nearly intact *Lady Washington* built in 1797.

Article IV: Scope of Regulations

Section 1. Activities Subject to Regulation

The following activities are subject to regulation under the NMSA. Such regulation may include prohibitions to ensure the protection and management of the conservation, recreational, historical, scientific, educational, cultural, archaeological, or aesthetic resources and qualities of the area. Listing an activity in the Terms of Designation does not mean that such activity is being or will be regulated. Listing an activity here means that Secretary of Commerce can regulate the activity, after complying with all applicable regulatory laws, without going through the designation procedures required by paragraphs (a) and (b) of section 304 of the NMSA, 16 U.S.C. 1434(a) and (b). Further, no regulation issued under the authority of the NMSA except an emergency regulation issued with the approval of the Governor of the State of New York may take effect in New York state waters within the sanctuary if the Governor

of the State of New York certifies to the Secretary of Commerce that such regulation is unacceptable within the forty-five day review period specified in NMSA.

Activities Subject to Regulation:

- Injuring or disturbing sanctuary resources;
- Possessing, transporting, or engaging in commerce of any sanctuary resource.
- Grappling into or anchoring on shipwreck sites.
- Deploying tethered underwater mobile systems at shipwreck sites.

Section 2. Emergencies

Where necessary to prevent or minimize the destruction of, loss of, or injury to a Sanctuary resource or quality; or minimize the imminent risk of such destruction, loss, or injury, any activity and all activities, including those not listed in Section 1, are subject to immediate temporary regulation, including prohibition. An emergency regulation shall not take effect without the approval of the Governor of New York or her/his designee or designated agency.

Article V: Alteration of This Designation

The terms of designation, as defined under Section 304(e) of the Act, may be modified only by the same procedures by which the original designation is made, including public hearings, consultations with interested Federal, Tribal, state, regional, and local authorities and agencies, review by the appropriate Congressional committees, and approval by the Secretary of Commerce, or his or her designee.

[FR Doc. 2023-00861 Filed 1-18-23; 8:45 am]

BILLING CODE 3510-NK-P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

20 CFR Part 726

RIN 1240-AA16

Black Lung Benefits Act: Authorization of Self-Insurers

AGENCY: Office of Workers' Compensation Programs, Labor.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: The Department is proposing revisions to regulations under the Black Lung Benefits Act (BLBA or the Act) governing authorization of self-insurers. These proposed rules will determine the process for coal mine operators to apply for authorization to self-insure, the requirements operators must meet to qualify to self-insure, the amount of security self-insured operators must provide, and the process for operators to appeal determinations made by the Office of Workers' Compensation Programs (OWCP).

DATES: The Department invites written comments on the proposed regulations from interested parties. Written comments must be received by March 20, 2023.

ADDRESSES: You may submit written comments by any of the following methods. To facilitate receipt and processing of comments, OWCP encourages interested parties to submit their comments electronically.

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions on the website for submitting comments.

- *Facsimile:* (202) 693-1395 (this is not a toll-free number). Only comments of ten or fewer pages, including a fax cover sheet and attachments, if any, will be accepted by fax.

- *Regular Mail/Hand Delivery/Courier:* Submit comments on paper to the Division of Coal Mine Workers' Compensation Programs, Office of Workers' Compensation Programs, U.S. Department of Labor, 200 Constitution Avenue NW, Suite S3229-DCWMC, Washington, DC 20210. The Department's receipt of U.S. mail may be significantly delayed due to security procedures. You must take this into consideration when preparing to meet the deadline for submitting comments.

Instructions: Your submission must include the agency name and the Regulatory Information Number (RIN) for this rulemaking. *Caution:* All comments received will be posted without change to <https://www.regulations.gov>. Please do not include any personally identifiable or confidential business information you do not want publicly disclosed.

Docket: For access to the rulemaking docket and to read background documents or comments received, go to <https://www.regulations.gov>. Although some information (e.g., copyrighted material) may not be available through the website, the entire rulemaking record, including any copyrighted material, will be available for inspection at OWCP. Please contact the individual named below if you would like to inspect the record.

FOR FURTHER INFORMATION CONTACT: Michael Chance, Director, Division of Coal Mine Workers' Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, 200 Constitution Avenue NW, Suite S3229-DCWMC, Washington, DC 20210. Telephone: 1-800-347-2502. This is a toll-free number. TTY/TDD callers may dial toll-free 1-877-889-5627 for further information.

SUPPLEMENTARY INFORMATION:

I. Background of This Rulemaking

The BLBA, 30 U.S.C. 901–944, provides for the payment of benefits to coal miners and certain of their dependent survivors for total disability or death due to pneumoconiosis, commonly known as black lung disease. 30 U.S.C. 901(a); *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 5 (1976). The Act places the primary responsibility for paying benefits on coal mine operators. 30 U.S.C. 932(b). When a coal miner is determined to be eligible for benefits, the operator responsible for paying benefits (the responsible operator) is generally the one that most recently employed the miner for a period of at least one year and is financially capable of paying benefits. 20 CFR 725.495(a)(1). If a responsible operator cannot be determined, is unable to pay, or defaults on its obligation to pay, the responsibility for paying benefits falls to the Black Lung Disability Trust Fund, which is financed by an excise tax on coal mined for domestic use and, as Treasury, borrowing from the U.S. Treasury's general fund. 30 U.S.C. 932(j), 934(b); 26 U.S.C. 4121, 9501.

Because coal mine operators are principally responsible for paying benefits, the Act requires every operator to secure the payment of benefits for which it may be found liable. 30 U.S.C. 932(b). Each operator must secure the payment of benefits either by purchasing commercial insurance or by qualifying as a self-insurer “in accordance with regulations prescribed by the Secretary.” 30 U.S.C. 933(a); *see also* 20 CFR 726.1.

The current regulations—Part 726 Subpart B—establish the standards for a coal mine operator to qualify as a self-insurer. They provide that, to qualify as a self-insurer, an operator must meet certain minimum requirements, including “obtain[ing] security . . . in a form approved by [OWCP] and . . . in an amount to be determined by [OWCP].” 20 CFR 726.101(b)(4). The regulations identify four forms of security that OWCP may allow an operator to provide: (1) Indemnity bonds; (2) deposits of negotiable securities; (3) letters of credit; or (4) trust funds under Section 501(c)(21) of the Internal Revenue Code. 20 CFR 726.104(b). The regulations further provide that “[OWCP] shall require the amount of security which it deems necessary and sufficient to secure the performance by the applicant of all obligations imposed upon him as an operator by the Act.” 20 CFR 726.105. The regulations also set forth a non-exhaustive list of factors that OWCP will

consider in setting the amount of security an operator must provide, including the operator's net worth, the existence of a guarantee by a parent corporation, and the operator's existing liability for benefits. *Id.*

The Department historically has not required self-insured operators to post security with a face value that would cover all of the operator's expected black lung liability. *See* 62 FR 3338, 3370 (Jan. 22, 1997). Instead, the Department has relied in part on a company's size as evidence of its ability to make future benefits payments. *Id.* Depending on the operator's assets, the Department usually required security sufficient to cover from three to fifteen years of the operator's payments on claims currently in award status, rather than the operator's total liability for current and future claims. *Id.* Under this model, most large operators therefore posted fewer years of payment relative to smaller operators.

A number of bankruptcies in the mining industry revealed weaknesses in that process and demonstrated that a more substantial security amount would be required to adequately protect the Trust Fund. Specifically, beginning in 2014, three large self-insured operators filed for bankruptcy. Because these operators had insufficient securities to cover the full amount of expected benefits, an estimated \$865 million in liabilities will ultimately transfer to the Trust Fund. *See* U.S. Government Accountability Office, *Federal Black Lung Benefits Program: Improved Oversight of Coal Mine Operator Insurance is Needed*, at 13 (Feb. 2020), available at <https://www.gao.gov/products/gao-20-21>.

In response, OWCP developed revised guidelines and procedures for authorizing coal mine operators to self-insure, which it began to implement in 2019. These guidelines were intended to standardize the process by which applicants provide financial and actuarial information to OWCP. OWCP required each company to calculate and report its projected black lung liabilities through actuarial reports using a set of standardized assumptions, including discount rate, claim cost trends, and the probability of awards. OWCP also developed a set of financial metrics and a methodology to assess each operator's solvency, profitability, and risk of default. This assessment would determine the proportion of the operator's projected liabilities it would be required to post as security. Operators determined to be at less risk of not meeting their obligations would be required to provide smaller amounts of security, while operators at higher

risk would be required to provide larger amounts of security. These guidelines were summarized in a December 2020 bulletin, *see* BLBA Bulletin No. 21–01 (Dec. 7, 2020).¹

Although the revised guidelines allowed OWCP to better identify and account for self-insured operators that presented significant bankruptcy risk, they proved problematic in several respects. The financial metrics were not able to consistently predict which operators were at risk of experiencing financial difficulties. The process contemplated by the guidelines also imposed significant burdens on OWCP in continuously monitoring the financial health of individual operators on a quarterly basis. In addition, although the guidelines were shared with the public in various ways while they were being developed, stakeholders raised procedural concerns about how the guidelines were developed.

Based on its experience administering the self-insurance program over the years and in response to stakeholder concerns, the Department now proposes to revise Subpart B and seeks comments on its proposal. The proposed rule would codify the practice of basing a self-insured operator's security requirement on an actuarial assessment of its total present and future black lung liability. The Department proposes to eliminate the financial scoring process. Instead, the Department proposes to require all self-insured operators to post security equal to 120 percent of their projected black lung liabilities, which ensures adequate coverage regardless of an operator's financial health.² The Department has determined that 120 percent is an appropriate level of security because, among other things, it protects the Trust Fund in the event an operator's actual liabilities exceed its projected liabilities. The proposed rule would also remove the requirement that an operator's average current assets over the preceding three years must exceed its current liabilities, which would not be necessary to protect the Trust Fund under the proposed security scheme.

¹ OWCP published a notice in the **Federal Register** seeking comment on the Bulletin in January 2021, pursuant to then-operative Executive Order 13891 and the Department's implementing regulation. 86 FR 1529 (Jan. 8, 2021). OWCP later withdrew the notice after the Executive Order and the Department's regulation were rescinded and the new Administration imposed a temporary regulatory freeze. 86 FR 8806 (Feb. 9, 2021).

² This means the applicant would have to purchase an instrument that would pay out up to 120% of the projected liability, not that the applicant would have to actually spend that amount on collateral. OWCP estimates that premiums on surety bonds will cost anywhere from 2 percent to 12 percent of the security amount, and we welcome comments on this estimation.

The proposed rule would also prospectively remove Section 501(c)(21) trust funds, which have proven to be less reliable, as an acceptable form of security. Furthermore, the proposed rule will clarify the process for operators to apply for authorization to self-insure, how long the authorization remains effective, the conditions under which OWCP will deny or revoke authorization to self-insure, and the process for operators to appeal OWCP's determinations.

The Department believes that the proposed rule will better protect the Trust Fund when a self-insured operator becomes insolvent. Moreover, by eliminating the need to continuously monitor each individual operator's financial situation, the proposed rule will lessen the administrative burden on OWCP to gather, review, and analyze operators' financial information, and lessen the burden on operators to collect and provide such information. The procedural changes will also provide greater clarity and certainty with respect to OWCP's and operators' respective obligations in the self-insurance authorization process. Based on all of these considerations, the Department has preliminarily determined the benefits of the proposed rule (e.g., the increased safeguards for the Trust Fund and taxpayers, the decreased administrative burden, etc.) would outweigh the purchase price of any additional surety bonds or other securities for operators who choose to self-insure.

The Department invites comments on the proposed rule from all interested parties. The Department is particularly interested in comments addressing the impact of the proposed rulemaking on coal mine operators currently participating in the self-insurance program and any resulting impact on their ability to continue participating in the program.

II. Statutory Authority

Section 426(a) of the BLBA, 30 U.S.C. 936(a), authorizes the Secretary of Labor to prescribe rules and regulations necessary for the administration and enforcement of the Act.

III. Summary of the Proposed Rule

A. General Provisions

The Department is proposing several general revisions to advance the goals set forth in Executive Order 13563, 76 FR 3821 (Jan. 21, 2011), on Improving Regulation and Regulatory Review. The Order states that regulations must be "accessible, consistent, written in plain language, and easy to understand." *Id.*;

see also E.O. 12866, 58 FR 51735 (Sept. 30, 1993) (agencies must draft "regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty."). Accordingly, the Department proposes numerous technical and stylistic changes to Subpart B to improve clarity, consistency, and readability.

The Department proposes to remove the imprecise term "shall" throughout the sections that it is amending, and to substitute "must," "must not," "will," or other situation-appropriate terms. No alteration in meaning either results from or is intended by these changes.

Consistent with the goal of making this regulation easier to understand, the Department proposes several additional technical changes. For instance, the Department proposes to replace references to "the Office" with "OWCP" because that acronym is more commonly used by stakeholders. As explained in current § 725.101(a)(21), "Office" and "OWCP" both mean "the Office of Workers' Compensation Programs, United States Department of Labor." Thus, no alteration in meaning either results from or is intended by this change.

The current regulations frequently refer to applications "for authority to become a self-insurer" or "for authorization to self-insure." Where appropriate, OWCP proposes to amend such references to include applications "to renew authorization to self-insure" or similar language. This change is intended to clarify, where necessary, whether and when the requirements of this Subpart B apply to renewal applications.

The technical and stylistic changes designated here are not included in the section-by-section explanation. All proposed substantive revisions to existing rules and all proposed new rules are discussed below.

B. Section-by-Section Explanation

20 CFR 726.101 Who May Be Authorized To Self-Insure

OWCP proposes substantially revising § 726.101 to update the minimum requirements an operator must meet to qualify for authorization to self-insure and remove the provisions requiring OWCP to continuously monitor each applicant's financial situation.

Paragraph (a) is retained in its entirety.

Current paragraph (b) establishes the minimum requirements that an operator must meet to qualify for authorization to self-insure. At present, paragraphs

(b)(1), (b)(3), and (b)(5) respectively provide that an operator must have been in the business of coal mining for at least three consecutive years prior to applying, the operator's average current assets over the prior three years must exceed its current liabilities by a specified amount, and the operator must have five or more employee-miners. Paragraphs (b)(2) and (b)(4) respectively provide that an operator must demonstrate the administrative capacity to fully service claims and that an operator must obtain security in a form approved by OWCP and in an amount determined by OWCP.

OWCP proposes to remove paragraphs (b)(1), (b)(3), and (b)(5). Because OWCP elsewhere proposes to require all self-insurers to post security equal to 120 percent of their projected black lung liabilities, the requirements of paragraphs (b)(1), (b)(3), and (b)(5) would no longer be necessary. OWCP has preliminarily determined that a 120 percent security level for all companies would better protect the Trust Fund in the event of an operator's default than percentages that vary based on a company's continuously-changing financial status. OWCP has likewise preliminarily determined that an actuarial assessment of liability for current and future claims is a better gauge of the dollar amounts the Trust Fund may be required to pay out, than consideration only of an operator's current claims. This change would also reduce the administrative burdens for both OWCP and self-insured operators.

Given the foregoing changes, OWCP proposes to renumber current paragraph (b)(2) as paragraph (b)(1), and paragraph (b)(4) as paragraph (b)(2).

Current paragraph (c) provides that no operator who is unable to meet the requirements of this section should apply for authorization to self-insure and that OWCP will not approve an application for self-insurance "until such time as the amount prescribed by [OWCP] has been secured in accordance with this subpart." OWCP proposes to revise paragraph (c) by removing the language prohibiting nonqualifying operators from applying. That requirement will serve no purpose and have no practical consequences in the revised regulation. OWCP also proposes to revise paragraph (c) by clarifying that no application will be approved until OWCP receives security in the amount and in the form determined by OWCP. Revised paragraph (c) will also specify that, if an applicant is seeking authorization to self-insure for the first time, the applicant is not authorized to self-insure while its application is under review. The purpose of this change is to

clarify the circumstances under which OWCP will approve a qualifying operator's application to self-insure.

OWCP also proposes to add a new paragraph (d), which will provide that no operator whose application for authorization to self-insure or to renew authorization to self-insure is denied may reapply until 12 months after a final decision denying such application. The purpose of this addition is to prevent non-qualifying operators from filing serial applications for authorization to self-insure. In turn, this addition would reduce the administrative burden on OWCP to review renewed applications. Moreover, if an operator disagrees with the amount of security OWCP has determined is appropriate, the operator can simply use the appeal process set forth in § 726.116 rather than filing a new application. Barring operators from reapplying within 12 months after a denial prevents operators from pursuing new applications while an appeal on the denied application is pending.

20 CFR 726.102 Application for Authority To Become a Self-Insurer; How Filed; Information To Be Submitted

OWCP proposes to amend paragraph (a) to require operators to file applications for authorization to self-insure (or to renew authorization to self-insure) electronically in a manner prescribed by OWCP, and to remove existing requirements that apply only to paper filings (*e.g.*, affixing a corporate seal). This change is intended to streamline the application process and reduce the administrative burden of processing physical mail and documents.

OWCP proposes to substantially revise paragraph (b) to change and update the information that must be submitted with an application for authorization to self-insure or to renew authorization to self-insure.

Current paragraphs (b)(1), (b)(2), (b)(3), and (b)(5) require an operator to submit several pieces of information, including a statement of the employer's payroll, a statement of the average number of employees engaged in coal mine employment within the preceding three years, a list of mines covered by any particular self-insurance agreement and a statement demonstrating the applicant's administrative capacity to service claims. OWCP requires operators to provide much of this information in the requisite application forms, namely, forms CM-2017 and CM-2017b, which are available on OWCP's website at <https://www.dol.gov/agencies/owcp/dcmwc/regs/compliance/blforms>.

Accordingly, OWCP proposes to retain current paragraphs (b)(1), (b)(2), (b)(3), and (b)(5), but renumber them after adding two more paragraphs.

OWCP proposes to add a new paragraph (b)(1) that will require an application to include any application forms required by OWCP. As noted above, those forms currently include CM-2017 and CM-2017b.

OWCP also proposes to add a new paragraph (b)(2) to require an applicant to include with its application an actuarial report using OWCP-mandated actuarial assumptions. Proposed paragraph (b)(2) would also provide that an operator must submit a new actuarial report every three years and allow an operator to submit an additional actuarial report using alternative assumptions.

With the additions of proposed paragraphs (b)(1) and (b)(2), current paragraphs (b)(1), (b)(2), (b)(3), and (b)(5) are respectively renumbered as (b)(3), (b)(4), (b)(5), and (b)(6).

Current paragraph (b)(4) requires an applicant to submit its gross and net assets and liabilities for the preceding three years. Because OWCP elsewhere proposes to eliminate the minimum requirement pertaining to an operator's assets and liabilities, it likewise proposes to remove current paragraph (b)(4).

Current paragraph (b)(6), which allows OWCP to request additional information or evidence from an applicant at OWCP's discretion, is retained and renumbered as paragraph (b)(7). OWCP proposes to make stylistic changes to new paragraph (b)(7) by removing unnecessary language. No alteration in meaning either results from or is intended by this change.

Paragraph (c), which specifies which entities may apply for authorization to self-insure, is retained in its entirety, but revised to clarify that the paragraph also applies to applications to renew authorization to self-insure.

20 CFR 726.103 Application for Authority To Self-Insure; Effect of Regulations Contained in This Part

Current § 726.103 is retained in its entirety.

20 CFR 726.104 Action by OWCP Upon Application of Operator

OWCP proposes deleting and replacing paragraph (a) to clarify what action OWCP must take with respect to an application and the timeframe within which OWCP will take such action. New paragraph (a) provides that OWCP will issue a written determination, either denying the application or determining the amount of security,

within 30 days after determining that an application is complete. New paragraph (a) also allows OWCP to extend the 30-day deadline if it determines that additional evidence is needed or that the applicant's evidence is not in compliance with OWCP's requirements.

OWCP proposes removing current paragraph (b)(4), which allows a self-insurer to give security by funding a trust pursuant to section 501(c)(21) of the Internal Revenue Code. Few self-insured operators use 501(c)(21) trusts as security and most of those operators use them in combination with other forms of security. Also, OWCP has determined that section 501(c)(21) trusts are a less reliable form of security and more burdensome for OWCP to monitor because, unlike other forms of security which generally guarantee a fixed dollar amount, the amounts kept in the trusts can fluctuate and significantly decrease as self-insurers use such trusts to pay claims and the costs of administration. The remaining provisions of paragraph (b) are retained.

OWCP proposes to add a new paragraph (c). New paragraph (c) provides that if the applicant is receiving authorization to self-insure for the first time, OWCP will notify the applicant that its authorization to self-insure is contingent upon submitting the required security and completed agreement and undertaking, and that the applicant's authorization will be effective for 12 months from the date such security and completed agreement and undertaking are received by OWCP. The purpose of this amendment is to clarify when a new applicant's authorization to self-insure becomes effective. Additionally, as explained in more detail below, under new § 726.111, OWCP will also notify the applicant of the date on which its authorization is effective, the date on which such authorization will expire, and the date by which the applicant must apply to renew that authorization if it intends to continue self-insuring its liabilities.

OWCP proposes to add a new paragraph (d) for procedures when OWCP renews the applicant's authorization to self-insure. Under proposed paragraph (d)(1), if there are no changes in the required security amount, OWCP would notify the applicant that the applicant's authorization to self-insure is effective for 12 months from the date a completed agreement and undertaking is received. Under proposed paragraph (d)(2), if changes are required to the existing security amount, OWCP would notify the applicant that the applicant's authorization to self-insure is not effective until the applicant has

submitted the required security and a completed agreement and undertaking. In the latter event, the applicant's authorization to self-insure will be effective for 12 months from the date such updated security and completed agreement and undertaking are received by OWCP. The purpose of this amendment is to clarify when a renewal applicant's reauthorization to self-insure becomes effective.

Current paragraph (c) is retained but renumbered as paragraph (e). OWCP proposes to amend this paragraph to provide that any applicant who cannot meet the security requirements imposed by OWCP should proceed to obtain a commercial policy or contract of insurance and submit proof of such coverage within 30 days after OWCP issues its decision. Current paragraph (c) also sets forth the process by which an applicant may appeal OWCP's determination on an application. Because OWCP elsewhere proposes to set forth new procedures for an applicant to appeal OWCP's determinations (see § 726.116), that language is now redundant. Accordingly, OWCP proposes to revise paragraph (c) to clarify that an applicant may appeal such determinations in the manner set forth in new § 726.116. For the same reasons, OWCP proposes to delete current paragraph (d), which describes what action OWCP will take with respect to such an appeal.

20 CFR 726.105 Fixing the Amount of Security

Current § 726.105 requires OWCP to set the amount of security each applicant is required to post by determining the amount "necessary and sufficient to secure the performance by the applicant of all obligations imposed upon him as an operator by the Act." The current regulation provides that OWCP will consider various factors including, but not limited to, the operator's net worth, the existence of a guarantee by a parent corporation, and the operator's existing liability for benefits.

OWCP proposes to delete current § 726.105 and replace it with a new § 726.105. Proposed § 726.105 would provide that any operator approved to self-insure must submit security equal to 120 percent of its actuarial estimated liabilities (all present and future liabilities) as determined by OWCP based on the actuarial report or reports submitted by the applicant (or on file with OWCP), other information submitted with the operator's application, or any other materials or information that OWCP deems relevant. This means the applicant would have to

purchase an instrument that would pay out up to 120% of the projected liability, not that the applicant would have to actually spend that amount on collateral. OWCP estimates that premiums on surety bonds will cost anywhere from 2 percent to 12 percent of the security amount, and we welcome comments on this estimation.

This change would better protect the Trust Fund in the event that a self-insured operator becomes insolvent or enters bankruptcy. This change will also better protect the Trust Fund in the event an insolvent operator's actual liabilities turn out to be greater than its projected liabilities. Generally, OWCP will continue to determine an operator's projected liabilities based on the operator's actuarial report and supporting information, including the information submitted with an operator's annual renewal application. Because those reports attempt to project future liabilities, however, they are inherently imperfect and open to potential error. This approach is also consistent with the practices of some state workers' compensation programs that set a security deposit amount based on accrued or projected liabilities. *See, e.g.*, 8 Alaska Admin. Code section 46.040 (setting security deposit amount at \$600,000 or 125% of the total accrued workers' compensation liability, whichever is greater); Ariz. Code section 23-961(a)(2) and Ariz. Admin. Code section 20-5-206(D) (setting guaranty bond amount at fixed dollar amount or 125% of the total outstanding accrued liability); La. Rev. Stat. section 23:1168(a)(4); La. Admin. Code tit. 40, Pt. I, section 1725 (requiring amount of securities or surety bond to be at least \$100,000, or at least 110% of the average workers' compensation losses incurred over the most recent three year period, or at least 110% of the total amount of unpaid workers' compensation reserves at the time of application, whichever is greatest); Minn. Stat. section 79A.04, subd. 2 (setting 110 percent security deposit for self-insurance); N.C. Code section 97-185(a1), (b2) (requiring security deposit of at least 100% of the individual self-insurer's total undiscounted outstanding claims liability per the most recent report from a qualified actuary, but not less than \$500,000 or such greater amount or such greater amount as the Commissioner prescribes based on, but not limited to, the financial condition of the individual self-insurer and the risk retained by the individual self-insurer); Tenn. Comp. R. & Regs. 0780-01-83-.05(2) (setting 125 percent security deposit); Tx. Labor 407.064(d) (requiring

security deposit of the greater of \$300,000 or 125% of applicant's incurred liabilities for compensation). Additionally, by adopting this change, OWCP would no longer have to continuously monitor or collect information about each operator's financial situation. Furthermore, as explained in greater detail below, the Department has determined that the anticipated benefits of this change outweigh the costs.

20 CFR 726.106 Type of Security

Current § 726.106 is retained in its entirety. OWCP proposes to make stylistic changes to § 726.106. No alteration in meaning either results from or is intended by these changes. In addition to these stylistic changes, OWCP proposes to revise paragraph (a) to clarify that an operator may not provide any form of security other than those provided for in § 726.104(b). This change merely clarifies existing requirements.

20 CFR 726.107 Deposits of Negotiable Securities With Federal Reserve Banks or the Treasurer of the United States; Authority To Sell Such Securities; Interest Thereon

OWCP proposes to substantially revise § 726.107 to clarify and update the treatment of negotiable securities.

New paragraph (a) retains the requirements that deposits of securities provided for by the regulations in this part must be made with any Federal Reserve bank or any branch of a Federal Reserve bank designated by OWCP, or the Treasurer of the United States. New paragraph (a) also adds a requirement that any such deposit must be held in the name of the Department of Labor.

New paragraph (b) provides that, if a self-insurer defaults on its obligations under the Act, OWCP has the power, in its discretion, to (1) collect the interest on such securities as it may become due; (2) sell any or all of the securities; and (3) apply the collected interest or proceeds from the sale of securities to the payment of any benefits for which the self-insurer may be liable. This paragraph largely restates existing requirements.

New paragraph (c) provides that, if a self-insurer with deposits of securities has neither defaulted nor appealed from a determination made by OWCP under § 726.104, OWCP will allow the self-insurer to collect interest on the security deposit. This change will replace existing provisions of current § 726.106, which provide that OWCP may authorize a self-insurer to collect interest on the securities deposited by a self-insurer when OWCP deems it

unnecessary to resort to such securities for the payment of benefits.

In light of these changes, OWCP also proposes to retitle § 726.107 to read: “How Negotiable Securities Are Handled.”

20 CFR 726.108 Withdrawal of Securities

OWCP proposes to substantially revise current § 726.108, to clarify the circumstances under which a self-insurer may make withdrawals of any form of security.

New paragraph (a) provides that no withdrawal of any form of security (indemnity bonds, negotiable securities, and/or letters of credit) may be made except upon express written authorization by OWCP.

New paragraph (b) provides that, if a self-insurer wishes to withdraw securities, it must submit a written request, which must include (1) an updated actuarial report using OWCP-mandated actuarial assumptions to support why the existing security levels are no longer applicable; or (2) replacement securities in the amount and form approved by OWCP.

These changes are intended to protect the Trust Fund by preventing a self-insured operator from taking actions with respect to its security deposit that could hinder OWCP’s ability to use those securities to pay benefits. Furthermore, because new § 726.108 applies to all forms of security, not only negotiable securities, OWCP proposes to retitle § 726.108 to read: “Withdrawal of Securities.”

20 CFR 726.109 Increase in the Amount of Security

OWCP proposes to delete and replace current § 726.109. New § 726.109 provides that OWCP may, at its discretion, increase the amount of security a self-insurer is required to post whenever OWCP determines that the amount of security on deposit is insufficient to secure the payment of benefits and medical expenses under the Act. OWCP might make such a determination, for example, if it learns that the data on which an operator’s liability estimate were based have significantly changed or an operator acquires new mines or employees.

New § 726.109 no longer allows OWCP to reduce an operator’s required security amount between self-insurance renewal authorizations. OWCP believes it is not necessary to allow for a reduction in an operator’s security amount in between renewals, which would occur every 12 months, because that process would simply allow an operator to relitigate OWCP’s original

determination, even after an operator has exhausted the appeal process. Disallowing operators from requesting decreases in their security amounts would thus preserve OWCP’s limited resources to review and process self-insurance applications. Furthermore, if an operator believes that its projected liabilities have decreased due to a change in circumstances, the operator will have an opportunity to request a lower security amount during the annual renewal process.

Furthermore, reducing an operator’s security amount could only increase the risk that an operator’s liabilities could transfer to the Trust Fund. This change thus better protects the Trust Fund, consistent with Congress’s intent that the coal operators who exposed coal miners to coal dust be responsible for paying black lung benefits, not taxpayers. If an operator disagrees with OWCP’s determination to increase its security amount, it would be free to appeal that determination using the appeals process set forth in § 726.116.

In light of these changes, OWCP proposes to retitle § 726.109 to read: “Increase in the Amount of Security.”

20 CFR 726.110 Filing of Agreement and Undertaking

OWCP proposes to amend § 726.110 to update the requirements for filing of an agreement and undertaking.

Current paragraphs (a) and (b) are retained. Current paragraph (a)(3) provides that, in an agreement and undertaking, the applicant must agree to provide security in a form approved by OWCP and in an amount established by OWCP “as elected in the application.” OWCP proposes to delete “as elected in the application” to make clear that OWCP, not the applicant, has the final say as to which form or forms of security a particular operator may or must post.

Paragraph (c) is new. It provides that any operator authorized to self-insure must notify OWCP of any changes to its business structure, including the purchase or sale of any coal mining operations, that could affect the operator’s liability for benefits under the Act. It further provides that the operator must provide such notification to OWCP within 30 days of such change, but clarifies that an operator’s liability following such a change remains governed by Subpart G of these regulations, 20 CFR 725.490–725.497. The purpose of this change is to ensure that operators promptly notify OWCP of changes that could require or justify an increase in the operator’s security amount.

Paragraph (d) is also new. It provides that OWCP may, at its discretion, request any information from a self-insured operator that may affect the operator’s liability for benefits under the Act. The purpose of this change is likewise to ensure that OWCP can request information that could require or justify an increase in the operator’s security amount.

20 CFR 726.111 Notice of Authorization to Self-Insure

Current § 726.111 is retained in its entirety. OWCP proposes to make stylistic changes to § 726.111. No alteration in meaning either results from or is intended by these changes. In addition to these stylistic changes, OWCP proposes to add a new sentence, providing that OWCP will also notify the applicant of the date on which its authorization is effective, the date on which such authorization will expire, and the date by which the applicant must apply to renew that authorization if it intends to continue self-insuring its liabilities. The purpose of this addition is to ensure that the appropriate dates and deadlines are clear and clearly communicated to the applicant.

20 CFR 726.112 Reports Required of Self-Insurer; Examination of Accounts of Self-Insurer

Current § 726.112 is retained in its entirety. OWCP proposes to make stylistic changes to § 726.112. No alteration in meaning either results from or is intended by these changes.

20 CFR 726.113 Disclosure of Confidential Information

Current § 726.113 is retained in its entirety. OWCP proposes to make stylistic changes to § 726.113. No alteration in meaning either results from or is intended by these changes.

20 CFR 726.114 Authorization and Reauthorization Timeframes

OWCP proposes to delete and replace current § 726.114 to substantially revise the timeframe for authorizations and reauthorizations.

New paragraph (a) provides that no initial or renewed authorization to self-insure may be granted for a period in excess of 12 months unless OWCP determines that extenuating circumstances justify a longer period. This change thus shortens the existing maximum allowable authorization period from 18 months to 12 months.³

³ The existing regulations provide an 18-month period only for a company’s initial self-insurance authorization. After the initial authorization, self-insurers “will receive from the Office each year a bond form for execution in contemplation of

The purpose of this change is to require self-insured operators to provide information to OWCP more frequently, thereby ensuring that the security amounts set by OWCP are based on up-to-date information. For instance, operators will be required to submit data concerning their existing claims and employee figures each year, which could alert OWCP to potential changes in an operator's projected liabilities. This process will also allow OWCP to better track other potentially relevant information, including a self-insured operator's subsidiaries, corporate officers, mines, and the like. Requiring renewal applications on an annual basis also makes sense insofar as most operators operate on twelve-month fiscal calendars. This approach would also give outside stakeholders confidence that OWCP is adequately enforcing compliance with these regulations and ensuring that self-insured operators post sufficient security.

New paragraph (b) provides that each operator authorized to self-insure must apply for reauthorization 90 days prior to the 12-month authorization expiration date. This change will ensure that OWCP has the opportunity to act on an operator's application for reauthorization to self-insure before the operator's existing authorization expires.

In light of these changes, OWCP proposes to retitle § 726.114 to read: "Authorization and Reauthorization Timeframes."

20 CFR 726.115 Revocation of Authorization to Self-Insure

OWCP proposes to restructure and make stylistic changes to current § 726.115 for clarity. No alteration in meaning either results from or is intended by these changes. In addition, OWCP proposes one substantive change. Current § 726.115 provides that the failure or insolvency of the surety on an operator's indemnity bond can provide good cause for OWCP to withdraw the operator's authorization to self-insure. OWCP proposes to revise § 726.115 to clarify that the same result will obtain if any other financial institution holding any form of security provided by an operator fails or becomes insolvent. OWCP believes this change simply recognizes that there is no valid reason to treat the failure of a surety any differently than the failure of any other financial institution holding security on

reauthorization, and the submission of such bond duly executed in the amount indicated by the Office will be deemed and treated as such self-insurer's application for reauthorization for the ensuing fiscal year." 20 CFR 726.114(a).

behalf of an operator. OWCP also proposes to change "communication of the Office" to "request made by OWCP" for clarity.

20 CFR 726.116 Appeal Process

Section 726.116 is new. It establishes and clarifies the process for an operator to appeal a self-insurance determination made by OWCP.

Paragraph (a) sets forth the process to file an appeal. It provides that any applicant who wishes to appeal a determination made by OWCP must submit a request for review to the Division of Coal Mine Workers' Compensation (DCMWC) within 30 days after such determination. It also provides that the 30-day deadline to appeal may not be extended. This method is consistent with general appellate practices and 30 days provides operators with sufficient time to determine whether to appeal a determination.

Paragraph (b) sets forth the process for submitting briefs and evidence. It provides that, within 30 days of submitting a request for review, the applicant must submit any evidence and/or briefing on which the applicant intends to rely. It also provides that DCMWC may, at its discretion, extend this deadline upon a showing of good cause by the applicant.

Paragraph (c) sets forth the process for requesting an informal conference on an appeal. Paragraph (c)(1) provides that an applicant may request an informal conference and that such requests must be made when the applicant submits briefing in support of its request for review. Paragraph (c)(2) provides that, if an applicant requests a conference, DCMWC will hold a conference between DCMWC, the Office of the Solicitor, and the applicant's representatives. Paragraph (c)(3) provides that, if the applicant does not request a conference, DCMWC may either decide the appeal on the record or schedule a conference on its own initiative. Paragraph (c)(4) provides that the conference will be limited to the issues identified in the applicant's written materials. Again, this method is consistent with general appellate practices and provides an applicant with an adequate opportunity to be heard on its appeal.

Paragraph (d) sets forth DCMWC's obligations in the review process. It provides that DCMWC will review the previous determination in light of the evidence and arguments submitted and issue a supplemental decision.

Paragraph (e) sets forth the process for further appeals. Paragraph (e)(1) provides that any applicant aggrieved by a supplemental determination made by

DCMWC may request further review by the Director of OWCP within 30 days of such supplemental determination. Paragraph (e)(2) provides that the Director of OWCP will review the supplemental determination and evidence of record only and that the applicant may not submit new evidence or arguments to the Director of OWCP. Paragraph (e)(3) provides that the Director of OWCP will issue a final agency decision within 30 days of receipt of an appeal. This requirement will ensure that there is a final agency action that is reviewable in the Federal courts as provided in the Administrative Procedure Act, 5 U.S.C. 701 *et seq.* See also 5 U.S.C. 704.

IV. Administrative Law Considerations

A. Information Collection Requirements

The Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*, and its implementing regulations, 5 CFR part 1320, require that the Department consider the impact of paperwork and other information collection burdens imposed on the public. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the Office of Management and Budget (OMB) under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person may generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Although the proposed rules contain information collections within the meaning of the PRA (*see* proposed § 726.102), these collections are not new. They are currently approved for use in the black lung program by OMB under Control Number 1240-0057 (CM-2017 Application or Renewal of Self-Insurance Authority; and CM-2017b Report of Claims Information for Self-Insured Operators). Aside from the removal of the collection associated with form CM-2017a, the requirements for completion of the forms and the information collected on the forms will not change if this rule is adopted in final. Since that is the only change being made to the collections, the overall burdens imposed by the information collections will be reduced if this proposal is adopted.

The information collection package for this proposal has been submitted to OMB for review under 44 U.S.C. 3504, paragraph (c) of the Paperwork Reduction Act of 1995, as amended.

Comments may be sent by the methods listed in the **ADDRESSES** section of this preamble.

OWCP is particularly interested in comments that address the following:

- Whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- The accuracy of OWCP's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimizing 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.

OMB Control Number: 1240–0057.

Affected Public: Business or other for-profit.

Number of Respondents: 61.

Frequency: Annually.

Number of Responses: 122.

Annual Burden Hours: 244.

Annual Respondent or Recordkeeper Cost: \$34,000.

OWCP Form(s): OWCP Forms CM–2017 (Application or Renewal of Self-Insurance Authority), CM–2017b (Report of Claims Information for Self-Insured Operators).

B. Executive Orders 12866 and 13563 (Regulatory Planning and Review)

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of the 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).

Under Executive Order 12866, the Office of Information and Regulatory Affairs of OMB determines whether a regulatory action is significant and, therefore, subject to the requirements of the E.O. and review by OMB. Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule that (1) has an annual effect on the economy of \$100 million or more, or adversely affects in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also

referred to as economically significant); (2) creates serious inconsistency or otherwise interferes with an action taken or planned by another agency; (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. It also instructs agencies to review “rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them.”

The Department has considered the proposed rule with these principles in mind and has determined that the anticipated benefits of this regulation outweigh the costs. The discussion below sets out the rule's anticipated economic impact, including factors favoring adoption of the proposal. The Office of Information and Regulatory Affairs of OMB has determined that the Department's rulemaking is not an “economically significant regulatory action” under Section 3(f)(1) of Executive Order 12866.

1. Economic Considerations

The proposed rule will have an economic impact on coal mine operators that currently participate in the self-insurance program, as well as any new applicants. The proposed rule nevertheless would be necessary to better protect the Trust Fund, reduce the administrative burdens on OWCP and operators, and bring clarity to the self-insurance process.

As explained in the preamble, prior security requirements have proven inadequate to protect the Trust Fund when a self-insured operator becomes insolvent. From 2014 to 2016, three self-insured coal operators entered bankruptcy with combined collateral of \$27.4 million; the resulting transfer of black lung liabilities to the Trust Fund was eventually estimated to be \$865 million. See U.S. Government Accountability Office, *Federal Black Lung Benefits Program: Improved Oversight of Coal Mine Operator Insurance is Needed*, at 13 (Feb. 2020), available at <https://www.gao.gov/products/gao-20-21>. Had this proposed rule been in effect at the time, the three operators would have had far more in collateral, producing dollar-for-dollar savings for the Trust Fund. Of note, the amount of the coal operators' future

black lung liability was originally estimated in 2019 to be around \$313 million to \$325 million. This was revised to \$865 million in 2020 due to a variety of factors, including increases in black lung benefit award rates and higher medical treatment costs. Because the amount of a coal operator's future black lung liability is inherently unpredictable to some degree and can increase over time, requiring collateral at 120% better protects the Trust Fund than a lower percentage.

Moreover, the existing financial scoring process has proven overly cumbersome and costly to OWCP in terms of time and resources. The proposed rule would eliminate the financial scoring process and require all self-insured operators to post security equal to 120 percent of their projected black lung liabilities. By requiring sufficient security based simply on projected liabilities, the financial scoring process is no longer needed, removing the burden on the agency to attempt to assess risk by collecting and analyzing the information in the form CM–2017a. The proposed rule would also remove certain minimum requirements that would become unnecessary, including the requirement that an operator's average current assets over the preceding three years exceed its current liabilities.

This analysis provides the Department's estimate of the economic impact of the proposed rule, both on the economy as a whole and on individual operators. The Department invites comments on this analysis from all interested parties. The Department is particularly interested in comments addressing the Department's evaluation of the impact of the proposed rule on operators that currently participate in the self-insurance program.

a. Data Considered

To determine the proposed rule's general economic impact, the Department calculated how the rulemaking would affect several stakeholder groups, including: (i) OWCP, (ii) taxpayers, (iii) commercially insured operators, and (iv) self-insured operators.

i. OWCP

The proposed rule change does not impose additional demands on OWCP resources and in fact will result in a reduction in administration costs.⁴ It

⁴ In the 2017 Information Collection Request, when the form CM–2017a was first approved, OWCP estimated that analyzing the information collected in that form would cost the agency \$3,279.94 annually. No longer requiring this form should save the agency this cost.

eliminates the need for OWCP to repeatedly perform annual financial health assessments on each self-insured operator. This produces a short-term savings in the administrative costs to perform the analysis, including both costs associated with OWCP time and contractors hired to assist OWCP in this analysis. The proposed rule would require OWCP to review actuarial liability estimates every three years and monitor authorized self-insureds for compliance with eligibility requirements, but these are not new costs because OWCP is already performing those functions under the current guidelines. The savings in administrative expenses is estimated to be, at a minimum, equivalent to the annual cost of one full-time financial analyst.

ii. Taxpayers

The proposed rule provides taxpayers with both short- and long-term benefits. In the short term, taxpayers will benefit from lower administration expenses, because savings can be used elsewhere in the government without requiring additional tax revenues. In the long term, the proposed rule reduces taxpayers' financial exposure by reducing the risk that the Trust Fund—which has borrowed from the U.S. Treasury's general fund nearly every year since 1979 to make needed expenditures—will need to assume liabilities of self-insured operators that become insolvent. The proposed rule would require security deposits that are 120 percent of the actuarial liability, instead of only partial security deposits as is currently the case for most self-insured operators. Under the current guidelines, the Trust Fund remains

partially exposed to the risk of coal operator bankruptcies for operators considered at low or medium risk of failing to meet their obligations; under the current guidelines, these operators must provide security for 70 percent and 85 percent respectively of their black lung liabilities. Even operators considered high risk under the current guidelines, and therefore required to provide security for 100 percent of their black lung liabilities, present some risk that their projected liabilities will prove too low. Moreover, due to the pending appeals discussed above, a number of operators have securities on deposit with OWCP that are substantially less than those required under the existing guidelines.

Requiring a 120 percent liability security deposit transfers the risk of insufficient securities to commercial security bond underwriters and banks that specialize in financial risk assessments and are better equipped than OWCP to assess the financial stability of coal mine operators (and who are compensated for assuming that risk via operators' purchase of surety bonds or other forms of security). The proposed rule would require self-insured operators to post additional security in the aggregate, which would cover the claims for which they are responsible if they were to default on their claim payments (based on the operators' current estimates of their actuarial liabilities). This means the burden for self-insured operators' liabilities would remain with them instead of transferring to the Trust Fund and, indirectly, to taxpayers.

iii. Commercially Insured Operators

The proposed rule will not impose additional costs on operators that secure

their BLBA liabilities through commercial insurance. The proposed rule affects only the eligibility criteria, security requirements, and other procedures for operators that secure their liabilities by qualifying to self-insure. At most, commercially insured operators might choose to reassess whether, in light of these changes, commercial insurance remains the most cost-effective option for securing their liabilities or, instead, whether to switch to self-insurance. The cost of any such assessment would be *de minimis*.

iv. Self-Insured Operators

The proposed rule could increase costs for current operators that are self-insured. In 2019, OWCP identified a total of 20 operators that were, or recently had been, actively mining coal and participating in the self-insurance program. Four of these operators have since gone bankrupt and are not included in this impact analysis. Of the remaining 16 self-insured operators, seven have commercial insurance for their current operations, but self-insure their legacy liabilities. Nine secure both their current and legacy liabilities through self-insurance.

The proposed rule would apply to the 16 operators noted above. Table 1 lists the 16 operators' actuarially estimated liabilities, securities currently on deposit, the present security requirement under current guidelines, and future security requirements under the proposed rule.

Table 1: Self-Insured Coal Mine Operators Actuarial Liabilities and Security Deposits

Table 1 - Self-Insured Coal Mine Operators Actuarial Liabilities and Security Deposits
all dollar amounts in thousands (,000)

Coal Mine Operator			Operator Reported Black Lung Actuarial Liability	Present - On Deposit		Present Rule		Proposed Rule	
				Operator Securities on Deposit	Ratio of Reported Securities to Actuarial Liability	Operator Securities Requirement	Ratio of Reported Securities to Actuarial Liability	Operator Securities Requirement	Ratio of Reported Securities to Actuarial Liability
ID No.	Name	Status							
1	Company 1	Active	162,939	24,400	15%	114,057	70%	195,527	120%
2	Company 2	Active	132,536	20,330	15%	92,775	70%	159,043	120%
3	Company 3	Active	111,518	6,900	6%	78,063	70%	133,822	120%
4	Company 4	Active	93,826	2,500	3%	65,678	70%	112,591	120%
5	Company 5	Legacy	57,730	8,400	15%	40,411	70%	69,276	120%
6	Company 6	Legacy	56,802	21,000	37%	39,761	70%	68,162	120%
7	Company 7	Active	30,139	1,500	5%	21,097	70%	36,167	120%
8	Company 8	Legacy	23,935	12,412	52%	16,755	70%	28,722	120%
9	Company 9	Active	21,400	14,079	66%	14,980	70%	25,680	120%
10	Company 10	Legacy	3,297	3,301	100%	3,297	100%	3,956	120%
11	Company 11	Active	656	558	85%	558	85%	787	120%
12	Company 12	Legacy	1,364	1,364	100%	1,159	85%	1,637	120%
13	Company 13	Legacy	1,333	1,133	85%	1,133	85%	1,600	120%
14	Company 14	Legacy	1,230	1,046	85%	1,046	85%	1,476	120%
15	Company 15	Active	746	634	85%	634	85%	895	120%
16	Company 16	Active	205	400	195%	174	85%	246	120%
Self-Insured Operators Total			699,656	119,957	17%	491,579	70%	839,587	120%

The proposed rule does not impose additional reporting or filing requirements on the coal operators currently in the self-insurance program beyond notifying OWCP of any business structure changes that could affect the operator's liability for benefits under the Act. If anything, the proposed rule decreases administrative burdens. Operators are required to continue updating their actuarial liability estimates on a three-year cycle but are no longer required to file quarterly financial reports. There will be a cost to the operators for the time required to review and understand the rule. Because of the small number of affected establishments, this rule familiarization cost is *de minimis* in aggregate and is not included in the rule's total cost estimate.

The proposed rule requires self-insured operators to adjust the amount of their security deposits to reach 120 percent of their reported actuarial black lung liability. Table 1 reflects that 15 of the 16 current self-insured operators would be required to increase their security deposits as a result. For each operator, the cost of the increase in security deposits depends on which security deposit option the operator employs (since different security options have different costs) and amount of the required increase.

Operators with security deposits in the form of indemnity bonds will incur a cost determined by the commercial bond underwriters. OWCP does not have direct information on the cost of these bonds, as pricing is a function of multiple qualitative and quantitative attributes of each operator and is determined by underwriters on a case-by-case basis. Each underwriter has their own pricing formula and offers various payment options. To estimate the cost impacts of the proposed rule, an annual premium ranging from 2 percent to 12 percent of the additional security was used as an estimate. This range is

based on a review of public data from several different surety companies; however, actual costs could be higher or lower.⁵ The agency welcomes comment on these assumptions and estimates. Additionally, this analysis focuses solely on surety bonds because that is both the most widely used option among currently self-insured operators and the most cost-effective option.

For operators with security deposits in the form of negotiable securities, the additional costs would consist of the opportunity costs of the additional deposits (*i.e.*, the difference in return between funds held in such accounts and funds invested elsewhere, such as in higher-performing investments or reinvested into the operations of the business itself). One common convention to estimate hypothetical returns on forgone investments is to use a company or industry-level Weighted Average Cost of Capital (WACC); the median WACC for the metals and mining industry is currently around 9.4 percent, although the WACC for coal mining companies specifically, and in particular for individual coal mining companies, may be higher or lower. The opportunity costs for these operators could be estimated by calculating the difference between their WACC and the annual return earned on their security deposit and multiplying that figure by the dollar increase in their security. OWCP has not quantified these costs for two principal reasons. First, as noted above, most self-insured operators use indemnity bonds as security. OWCP does not anticipate that these operators

⁵ In reaching this estimate, OWCP reviewed publicly available estimates of surety bond premiums from BondExchange; Bryant Surety Bonds; Insureon; JW Surety Bonds; Lance Surety Bond Associates, Inc.; NNA Surety Bonds; Surety Bonds Direct; Surety Solutions; and Value Penguin. Note that these are for surety bonds generally, not surety bonds for coal companies specifically. The 2 to 12 percent range was then developed based on this public data.

will begin using negotiable securities. Second, annual indemnity bond costs are likely to be lower than the one-time payment of negotiable securities and associated opportunity costs, making indemnity bonds the more cost-effective option. As this economic analysis demonstrates, OWCP predicts that any increased indemnity bond costs associated with this rulemaking will not have a significant impact on self-insured operators. Furthermore, any operators that currently use negotiable securities to secure some or all of their liabilities can continue using those securities in combination with indemnity bonds to comply with any increased security requirement (*i.e.*, some portion of the operator's liabilities could be secured with negotiable securities and the remainder could be secured with indemnity bonds).

Table 2 calculates the estimated increased costs of a larger indemnity bond for each operator and compares this figure to each operator's annual revenues. Annual revenues are represented by a three-year average over the 2018–2020 time period, as reported by S&P or operator-provided financial statements. Annual costs are estimated as the average of the maximum and minimum annual premium (*i.e.*, the midpoint of the 2 percent to 12 percent range). As shown in Table 2, the estimated annual impact for operators as a percentage of annual revenue ranges from a high of 0.941 percent to less than 0.1 percent (including one negative value).⁶

OWCP invites additional information from commenters on the cost of these bonds.

⁶ Surety bonds are generally paid for annually, and the premium is paid up front at the beginning of the year or charged a finance fee for a payment plan. Discounting is not presented in Table 2 because the average estimated cost represents one annual premium payment, rather than the total net present value of all future payments.

Table 2: Estimated Annual Cost of Increased Security Deposit in the Form of Indemnity Bonds

Table 2 - Estimated Annual Cost of Increased Security Deposit
all dollar amounts in thousands (\$000)

Coal Mine Operator		Proposed Security Deposit = 120%				Minimum Estimated Cost of Change in Securities	Maximum Estimated Cost of Change in Securities	Average Estimated Cost of Change in Securities	Average Annual Revenue	Estimated Operator Impact as a Percent of Revenue
		Operator Reported Black Lung Actuarial Liability	Operator Securities on Deposit	Operator Securities Proposed Requirement	Change in Secured Position ¹					
ID No.	Name									
1	Company 1	162,939	24,400	195,527	171,127	3,423	20,535	11,979	1,272,800	0.941%
2	Company 2	132,536	20,330	159,043	138,713	2,774	16,646	9,710	4,362,100	0.223%
3	Company 3	111,518	6,900	133,822	126,922	2,538	15,231	8,885	2,060,967	0.431%
4	Company 4	93,826	2,500	112,591	110,091	2,202	13,211	7,706	1,816,233	0.424%
5	Company 5	57,730	8,400	69,276	60,876	1,218	7,305	4,261	1,461,400	0.292%
6	Company 6	56,802	21,000	68,162	47,162	943	5,659	3,301	1,143,000	0.289%
7	Company 7	30,139	1,500	36,167	34,667	693	4,160	2,427	1,764,233	0.138%
8	Company 8	23,935	12,412	28,722	16,310	326	1,957	1,142	1,603,500	0.071%
9	Company 9	21,400	14,079	25,680	11,601	232	1,392	812	15,558,533	0.005%
10	Company 10	3,297	3,301	3,956	655	13	79	46	134,933	0.034%
11	Company 11	656	558	787	230	5	28	16	70,826	0.023%
12	Company 12	1,364	1,364	1,637	272	5	33	19	636,657	0.003%
13	Company 13	1,333	1,133	1,600	467	9	56	33	11,080,000	0.000%
14	Company 14	1,230	1,046	1,476	430	9	52	30	6,014,500	0.001%
15	Company 15	746	634	895	261	5	31	18	68,545	0.027%
16	Company 16	205	400	246	(154)	(3)	(18)	(11)	1,728,700	-0.001%
Self-Insured Operators Total		699,656	119,957	839,587	719,631	14,393	86,356	50,374	50,776,928	0.099%
Commercially Insured Operators Total²										0.000%
Coal Mine Industry Total (Self-Insured + Commercially Insured)										0.053%

1. The change represents the difference between the proposed requirement and the securities currently on deposit.
 2. Commercially Insured Operators includes all other coal mine operators other than the self-insured operators listed.

b. Economic Impact Summary

The Office of Management and Budget uses a \$100 million-dollar annual threshold for determining the proposed rule’s economic significance. *See, e.g.*, E.O. 12866 (defining regulation that has annual effect on the economy of \$100 million or more as “significant”). Based on this test, the self-insurance proposal would not be “economically significant.”

Operator securities on deposit are estimated to change by nearly \$720 million. This, however, represents an estimate of the projected liabilities over the lifetime of all claims for all self-insured companies. Even if they were all to go bankrupt simultaneously—which is extremely unlikely—the estimated liabilities represent benefits payments over the lifetime of the impacted miners and survivors. As an illustration, consider the annual payout in recent years from the estimated \$865 million transfer of black lung liabilities to the Trust Fund as a result of the three bankruptcies from 2014 to 2016. From fiscal years 2015 through 2022, the Trust Fund paid out between \$8 million and \$30 million per year to active beneficiaries as a direct result of those three bankruptcies. OWCP does not have the ability to predict bankruptcies with certainty, as explained elsewhere in this preamble as a rationale for proposing to eliminate the financial scoring process. Nevertheless, given the fact that \$865 million in projected

liabilities has thus far not resulted in more than \$30 million in disbursements to active beneficiaries per year, OWCP predicts that the share of benefits paid from this additional \$720 million in securities on deposit will not exceed \$30 million in any given year.

Furthermore, OWCP estimates ranges from approximately \$14 million to \$86 million on an annual basis, with a mid-range estimate of \$50 million. In Table 2 above, the minimum and maximum estimated costs of change in securities are based on 2 percent and 12 percent, respectively, of the total change in secured position for each operator. OWCP used an annual premium ranging from 2 percent to 12 percent of the additional security based on a review of public data from several different surety companies. OWCP used estimates for surety bonds because that is both the most widely used option among currently self-insured operators and likely to be the most cost-effective option.

The combined opportunity cost on the current self-insurance operators is less than 0.1 percent of aggregate average annual revenues. Even for the operator facing the largest increase as a portion of revenues (Company 1 in Table 2), the expected impact is less than 1 percent of average annual revenues. The impact on the coal industry overall is smaller than that of the self-insured operator group because there is no impact (0.0 percent) on commercially insured operators.

2. Other Considerations

The Department considered alternative options and methods before proposing these changes to the self-insurance program. Specifically, the Department considered imposing a 100 percent security requirement (20 points lower than the proposed rule) or a 140 percent security requirement (20 points greater than the proposed rule). These alternative requirements were subjectively selected for the purpose of sensitivity testing. In both cases the overall impact remains below the aggregate 1 percent of revenue thresholds.

After considering these alternatives, the Department determined that the 120 percent security requirement is more cost-effective than the 100 percent or 140 percent requirements. Relative to the hypothetical 100 percent requirement, the 120 percent requirement better protects the Trust Fund because if an operator’s actuarial estimates prove too low, any liabilities not covered by the operator’s securities would ultimately transfer to the Trust Fund. Even when operators use OWCP’s mandated actuarial assumptions, the operator’s actuarial report will reflect, ultimately, a best estimate of the operator’s existing and future liabilities. Insofar as any projection of future events is inherently fallible, an operator’s actual liabilities could turn out to be greater than its earlier estimates. Indeed, prior operator

bankruptcies have demonstrated that an operator’s actual black lung liabilities can far exceed their prior actuarially projected liabilities. See U.S. Government Accountability Office, *Federal Black Lung Benefits Program: Improved Oversight of Coal Mine Operator Insurance is Needed*, at 13 (Feb. 2020), available at <https://www.gao.gov/products/gao-20-21> (noting that the estimated transfer in benefit liabilities to the Trust Fund pursuant to three bankruptcies went from \$325 million in 2019 to \$865 million in 2020). This approach is also consistent with the practices of some state workers’ compensation programs, as described in more detail in the Section-by-Section Explanation. See, e.g., Minn. Stat. section 79A.04, subd. 2 (setting 110 percent security deposit for self-insurance); Tenn. Comp. R. & Regs.

0780–01–83-.05(2) (setting 125 percent security deposit).

The hypothetical 140 percent requirement, by contrast, proved too onerous. As reflected in Table 2B below, although the overall impact of the 140 percent requirement remained below the aggregate 1 percent of revenue thresholds, it did have an impact on at least one operator in excess of the 1 percent of revenue threshold.

OWCP also considered not proposing any changes, thereby maintaining the current existing security levels. As with the alternative of requiring 100 percent for all operators, this approach would not adequately protect the Trust Fund and would maintain the challenges and administrative burden of the financial scoring model described earlier in this preamble. That model was not able to consistently predict which operators were at risk of experiencing financial

difficulties, and it imposed significant burdens on OWCP to continuously monitor the financial health of individual operators on a quarterly basis. OWCP therefore considered, but ultimately rejected, maintaining the financial scoring model.

In light of all of these considerations, the Department has preliminarily determined that setting a security requirement as a single percentage of projected black lung liabilities, regardless of assessments of financial health, and setting that percentage at 120 percent strikes the right balance between adequately protecting the Trust Fund and accommodating operators’ interests. OWCP seeks comment on this preliminary determination.

Table 2A: Estimated Annual Costs of Increased Security Deposit at 100 Percent

Table 2A - Estimated Annual Cost of Increased Security Deposit
all dollar amounts in thousands (,000)

Coal Mine Operator		Proposed Security Deposit = 100%				Minimum Estimated Cost of Change in Securities	Maximum Estimated Cost of Change in Securities	Average Estimated Cost of Change in Securities	Average Annual Revenue	Estimated Operator Impact as a Percent of Revenue
		Operator Reported Black Lung Actuarial Liability	Operator Securities on Deposit	Operator Securities Proposed Requirement	Change in Secured Position ¹					
ID No.	Name									
1	Company 1	162,939	24,400	162,939	138,539	2,771	16,625	9,698	1,272,800	0.762%
2	Company 2	132,536	20,330	132,536	112,206	2,244	13,465	7,854	4,362,100	0.180%
3	Company 3	111,518	6,900	111,518	104,618	2,092	12,554	7,323	2,060,967	0.355%
4	Company 4	93,826	2,500	93,826	91,326	1,827	10,959	6,393	1,816,233	0.352%
5	Company 5	57,730	8,400	57,730	49,330	987	5,920	3,453	1,461,400	0.236%
6	Company 6	56,802	21,000	56,802	35,802	716	4,296	2,506	1,143,000	0.219%
7	Company 7	30,139	1,500	30,139	28,639	573	3,437	2,005	1,764,233	0.114%
8	Company 8	23,935	12,412	23,935	11,523	230	1,383	807	1,603,500	0.050%
9	Company 9	21,400	14,079	21,400	7,321	146	879	512	15,558,533	0.003%
10	Company 10	3,297	3,301	3,297	(4)	(0)	(1)	(0)	134,933	0.000%
11	Company 11	656	558	656	98	2	12	7	70,826	0.010%
12	Company 12	1,364	1,364	1,364	(0)	(0)	(0)	(0)	636,657	0.000%
13	Company 13	1,333	1,133	1,333	200	4	24	14	11,080,000	0.000%
14	Company 14	1,230	1,046	1,230	184	4	22	13	6,014,500	0.000%
15	Company 15	746	634	746	112	2	13	8	68,545	0.011%
16	Company 16	205	400	205	(195)	(4)	(23)	(14)	1,728,700	-0.001%
Self-Insured Operators Total		699,656	119,957	699,656	579,700	11,594	69,564	40,579	50,776,928	0.080%
Commercially Insured Operators Total²										0.000%
Coal Mine Industry Total (Self-Insured + Commercially Insured)										0.043%

1. The change represents the difference between the proposed requirement and the securities currently on deposit.
2. Commercially Insured Operators includes all other coal mine operators other than the self-insured operators listed.

Table 2B: Estimated Annual Costs of Increased Security Deposit at 140 Percent

Table 2B - Estimated Annual Cost of Increased Security Deposit

all dollar amounts in thousands (000)

Coal Mine Operator		Proposed Security Deposit = 140%				Minimum Estimated Cost of Change in Securities	Maximum Estimated Cost of Change in Securities	Average Estimated Cost of Change in Securities	Average Annual Revenue	Estimated Operator Impact as a Percent of Revenue
		Operator Reported Black Lung Actuarial Liability	Operator Securities on Deposit	Operator Securities Proposed Requirement	Change in Secured Position ¹					
ID No.	Name									
1	Company 1	162,939	24,400	228,115	203,715	4,074	24,446	14,260	1,272,800	1.120%
2	Company 2	132,536	20,330	185,550	165,220	3,304	19,826	11,565	4,362,100	0.265%
3	Company 3	111,518	6,900	156,125	149,225	2,985	17,907	10,446	2,060,967	0.507%
4	Company 4	93,826	2,500	131,356	128,856	2,577	15,463	9,020	1,816,233	0.497%
5	Company 5	57,730	8,400	80,822	72,422	1,448	8,691	5,070	1,461,400	0.347%
6	Company 6	56,802	21,000	79,523	58,523	1,170	7,023	4,097	1,143,000	0.358%
7	Company 7	30,139	1,500	42,195	40,695	814	4,883	2,849	1,764,233	0.161%
8	Company 8	23,935	12,412	33,509	21,097	422	2,532	1,477	1,603,500	0.092%
9	Company 9	21,400	14,079	29,960	15,881	318	1,906	1,112	15,558,533	0.007%
10	Company 10	3,297	3,301	4,616	1,314	26	158	92	134,933	0.068%
11	Company 11	656	558	919	361	7	43	25	70,826	0.036%
12	Company 12	1,364	1,364	1,910	545	11	65	38	636,657	0.006%
13	Company 13	1,333	1,133	1,866	733	15	88	51	11,080,000	0.000%
14	Company 14	1,230	1,046	1,722	676	14	81	47	6,014,500	0.001%
15	Company 15	746	634	1,044	410	8	49	29	68,545	0.042%
16	Company 16	205	400	287	(113)	(2)	(14)	(8)	1,728,700	0.000%
Self-Insured Operators Total		699,656	119,957	979,519	859,562	17,191	103,147	60,169	50,776,928	0.118%
Commercially Insured Operators Total²										0.000%
Coal Mine Industry Total (Self-Insured + Commercially Insured)										0.063%

1. The change represents the difference between the proposed requirement and the securities currently on deposit.
2. Commercially insured Operators includes all other coal mine operators other than the self-insured operators listed.

C. Regulatory Flexibility Act and Executive Order 13272 (Proper Consideration of Small Entities in Agency Rulemaking)

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601 *et seq.*, requires an agency to prepare a regulatory flexibility analysis when it proposes regulations that will have “a significant economic impact on a substantial number of small entities” or to certify that the proposed regulations will have no such impact, and to make the analysis or certification available for public comment.

The Department has determined that a regulatory flexibility analysis under the RFA is not required for this rulemaking. For the mining industry, SBA uses three levels of employee counts to define small mining operations:

- NAICS 212111 Bituminous Coal and Lignite Surface Mining—1,250 employees
- NAICS 212112 Bituminous Coal Underground Mining—1,500 employees
- NAICS 212113 Anthracite Mining—250 employees

According to the SBA criteria, 6 of the 16 self-insured operators, or 38 percent, are considered small firms. Under this proposed rule, the combined impact on these 6 operators would be 0.2 percent of annual revenues, with a range from 0.1 percent to 0.4 percent. Again, these impacts are very small, and for that reason the proposed rule is not considered to have a significant economic impact on a substantial number of small operators. The overall impact on the large operators is less than 0.1 percent of annual revenues.⁷

⁷The RFA does not define “significant” or “substantial.” 5 U.S.C. 601. It is widely accepted, however, that “[t]he agency is in the best position to gauge the small entity impacts of its regulations.” SBA Office of Advocacy, “A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act,” at 18 (August 2017), available at <https://cdn.advocacy.sba.gov/wp-content/uploads/2019/06/21110349/How-to-Comply-with-the-RFA.pdf>. One measure for determining whether an economic impact is “significant” is the percentage of revenue affected. For this rule, the Department used as a standard of significant economic impact

Details of the factual basis for economic significance are provided in the Industry Profile and Analysis section of this report. Tables 3A and 3B show the impact on small and large self-insured operators.

whether the costs for a small entity equal or exceed 3 percent of the entity’s annual revenue.

The Department has used the threshold of 3 percent of revenues for the definition of significant economic impact in a number of recent rulemakings. *See, e.g.*, Wage and Hour Division, Establishing a Minimum Wage for Contractors, Notice of Proposed Rulemaking, 79 FR 34568, 34603 (June 17, 2014); Office of Federal Contract Compliance Programs, Government Contractors, Requirement To Report Summary Data on Employee Compensation, Notice of Proposed Rulemaking, 79 FR 46562, 46591 (Aug. 8, 2014). The 3 percent standard is also consistent with the standards utilized by various other Federal agencies in conducting their regulatory flexibility analyses. *See, e.g.*, Department of Health and Human Services Centers for Medicare & Medicaid Services, “Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II; Final Rule,” 79 FR 27105, 27151 (May 12, 2014).

Table 3A: Small Self-Insured Coal Mine Operators

Table 3A - Small Self-Insured Coal Mine Operators

Coal Mine Operator				Rule Change Impact	Average Annual Revenue (in millions)	Employee Counts			3 Yr Average
ID No.	Name	Status	Operations Type			2018	2019	2020	
5	Company 5	Legacy	Surface	0.292%	1,461	1,180	1,171	1,133	1,161
6	Company 6	Legacy	Underground	0.289%	1,143	1,395	1,417	1,401	1,404
10	Company 10	Legacy	Surface	0.034%	135	400	400	500	433
11	Company 11	Active	Surface	0.023%	71	183	183	183	183
12	Company 12	Legacy	Surface	0.003%	637	950	950	950	950
15	Company 15	Active	Anthracite	0.027%	69	142	142	142	142
Small Self-Insured Operators Total				0.218%	3,515	4,250	4,263	4,309	4,274

Table 3B: Large Self-Insured Coal Mine Operators

Table 3B - Large Self-Insured Coal Mine Operators

Coal Mine Operator				Rule Change Impact	Average Annual Revenue (in millions)	Employee Counts			3 Yr Average
ID No.	Name	Status	Operations Type			2018	2019	2020	
1	Company 1	Active	Surface	0.941%	1,273	1,772	1,792	1,494	1,686
2	Company 2	Active	Surface	0.223%	4,362	7,400	6,600	4,600	6,200
3	Company 3	Active	Surface	0.431%	2,061	3,822	3,700	3,203	3,575
4	Company 4	Active	Surface	0.424%	1,816	4,420	4,360	3,250	4,010
7	Company 7	Active	Underground	0.138%	1,764	3,599	3,602	2,902	3,368
8	Company 8	Legacy	Surface	0.050%	1,604	6,000	6,000	6,000	6,000
9	Company 9	Active	Surface	0.000%	15,559	17,582	17,408	16,787	17,259
13	Company 13	Legacy	Surface	0.000%	11,080	12,097	12,097	11,316	11,837
14	Company 14	Legacy	Surface	0.001%	6,015	5,547	5,547	5,539	5,544
16	Company 16	Active	Surface	-0.001%	1,729	2,863	2,944	3,011	2,939
Large Self-Insured Operators Total				0.016%	47,262	65,102	64,050	58,102	62,418

Based on these facts, the Department certifies that this proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Thus, an initial regulatory flexibility analysis is not required. The Department, however, invites comments from members of the public who believe the proposed rule would have a significant economic impact on a substantial number of small coal mine operators. The Department has provided the Chief Counsel for Advocacy of the Small Business Administration with a copy of this certification. See 5 U.S.C. 605.

Industry Profile and Analysis

Types of Operations

The United States coal mine industry consists of hundreds of mines controlled by hundreds of operators. Coal mine operators vary in size from owners of multiple mines to operators of single mines. The two main categories

of coal mining operations are surface and underground, but many operators are also involved in other coal-related enterprises, including steel production, mining technology and support services, petroleum products, other mineral mining operations, and energy generation. Coal mining is the only focus of some operators, while for others it is only incidental to their main enterprise. For purposes of this analysis, operators engaged in surface mining or with multiple streams of revenue were classified as Surface operations (NAICS = 212111). Other operators were classified as Underground (NAICS = 212112) or Anthracite (NAICS = 212113) depending on their main source of revenues. The SBA classification of small entities was applied according to the operator's NAICS code type of operations.

Revenues Versus Coal Production

Typically, coal operators are analyzed on the basis of measures such as coal

production, coal reserves, and mine productivity. Among self-insured operators, there are differences in the proportion of coal mining operations covered by self-insurance, and the proportion of operators' total operations that are mining related. To determine the impact of the rule change, total company revenues were used, because an individual operator could have multiple revenue streams available to support their workers' compensation costs. As noted, 38 percent of the self-insured operators are classified as "small" using employee counts, under the SBA's definitions. However, 50 percent are classified as "major" coal producers based on coal production. The "major" classification is based on the US Energy Information Administration ("EIA") criterion—of producing more than 5 million short tons of coal per year.

Table 4: Coal Production by Operator

Coal Mine Operator			Coal Production 1000mst					% of Production	Business Size
ID No.	Name	Major US Coal Producer	2018	2019	2020	3 Yr Average			
1	Company 1	Yes	27,592	27,285	18,790	24,556	3.7%	Large	
2	Company 2	Yes	155,523	138,731	104,814	133,023	20.0%	Large	
3	Company 3	Yes	100,254	87,892	61,705	83,284	12.5%	Large	
4	Company 4	Yes	22,811	22,317	13,897	19,675	3.0%	Large	
5	Company 5	No	384	108	175	222	0.0%	Small	
6	Company 6	Yes	7,735	8,469	7,864	8,023	1.2%	Small	
7	Company 7	Yes	40,343	40,555	26,900	35,933	5.4%	Large	
8	Company 8	No	1,209	1,334	1,028	1,190	0.2%	Large	
9	Company 9	No	1,276	1,354	456	1,028	0.2%	Large	
10	Company 10	Yes	37,282	35,755	30,801	34,613	5.2%	Small	
11	Company 11	No	411	381	357	383	0.1%	Small	
12	Company 12	Yes	9,057	8,707	8,146	8,637	1.3%	Small	
13	Company 13	No	2,211	2,120	1,612	1,981	0.3%	Large	
14	Company 14	No	0	0	0	0	0.0%	Large	
15	Company 15	No	138	150	115	134	0.0%	Small	
16	Company 16	No	4,085	3,716	3,737	3,846	0.6%	Large	
Self-Insured Operators Total			410,310	378,875	280,397	356,527	53.5%		
Coal Mine Industry Total			756,167	706,309	535,434	665,970	100.0%		
							% of Production		
Major US Coal Producer: Self Insured			400,597	369,711	272,917	347,742	60.2%		
Major US Coal Producer: Commercially Insured			265,533	239,179	185,690	230,134	39.8%		
Total Major US Coal Producers			666,130	608,890	458,607	577,876	100.0%		
Non-Major Self Insured			9,713	9,164	7,480	8,786	10.0%		
Non-Major Commercially Insured			80,324	88,255	69,347	79,309	90.0%		
Total Non-Major US Coal Producers			90,037	97,419	76,827	88,094	100.0%		

D. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531 *et seq.*, directs agencies to assess the effects of Federal regulatory actions on state, local, and tribal governments, and the private sector, “other than to the extent that such regulations incorporate requirements specifically set forth in law.” The proposed rule does not include any Federal mandate that may result in increased expenditures by state, local, or tribal Governments, or increase expenditures by the private sector by more than \$100 million, and therefore is not covered by the Unfunded Mandates Reform Act.

E. Executive Order 13132 (Federalism)

The Department has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism and has determined that it does not have “federalism implications.” E.O. 13132, 64 FR 43255 (Aug. 4, 1999). The proposed 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” if promulgated as a final rule. *Id.*

F. Executive Order 12988 (Civil Justice Reform)

The proposed rule meets the applicable standards in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

G. Congressional Review Act

The proposed rule is not a “major rule” as defined in the Congressional Review Act, 5 U.S.C. 801 *et seq.* If promulgated as a final rule, this rule will not result in: an annual effect on the economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, state, or local Government agencies, or geographic regions; or 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.

List of Subjects in 20 CFR Part 726

Administrative practice and procedure, Black lung benefits, Coal miners, Mines, Penalties.

For the reasons set forth in the preamble, the Department of Labor

proposes to amend 20 CFR part 726 as follows:

PART 726—BLACK LUNG BENEFITS; REQUIREMENTS FOR COAL MINE OPERATOR’S INSURANCE

■ 1. The authority citation for part 726 continues to read as follows:

Authority: 5 U.S.C. 301; 30 U.S.C. 901 *et seq.*, 902(f), 925, 932, 933, 934, 936; 33 U.S.C. 901 *et seq.*; 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990 (as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015)); Pub. L. 114–74 at sec. 701; Reorganization Plan No. 6 of 1950, 15 FR 3174; Secretary’s Order 10–2009, 74 FR 58834.

■ 2. For the reasons set forth in the preamble, revise Subpart B as follows:

Subpart B—Authorization of Self-Insurers

- Sec. 726.101 Who May be Authorized to Self-Insure.
- 726.102 Application for Authority to Become a Self-Insurer; How Filed; Information to be Submitted.
- 726.103 Application for Authority to Self-Insure; Effect of Regulations Contained in this Part.
- 726.104 Action by OWCP upon Application of Operator.
- 726.105 Fixing the Amount of Security.
- 726.106 Type of Security.

- 726.107 How Negotiable Securities Are Handled.
 726.108 Withdrawal of Securities.
 726.109 Increase in the Amount of Security.
 726.110 Filing of Agreement and Undertaking.
 726.111 Notice of Authorization to Self-Insure.
 726.112 Reports Required of Self-Insurer; Examination of Accounts of Self-Insurer.
 726.113 Disclosure of Confidential Information.
 726.114 Authorization and Reauthorization Timeframes.
 726.115 Revocation of Authorization to Self-Insure.
 726.116 Appeal Process.

§ 726.101 Who May be Authorized to Self-Insure.

(a) Pursuant to section 423 of part C of title IV of the Act, authorization to self-insure against liability incurred by coal mine operators on account of the total disability or death of miners due to pneumoconiosis may be granted or denied in the discretion of the Secretary. The provisions of this subpart describe the minimum requirements established by the Secretary for determining whether any particular coal mine operator may be authorized as a self-insurer.

(b) The minimum requirements which must be met by any operator seeking authorization to self-insure are as follows:

(1) The operator must demonstrate the administrative capacity to fully service such claims as may be filed against it; and,

(2) Such operator must obtain security, in a form approved by OWCP (see § 726.104) and in an amount to be determined by OWCP (see § 726.105).

(c) No application will be approved until OWCP receives security in the amount and in the form determined by OWCP. If the applicant is seeking authorization to self-insure for the first time, it is not authorized to self-insure while its application is under review.

(d) No operator whose application for authorization to self-insure or to renew authorization to self-insure may reapply until 12 months after a final decision denying such application.

§ 726.102 Application for Authority to Become a Self-Insurer; How Filed; Information to be Submitted.

(a) How filed. An application for authorization to self-insure or to renew authorization to self-insure must be submitted electronically in the manner prescribed by OWCP. Such application must be signed by the applicant and if the applicant is not an individual, by the principal officer of the applicant duly authorized to make such application.

(b) Information to be submitted. Each application for authority to self-insure or to renew authorization to self-insure must contain the following:

(1) Any application forms required by OWCP.

(2) An actuarial report using OWCP-mandated assumptions, unless the applicant has submitted an actuarial report within the preceding 3 years. An applicant must submit a new actuarial report every 3 years. The operator may submit an additional actuarial report using alternate assumptions. Such additional report must be accompanied by a statement from the applicant explaining why it believes the alternative assumptions are appropriate.

(3) A statement of the employer's payroll report for each of the preceding 3 years.

(4) A statement of the average number of employees engaged in employment within the purview of the Act for each of the preceding 3 years.

(5) A list of the mine or mines to be covered by any particular self-insurance agreement. Each such mine or mines listed shall be described by name and reference shall be made to the Federal Identification Number assigned such mine by the Bureau of Mines, U.S. Department of the Interior.

(6) A statement demonstrating the applicant's administrative capacity to provide or procure adequate servicing for a claim including both medical and dollar claims.

(7) In addition to the aforementioned, OWCP may in its discretion, require the applicant to submit such further information or such evidence as OWCP may deem necessary.

(c) Who may file. An application for authorization to self-insure (including an application to renew authority to self-insure) may be filed by any parent or subsidiary corporation, partner or partnership, party to a joint venture or joint venture, individual, or other business entity which may be determined liable for the payment of black lung benefits under part C of title IV of the Act, regardless of whether such applicant is directly engaged in the business of mining coal. However, in each case for which authorization to self-insure is granted, the agreement and undertaking filed pursuant to § 726.110 and the security deposit must be respectively filed by and deposited in the name of the applicant only.

§ 726.103 Application for Authority to Self-Insure; Effect of Regulations Contained in this Part.

As appropriate, each of the regulations, interpretations and requirements contained in this part 726

including those described in subpart C of this part are binding upon each applicant under this subpart, and the applicant's consent to be bound by all requirements of the said regulations are deemed to be included in and a part of the application, as fully as though written therein.

§ 726.104 Action by OWCP upon Application of Operator.

(a) Within 30 days after determining that an applicant's application for authorization to self-insure or to renew authorization to self-insure is complete, OWCP will issue a written determination either denying the application or determining the amount of security which must be given by the applicant to guarantee the payment of benefits and the discharge of all other obligations which may be required of such applicant under the Act. OWCP may extend the 30-day deadline if it determines that additional evidence is needed or that the applicant's evidence is not in compliance with OWCP's requirements.

(b) The applicant will thereafter be notified that they may give security in the amount fixed by OWCP (see § 726.105):

(1) In the form of an indemnity bond with sureties satisfactory to OWCP;

(2) By a deposit of negotiable securities with a Federal Reserve Bank in compliance with §§ 726.106(c) and 726.107; or

(3) In the form of a letter of credit issued by a financial institution satisfactory to OWCP (except that a letter of credit is not sufficient by itself to satisfy a self-insurer's obligations under this part).

(c) If the applicant is receiving authorization to self-insure for the first time, OWCP will notify the applicant that:

(1) its authorization to self-insure is contingent upon submitting the required security and completed agreement and undertaking; and

(2) the applicant's authorization to self-insure is effective for 12 months from the date such security and completed agreement and undertaking are received by OWCP.

(d) If OWCP renews the applicant's authorization to self-insure, OWCP will notify the applicant that:

(1) If there are no changes in the required security amount, the applicant's authorization to self-insure is granted and effective for 12 months from the date the applicant's completed agreement and undertaking is received by OWCP or

(2) If changes are needed to the existing security amount, the applicant's

authorization to self-insure is not granted until the applicant has submitted the required security and signed agreement and undertaking. The applicant's authorization to self-insure will be effective for 12 months from the date such updated security and completed agreement and undertaking are received by OWCP.

(e) Any applicant who cannot meet the security deposit requirements imposed by OWCP should proceed to obtain a commercial policy or contract of insurance and submit proof of such coverage within 30 days after OWCP notifies the applicant of its decision. Any applicant for authorization to self-insure whose application has been denied or who believes that the security deposit requirements imposed by OWCP are excessive may appeal such determination in the manner set forth in § 726.116.

§ 726.105 Fixing the Amount of Security.

Any operator approved to self-insure must submit 120 percent of the actuarial estimated liabilities (all present and future liabilities), as determined by OWCP based on the actuarial report or reports submitted with the operator's application or on file with OWCP, other information submitted with the operator's application, or any other materials or information that OWCP deems relevant.

§ 726.106 Type of Security.

(a) OWCP will determine the type or types of security which an applicant must or may procure. An operator may not provide any form of security other than those provided for in § 726.104(b).

(b) In the event the indemnity bond option is selected, the bond must be in such form and contain such provisions as OWCP prescribes: *Provided* that only corporations may act as sureties on such indemnity bonds. In each case in which the surety on any such bond is a surety company, such company must be one approved by the U.S. Treasury Department under the laws of the United States and the applicable rules and regulations governing bonding companies (see Department of Treasury's Circular-570).

(c) If the form of negotiable securities is selected, the operator must deposit the amount fixed by OWCP in any negotiable securities acceptable as security for the deposit of public moneys of the United States under regulations issued by the Secretary of the Treasury. (See 31 CFR part 225.) The approval, valuation, acceptance, and custody of such securities is hereby committed to the several Federal

Reserve Banks and the Treasurer of the United States.

§ 726.107 How Negotiable Securities Are Handled.

(a) Deposits of securities provided for by the regulations in this part must be made with any Federal Reserve bank or any branch of a Federal Reserve bank designated by OWCP, or the Treasurer of the United States, and must be held in the name of the Department of Labor.

(b) If the self-insurer defaults on its obligations under the Act, OWCP has the power, in its discretion, to:

- (1) collect the interest as it may become due;
- (2) sell any or all of the securities; and
- (3) apply the collected interest or proceeds from the sale of securities to the payment of any benefits for which the self-insurer may be liable.

(c) If a self-insurer with deposits of securities has neither defaulted nor appealed from a determination made by OWCP under § 726.104, OWCP may allow the self-insurer to collect interest on the security deposit.

§ 726.108 Withdrawal of Securities.

(a) Withdrawal of any form of security (indemnity bonds, negotiable securities, and/or letters of credit) is prohibited except upon express written authorization by OWCP.

(b) If a self-insurer wishes to withdraw securities, it must submit a written request, and must submit either an updated actuarial report using OWCP-mandated actuarial assumptions to support why the existing security levels are no longer applicable or replacement securities in the amount and form approved by OWCP. If OWCP approves the operator's request to withdraw and replace its securities, the operator must provide the replacement securities before it withdraws its existing securities.

§ 726.109 Increase in the Amount of Security.

OWCP may, at its discretion, increase the amount of security a self-insurer is required to post whenever it determines that the amount of security on deposit is insufficient to secure the payment of benefits and medical expenses under the Act.

§ 726.110 Filing of Agreement and Undertaking.

(a) In addition to the requirement that adequate security be procured as set forth in this subpart, the applicant for the authorization to self-insure must, as a condition precedent to receiving such authorization, execute and file with OWCP an agreement and undertaking in a form prescribed and provided by

OWCP in which the applicant must agree:

(1) To pay when due, as required by the Act, all benefits payable on account of total disability or death of any of its employee-miners;

(2) To furnish medical, surgical, hospital, and other attendance, treatment, and care as required by the Act;

(3) To provide security in a form approved by OWCP (see § 726.104) and in an amount established by OWCP (see § 726.105);

(4) To authorize OWCP to sell any negotiable securities so deposited or any part thereof, and to pay from the proceeds thereof such benefits, medical, and other expenses and any accrued penalties imposed by law as OWCP may find to be due and payable.

(b) When an applicant has provided the requisite security, it must submit to OWCP a completed agreement and undertaking, together with satisfactory proof that its obligations and liabilities under the Act have been secured.

(c) Any operator authorized to self-insure must notify OWCP of any changes to its business structure, including the purchase, sale, or lease of any coal mining operations, that could affect the operator's liability for benefits under the Act. The operator must provide such notification to OWCP within 30 days of such change. In all events, however, an operator's liability following a change or sale is governed by Subpart G of these regulations, 20 CFR 725.490-725.497.

(d) OWCP may, at its discretion, require an operator to provide any information that may affect the operator's liability for benefits under the Act.

§ 726.111 Notice of Authorization to Self-Insure.

Upon receipt of a completed agreement and undertaking and satisfactory proof that adequate security has been provided, OWCP will notify an applicant for authorization to self-insure in writing that it is authorized to self-insure to meet the obligations imposed upon such operator by section 415 and part C of title IV of the Act. OWCP will also notify the applicant of the date on which its authorization is effective, the date on which such authorization will expire, and the date by which the applicant must apply to renew such authorization if the applicant intends to continue self-insuring its liabilities under the Act.

§ 726.112 Reports Required of Self-Insurer; Examination of Accounts of Self-Insurer.

(a) Each operator who has been authorized to self-insure under this part must submit to OWCP reports containing such information as OWCP may from time to time require or prescribe.

(b) Whenever it deems it to be necessary, OWCP may inspect or examine the books of account, records, and other papers of a self-insurer for the purpose of verifying any financial statement submitted to OWCP by the self-insurer or verifying any information furnished to OWCP in any report required by this section, or any other section of the regulations in this part, and such self-insurer must permit OWCP or its duly authorized representative to make such an inspection or examination as OWCP may require. In lieu of this requirement OWCP may in its discretion accept an adequate report of a certified public accountant.

(c) Failure to submit or make available any report or information requested by OWCP from an authorized self-insurer pursuant to this section may, in appropriate circumstances, result in a revocation of the authorization to self-insure.

§ 726.113 Disclosure of Confidential Information.

Any financial information or records, or other information relating to the business of an authorized self-insurer or applicant for the authorization of self-insurance obtained by OWCP is exempt from public disclosure to the extent provided in 5 U.S.C. 552(b) and the applicable regulations of the Department of Labor promulgated thereunder. (See 29 CFR part 70.)

§ 726.114 Authorization and Reauthorization Timeframes.

(a) No initial or renewed authorization to self-insure may be granted for a period in excess of 12 months unless OWCP determines that extenuating circumstances exist to allow an extension.

(b) If an applicant is seeking to renew its authority to self-insure, the applicant must file its application no later than 90 days before its existing authorization period ends.

§ 726.115 Revocation of Authorization to Self-Insure.

OWCP may suspend or revoke the authorization of any self-insurer for good cause, including but not limited to:

(a) failure by a self-insurer to comply with any provision or requirement of law or of the regulations in this part, or

with any lawful order or request made by OWCP;

(b) the failure or insolvency of the surety on its indemnity bond, if such bond is used as security, or any other financial institution holding any form of security provided by an operator; or

(c) impairment of financial responsibility of such self-insurer.

§ 726.116 Appeal Process.

(a) How to appeal. Any applicant that wishes to appeal OWCP's determination on an application must submit a written request for review to OWCP in the form and manner prescribed by OWCP within 30 days of such determination. This deadline may not be extended.

(b) What to submit. Within 30 days after filing written request for review, the applicant must submit any evidence and/or briefing on which it intends to rely. OWCP may, at its discretion, extend this deadline at the applicant's request upon a showing of good cause.

(c) Conferences.

(1) The applicant may request an informal conference to present its position. Such request must be made in writing when the applicant submits evidence and briefing in support of its request for review.

(2) If the applicant requests a conference, OWCP will hold one with the applicant's representatives.

(3) If the applicant does not request a conference, OWCP may either decide the appeal on the record or, at its discretion, schedule a conference on its own initiative.

(4) The conference will be limited to the issues identified in the applicant's written materials.

(d) OWCP's review. OWCP will review the previous determination in light of any new evidence or additional information submitted and issue a supplemental determination.

(e) Further appeals.

(1) Any applicant aggrieved by a supplemental determination made by OWCP may request further review by the Director of OWCP within 30 days of such supplemental determination.

(2) The Director of OWCP will review the supplemental decision and evidence of record only. The applicant may not submit new evidence or arguments to the Director of OWCP.

(3) The Director of OWCP will issue a final agency decision.

Signed at Washington, DC.

Christopher J. Godfrey,

Director, Office of Workers' Compensation Programs.

[FR Doc. 2023-00534 Filed 1-18-23; 8:45 am]

BILLING CODE 4510-CK-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2022-0927]

RIN 1625-AA08

Special Local Regulations; Sector Ohio Valley Annual and Recurring Special Local Regulations, Update

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes amending and updating its special local regulations for recurring marine parades, regattas, and other events that take place in the Coast Guard Sector Ohio Valley area of responsibility (AOR). This proposed rulemaking would update the current list of recurring special local regulations with revisions, additions, and removals of events that no longer take place in the Sector Ohio Valley AOR. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before February 21, 2023.

ADDRESSES: You may submit comments identified by docket number USCG-2022-0927 using the Federal Decision Making Portal at <https://www.regulations.gov>. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Petty Officer Bryan Crane, Sector Ohio Valley, U.S. Coast Guard; telephone (502)-779-5334, email SECOHV-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

AOR Area of responsibility
CFR Code of Federal Regulations
COTP Captain of the Port Sector Ohio Valley
DHS Department of Homeland Security
E.O. Executive order
FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Captain of the Port Sector Ohio Valley (COTP) proposes to update the current list of recurring special local

regulations found in Table 1 of title 33 of the Code of Federal Regulations (CFR) section 100.801 for events occurring within the Sector Ohio Valley area of responsibility within the Coast Guard's Eighth District.

This proposed rule would update the list of annually recurring special local regulations under 33 CFR 100.801, Table 1, for annual special local regulations in the Sector Ohio Valley's Area of Responsibility (AOR). The Coast Guard will address all comments through response via the rulemaking process, including additional revisions to this regulatory section. Additionally, the public would be informed of these recurring events through local means and planned by the local communities. The current list of annual and recurring special local regulations occurring in Sector Ohio Valley's AOR is published in 33 CFR 100.801, Table 1 titled "Ohio Valley Annual and Reoccurring Marine Events." The most recent list was published on February 3, 2022 (87 FR 6026).

The Coast Guard's authority for establishing a special local regulation is contained in 46 U.S.C. 70041(a). The Coast Guard proposes to amend and update the special local regulations in 33 CFR 100.801, Table 1, to include the most up to date list of recurring special local regulations for events held on or around the navigable waters within Sector Ohio Valley's AOR. These events would include marine parades, boat races, swim events, and other marine related events. The current list under 33 CFR 100.801, Table 1, requires amendment to provide new information on existing special local regulations, add new special local regulations expected to recur annually or biannually, and to remove special local regulations that no longer occur. Issuing individual regulations for each new special local regulation, amendment, or removal of an existing special local regulation creates unnecessary administrative costs and burdens. This single proposed rulemaking will considerably reduce administrative

overhead and provide the public with notice through publication in the **Federal Register** of recurring special local regulations in the AOR.

III. Discussion of Proposed Rule

Part 100 of 33 CFR contains regulations describing regattas and marine parades conducted on U.S. navigable waters in order to ensure the safety of life in the regulated areas. Section 100.801 provides the regulations applicable to events taking place in the Eighth Coast Guard District and also provides a table listing each event and special local regulations. This section requires amendment from time to time to properly reflect the recurring special local regulations. This proposed rule would update § 100.801, Table 1 titled "Ohio Valley Annual and Reoccurring Marine Events."

This proposed rule would add 8 new recurring special local regulations to Table 1 of § 100.801 for Sector Ohio Valley, as follows:

Date	Event/sponsor	Ohio valley location	Regulated area
1 day in March	Oak Ridge Rowing Association/ US Rowing U19 ID Camp.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
1 day in May	Oak Ridge Rowing Association/ AAC Championship.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
3 days in May	Oak Ridge Rowing Association/ ARCA Championship.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
1 day—First week in July	Cincinnati Parks-Sawyer Point/ Cincinnati Parks Board.	Cincinnati, OH	Ohio River, Mile 469–470 (Ohio).
1 day—First week in July	City of New Richmond, Riverdays/VFW.	New Richmond, OH ...	Ohio River, Mile 449.5–450.5 (Ohio).
1 day in August	THREE RIVERS REGATTA	Knoxville, TN	Tennessee River, Mile 652–653 (Tennessee).
1 day in August	K-Town On The River	Knoxville, TN	Tennessee River, Mile 648–650 (Tennessee).
3 days in August	Pro Watercross Music City Grand Prix.	Nashville, TN	Cumberland River, Mile 190–191 (Tennessee).

These new recurring special local regulations would be reflected in the table in the general date order in which they will occur, and the current

recurring special local regulations would be reordered, as shown in the proposed regulatory text below.

Additionally, this proposed rule would amend 11 recurring special local regulations in Table 1 of § 100.801 for Sector Ohio Valley, as follows:

Date	Event/sponsor	Ohio valley location	Regulated area	Previously
3 days—A weekend in May or June.	Oak Ridge Rowing Association/ Dogwood Masters.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).	3 days—Third weekend in May.
3 days in June	Lake Guntersville Hydrofest.	Guntersville, AL ..	Tennessee River, Mile 355.5–356.5 (Alabama).	1 day in June and Guntersville Lake Hydrofest.
1 day in June	Music City Triathlon	Nashville, TN	Cumberland River, Mile 189.7–192.3 (Tennessee).	1 day—fourth weekend in July.
1 day—Third or Fourth weekend in July.	Tri-Louisville	Louisville, KY	Ohio River, Mile 600.5–604 (Kentucky)	1 day—one weekend in June.
1 day in August	Riverbluff Triathlon	Ashland City, TN	Cumberland River, Mile 157–159 (Tennessee).	1 day—First or second weekend in August.
1 day in October	Cumberland River Compact/ Cumberland River Dragon Boat Festival.	Nashville, TN	Cumberland River, Mile 189.7–192.1 (Tennessee).	1 day—One of the first three weekends in September.
1 day in October	Shoals Scholar Dollar	Florence, AL	Tennessee River, Mile 255–257 (Alabama).	Shoals Dragon Boat Festival and 1 day—One weekend in September.

Date	Event/sponsor	Ohio valley location	Regulated area	Previously
2 days in October	Music City Head Race	Nashville, TN	Cumberland River, Mile 190–195 (Tennessee).	3 days—First or Second weekend in October and Cumberland River, Mile 189.5–196.0 (Tennessee).
2 days—Second Weekend in July. 1 day—Second weekend in December.	New Martinsville Vintage Regatta. Charleston Lighted Boat Parade.	New Martinsville, WV. Charleston, WV ..	Ohio River Mile 127.5–128.5 (West Virginia). Kanawha River, Mile 54.3–60.3 (West Virginia).	2 days—One weekend in June. 1 day—One weekend in November or December.
3 days—The weekend of Labor Day.	Portsmouth River Days ...	Portsmouth, OH ..	Ohio River, Mile 355.5–356.8 (Ohio) ...	Portsmouth Boat Race/ Breakwater Powerboat Association.

Lastly, this proposed rule would remove 4 recurring special local regulations in Table 1 of § 100.801 for Sector Ohio Valley as follows:

Date	Event/sponsor	Ohio valley location	Regulated area
2 days—One weekend in July 1 day—Last weekend in July or first weekend in August.	Huntington Classic Regatta Healthy TriState.org/St.Marys Tri State Kayathalon.	Huntington, WV Huntington, WV	Ohio River, Mile 307.3–309.3 (West Virginia). Ohio River, Mile 305.1–308.3 (West Virginia).
3 days—One weekend in August	Pro Water Cross Championships.	Charleston, WV	Kanawha River, Mile 56.7–57.6 (West Virginia).
1 day—One weekend in August	YMCA River Swim	Charleston, WV	Kanawha River, Mile 58.3–61.8 (West Virginia).

The effect of this proposed rule would be to restrict general navigation during these events. Vessels intending to transit the designated waterways during effective periods of the special local regulations would only be allowed to transit the area when the COTP or designated representative, has deemed it would be safe to do so or at the completion of the event.

IV. Regulatory Analyses

We developed this proposed 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 NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

The Coast Guard expects the economic impact of this proposed rule to be minimal, therefore a full regulatory evaluation is unnecessary. This proposed rule would establish special local regulations limiting access to

certain areas described in 33 CFR 100.801, Table 1. The effect of this proposed rulemaking would not be significant because these special local regulations are limited in scope and duration. Additionally, the public would be given advance notification through local forms of notice, the **Federal Register**, and/or Notices of Enforcement. Thus, the public would be able to plan their operations and activities around enforcement times of the special local regulations. Broadcast Notices to Mariners, Local Notices to Mariners, and Safety Marine Information Broadcasts would also inform the community of these special local regulations. Vessel traffic would be permitted to request permission from the COTP or a designated representative to enter the restricted areas.

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 proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated area may be small entities, for reasons stated in section IV.A. above, this proposed rule would not have a significant economic impact on any owner or operator because they are limited in scope and will be in effect for short periods of time.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this proposed rule would economically affect it.

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 proposed rule. If the proposed 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. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would 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 proposed 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 proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would 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. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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 proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed 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 made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. of the Instruction because it involves establishment of special local regulations related to marine event permits for marine parades, regattas, and other marine events. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2022–0927 in the search box and click “Search.” Next, look for this document in the Search Results column,

and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

- 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

- 2. In § 100.801, revise and republish table 1 to read as follows:

§ 100.801 Annual Marine Events in the Eighth Coast Guard District.

* * * * *

TABLE 1 TO § 100.801—SECTOR OHIO VALLEY ANNUAL AND RECURRING MARINE EVENTS

Date	Event/sponsor	Ohio valley location	Regulated area
1. 3 days—Second or third week-end in March.	Oak Ridge Rowing Association/ Cardinal Invitational.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
2. 1 day in March	Oak Ridge Rowing Association/ US Rowing U19 ID Camp.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
3. 1 day—Third weekend in March.	Vanderbilt Rowing/Vanderbilt Invite.	Nashville, TN	Cumberland River, Mile 188.0–192.7 (Tennessee).
4. 2 days—Fourth weekend in March.	Oak Ridge Rowing Association/ Atomic City Turn and Burn.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).

TABLE 1 TO § 100.801—SECTOR OHIO VALLEY ANNUAL AND RECURRING MARINE EVENTS—Continued

Date	Event/sponsor	Ohio valley location	Regulated area
5. 3 days—One weekend in April	Big 10 Invitational Regatta	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
6. 1 day—One weekend in April	Lindamood Cup	Marietta, OH	Muskingum River, Mile 0.5–1.5 (Ohio).
7. 3 days—Third weekend in April.	Oak Ridge Rowing Association/SIRA Regatta.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
8. 2 days—Third or fourth Friday and Saturday in April.	Thunder Over Louisville	Louisville, KY	Ohio River, Mile 597.0–604.0 (Kentucky).
9. 1 day—During the last week of April or first week of May.	Great Steamboat Race	Louisville, KY	Ohio River, Mile 595.0–605.3 (Kentucky).
10. 3 days—Fourth weekend in April.	Oak Ridge Rowing Association/Dogwood Junior Regatta.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
11. 1 day in May	Oak Ridge Rowing Association/AAC Championship.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
12. 3 days in May	Oak Ridge Rowing Association/ARCA Championship.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
13. 3 Days in May	US Rowing Southeast Youth Championship Regatta.	Oak Ridge, TN	Clinch River, Mile 48.5–52 (Tennessee).
14. 3 days—Second weekend in May.	Vanderbilt Rowing/ACRA Henley	Nashville, TN	Cumberland River, Mile 188.0–194.0 (Tennessee).
15. 3 days—Second weekend in May.	Oak Ridge Rowing Association/Big 12 Championships.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
16. 3 days—A weekend in May or June.	Oak Ridge Rowing Association/Dogwood Masters.	Oak Ridge, TN	Clinch River, Mile 48.5–52.0 (Tennessee).
17. 1 day—Third weekend in May	World Triathlon Corporation/IRONMAN 70.3.	Chattanooga, TN	Tennessee River, Mile 462.7–467.5 (Tennessee).
18. 1 day—During the last weekend in May or on Memorial Day.	Mayor's Hike, Bike and Paddle	Louisville, KY	Ohio River, Mile 601.0–604.5 (Kentucky).
19. 1 day—The last week in May	Chickamauga Dam Swim	Chattanooga, TN	Tennessee River, Mile 470.0–473.0 (Tennessee).
20. 2 days—Last weekend in May or first weekend in June.	Visit Knoxville/Racing on the Tennessee.	Knoxville, TN	Tennessee River, Mile 647.0–648.0 (Tennessee).
21. 2 days—Last weekend in May or one weekend in June.	Outdoor Chattanooga/Chattanooga Swim Festival.	Chattanooga, TN	Tennessee River, Mile 454.0–468.0 (Tennessee).
22. 2 days—First weekend of June.	Thunder on the Bay/KDBA	Pisgah Bay, KY	Tennessee River, Mile 30.0 (Kentucky).
23. 1 day—First weekend in June	Visit Knoxville/Knoxville Powerboat Classic.	Knoxville, TN	Tennessee River, Mile 646.4–649.0 (Tennessee).
24. 3 days—One of the last three weekends in June.	Lawrenceburg Regatta/Whiskey City Regatta.	Lawrenceburg, IN	Ohio River, Mile 491.0–497.0 (Indiana).
25. 3 days—One of the last three weekends in June.	Hadi Shrine/Evansville Shriners Festival.	Evansville, IN	Ohio River, Mile 790.0–796.0 (Indiana).
26. 3 days—Third weekend in June.	TM Thunder LLC/Thunder on the Cumberland.	Nashville, TN	Cumberland River, Mile 189.6–192.3 (Tennessee).
27. 1 day—Third or fourth weekend in June.	Greater Morgantown Convention and Visitors Bureau/Mountaineer Triathlon.	Morgantown, WV	Monongahela River, Mile 101.0–102.0 (West Virginia).
28. 1 day—Fourth weekend in June.	Team Magic/Chattanooga Waterfront Triathlon.	Chattanooga, TN	Tennessee River, Mile 462.7–466.0 (Tennessee).
29. 3 days in June	Lake Guntersville Hydrofest	Guntersville, AL	Tennessee River 355.5–365.5 (Alabama).
30. 1 day in June	Music City Triathlon	Nashville, TN	Cumberland River, Mile 189.7–192.3 (Tennessee).
31. 3 days—The last weekend in June or one of the first two weekends in July.	Madison Regatta	Madison, IN	Ohio River, Mile 554.0–561.0 (Indiana).
32. 1 Day in July	Three Rivers Regatta	Knoxville, TN	Tennessee River, Mile 642–653 (Tennessee).
33. 1 Day in July	Tri-Louisville	Louisville, KY	Ohio River, Mile 600.5–604.0 (Kentucky).
34. 1 Day in July	PADL	Cannelton, IN	Ohio River, Miles 719.0–727.0 (Kentucky).
35. 1 day—First week in July	Cincinnati Parks-Sawyer Point/Cincinnati Parks Board.	Cincinnati, OH	Ohio River, Miles 469–470 (Ohio).
36. 1 day—First week in July	City of New Richmond, Riverdays/VFW.	New Richmond, OH ...	Ohio River, Mile 449.5–450.5 (Ohio).
37. 1 day—During the first week of July.	Evansville Freedom Celebration/4th of July Freedom Celebration.	Evansville, IN	Ohio River, Mile 790.0–797.0 (Indiana).
38. First weekend in July	Eddyville Creek Marina/Thunder Over Eddy Bay.	Eddyville, KY	Cumberland River, Mile 46.0–47.0 (Kentucky).
39. 2 days—One of the first two weekends in July.	Thunder on the Bay/KDBA	Pisgah Bay, KY	Tennessee River, Mile 30.0 (Kentucky).
40. 1 day—Second weekend in July.	Bradley Dean/Renaissance Man Triathlon.	Florence, AL	Tennessee River, Mile 254.0–258.0 (Alabama).
41. 2 days—Second weekend in July.	New Martinsville Vintage Regatta.	New Martinsville, WV	Ohio River Mile 127.5–128.5 (West Virginia).

TABLE 1 TO § 100.801—SECTOR OHIO VALLEY ANNUAL AND RECURRING MARINE EVENTS—Continued

Date	Event/sponsor	Ohio valley location	Regulated area
42. 1 day—Third or fourth Sunday of July.	Tucson Racing/Cincinnati Triathlon.	Cincinnati, OH	Ohio River, Mile 468.3–471.2 (Ohio).
43. 2 days—One of the last three weekends in July.	Dare to Care/KFC Mayor's Cup Paddle Sports Races/Voyageur Canoe World Championships.	Louisville, KY	Ohio River, Mile 600.0–605.0 (Kentucky).
44. 2 days—Last two weeks in July or first three weeks of August.	Friends of the Riverfront Inc./Pittsburgh Triathlon and Adventure Races.	Pittsburgh, PA	Allegheny River, Mile 0.0–1.5 (Pennsylvania).
45. 1 day—Last weekend in July	Maysville Paddlefest	Maysville, KY	Ohio River, Mile 408–409 (Kentucky).
46. 2 days—One weekend in July.	Marietta Riverfront Roar Regatta	Marietta, OH	Ohio River, Mile 171.6–172.6 (Ohio).
47. 1 day in August	Three Rivers Regatta	Knoxville, TN	Tennessee River 652–653 (Tennessee).
48. 1 day in August	K-Town On The River	Knoxville, TN	Tennessee River 648–650 (Tennessee).
49. 3 days in August	Pro Watercross Music City Grand Prix.	Nashville, TN	Cumberland River 190–191 (Tennessee).
50. 1 day—first Sunday in August	Above the Fold Events/Riverbluff Triathlon.	Ashland City, TN	Cumberland River, Mile 157.0–159.5 (Tennessee).
51. 3 days—First week of August	EQT Pittsburgh Three Rivers Regatta.	Pittsburgh, PA	Allegheny River mile 0.0–1.0, Ohio River mile 0.0–0.8, Monongahela River mile 0.5 (Pennsylvania).
52. 2 days—First weekend of August.	Thunder on the Bay/KDBA	Pisgah Bay, KY	Tennessee River, Mile 30.0 (Kentucky).
53. 1 day in August	Riverbluff Triathlon	Ashland City, TN	Cumberland River, Mile 157.0–159.0 (Tennessee).
54. 1 day—One of the first two weekends in August.	Green Umbrella/Ohio River Paddlefest.	Cincinnati, OH	Ohio River, Mile 458.5–476.4 (Ohio and Kentucky).
55. 3 days—Third full weekend (Saturday and Sunday) in August.	Ohio County Tourism/Rising Sun Boat Races.	Rising Sun, IN	Ohio River, Mile 504.0–508.0 (Indiana and Kentucky).
56. 3 days—Second or Third weekend in August.	Kittanning Riverbration Boat Races.	Kittanning, PA	Allegheny River mile 42.0–46.0 (Pennsylvania).
57. 3 days—One of the last two weekends in August.	Thunder on the Green	Livermore, KY	Green River, Mile 69.0–72.5 (Kentucky).
58. 1 day—Fourth weekend in August.	Team Rocket Tri-Club/Rocketman Triathlon.	Huntsville, AL	Tennessee River, Mile 332.2–335.5 (Alabama).
59. 1 day—Last weekend in August.	Tennessee Clean Water Network/Downtown Dragon Boat Races.	Knoxville, TN	Tennessee River, Mile 646.3–648.7 (Tennessee).
60. 2 days—One weekend in August.	POWERBOAT NATIONALS—Ravenswood Regatta.	Ravenswood, WV	Ohio River, Mile 220.5–221.5 (West Virginia).
61. 2 days—One weekend in August.	Powerboat Nationals-Parkersburg Regatta/Parkersburg Homecoming.	Parkersburg, WV	Ohio River Mile 183.5–285.5 (West Virginia).
62. 3 days—One weekend in August.	Grand Prix of Louisville	Louisville, KY	Ohio River, Mile 601.0–605.0 (Kentucky).
63. 3 days—One weekend in August.	Evansville HydroFest	Evansville, IN	Ohio River, Mile 790.5–794.0 (Indiana).
64. 3 days—One weekend in the month of August.	Owensboro HydroFair	Owensboro, KY	Ohio River, Mile 794.0–760.0 (Kentucky).
65. 1 day—First or second weekend of September.	SUP3Rivers The Southside Outside.	Pittsburgh, PA	Monongahela River mile 0.0–3.09 Allegheny River mile 0.0–0.6 (Pennsylvania).
66. 1 day—First weekend in September or on Labor Day.	Mayor's Hike, Bike and Paddle	Louisville, KY	Ohio River, Mile 601.0–610.0 (Kentucky).
67. 2 days—Sunday before Labor Day and Labor Day.	Cincinnati Bell, WEBN, and Proctor and Gamble/Riverfest.	Cincinnati, OH	Ohio River, Mile 463.0–477.0 (Kentucky and Ohio) and Licking River Mile 0.0–3.0 (Kentucky).
68. 2 days—Labor Day weekend	Wheeling Vintage Race Boat Association Ohio/Wheeling Vintage Regatta.	Wheeling, WV	Ohio River, Mile 90.4–91.5 (West Virginia).
69. 3 days—The weekend of Labor Day.	Portsmouth River Days	Portsmouth, OH	Ohio River, Mile 355.5–356.8 (Ohio).
70. 2 days—One of the first three weekends in September.	Louisville Dragon Boat Festival	Louisville, KY	Ohio River, Mile 602.0–604.5 (Kentucky).
71. 2 days—One of the first three weekends in September.	State Dock/Cumberland Poker Run.	Jamestown, KY	Lake Cumberland (Kentucky).
72. 3 days—One of the first three weekends in September.	Fleur de Lis Regatta	Louisville, KY	Ohio River, Mile 594.0–598.0 (Kentucky).
73. 1 day—Second weekend in September.	City of Clarksville/Clarksville Riverfest Cardboard Boat Regatta.	Clarksville, TN	Cumberland River, Mile 125.0–126.0 (Tennessee).

TABLE 1 TO § 100.801—SECTOR OHIO VALLEY ANNUAL AND RECURRING MARINE EVENTS—Continued

Date	Event/sponsor	Ohio valley location	Regulated area
74. 1 day—One Sunday in September.	Ohio River Sternwheel Festival Committee Sternwheel race reenactment.	Marietta, OH	Ohio River, Mile 170.5–172.5 (Ohio).
75. 1 Day—One weekend in September.	Parkeburg Paddle Fest	Parkersburg, WV	Ohio River, Mile 184.3–188 (West Virginia).
76. 2 days—One of the last three weekends in September.	Madison Vintage Thunder	Madison, IN	Ohio River, Mile 556.5–559.5 (Indiana).
77. 1 day—Third Sunday in September.	Team Rocket Tri Club/Swim Hobbs Island.	Huntsville, AL	Tennessee River, Mile 332.3–338.0 (Alabama).
78. 1 day—Fourth or fifth weekend in September.	Knoxville Open Water Swimmers/Bridges to Bluffs.	Knoxville, TN	Tennessee River, Mile 641.0–648.0 (Tennessee).
79. 1 day—Fourth or fifth Sunday in September.	Green Umbrella/Great Ohio River Swim.	Cincinnati, OH	Ohio River, Mile 468.8–471.2 (Ohio and Kentucky).
80. 1 day—One of the last two weekends in September.	Ohio River Open Water Swim ...	Prospect, KY	Ohio River, Mile 587.0–591.0 (Kentucky).
81. 2 days—One of the last three weekends in September or the first weekend in October.	Captain Quarters Regatta	Louisville, KY	Ohio River, Mile 594.0–598.0 (Kentucky).
82. 3 days—One of the last three weekends in September or one of the first two weekends in October.	Owensboro Air Show	Owensboro, KY	Ohio River, Mile 754.0–760.0 (Kentucky).
83. 1 day—Last weekend in September.	World Triathlon Corporation/IRONMAN Chattanooga.	Chattanooga, TN	Tennessee River, Mile 462.7–467.5 (Tennessee).
84. 3 days—Last weekend of September and/or first weekend in October.	New Martinsville Records and Regatta Challenge Committee.	New Martinsville, WV	Ohio River, Mile 128–129 (West Virginia).
85. 2 days—First weekend of October.	Three Rivers Rowing Association/Head of the Ohio Regatta.	Pittsburgh, PA	Allegheny River mile 0.0–5.0 (Pennsylvania).
86. 1 day in October	Chattajack	Chattanooga, TN	Tennessee River, Miles 462.7–465.5 (Tennessee).
87. 1 day in October	Cumberland River Compact/Cumberland River Dragon Boat Festival.	Nashville, TN	Cumberland River, Mile 189.7–192.1 (Tennessee).
88. 1 day in October	Outdoor Chattanooga/Swim the Suck.	Chattanooga, TN	Tennessee River, Miles 452.0–454.5 (Tennessee).
89. 1 day—First or second weekend in October.	Lookout Rowing Club/Chattanooga Head Race.	Chattanooga, TN	Tennessee River, Mile 463.0–468.0 (Tennessee).
90. 1 day in October	Shoals Scholar Dollar	Florence, AL	Tennessee River 255–257 (Alabama).
91. 2 days in October	Music City Head Race	Nashville, TN	Cumberland River 190–195 (Tennessee).
92. 2 days—First or second week of October.	Head of the Ohio Rowing Race	Pittsburgh, PA	Allegheny River, Mile 0.0–3.0 (Pennsylvania).
93. 2 days—One of the first three weekends in October.	Norton Healthcare/Ironman Triathlon.	Louisville, KY	Ohio River, Mile 600.5–605.5 (Kentucky).
94. 2 days—Two days in October	Secret City Head Race Regatta	Oak Ridge, TN	Clinch River, Mile 49.0–54.0 (Tennessee).
95. 3 days—First weekend in November.	Atlanta Rowing Club/Head of the Hooch Rowing Regatta.	Chattanooga, TN	Tennessee River, Mile 463.0–468.0 (Tennessee).
96. 1 day—Second weekend in December.	Charleston Lighted Boat Parade	Charleston, WV	Kanawha River, Mile 54.3–60.3 (West Virginia).

* * * * *

Dated: January 11, 2023.

H.R. Mattern,

Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2023–00925 Filed 1–18–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

[Docket Number COE–2022–0009]

Establishment of Three Danger Zones for the Naval Support Activity Annapolis, Annapolis, Maryland, in the Waters of Carr Creek and Whitehall Bay

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

ACTION: Proposed rule; reopening of comment period.

SUMMARY: On December 5, 2022, the U.S. Army Corps of Engineers (Corps) published a proposed rule to establish three danger zones in the waters of Carr Creek and Whitehall Bay in the vicinity of the Naval Support Activity Annapolis. The comment period ended on January 4, 2023. The Corps received numerous requests to extend the comment period, so we are reopening the comment period for 45 days. Comments previously submitted on the proposed rule do not need to be resubmitted, as they have already been incorporated into the administrative

record and will be fully considered in the Corps' decision-making process for this rulemaking action.

DATES: The comment period for the proposed rule published at 87 FR 74348 on December 5, 2022 is reopened. Written comments must be submitted on or before March 6, 2023.

ADDRESSES: You may submit comments, identified by docket number COE-2022-0009, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Email: david.b.olson@usace.army.mil. Include the docket number, COE-2022-0009 in the subject line of the message.

Mail: U.S. Army Corps of Engineers, Attn: CECW-CO-R (David B. Olson), 441 G Street NW, Washington, DC 20314-1000.

Hand Delivery/Courier: Due to security requirements, we cannot receive comments by hand delivery or courier.

Instructions: Instructions for submitting comments are provided in the proposed rule published on December 5, 2022 (87 FR 74348). Consideration will be given to all comments received by March 6, 2023.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson, Headquarters, Operations and Regulatory Division, Washington, DC at 202-761-4922.

SUPPLEMENTARY INFORMATION: In the December 5, 2022, issue of the **Federal Register** (87 FR 74348), the Corps published a proposed rule to establish three permanent danger zones in the waters of Carr Creek and Whitehall Bay in the vicinity of the Naval Support Activity Annapolis, Annapolis, Maryland. The establishment of the proposed danger zone in Carr Creek is necessary to enable safe operation of the United States Naval Academy firing range and to reflect the routine and periodic usage of the firing range for training Sailors, Midshipmen, and law enforcement personnel. The establishment of the two proposed danger zones in Whitehall Bay is necessary to enable the safe operation of the United States Naval Academy firing range and to reflect irregular and infrequent usage of the range for training Sailors, Midshipmen, and law enforcement personnel. The firing range faces Carr Creek and, during times of operation, may present a danger to vessels located in the proposed danger zones. According to the installation, the firing range is normally in operation for live firing approximately 4 to 6 times per year.

The Corps has received numerous requests for an extension of the comment period for the proposed rule. Because the original comment period ended on January 4, 2023, we are reopening the comment period for 45 days. Comments must be received by March 6, 2023.

Thomas P. Smith,

Chief, Operations and Regulatory Division.

[FR Doc. 2023-00889 Filed 1-18-23; 8:45 am]

BILLING CODE 3720-58-P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 11

[Docket No. DOI-DOI-2022-0016; 23XD1618EN, DS61600000, DMNHQ0000.000000]

RIN 1090-AB26

Natural Resource Damages for Hazardous Substances

AGENCY: Office of Restoration and Damage Assessment, Interior.

ACTION: Advance notice of proposed rulemaking; request for public comment.

SUMMARY: The Office of Restoration and Damage Assessment (ORDA) is seeking comments and suggestions from state, tribal, and federal natural resource co-trustees, other affected parties, and the interested public on revising the simplified Type A procedures in the regulations for conducting natural resource damage assessments and restoration (NRDAR) for hazardous substance releases.

DATES: We will accept comments through March 20, 2023.

ADDRESSES: You may submit comments to ORDA on this advance notice of proposed rulemaking (ANPRM); request for public comment by any of the following methods. Please reference the Regulation Identifier Number (RIN) 1090-AB26 in your comments.

- *Electronically:* Go to <https://www.regulations.gov>. In the "Search" box enter "DOI-2022-0016." Follow the instructions to submit public comments. We will post all comments.

- Hand deliver or mail comments to the Office of Restoration and Damage Assessment, U.S. Department of the Interior, 1849 C Street Northwest, Mail Stop/Room 2627, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Emily Joseph, Director, Office of Restoration and Damage Assessment at

(202) 208-4438 or email to emily_joseph@ios.doi.gov.

SUPPLEMENTARY INFORMATION: We are proposing to revise the simplified (Type A) procedures for assessment of natural resource damages resulting from releases of hazardous substances. The Department of the Interior has previously developed two types of natural resource damage assessment regulations: Standard procedures for simplified assessments requiring minimal field observations (Type A Rule); and site-specific procedures for detailed assessments in individual cases (Type B Rule).

The Type B Rule was last revised in 2008 to emphasize natural resource restoration over economic damages, resolve a timing inconsistency, and respond to two previous Court decisions addressing the regulations: *State of Ohio v. U.S. Department of the Interior*, 880 F.2d 432 (D.C. Cir. 1989); and *Kennecott Utah Copper Corp. v. U.S. Department of the Interior*, 88 F.3d 1191 (D.C. Cir. 1996).

The Type A Rule was last revised in November 1997. It provides two distinct formulas for modeling damages for natural resource injuries caused by hazardous substance releases to coastal and marine environments and Great Lakes environments, respectively. In accordance with the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA) 42 U.S.C. 9601 *et seq.*, damages calculated in accordance with Type A or Type B procedures are entitled to a "rebuttable presumption" of correctness in any administrative or judicial proceeding. The rebuttable presumption for the Type A procedure under the current version of the rule is limited to damages of \$100,000 or less.

Background

Since its promulgation, the Type A Rule has rarely been utilized to resolve CERCLA Natural Resource Damage Assessment and Restoration (NRDAR) claims. This may be partly due to the Type A Rule's restrictive scope—to two specific aquatic environments when relatively low-impact, single substance spills occur. Additionally, the model equation for each Type A environment is the functional part of the rule itself—with no provisions to reflect evolving toxicology, ecology, technology, or other scientific understanding without a formal amendment to the Type A Rule each time a parameter is modified. The result is an inefficient and inflexible rule that is not currently useful as a means to resolve NRDAR claims and promote natural resource restoration.

For these reasons, the Department is now seeking to modernize the Type A process and develop a more flexible and enduring rule than what is provided by the two existing static models.

The Department is proposing to reformulate the Type A Rule as a procedural structure for negotiated settlements by utilizing tools tailored to incidents of smaller scale and scope. We believe that this aligns better with the original statutory purpose of providing a streamlined and simplified assessment process as a companion to the more complex Type B Rule—to reduce transaction costs and expedite restoration in a broader range of less complex and contentious cases. Our objective is to essentially formalize beneficial practices that have evolved since the 1997 promulgation of the Type A Rule. Specifically, Trustees have utilized well-established methodologies such as habitat equivalency analysis (HEA), resource equivalency analysis (REA), and other relatively simple models to assess natural resource injury in smaller incidents that do not necessarily warrant the more prescriptive Type B procedures.

Pursuing a case under the new Type A would be initiated by the Trustees involved in the case. The new Type A Rule would be intended for use when the potentially responsible parties (PRPs) and all trustees with jurisdiction over the injured natural resources agree that the simplified procedures of the rule provide an appropriate means of assessing and resolving the claim. An assessment of damages performed cooperatively in this manner would be entitled to a rebuttable presumption of correctness when undergoing administrative or judicial review.

However, rather than limiting the rule's applicability to a narrow range of cases and a pre-determined, static model, the Department of the Interior (Department) proposes to consider ways to expand the rule's scope through a structured process that will utilize a range of methods that have become widely used and accepted since the original rule was formulated, including existing habitat and resource equivalency analyses, and benefits transfers from similar cases. These methodologies are referenced in the current version of the CERCLA NRDAR rule (*See* 43 CFR 11.83) and have proven adaptable and functional enough to support negotiated resolution of a wide range of NRDAR claims that have withstood public and judicial scrutiny over the past two decades. We are seeking additional public input on what specific methodologies or procedures

could be utilized under a revised Type A Rule.

In recognition of the evidentiary constraints of models when compared to more robust site-specific observation and information, the current Type A Rule limits the amount of damages that could be eligible for the Type A rebuttable presumption to \$100,000 or less. We recognize that \$100,000—unadjusted for more than 25 years of inflation from 1997—likely represents an extremely narrow range of present day NRDAR claims. More importantly, it would be challenging for NRDAR trustees and PRPs to engage in even a streamlined cooperative process that is cost-effective in the context of \$100,000 in total damages. Accordingly, we are seeking public input on the appropriate amount of damages eligible for a rebuttable presumption when utilizing a new Type A process.

We are also seeking public input on potential non-monetary limitations for using the Type A Rule—including whether the Type A Rule can be utilized at a site with multiple PRPs, and whether PRPs voluntarily participating in a Type A process need to agree to pay the reasonable cost of that process. Additionally, we are seeking public input on whether the revised Type A should include reasonable assessment costs within the cap applicable for the Type A Rule, and whether there should be a time limit—accompanied by a tolling agreement—to how long a Type A process could take. Finally, we are seeking public input as to whether the Type A claim should continue to be eligible to be combined with a Type B assessment or with other Type A processes at the same site—which could result in applying the Type A Rule to only certain discrete natural resource categories at a site.

The Department anticipates that NRDAR claims resolved through the revised Type A Rule will be subject to a 30-day public notice and review process before finalization. As part of this public notice and review, NRDAR trustees would make available the application of the model they relied on (including the data inputs) and any relevant supporting information. As with the current rule, Trustees would consider, and when appropriate, respond to any public comments. Any changes to the voluntary agreement as a result of public comment would also be approved by the settling PRPs in order to finally resolve the claim.

Consistent with CERCLA section 111(i) (42 U.S.C. 9611(i)), Trustees would continue to expend damages recovered under the Type A Rule pursuant to a Restoration Plan. Trustees

would also continue to have the ability to select appropriate restoration projects without being restricted to selecting the general restoration methods used by the Type A equivalency model they employ to calculate their NRDAR claim. Trustees would maintain the discretion to spend recovered sums on other actions to restore, replace, or acquire the equivalent of injured resources or services.

Description of Information Requested

This advance notice of proposed rulemaking seeks comments on the questions posed above to re-formulate the Type A Rule, including: (1) which assessment methodologies would be appropriate for use in simplified assessments under a revised Type A rule, (2) the amount of damages eligible for a rebuttable presumption when utilizing a new Type A process, (3) whether to include reasonable costs of assessment within the total cap for application of the Type A Rule, (4) whether PRPs voluntarily participating in a Type A process need to agree to pay the reasonable cost of that process, (5) whether the Type A Rule is appropriate for a site with multiple PRPs, and (6) how long a Type A process could last. The Department would also appreciate comments that address interest in using revised Type A procedures, along with suggestions that improve the efficiency and cost effectiveness of the NRDAR Type A process.

Public Comment Procedures

The Department is not obligated to consider comments that we receive after the close of the comment period for this ANPRM, or comments that are delivered to an address other than those listed in this notice. After the comment period for this ANPRM closes, the Department will review all comment submissions. Upon consideration, the Department may publish a notice of proposed rulemaking.

We are particularly interested in receiving comments and suggestions about the topics identified in the Description of Information Requested section. Written comments that are specific, explain the rationale for the comment or suggestion, address the issues outlined in this notice, and where possible, refer to specific statutes, existing regulations, case law, or NRDAR practices are most useful.

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—might be made publicly available at any time.

While you may ask us in your comment to withhold your personal identifying information from public review we cannot guarantee that we will do so.

(Authority: 42 U.S.C. 9601, secs. 104, 107, 111(i), 122)

Emily Joseph,

Director, Office of Restoration and Damage Assessment.

[FR Doc. 2023-00927 Filed 1-18-23; 8:45 am]

BILLING CODE 4334-63-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 217

[Docket No 221214-0271]

RIN 0648-BL52

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Revolution Wind Offshore Wind Farm Project Offshore Rhode Island; Extension of Public Comment Period

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

ACTION: Notice; extension of public comment period.

SUMMARY: On December 23, 2022, NMFS published a proposed rule, with a 30-day public comment period ending January 23, 2023, in response to Revolution Wind, LLC's (Revolution Wind's) request for regulations and an associated Letter of Authorization (LOA), pursuant to the Marine Mammal Protection Act (MMPA). The proposed regulations would allow for the taking of marine mammals, by Level A harassment and Level B harassment, incidental to the Revolution Wind Offshore Wind Farm Project offshore of

Rhode Island. In response to a request, NMFS is announcing an extension of the public comment period by an additional 15 days. The public comment period on the proposed rule is extended from January 23, 2023, to February 7, 2023.

DATES: The deadline for receipt of comments on the proposed rule published on December 23, 2022 (87 FR 79072), is extended from January 23, 2023, to February 7, 2023.

ADDRESSES: Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to www.regulations.gov and enter NOAA-NMFS-2022-0127 in the Search box. Click on the "Comment" icon, complete the required fields, and enter or attach your comments.

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 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), 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). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Carter Esch, Office of Protected Resources, NMFS, (301) 427-8401.

SUPPLEMENTARY INFORMATION:

Background

On December 23, 2022, NMFS published a proposed rulemaking in response to Revolution Wind's request that NMFS authorize the taking, by Level A harassment and Level B

harassment, of marine mammals incidental to the Revolution Wind Offshore Wind Farm Project, located offshore of Rhode Island in and around lease area OCS-A-0486. When published, the proposed rule (87 FR 79072; December 23, 2022) allowed for a 30-day public comment period, ending on January 23, 2023. On December 23, 2022, we received a request from the Natural Resource Defense Council (NRDC) for a 15-day extension of the public comment period. NMFS considered the request and the permitting timelines for this project and, in this case, is extending the comment period on the proposed rule for an additional 15 days to provide further opportunity for public comment. This extension provides a total of 45 days for public input on the proposed rule.

All comments and information submitted previously regarding the proposed rule for Revolution Wind will be fully considered during the development of the final rule and LOA, if determined to be promulgated and issued, and do not need to be resubmitted.

Information Solicited

Interested persons may submit information, suggestions, and comments concerning the proposed rulemaking for the Revolution Wind Offshore Wind Farm Project (see **ADDRESSES**). NMFS will consider all information, suggestions, and comments from both the initial and extended public comment periods during the development of final regulations governing the incidental taking of marine mammals by Revolution Wind, if appropriate.

Dated: January 12, 2023.

Kimberly Damon-Randall,

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

[FR Doc. 2023-00900 Filed 1-18-23; 8:45 am]

BILLING CODE 3510-22-P

Notices

Federal Register

Vol. 88, No. 12

Thursday, January 19, 2023

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

Food and Nutrition Service

Summer Food Service Program; 2023 Reimbursement Rates; Correction

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice; correction.

SUMMARY: The Food and Nutrition Service published a document in the **Federal Register** of January 6, 2023, concerning reimbursement rates for meals served in the Summer Food Service Program for Children. The document contained an incorrect table heading.

FOR FURTHER INFORMATION CONTACT: Mike Rizzo 703-305-4364.

SUPPLEMENTARY INFORMATION: In the January 6, 2023, notice originally published in the **Federal Register**, the heading in the table with the combined reimbursement rates ran with the incorrect year. The entire table is being

reproduced in this correction for convenience.

Correction

In the **Federal Register** issue of January 6, 2023, in FR Doc 88-1039, on page 1041 make the following correction:

On page 1041, the table heading “2022 Reimbursement Rates (Combined)” should read “2023 Reimbursement Rates (Combined).”

2023 Reimbursement Rates (Combined)

Per Meal Rates in whole or fractions of U.S. dollars	All States except Alaska and Hawaii	All States except Alaska and Hawaii	Alaska	Alaska	Hawaii	Hawaii
Site Types	Rural or Self-prep Sites	All Other Types of Sites	Rural or Self-prep Sites	All Other Types of Sites	Rural or Self-prep Sites	All Other Types of Sites
Breakfast	2.8250	2.7725	4.5825	4.4975	3.3075	3.2450
Lunch or Supper	4.9500	4.8700	8.0300	7.9000	5.7975	5.7050
Snack	1.1675	1.1400	1.8975	1.8525	1.3700	1.3375

Cynthia Long,
 Administrator, Food and Nutrition Service.
 [FR Doc. 2023-00933 Filed 1-18-23; 8:45 am]
 BILLING CODE 3410-30-P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

[Docket #: RBS-22-BUSINESS-0027]

Notice of Funding Opportunity for the Rural Business Development Grant Program To Provide Technical Assistance for Rural Transportation Systems for Fiscal Year 2023

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: This notice is to invite applications for grants to provide technical assistance for passenger rural transportation (RT) systems under the Rural Business Development Grant (RBDG) program and the terms for such funding. Grant funds will provide technical assistance for RT systems including designated funds to provide technical assistance to RT systems operating within Tribal lands of Federally Recognized Native American Tribes (FRNAT) (collectively “Programs”). This notice is being issued in order to allow applicants sufficient time to leverage financing, prepare and submit their applications and give the Agency time to process applications

within fiscal year (FY) 2023. Based on FY 2023 appropriated funding, the Agency estimates that approximately \$750,000 available for FY 2023. Successful applications will be selected by the Agency for funding and subsequently awarded to the extent that funding may ultimately be made available through appropriations. All applicants are responsible for any expenses incurred in developing their applications.

DATES: The deadline for completed applications to be received in the United States Department of Agriculture (USDA) Rural Development (RD) State Office is no later than 4:30 p.m. (local time) on April 19, 2023, to be eligible for FY 2023 grant funding. Applications

received after the deadline will be ineligible for funding.

ADDRESSES: This funding announcement will also be announced on www.Grants.gov. Applications must be submitted to the USDA RD State Office where the Project is located. A list of the USDA RD State Office contacts can be found at: <http://www.rd.usda.gov/contact-us/state-offices>.

FOR FURTHER INFORMATION CONTACT: Cindy Mason at cindy.mason@usda.gov, Business Loan and Grant Analyst, Program Management Division, Rural Business-Cooperative Service (RBCS), USDA, 1400 Independence Avenue SW, MS 3226, Room 5160-South, Washington, DC 20250-3226, or call 202-720-1400. Persons with disabilities that require alternative means for communication should contact the USDA Target Center at (202) 720-2600 (voice).

For further information on submitting program applications under this notice, please contact the USDA RD office for the State in which the applicant is located. A list of USDA RD Office contacts is provided at the following link: <http://www.rd.usda.gov/contact-us/state-offices>.

SUPPLEMENTARY INFORMATION:

Overview

Federal Awarding Agency Name: Rural Business-Cooperative Service.

Funding Opportunity Title: Rural Business Development Grants—Technical Assistance for Rural Transportation Systems.

Announcement Type: Notice of funding opportunity.

Funding Opportunity Number: RDBCP-RBDG-2023.

Assistance Listing: 10.351.

Dates: The deadline for completed applications to be received in the USDA RD State Office is no later than 4:30 p.m. (local time) on April 19, 2023, to be eligible for FY 2023 grant funding. Applications received after the deadline will be ineligible for funding.

Rural Development Key Priorities: The Agency encourages applicants to consider projects that will advance the following key priorities (more details available at <https://www.rd.usda.gov/priority-points>):

- Assisting rural communities recover economically through more and better market opportunities and through improved infrastructure;
- Ensuring all rural residents have equitable access to RD programs and benefits from RD funded projects; and
- Reducing climate pollution and increasing resilience to the impacts of climate change through economic support to rural communities.

A. Program Description

1. *Purpose of the Program.* The purpose of this program is to improve the economic conditions of Rural Areas by providing technical assistance that will enhance the operation of rural transportation systems.

2. *Statutory Authority.* This program is authorized under section 310B(c) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1932(c)) and implemented by 7 CFR part 4280, subpart E. The program is administered on behalf of RBCS by the USDA RD State Offices. Assistance provided to rural areas under the program has historically included the provision of on-site technical assistance to Tribal, local and regional governments, public transit agencies, and related nonprofit and for-profit organizations in rural areas; the development of training materials; and the provision of necessary training assistance to local officials and agencies in rural areas.

The Consolidated Appropriations Act, 2023, section 736 of the Consolidated Appropriations Act, 2023, designated funding for projects in Persistent Poverty counties. Persistent Poverty counties is defined in section 736 as “any county that has had 20 percent or more of its population living in poverty over the past 30 years, as measured by the 1990 and 2000 decennial censuses, and 2007–2011 American Community Survey 5-year average, or any territory or possession of the United States”. Another provision in section 736 expands the eligible population in Persistent Poverty counties to include any county seat of such a persistent poverty county that has a population that does not exceed the authorized population limit by more than 10 percent. This provision expands the current 50,000 population limit to 55,000 for only county seats located in Persistent Poverty counties. Therefore, beneficiaries of technical assistance services located in Persistent Poverty County seats with populations up to 55,000 (per the 2010 Census) are eligible.

3. *Definitions.* The definitions applicable to this notice are published at 7 CFR 4280.403.

4. *Application Awards.* The Agency will review, evaluate, and score applications received in response to this notice based on the provisions in 7 CFR part 4280, subpart E and as indicated in this notice. Awards under the RBDG Technical Assistance for RT Systems program will be made on a competitive basis using specific selection criteria contained in 7 CFR part 4280, subpart E, and in accordance with section

310B(c) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1932(c)). The Agency advises all interested parties that the applicant bears the burden in preparing and submitting an application in response to this notice whether or not funding is appropriated for this program in FY 2023.

B. Federal Award Information

Type of Award: Grants.

Fiscal Year Funds: FY 2023.

Available Funds: \$750,000. RBCS may at its discretion, increase the total level of funding available in this funding round, or in any category in this funding round, from any available source provided the awards meet the requirements of the statute which made the funding available to the Agency.

Award Amounts: The Agency will award a maximum of \$500,000 for RT systems and \$250,000 for FRNAT RT projects. The amounts are determined by the specific funding provided for the program in the FY 2023 Appropriations Act.

Anticipated Award Date: Prior to September 30, 2023.

Performance Period: October 1, 2023, through September 30, 2024.

Renewal or Supplemental Awards: None.

Type of Assistance Instrument: Financial Assistance Agreement.

C. Eligibility Information

1. *Eligible Applicants.* Eligible applicants must meet the eligibility requirements of 7 CFR 4280.416, Applicant Eligibility. The Agency requires the information provided in 7 CFR 4280.427 to make an eligibility determination that an applicant is a national organization.

For the funding for Technical Assistance for RT systems, applicants must be qualified national organizations with experience in providing technical assistance and training to rural communities nationwide for the purpose of improving passenger transportation services or facilities. To be considered “national,” RBCS requires a qualified organization to provide evidence that it can operate RT assistance programming nationwide. An entity can qualify if they can work in partnership with other entities to fulfill the national requirement as long as the applicant will have ultimate control of the grant administration. For the funding for RT systems to FRNATs, an entity can qualify if they can work in partnership with other entities to support all federally recognized tribes in all States, as long as the applicant will have ultimate control of the grant

administration. There is not a requirement to use the grant funds in a multi-State area. Grants will be made to qualified national organizations for the provision of technical assistance and training to rural communities for the purpose of improving passenger transportation services or facilities.

For the FRNAT grant, which must benefit FRNATs, at least 75 percent of the benefits of the Project must be received by members of FRNATs.

2. *Cost Sharing or Matching.* There are no cost sharing or matching requirements associated with this grant.

3. *Other.* Applications will only be accepted from qualified national organizations to provide Technical Assistance for RT. Applicants proposing projects with Tribes must submit documentation in support of the application from the Tribes they propose to serve. This support is best documented through a resolution from the appropriate Tribal council/government. Alternative documentation of support may be considered on a case-by-case basis.

D. Application and Submission Information

1. *Address to Request Application Package.* Entities wishing to apply for assistance should contact the USDA RD State Office provided in the **ADDRESSES** section of this notice to obtain copies of the application package.

2. *Content and Form of Application Submission.* An application must contain all of the required elements listed in 7 CFR 4280.427 and the following:

- Environmental documentation in accordance with 7 CFR part 1970, “Environmental Policies and Procedures;”
- SF LLL, “Disclosure of Lobbying Activities;”
- RD 400–1, “Equal Opportunity Agreement;”
- RD 400–4, “Assurance Agreement;”
- Letter providing Board authorization to obtain assistance.

Each application received in a USDA RD State Office will be reviewed to determine if it is consistent with the eligible purposes contained in section 310B(c) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1932(c)). Each selection scoring criterion outlined in 7 CFR 4280.435 must be addressed in the application. Failure to address any of the criteria will result in a zero-point score for that criterion and will impact the overall evaluation of the application. 7 CFR part 4280, subpart E, is available at <https://www.ecfr.gov/current/title-7/subtitle-B/chapter-XLII/part-4280/subpart-E>, or

will be provided to any interested applicant making a request to a USDA RD State Office.

All projects to receive technical assistance through these passenger transportation grant funds are to be identified when the applications are submitted to the USDA RD State Office. Multiple project applications must identify each individual project, indicate the amount of funding requested for each individual Project, and address the criteria as stated above for each individual Project.

3. System for Award Management and Unique Entity Identifier.

(a) At the time of application, each applicant must have an active registration in the System for Award Management (SAM) before submitting its application in accordance with 2 CFR part 25 (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-I/part-25>). To register in SAM, entities will be required to create a Unique Entity Identifier (UEI). Instructions for obtaining the UEI are available at <https://sam.gov/content/entity-registration>.

(b) Applicant must maintain an active SAM registration, with current, accurate and complete information, while it has an active Federal award or an application under consideration by a Federal awarding agency.

(c) Applicant must ensure they complete the Financial Assistance General Certifications and Representations in SAM.

(d) Applicants must provide a valid UEI in its application, unless determined exempt under 2 CFR 25.110 (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-I/part-25/subpart-A/section-25.110>).

(e) The Agency will not make an award until the applicant has complied with all SAM requirements including providing the UEI. If an applicant has not fully complied with the requirements by the time the Agency is ready to make an award, the Agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

4. Submission Dates and Times.

(a) *Application Technical Assistance Deadline Date.* Prior to official submission of grant applications, applicants may request technical assistance or other application guidance from the Agency. All requests for technical assistance or application guidance must be made prior to February 21, 2023. Technical assistance is not meant to be an analysis or assessment of the quality of the

materials submitted, a substitute for Agency review of completed applications, or a determination of eligibility, if such determination requires in-depth analysis.

(b) *Application Deadline Date.* Paper applications are due no later than 4:30 p.m. (local time) on April 19, 2023. The Agency will determine the paper application receipt date based on the actual date postmarked. Electronic applications must be submitted to the USDA RD State Office State Offices | Rural Development (usda.gov) no later than 11:59 p.m. Eastern Time on April 19, 2023.

The deadline date means that the completed application package must be received in the USDA RD State Office by the deadline date established above. If the due date falls on a Saturday, Sunday, or Federal holiday, the application is due the next business day. All application documents identified in this notice and in 7 CFR part 4280, subpart E, are required to be considered a complete application.

(c) *Applications Received After Deadline Date.* If complete applications are not received by the deadline established above, the application will neither be reviewed nor considered under any circumstances. The Agency will not solicit or consider scoring or eligibility information that is submitted after the application deadline. The Agency reserves the right to contact applicants to seek clarification information on materials contained in the submitted application.

5. *Intergovernmental Review.* Executive Order (E.O.) 12372, “Intergovernmental Review of Federal Programs,” applies to this program. This E.O. requires that Federal agencies provide opportunities for consultation on proposed assistance with State and local governments. Many states have established a Single Point of Contact (SPOC) to facilitate this consultation. For a list of States that maintain a SPOC, please see the White House website: <https://www.whitehouse.gov/omb/management/office-federal-financial-management/>. If your State has a SPOC, you may submit a copy of the application directly for review. Any comments obtained through the SPOC must be provided to your State Office for consideration as part of your application. If your State has not established a SPOC, or if you do not want to submit a copy of the application, our State Offices will submit your application to the SPOC or other appropriate agency or agencies.”

6. *Funding Restrictions.* These grants are for RT Technical Assistance grants only and no construction or equipment

purchases are permitted. If the grantee has a previously approved indirect cost rate, it is permissible, otherwise, the applicant may elect to charge the 10 percent indirect cost permitted under 2 CFR 200.414(f) or request a determination of its Indirect Cost Rate. Due to the time required to evaluate Indirect Cost Rates, it is likely that all funds will be awarded by the time the Indirect Cost Rate is determined. No foreign travel is permitted. Pre-Federal award costs will only be permitted with prior written approval by the Agency.

None of the funds made available may be used to enter into a contract, memorandum of understanding, or cooperative agreement with, make a grant to, or provide a loan or loan guarantee to, any corporation that has any

(a) Unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability

(b) Any corporation that was convicted of a felony criminal violation under any Federal law within the preceding 24 months where the awarding agency is aware of the unpaid tax liability and/or conviction, unless a Federal agency has considered suspension or debarment of the corporation and has determined that further action is not necessary to protect the interests of the Government.

7. Other Submission Requirements.

General Submission Requirements.

The organization submitting the application will be considered the lead entity. The program manager must be associated with the lead entity submitting the application. Applications will not be considered for funding if they do not provide sufficient information to determine eligibility or are missing required elements.

There is no limit on the number of applications an applicant may submit under this announcement. There are no specific formats, specific limitations on number of pages, font size and type face, margins, paper size, number of copies, sequence, or assembly requirements. The component pieces of this application should contain original signatures on the original application.

Electronic Submittals. Applicants submitting an electronic application, should contact the State Office serving the State where the project will primarily take place. A list of State Offices may be found at <https://www.rd.usda.gov/about-rd/state-offices>.

Paper Submittals. Applicants submitting a paper application should send it to the USDA RD State Office located in the state where the project will primarily take place. You can find State Office contact information at: <http://www.rd.usda.gov/contact-us/state-offices>.

All forms requiring signatures must include an original signature. If the applicant wishes to hand deliver its application, the addresses for these deliveries are in the **ADDRESSES** section of this notice.

E. Application Review Information

1. **Criteria.** All eligible and complete applications will be evaluated and scored based on the scoring criteria contained in 7 CFR 4280.435. The Agency will select grantees subject to the grantees' satisfactory submission of the items required by 7 CFR 4280.427, and the USDA RD Letter of Conditions. Failure to address any criteria in 7 CFR 4280.427 by the application deadline will result in the application being determined ineligible, and the application will not be considered for funding. The amount of an RT grant may be adjusted, at the Agency's discretion, to enable the Agency to award RT grants to the applications with the highest priority scores in each category.

2. **Review and Selection Process.** USDA RD State Offices will review applications to determine if they are eligible for assistance based on the application and project eligibility requirements contained in 7 CFR 4280.416 and 4280.417, respectively, and as stated in this notice. If determined eligible, your application will be submitted to the National Office. Funding of the projects is subject to the applicant's satisfactory submission of the additional items required by that subpart and the USDA RD Letter of Conditions. The Agency reserves the right to offer the applicant a grant award in an amount less than the amount the applicant requested.

The Agency reserves the right to award additional discretionary points under 7 CFR 4280.435(k). Discretionary points may only be assigned to initial grants. Assignment of discretionary points must include a written justification. Permissible justifications include projects that meet special Secretary of Agriculture initiatives such as projects that assist communities recover economically through more and better market opportunities and through improved infrastructure; ensuring all rural residents have equitable access to RD programs and benefits from RD funded projects; and reducing climate

pollution and increasing resilience to the impacts of climate change through economic support to rural communities. The website <https://www.rd.usda.gov/priority-points> has additional data on the Secretary of Agriculture initiatives.

F. Federal Award Administration Information

1. **Federal Award Notices.** Successful applicants will receive notification for funding from their USDA RD State Office. Applicants must comply with all applicable statutes and regulations before the grant award will be approved. Unsuccessful applications will receive notification by mail.

2. Administrative and National Policy Requirements.

All successful applicants will be notified by letter, which will include a Letter of Conditions, and a Letter of Intent to Meet Conditions. This letter is not an authorization to begin performance. If the applicant wishes to consider beginning performance prior to the grant being officially closed, all pre-award costs must be approved in writing and in advance by the Agency. The grant will be considered officially awarded when all conditions in the Letter of Conditions have been met and the Agency obligates the funding for the Project.

Additional requirements that apply to grantees selected for this program can be found in 7 CFR part 4280, subpart E; the Grants and Agreements regulations applicable to the U.S. Department of Agriculture in 2 CFR part 400, which incorporates the Office of Management and Budget (OMB) regulations at 2 CFR part 200, and successor regulations. In addition, all recipients of Federal financial assistance are required to report information about first tier subawards and executive compensation (see 2 CFR part 170). You will be required to have the necessary processes and systems in place to comply with the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282) reporting requirements (see 2 CFR 170.200(b), unless you are exempt under 2 CFR 170.110(b)).

The following additional requirements apply to grantees selected for this program:

(a) Form RD 4280–2 “Rural Business-Cooperative Service Financial Assistance Agreement.”

(b) Letter of Conditions.

(c) Form RD 1940–1, “Request for Obligation of Funds.”

(d) Form RD 1942–46, “Letter of Intent to Meet Conditions.”

(e) Form RD 400–4, “Assurance Agreement.” Each prospective recipient must sign Form RD 400–4 which assures

USDA that the recipient is in compliance with title VI of the Civil Rights Act of 1964, 7 CFR part 15, and other Agency regulations. Form RD 400-4 also provides that no person will be discriminated against based on race, color, or national origin, in regard to any program or activity for which the recipient receives Federal financial assistance. The grant recipient must include the required nondiscrimination statements in any of their advertisements and brochures.

Program participants will be required to collect and maintain data provided by recipients on race, sex, and national origin and ensure recipients collect and maintain this data. Race and ethnicity data will be collected in accordance with OMB **Federal Register** notice, "Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity," (62 FR 58782), October 30, 1997. Data on recipients' sex will be collected in accordance with title IX of the Education Amendments of 1972. These items should not be submitted with the application but should be available upon request by the Agency.

The applicant and the ultimate recipient must comply with title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, Americans with Disabilities Act (ADA), section 504 of the Rehabilitation Act of 1973, Age Discrimination Act of 1975, Executive Order 12250, Executive Order 13166 regarding Limited English Proficiency (LEP), and 7 CFR part 1901, subpart E.

(f) SF LLL, "Disclosure of Lobbying Activities," if applicable.

(g) Form SF 270, "Request for Advance or Reimbursement."

3. Reporting. A Financial Status Report and a Project performance activity report will be required of all grantees on a quarterly basis until initial funds are expended and yearly thereafter, if applicable, based on the Federal fiscal year. The grantee will complete the Project within the total time available to it in accordance with the Scope of Work and any necessary modifications thereof prepared by the grantee and approved by the Agency. A final Project performance report will be required with the final Financial Status Report. The final report may serve as the last quarterly report. The final report must provide complete information regarding the jobs created and supported as a result of the grant if applicable. Grantees must continuously monitor performance to ensure that time schedules are being met, projected work by time periods is being accomplished, and other performance objectives are being achieved. Grantees must submit

an original of each report to the Agency no later than 30 days after the end of the quarter. The Project performance reports must include, but not be limited to, the following:

(a) A comparison of actual accomplishments to the objectives established for that period;

(b) Problems, delays, or adverse conditions, if any, which have affected or will affect attainment of overall Project objectives, prevent meeting time schedules or objectives, or preclude the attainment of Project work elements during established time periods. This disclosure shall be accompanied by a statement of the action taken or planned to resolve the situation;

(c) Objectives and timetable established for the next reporting period;

(d) Any special reporting requirements, such as jobs supported and created, businesses assisted, or Economic Development which results in improvements in median household incomes, and any other specific requirements, should be placed in the reporting section in the Letter of Conditions; and

(e) Within 90 days after the conclusion of the Project, the grantee will provide a final Project evaluation report. The last quarterly payment will be withheld until the final report is received and approved by the Agency. Even though the grantee may request reimbursement monthly, the last three months of reimbursements will be withheld until a final Project, Project performance, and financial status report are received and approved by the Agency.

G. Federal Awarding Agency Contact(s)

For general questions about this announcement, please contact your USDA RD State Office provided in the **ADDRESSES** section of this notice.

H. Other Information

1. Paperwork Reduction Act. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the information collection requirements associated with this program, as covered in this Notice, have been approved by the Office of Management and Budget (OMB) under OMB Control Number 0570-0070.

2. National Environmental Policy Act. All recipients under this Notice are subject to the requirements of 7 CFR part 1970 (<https://www.ecfr.gov/current/title-7/subtitle-B/chapter-XVIII/subchapter-H/part-1970>). However, awards for technical assistance and training under this Notice are classified as a Categorical Exclusion according to

7 CFR 1970.53(b) ([https://www.ecfr.gov/current/title-7/subtitle-B/chapter-XVIII/subchapter-H/part-1970#p-1970.53\(b\)](https://www.ecfr.gov/current/title-7/subtitle-B/chapter-XVIII/subchapter-H/part-1970#p-1970.53(b))), and usually do not require any additional documentation. RBCS will review each grant application to determine its compliance with 7 CFR part 1970 (<https://www.ecfr.gov/current/title-7/subtitle-B/chapter-XVIII/subchapter-H/part-1970>). The applicant may be asked to provide additional information or documentation to assist RBCS with this determination.

3. Federal Funding Accountability and Transparency Act. All applicants, in accordance with 2 CFR part 25 (<https://www.ecfr.gov/current/title-2/part-25>), must be registered in SAM and have a UEI number as stated in section D.3 of this notice. All recipients of Federal financial assistance are required to report information about first tier subawards and executive total compensation in accordance with 2 CFR part 170 (<https://www.ecfr.gov/current/title-2/part-170>).

4. Civil Rights Act. All grants made under this notice are subject to title VI of the Civil Rights Act of 1964 as required by the USDA (7 CFR part 15, subpart A—Nondiscrimination in Federally-Assisted Programs of the Department of Agriculture—Effectuation of title VI of the Civil Rights Act of 1964) and section 504 of the Rehabilitation Act of 1973, title VIII of the Civil Rights Act of 1968, title IX, Executive Order 13166 (Limited English Proficiency), Executive Order 11246, and the Equal Credit Opportunity Act of 1974.

5. Nondiscrimination Statement. In accordance with Federal civil rights laws and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Mission Areas, agencies, staff offices, 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.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (e.g., Braille, large print,

audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720-2600 (voice and TTY); or the 711 Relay Service.

To file a program discrimination complaint, a complainant should complete a Form AD-3027, USDA Program Discrimination Complaint Form, which can be obtained online at <https://www.usda.gov/sites/default/files/documents/ad-3027.pdf>, from any USDA office, by calling (866) 632-9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD-3027 form or letter must be submitted 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; or

(2) *Fax*: (833) 256-1665 or (202) 690-7442; or

(3) *Email*: program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.

Karama Neal,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2023-00895 Filed 1-18-23; 8:45 am]

BILLING CODE 3410-XY-P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

[Docket No. RBS-23-BUSINESS-0001]

Notice of Request for Approval of a New Information Collection

AGENCY: Rural Housing Service, Rural Business-Cooperative Service, and Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Rural Business-Cooperative Service, Rural Housing Service, and the Rural Utilities Service, agencies of the Rural Development mission area within the U.S. Department of Agriculture (USDA), hereinafter collectively referred to as the Agency to request approval for a new information collection in support of compliance with federal assistance

requests and following applicable conditions when accepting loan and grant monies.

DATES: Comments on this notice must be received by March 20, 2023.

ADDRESSES: Comments may be submitted by the following method:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

FOR FURTHER INFORMATION CONTACT:

Lynn Gilbert, Rural Development Innovation Center—Regulations Management Division, USDA, 1400 Independence Avenue SW, South Building, Washington, DC 20250-1522. Telephone: (202) 690-2682. Email lynn.gilbert@usda.gov.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that Rural Development is submitting to OMB for a new collection.

Comments are invited on: (a) 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; (b) The accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) Ways to enhance the quality, utility and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent by the Federal eRulemaking Portal: Go to <http://www.regulations.gov> and, in the lower "Search Regulations and Federal Actions" box, select "RBS" from the agency drop-down menu, then click on "Submit." In the Docket ID column, select RBS-23-BUSINESS-0001 to submit or view public comments and to view supporting and related materials available electronically. Information on using *Regulations.gov*, including

instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's "User Tips" link.

Title: 7 CFR 4280—Common Forms Package for Financial Assistance Forms for Loans/Grants.

OMB Number: 0575-New.

Expiration Date of Approval: Three years from approval date.

Type of Request: New information collection.

Abstract: The information collection under OMB Number 0575-New will enable the Agencies to effectively monitor a recipient's compliance with their loan and/or grant agreement and conditions upon being approved for the federal program they have applied for and accepted terms for.

The Agencies will use the forms contained in this information collection for several programs. One example is to provide funds to Agriculture Innovation Centers (Centers) which provide agricultural producers with technical and business development assistance. The Agencies also administers funding programs to intermediaries for the purpose of promoting rural economic development and job creation projects through the Rural Microentrepreneur Assistance Program (RMAP). This program provides rural microentrepreneurs with the skills necessary to establish new rural microenterprises; to provide continuing technical and financial assistance related to the successful operation of rural microenterprises; and to assist with the cost of providing other activities and services related to the successful operation of rural microenterprise development organizations (MDOs) and rural microenterprises.

The Agencies collect information from applicants to confirm eligibility for the program and to evaluate the quality of the applications. Recipients of awards are required to submit reporting and payment request information to facilitate monitoring of the award and disbursement of funds.

The Agencies need to receive the information contained in this collection of information to select the projects it believes will provide the most long-term economic benefit to rural areas. Through this collection of information, the Agencies can also make sure the funds are used for the intended purposes and, in the case of the loan, that the funds will be repaid. Agencies must determine that loans made from revolving loan funds established with grants are used for eligible purposes.

Estimate of Burden: Rural Development is requesting approval for one respondent and a one-hour place holder in order for OMB to issue a control number for these forms. The burden for each of the forms will be accounted for within the individual Rural Development program collection packages using the form(s).

Respondents: Recipients of Rural Development Federal financial assistance, loan, and loan guarantee programs.

Estimated Number of Responses per Respondent per Form in package:

Form No.	Responses per respondent
4280-2, 4280-4	1

Comments from interested parties are invited on: (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) 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Karama Neal,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2023-00937 Filed 1-18-23; 8:45 am]

BILLING CODE 3410-XY-P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Mississippi Advisory Committee to the U.S. Commission on Civil Rights

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 Mississippi Advisory Committee

(Committee) will hold a meeting on Monday, January 23, 2023 at 12:00 p.m.-1:30 p.m. Central time. The Committee will hear from the litigants and defendants of the police abuse case the Committee is considering for study.

DATES: The meeting will take place on Monday, January 23, 2022 at 12:00 p.m. Central Time.

Public Call Information: Dial: 833-435-1820, Confirmation Code: 160 106 3485.

Join ZoomGov Meeting: <https://www.zoomgov.com/j/1601063485>.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at dbarreras@usccr.gov or (312) 353-8311.

SUPPLEMENTARY INFORMATION: Members of the public may 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. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individual who is deaf, deafblind and hard of hear 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 confirmation code.

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 mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353-8324, or 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, Mississippi 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 and roll call
- II. Testimony from Litigants and Defendants
- III. Public comment
- IV. Next steps
- V. 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 expiration of Committee member appointment terms.

Dated: January 13, 2023.

David Mussatt,

Supervisor Chief, Regional Programs Unit.

[FR Doc. 2023-00976 Filed 1-18-23; 8:45 am]

BILLING CODE 6335-01-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-427-833]

Certain Preserved Mushrooms From France: Antidumping Duty Order

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

SUMMARY: Based on affirmative final determinations by the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC), Commerce is issuing an antidumping duty order on certain preserved mushrooms (preserved mushrooms) from France.

DATES: Applicable January 19, 2023.

FOR FURTHER INFORMATION CONTACT: Christopher Williams, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-5166.

SUPPLEMENTARY INFORMATION:

Background

In accordance with sections 735(d) and 777(i) of the Tariff Act of 1930, as amended (the Act), on November 28, 2022, Commerce published its affirmative final determination in the less-than-fair-value (LTFV) investigation of preserved mushrooms from France.¹

¹ See *Certain Preserved Mushrooms from France: Final Affirmative Determination of Sales at Less*

On January 12, 2023, the ITC notified Commerce of its final determination, pursuant to section 735(d) of the Act, that an industry in the United States is materially injured within the meaning of section 735(b)(1)(A)(i) of the Act by reason of LTFV imports of preserved mushrooms from France.²

Scope of the Order

The product covered by this order is preserved mushrooms from France. For a complete description of the scope of the order, see the appendix to this notice.

Antidumping Duty Order

On January 12, 2023, in accordance with sections 735(b)(1)(A)(i) and 735(d) of the Act, the ITC notified Commerce of its final determination that an industry in the United States is materially injured by reason of imports of preserved mushrooms from France. Therefore, Commerce is issuing this antidumping duty order in accordance with sections 735(c)(2) and 736 of the Act. Because the ITC determined that imports of preserved mushrooms from France are materially injuring a U.S. industry, unliquidated entries of such merchandise from France, entered or withdrawn from warehouse for consumption, are subject to the assessment of antidumping duties.

Therefore, in accordance with section 736(a)(1) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise, for all relevant entries of preserved mushrooms from France. Antidumping duties will be assessed on unliquidated entries of preserved mushrooms from France, entered, or withdrawn from warehouse, for consumption, on or after September 13, 2022, the date of publication of the *Preliminary Determination*, but will not include entries occurring after the expiration of the provisional measures period and before publication of the ITC's final injury determination, as further described below.³

² *Than Fair Value*, 87 FR 72963 (November 28, 2022) (*Final Determination*).

³ See ITC's Letter, Investigation No. 731-TA-1587 (Final), dated January 12, 2023.

⁴ See *Certain Preserved Mushrooms from France: Preliminary Affirmative Determination of Sales at Less Than Fair Value*, 87 FR 55997 (September 13, 2022) (*Preliminary Determination*).

Continuation of Suspension of Liquidation and Cash Deposits

In accordance with section 736 of the Act, Commerce will instruct CBP to continue to suspend liquidation on all relevant entries of preserved mushrooms from France which are entered, or withdrawn from warehouse, for consumption on or after the date of publication of the ITC's notice of final determination in the **Federal Register**. These instructions suspending liquidation will remain in effect until further notice.

Commerce will also instruct CBP to require cash deposits equal to the amounts indicated below. Accordingly, effective on the date of publication in the **Federal Register** of the notice of the ITC's final affirmative injury determination, CBP will require, at the same time as importers would normally deposit estimated duties on this subject merchandise, a cash deposit equal to the cash deposit rates listed in the table below. The all-others rate applies to all producers or exporters not specifically listed, as appropriate.

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margins for this antidumping order are as follows:

Exporter/producer	Weighted-average dumping margin (percent)
Bonduelle Europe Long Life France Champignon	* 360.88
All-Others	224.68

* Rate based on adverse facts available.

Provisional Measures

Section 733(d) of the Act states that suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months, except where exporters representing a significant proportion of exports of the subject merchandise request that Commerce extend the four-month period to no more than six months. Commerce's *Preliminary Determination* was published on September 13, 2022.⁴ Commerce's *Final Determination* was not extended and was published on November 28, 2022.⁵ As such, the four-month period beginning on the date of publication of the *Preliminary Determination* ended on January 10, 2023.

Therefore, in accordance with section 733(d) of the Act, Commerce will

⁴ *Id.*

⁵ See *Final Determination*.

instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, unliquidated entries of preserved mushrooms from France, entered or withdrawn from warehouse, for consumption after January 10, 2023, the date on which provisional measures expired, through the day preceding the date of publication of the ITC's final affirmative injury determination in the **Federal Register**. Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC's final affirmative injury determination in the **Federal Register**.

Establishment of the Annual Inquiry Service Lists

On September 20, 2021, Commerce published the final rule titled "*Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*" in the **Federal Register**.⁶ On September 27, 2021, Commerce also published the notice titled "*Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*" in the **Federal Register**.⁷ The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope ruling application or request for circumvention inquiry shall serve a copy of the application or request on the persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.⁸

In accordance with the *Procedural Guidance*, for orders published in the **Federal Register** after November 4, 2021, Commerce will create an annual inquiry service list segment in Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), available at <https://access.trade.gov>, within five business days of publication of the notice of the order. Each annual inquiry service list will be saved in ACCESS, under each case number, and

⁶ See *Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*, 86 FR 52300 (September 20, 2021) (*Final Rule*).

⁷ See *Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*, 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

⁸ *Id.*

under a specific segment type called “AISL-Annual Inquiry Service List.”⁹

Interested parties who wish to be added to the annual inquiry service list for an order must submit an entry of appearance to the annual inquiry service list segment for the order in ACCESS within 30 days after the date of publication of the order. For ease of administration, Commerce requests that law firms with more than one attorney representing interested parties in an order designate a lead attorney to be included on the annual inquiry service list. Commerce will finalize the annual inquiry service list within five business days thereafter. As mentioned in the *Procedural Guidance*, the new annual inquiry service list will be in place until the following year, when the *Opportunity Notice* for the anniversary month of the order is published.

Commerce may update an annual inquiry service list at any time as needed based on interested parties’ amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website at <https://access.trade.gov>.

Special Instructions for Petitioners and Foreign Governments

In the *Final Rule*, Commerce stated that, “after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.”¹⁰ Accordingly, as stated above, the petitioners and foreign governments should submit their initial entry of appearance after publication of this notice in order to appear in the first annual inquiry service list. Pursuant to 19 CFR 351.225(n)(3), the petitioners and foreign governments will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service list. However, the petitioners and foreign

⁹ This segment will be combined with the ACCESS Segment Specific Information (SSI) field, which will display the month in which the notice of the order or suspended investigation was published in the *Federal Register*, also known as the anniversary month. For example, for an order under case number A-000-000 that published in the *Federal Register* in January, the relevant segment and SSI combination will appear in ACCESS as “AISL-January Anniversary.” Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

¹⁰ See *Final Rule*, 86 FR at 52335.

governments are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

Notification to Interested Parties

This notice constitutes the antidumping duty order with respect to preserved mushrooms from France pursuant to section 736(a) of the Act. Interested parties can find a list of antidumping duty orders currently in effect at <https://www.trade.gov/data-visualization/adcvd-proceedings>.

This order is published in accordance with section 736(a) of the Act and 19 CFR 351.211(b).

Dated: January 12, 2023.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Order

The merchandise covered by this order is certain preserved mushrooms, whether imported whole, sliced, diced, or as stems and pieces. The preserved mushrooms covered under this order are the genus *Agaricus*. “Preserved mushrooms” refer to mushrooms that have been prepared or preserved by cleaning, blanching, and sometimes slicing or cutting. These mushrooms are then packed and heat sterilized in containers each holding a net drained weight of not more than 12 ounces (340.2 grams), including but not limited to cans or glass jars, in a suitable liquid medium, including but not limited to water, brine, butter, or butter sauce. Preserved mushrooms may be imported whole, sliced, diced, or as stems and pieces.

Excluded from the scope are “marinated,” “acidified,” or “pickled” mushrooms, which are prepared or preserved by means of vinegar or acetic acid, but may contain oil or other additives. To be prepared or preserved by means of vinegar or acetic acid, the merchandise must be a minimum 0.5 percent by weight acetic acid.

The merchandise subject to this order is classifiable under subheadings 2003.10.0127, 2003.10.0131, and 2003.10.0137 of the Harmonized Tariff Schedule of the United States (HTSUS). The subject merchandise may also be classified under HTSUS subheadings 2003.10.0143, 2003.10.0147, and 2003.10.0153. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope is dispositive.

[FR Doc. 2023-00931 Filed 1-18-23; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-469-818]

Ripe Olives From Spain: Implementation of Determination Under Section 129 of the Uruguay Round Agreements Act

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

SUMMARY: On December 20, 2022, the U.S. Department of Commerce (Commerce) issued its final determination under section 129 of the Uruguay Round Agreements Act (URAA), regarding the countervailing duty (CVD) investigation of ripe olives from Spain. On January 12, 2023, the U.S. Trade Representative (USTR) directed Commerce to implement the section 129 final determination, which renders Commerce’s determinations in the CVD investigation not inconsistent with the World Trade Organization (WTO) dispute settlement findings in *United States—Antidumping and Countervailing Duties on Ripe Olives from Spain*, WT/DS577 (December 20, 2021) (DS577). As a result, Commerce is now implementing the section 129 final determination.

DATES: Applicable January 12, 2023.

FOR FURTHER INFORMATION CONTACT: Mary Kolberg or Dusten Hom, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-1785 and (202) 482-5075, respectively.

SUPPLEMENTARY INFORMATION:

Nature of the Proceeding

Section 129 of the URAA governs the nature and effect of determinations issued by Commerce to implement findings by WTO dispute settlement panels and the Appellate Body. Specifically, section 129(b)(2) of the URAA provides that “notwithstanding any provision of the Tariff Act of 1930,” upon a written request from USTR, Commerce shall issue a determination that would render its actions not inconsistent with an adverse finding of a WTO panel or the Appellate Body.¹ The Statement of Administrative Action Accompanying the URAA, H.R. Doc. 103-316, Vol. 1 (1994) (SAA), variously refers to such a determination by Commerce as a “new,” “second,” and

¹ See 19 U.S.C. 3538(b)(2).

“different” determination.² After consulting with Commerce and the appropriate congressional committees, USTR may direct Commerce to implement, in whole or in part, the new determination made under section 129 of the URAA.³ Pursuant to section 129(c) of the URAA, the new determination shall apply with respect to unliquidated entries of the subject merchandise that are entered or withdrawn from warehouse, for consumption, on or after the date on which USTR directs Commerce to implement the new determination.⁴ The new determination is subject to judicial review, separate and apart from judicial review of Commerce’s original determination.⁵

Background

On July 11, 2022, Commerce informed interested parties that it was initiating administrative action under section 129 of the URAA to comply with the recommendations and rulings of the WTO Dispute Settlement Body in

DS577.⁶ On September 23, 2022, Commerce addressed each of the issues and conclusions of the panel in DS577 through a preliminary determination memorandum.⁷ We invited interested parties to comment on the Preliminary Determination.⁸ After receiving case briefs and rebuttal comments from the interested parties, Commerce issued its final determination for the section 129 determination on December 20, 2022.⁹ On January 12, 2023, USTR notified Commerce that, consistent with section 129(b)(3) of the URAA, consultations with Commerce and the appropriate congressional committees with respect to the December 20, 2022 determination have been completed and USTR directed Commerce to implement the determination in accordance with section 129(b)(4) if the URAA.

Final Determination: Analysis of Comments Received

The issues raised in the comments and rebuttal comments submitted by the interested parties to this proceeding are

addressed in the Final Determination. The Final Determination is a public document and is on file electronically via Enforcement and Compliance’s Antidumping and CVD Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Final Determination can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Final Determination: Recalculating Countervailing Duty Rates

The recalculated countervailable subsidy rates, as included in the Final Determination and which remain unchanged from the Preliminary Determination in this section 129 proceeding for each company, are as follows:

Exporter/producer	Investigation subsidy rate (percent <i>ad valorem</i>)	Revised subsidy rate (percent <i>ad valorem</i>)
Aceitunas Guadalquivir S.L.U. ¹⁰	27.02	11.63
All Others	14.97	11.08

Implementation of the Revised Cash Deposit Requirements

As noted above, on January 12, 2023, in accordance with sections 129(b)(4) and 129(c)(1)(B) of the URAA, USTR directed Commerce to implement this final determination. With respect to the investigation, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of entries of subject merchandise that were entered, or withdrawn from warehouse, for consumption on or after the date of such implementation. In the final section 129 determination, the rates for Agro Sevilla Aceitunas S.Coop And. and Angel Camacho Alimentacion, S.L. remained unchanged from the investigation. However, these companies have a superseding cash deposit rate (*i.e.*, there have been final results published in a

subsequent administrative review), and thus, we will not issue revised cash deposit instructions to CBP for these companies. Similarly, while the rate for Aceitunas Guadalquivir S.L.U. changed in the final section 129 determination, because this company has a superseding cash deposit rate, we will not issue revised cash deposit instructions to CBP for this company. For all other producers or exporters that do not have their own rate, we will direct CBP to require a cash deposit equal to the revised all-others rate above. This notice of implementation of this section 129 final determination is published in accordance with section 129(c)(2)(A) of the URAA.

Dated: January 12, 2023.

Lisa W. Wang,
Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–00930 Filed 1–18–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Advisory Committee on Earthquake Hazards Reduction Meeting

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

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Earthquake Hazards Reduction (ACEHR or Committee) will hold an open virtual

Countervailing Duty Investigation,” dated December 20, 2022 (Final Determination).

¹⁰ Commerce found the following companies to be cross-owned with Aceitunas Guadalquivir S.L.U.: Coromar Inv., S.L.; AG Explotaciones Agricolas, S.L.U.; and Grupo Aceitunas Guadalquivir, S.L. See *Ripe Olives from Spain: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order*, 83 FR 37469 (August 1, 2018).

² See SAA at 1025, 1027.

³ See 19 U.S.C. 3538(b)(4).

⁴ See 19 U.S.C. 3538(c).

⁵ See 19 U.S.C. 1516a(a)(2)(B)(vii).

⁶ See *Notice of Commencement of a Compliance Proceeding Pursuant to Section 129 of the Uruguay Round Agreements Act*, 87 FR 41109 (July 11, 2022).

⁷ See Memorandum, “Ripe Olives from Spain: Preliminary Section 129 Determination Regarding the Countervailing Duty Investigation,” dated September 23, 2022 (Preliminary Determination).

⁸ *Id.* at 22–23; see also Commerce’s Letter, “Ripe Olives from Spain: Deadline for Submission of Factual Information and Extension of Deadline for Case and Rebuttal Brief,” dated October 17, 2022.

⁹ See Memorandum, “Ripe Olives from Spain: Final Section 129 Determination Regarding the

meeting via web conference on Monday, May 8, 2023, from 1:00 p.m. to 4:00 p.m. and Tuesday, May 9, 2023, from 1:00 p.m. to 4:00 p.m. Eastern Time. The primary purpose of this meeting is for the Committee to discuss their 2023 Biennial Report on the Effectiveness of the National Earthquake Hazards Reduction Program (NEHRP). The agenda may change to accommodate Committee business. The final agenda will be posted on the NEHRP website at <https://nehrrp.gov/committees/meetings.htm>.

DATES: The ACEHR will meet on Monday, May 8, 2023, from 1:00 p.m. to 4:00 p.m. and Tuesday, May 9, 2023, from 1:00 p.m. to 4:00 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: Tina Faecke, Management and Program Analyst, NEHRP, Engineering Laboratory, NIST. Ms. Faecke's email address is tina.faecke@nist.gov and her phone number is (240) 477-9841.

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7704(a)(5) and the Federal Advisory Committee Act, as amended, 5 U.S.C. app. The Committee is composed of 13 members, appointed by the Director of NIST, who were selected for their established records of distinguished service in their professional community, their knowledge of issues affecting NEHRP, and to reflect the wide diversity of technical disciplines, competencies, and communities involved in earthquake hazards reduction. In addition, the Chairperson of the U.S. Geological Survey Scientific Earthquake Studies Advisory Committee serves as an ex-officio member of the Committee.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. app., notice is hereby given that the ACEHR will meet on Monday, May 8, 2023, from 1:00 p.m. to 4:00 p.m. and Tuesday, May 9, 2023, from 1:00 p.m. to 4:00 p.m. Eastern Time. 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 for the Committee to discuss their 2023 Biennial Report on the Effectiveness of NEHRP. The agenda may change to accommodate Committee business. The final agenda will be posted on the NEHRP website at <https://nehrrp.gov/committees/meetings.htm>.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's business are invited to request a place on the agenda. Approximately fifteen minutes will be reserved for public comments and speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received. This meeting will be recorded. Public comments can be provided via email or by web conference attendance. Questions from the public will not be considered during this period. All those wishing to speak must submit their request by email to Tina Faecke at tina.faecke@nist.gov by 5:00 p.m. Eastern Time, May 1, 2023. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to participate are invited to submit written statements electronically by email to tina.faecke@nist.gov.

Anyone wishing to attend this meeting via web conference must register by 5:00 p.m. Eastern Time, May 1, 2023, to attend. Please submit your full name, the organization you represent (if applicable), email address, and phone number to Tina Faecke at tina.faecke@nist.gov. After pre-registering, participants will be provided with instructions on how to join the web conference.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2023-00959 Filed 1-18-23; 8:45 am]

BILLING CODE 3510-13-P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; NIST Generic Clearance for Diversity, Equity, Inclusion, and Accessibility (DEIA) Data Collections

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information

collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on October 21, 2022, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Institute of Standards and Technology (NIST), Commerce.

Title: NIST Generic Clearance for Diversity, Equity, Inclusion, and Accessibility (DEIA) Data Collections.

OMB Control Number: 0693-XXXX.

Form Number(s): None.

Type of Request: Regular.

Number of Respondents: 30,000.

Average Hours per Response: Varies, dependent upon the data collection method.

Burden Hours: 15,000.

Needs and Uses: Executive Orders 14035 and 13985 have tasked the Federal Government with advancing equity within the Federal Government workforce (E.O. 14035) and advancing racial equity and support for underserved communities through the Federal Government (E.O. 13985). Data collection, monitoring, and feedback are key elements of the Federal Government approach to integrating diversity, equity, inclusion, and accessibility (DEIA) in all ways of working. Executive Order 14035 on "Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce," released on June 25, 2021, calls for a data-driven, whole-of-government approach to cultivating DEIA across the Federal Government, asking agencies to "identify areas where evidence is lacking and propose opportunities to build evidence to advance diversity, equity, inclusion, and accessibility and address those gaps identified." Executive Order 13985 on "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," released on January 25, 2021, charges agencies with advancing equitable service delivery through increased engagement with underserved communities and improved data collection to "measure equity and capture the diversity of the American people." This generic clearance will provide NIST with the tools necessary to carry out this endeavor.

Affected Public: Federal government; households and individuals; the private sector.

Frequency: Varies, depending on collection.

Respondent's Obligation: Select from the following options: Voluntary.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the

Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and entering the title of the collection.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2023–00988 Filed 1–18–23; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Industrial Advisory Committee; Meeting

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

ACTION: Notice of open meeting.

SUMMARY: The Industrial Advisory Committee (Committee) will hold an open meeting via web conference on Tuesday, February 7, 2023, from 10 a.m. to 3 p.m. Eastern Time. The primary purposes of this meeting are to update the Committee on the progress of the CHIPS R&D Programs, receive updates from the Committee working groups, and allow the Committee to deliberate and discuss the progress that has been made. The final agenda will be posted on the NIST website at <https://www.nist.gov/chips/industrial-advisory-committee>.

DATES: The Industrial Advisory Committee will meet on Tuesday, February 7, 2023, from 10 a.m. to 3 p.m. Eastern Time. The meeting will be open to the public.

ADDRESSES: The meeting will be held via web conference. For instructions on how to attend and/or participate in the meeting, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Tamiko Ford at Tamiko.Ford@NIST.gov or (202) 594–6793.

SUPPLEMENTARY INFORMATION: The Committee was established pursuant to 15 U.S.C. 4656(b). The Committee is currently composed of 24 members, appointed by the Secretary of

Commerce, to provide advice to the United States Government on matters relating to microelectronics research, development, manufacturing, and policy. Background information on the CHIPS Act and information on the Committee is available at <https://www.nist.gov/chips/industrial-advisory-committee>.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the Industrial Advisory Committee will meet on Tuesday, February 7, 2023, from 10 a.m. to 3 p.m. Eastern Time. 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 purposes of this meeting are to update the Committee on the progress of the CHIPS R&D Programs, receive updates from the Committee working groups, and allow the Committee to deliberate and discuss the progress that has been made. The final agenda will be posted on the NIST website at <https://www.nist.gov/chips/industrial-advisory-committee>.

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 submit comments in advance of the meeting. Written comments may be submitted via the registration link. Approximately ten minutes will be reserved for public comments, which will be read on a first-come, first-served basis. Please note that all submitted comments, including those not read during the meeting, will be treated as public documents and will be made available for public inspection. Comments read during this period will not be considered for response. All comments must be submitted via the registration link <https://events.nist.gov/profile/18811> by 5 p.m. Eastern Time, Friday, February 3, 2023.

Anyone wishing to attend must register by 5 p.m. Eastern Time, Friday, February 3, 2023, to attend. Please submit your full name, the organization you represent (if applicable), email address, and phone number via <https://events.nist.gov/profile/18811>. Non-U.S. citizens must submit additional information; please contact Tamiko Ford at Tamiko.Ford@nist.gov.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2023–00958 Filed 1–18–23; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Fisheries Finance Program Requirements

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public’s reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before March 20, 2023.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at NOAA.PRA@noaa.gov. Please reference OMB Control Number 0648–0012 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Brian Summers, Loan Specialist, NOAA/NMFS/FFP/FMB5, 1315 East West Highway, Silver Spring, MD 20910, (301) 427–8783, brian.summers@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for an extension of a currently approved information collection. The National Oceanic and Atmospheric Administration (NOAA) operates the Fisheries Finance Program, a direct government loan program that provides long term financing for the cost of construction or reconstruction of fishing vessels, shoreside fishery facilities, aquaculture facilities, and individual fishing quotas in the Northwest Halibut/Sablefish and Alaskan Crab Fisheries. To be eligible

for this benefit program, an applicant must be an aquaculture operator or fisherman and a U.S. citizen. They must also meet all of the following:

- Have good credit and earnings record, net worth, and liquidity behind the project, and
- The project must be fully secured with their assets, including personal guarantees (non-recourse credit is not available), and
- Have at least a three-year history of owning or operating the fisheries project that will be the subject of the proposed application, or a three-year history owning or operating a comparable project.

Application information is required to determine loan eligibility pursuant to 50 CFR part 253 and to determine the type and amount of financial assistance available to the applicant. Applicants are required to submit NOAA FORM 88–1, and supporting financial documents. An annual financial statement is required from the recipients to monitor the financial status of the loan. Small stylistic changes have been made to the NOAA FORM 88–1 to make the form easier for the applicant to understand and to fill electronically, but the information collected is not changed.

II. Method of Collection

Electronic Applications.

III. Data

OMB Control Number: 0648–0012.

Form Number(s): 88–1.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Individuals or households; business or other for-profit organizations.

Estimated Number of Respondents: 336.

Estimated Time per Response: Program Application, 10 hours; Annual Financial Statement, 2 hours; Guarantor Consent, 5 minutes.

Estimated Total Annual Burden Hours: 1,184.

Estimated Total Annual Cost to Public: \$0.

Respondent's Obligation: Required to obtain or retain benefits.

Legal Authority: 50 CFR part 253.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and

cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may 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.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2023–00981 Filed 1–18–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Reporting Requirements for Sea Otter Interactions With the Pacific Sardine Fishery; Coastal Pelagic Species Fishery Management Plan

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on September 6, 2022 (87 FR 54484) during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration (NOAA), Commerce.

Title: Reporting Requirements for Sea Otter Interactions with Coastal Pelagic Species Fisheries.

OMB Control Number: 0648–0566.

Form Number(s): None.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 2.

Average Hours per Response: 15 minutes.

Total Annual Burden Hours: 30 minutes.

Needs and Uses: This request is for extension of a currently approved collection. On May 30, 2007, NMFS published a final rule (72 FR 29891) implementing a requirement under the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP) to report any interactions that may occur between a CPS vessel and/or fishing gear and sea otters. In accordance with the regulations implementing the Endangered Species Act (ESA), NOAA's National Marine Fisheries Service (NMFS) initiated an ESA section 7 consultation with the United States Fish and Wildlife Service (USFWS) regarding the effects of implementing the final rule (72 FR 29891), which codified Amendment 11 to the CPS FMP.

USFWS determined that formal consultation was necessary on the possible effects to the threatened southern sea otter. USFWS completed a biological opinion for this action and although it was concluded that fishing activities were not likely to jeopardize the continued existence of the southern sea otter, that there remained the potential to incidentally take southern sea otters. USFWS determined that certain measures should be put in place to ensure the continued protection of the species, including certain reporting requirements.

Specifically, these reporting requirements are:

(1) If a southern sea otter is entangled in a net, regardless of whether the animal is injured or killed, the vessel operator must report this interaction within 24 hours to the Regional Administrator.

(2) While fishing for CPS, vessel operators must record all observations of otter interactions (defined as otters within encircled nets or coming into contact with nets or vessels, including but not limited to entanglement) with their purse seine net(s) or vessel(s). With the exception of an entanglement, which must be initially reported as described in paragraph (1) of this section, all other observations must be

reported within 20 days to the Regional Administrator.

(3) When contacting NMFS after an interaction, vessel operators must provide the location (latitude and longitude) of the interaction and a description of the interaction itself. If available, location information should also include water depth, distance from shore, and relation to port or other landmarks. Descriptive information of the interaction should include: whether or not the otters were seen inside or outside the net; if inside the net, had the net been completely encircled; whether any otters came in contact with either the net or the vessel; the number of otters present; duration of interaction; the otter's behavior during interaction; measures taken to avoid interaction.

Affected Public: Business or other for-profit organizations.

Frequency: As necessary.

Respondent's Obligation: Mandatory.

Legal Authority: 50 CFR 660.520(a).

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0566.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2023–00980 Filed 1–18–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Evaluation of New York State Coastal Management Program; Notice of Public Meeting; Request for Comments

AGENCY: Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Notice of public meeting and opportunity to comment.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA),

Office for Coastal Management, will hold a virtual public meeting to solicit input on the performance evaluation of the New York Coastal Management Program. NOAA also invites the public to submit written comments.

DATES: NOAA will hold a virtual public meeting on Wednesday, March 1, 2023, at 12 p.m. ET. NOAA will also consider all relevant written comments received by Friday, March 10, 2023.

ADDRESSES: Comments may be submitted by one of the following methods:

- **Virtual Public Meeting:** Provide oral comments during the virtual public meeting on Wednesday, March 1, 2023, at 12 p.m. ET by registering as a speaker at <https://forms.gle/5JjX5CUYjw9tG4pA8>. Please register by 8 p.m. ET, Tuesday, February 28, 2023. Upon registration, NOAA will send a confirmation email. The lineup of speakers will be based on the date and time of registration. One hour prior to the start of the meeting on March 1, 2023, NOAA will send an email to all registered speakers with a link to the public meeting and information about participating.

- **Email:** Send written comments to Carrie Hall, Evaluator, NOAA Office for Coastal Management, at CZMA.evaluations@noaa.gov.

Written comments received are considered part of the public record, and the entirety of the comment, including the name of the commenter, email address, attachments, and other supporting materials, will be publicly accessible. Sensitive personally identifiable information, such as account numbers and Social Security numbers, should not be included with the comment. Comments that are not related to the performance evaluation of the New York Coastal Management Program or that contain profanity, vulgarity, threats, or other inappropriate language will not be considered.

FOR FURTHER INFORMATION CONTACT:

Carrie Hall, Evaluator, NOAA Office for Coastal Management, by email at Carrie.Hall@noaa.gov or by phone at (240) 410–3422. Copies of the previous evaluation findings and Assessment and Strategies may be viewed and downloaded at <https://coast.noaa.gov/czm/evaluations/>. A copy of the evaluation notification letter and most recent progress report may be obtained upon request by contacting Carrie Hall.

SUPPLEMENTARY INFORMATION: Section 312 of the Coastal Zone Management Act (CZMA) requires NOAA to conduct periodic evaluations of federally approved coastal management programs. The evaluation process

includes holding one or more public meetings, considering public comments, and consulting with interested Federal, State, and local agencies and members of the public. During the evaluation, NOAA will consider the extent to which the State of New York has met the national objectives, adhered to the management program approved by the Secretary of Commerce, and adhered to the terms of financial assistance under the CZMA. When the evaluation is complete, NOAA's Office for Coastal Management will place a notice in the **Federal Register** announcing the availability of the final evaluation findings.

Keelin Kuipers,

Deputy Director, Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2023–00941 Filed 1–18–23; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC631]

Gulf of Mexico Fishery Management Council; Public Meeting; Correction

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

ACTION: Notice of an addendum to a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold a four-day meeting to consider actions affecting the Gulf of Mexico fisheries in the exclusive economic zone (EEZ). The meeting is a hybrid that is open to the public offering both in-person and virtual options for participation.

DATES: The meeting will convene Monday, January 30 through Wednesday, February 1 at 8 a.m.–5 p.m. and Thursday, February 2, 2023, at 8 a.m.–4:30 p.m., CST.

ADDRESSES: The meeting will take place at the Hilton Baton Rouge Capitol Center hotel, located at 201 Lafayette Street, Baton Rouge, LA 70801. Please note, in-person meeting attendees will be expected to follow any current safety protocols as determined by the Council, hotel and the City of Baton Rouge, if any. Such precautions may include masks, room capacity restrictions, and/or social distancing. If you prefer to “listen in”, you may access the log-on

information by visiting our website at www.gulfcouncil.org.

Council address: Gulf of Mexico Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348-1630.

FOR FURTHER INFORMATION CONTACT: Dr. Carrie Simmons, Executive Director, Gulf of Mexico Fishery Management Council; telephone: (813) 348-1630.

SUPPLEMENTARY INFORMATION: The original meeting notice published in the **Federal Register** on January 10, 2023 (88 FR 1366). This notice adds an additional agenda item to the Tuesday, January 31, 2023 agenda. All other previously published information remains unchanged.

The agenda for January 31st should now read as follows:

Tuesday, January 31, 2023; 8 a.m.–5 p.m., CST

The *Reef Fish* Committee will reconvene to review and discuss the Individual Fishing Quota (IFQ) Focus Group Outcomes, Program Priorities List and Draft Amendment 56: Modifications to the *Gag Grouper* Catch Limits, Sector Allocations, and Fishing Seasons. The Committee will have a 30-minute break for a working lunch. Following the break, the Committee will review Draft Options: Modifications to Recreational and Commercial *Greater Amberjack* Management Measures. The Committee will review the Revised Recreational *Red Snapper* Calibration Ratios, and the January 2023 Gulf SSC Summary Report including catch level recommendations for SEDAR 75 Gray Snapper Stock Assessment and 2023 Red Grouper Interim Analysis.

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

Dated: January 12, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023-00898 Filed 1-18-23; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XC675]

Endangered Species; Take of Anadromous Fish

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

ACTION: Notice of receipt; for modification and renewal of an existing

scientific research and enhancement permit.

SUMMARY: Notice is hereby given that NMFS received an application from the Wiyot Tribe in Loleta, California for modification and renewal of an U.S. Endangered Species Act (ESA) Section 10(a)(1)(A) scientific and enhancement permit (Permit 22270-2R). The purpose of the permit is to enhance the survival of threatened Southern Oregon/Northern California Coast (SONCC) Evolutionary Significant Unit (ESU) of coho salmon (*Oncorhynchus kisutch*); threatened California Coast (CC) ESU Chinook salmon (*O. tshawytscha*); and threatened Northern California (NC) Distinct Population Segment (DPS) of steelhead (*O. mykiss*) by segregating and removing predatory non-native Sacramento River pikeminnow using a variety of techniques. The University of California at Berkeley and Stillwater Sciences are co-investigators on the permit and will assist with implementation of the permit activities. The public is hereby notified that the application for Permit 22270-2R is available for review and comment before NMFS either approves or disapproves the application.

DATES: Written comments on the permit application must be received at the appropriate email address (see **ADDRESSES**) on or before February 21, 2023.

ADDRESSES: Written comments on the permit application should be submitted to Matt Goldsworthy via email at Matt.Goldsworthy@noaa.gov with "Permit 22270-2R" referenced in the subject line. The permit application and Weir Operations Plan is available for review online at the Authorizations and Permits for Protected Species website: https://apps.nmfs.noaa.gov/preview/preview_open_for_comment.cfm.

FOR FURTHER INFORMATION CONTACT: Matt Goldsworthy (phone: 707-357-1338 or email: Matt.Goldsworthy@noaa.gov).

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

Southern Oregon/Northern California Coast (SONCC) Evolutionary Significant Unit (ESU) of coho salmon (*Oncorhynchus kisutch*); California Coast (CC) ESU of Chinook salmon (*O. tshawytscha*); and Northern California (NC) Distinct Population Segment (DPS) of steelhead (*O. mykiss*).

Authority

Scientific research and enhancement permits are issued in accordance with Section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et seq.*) and regulations

governing listed fish and wildlife permits (50 CFR 222-227). NMFS issues permits based on findings that such permits: (1) are applied for in good faith; (2) would not operate to the disadvantage of the listed species which are the subject of the permits; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA. Authority to take listed species is subject to conditions set forth in the permits.

This notice is provided pursuant to Section 10(c) of the ESA. NMFS will evaluate the application, associated documents, and any comment submitted to determine whether the application meets the requirements of Section 10(a) of the ESA and Federal regulations. The final permit decisions will not be made until after the end of the 30-day comment period and consideration of any comment submitted therein. NMFS will publish notice of its final action in the **Federal Register**.

Those individuals requesting a hearing on the application listed in this notice should provide the specific reasons why a hearing on the application would be appropriate (see **ADDRESSES**). Such a hearing is held at the discretion of the Assistant Administrator for NOAA Fisheries.

Permit Application Received:

Permit 22270-2R

The Wiyot Tribe in Loleta, California applied for modification and renewal of a Section 10(a)(1)(A) scientific research and enhancement permit (Permit 22270-2R). The University of California at Berkeley and Stillwater Sciences are co-investigators on the permit and will assist with implementation of the permit activities. The application involves research and activities to enhance the survival of threatened Southern Oregon/Northern California Coast (SONCC) Evolutionary Significant Unit (ESU) of coho salmon (*Oncorhynchus kisutch*); threatened California Coast (CC) ESU Chinook salmon (*O. tshawytscha*); and threatened Northern California (NC) Distinct Population Segment (DPS) of steelhead (*O. mykiss*) by segregating and removing predatory non-native river pikeminnow (*Ptychocheilus grandis*) using a variety of techniques.

This project's objectives are to: (1) remove large numbers of predatory non-native Sacramento River pikeminnow from the mainstems of the South Fork Eel River, Van Duzen River, and Lower Eel River to increase survival of listed salmonids and other native species; (2) continue to refine methods and strategies for pikeminnow population

suppression across a range of habitats; (3) operate a resistance board weir to segregate pikeminnow from the South Fork Eel River headwaters and further suppress their population; and (4) evaluate pikeminnow and salmonid responses to suppression activities. This work, which may occur for up to five years, will affect SONCC coho salmon, CC Chinook salmon, and NC steelhead.

Suppression techniques will include boat electrofishing, seining, active gillnetting, spearfishing, hook-and-line, and the weir trap box. Suppression timing, gear types, and methods are designed to minimize encountering and impacting salmonids. Importantly, prior to conducting suppression, sites will be snorkeled and will be avoided if salmonids are present. The weir will be operated after April 1, by which time most steelhead will have spawned and emigrated. A small proportion of adult steelhead will move through the weir.

To investigate how pikeminnow suppression influences their movement and survival, juvenile coho salmon, Chinook salmon and steelhead will be captured with downstream migrant traps, a portion of juvenile coho salmon and juvenile steelhead will be acoustically-tagged, released, and tracked with a network of receivers.

Field activities for the various proposed research and enhancement components will occur annually as described for each location below for a duration of approximately 5 years through December 31, 2028.

Resistance Board Weir Operations Plan

The seasonal resistance board weir will be constructed in the mainstem South Fork Eel River just downstream from Indian Creek, 83 river kilometers upstream from the mainstem Eel River. For details on the specifics of the weir design, operation, and measures to reduce impacts on native fish see the supplemental document "Weir Operation Plan." The primary goals of this method are to: (1) segregate migratory pikeminnow from prime salmon rearing habitat in the upper mainstem South Fork Eel River; (2) capture and euthanize large numbers of these introduced predatory fish and (3) better understand the life history timing of pikeminnow and native salmonids.

Other Suppression Techniques

Suppression techniques will include boat electrofishing, seining, active gillnetting, spearfishing, hook-and-line, and the resistance board weir (discussed above). Boat electrofishing will only be conducted in the lower reaches of the South Fork Eel River that do not contain salmonids during the summer sampling

period. Prior to electrofishing, each sample site will be snorkeled to determine where pikeminnow are and to verify that no salmonids are present.

Seining will be conducted in the South Fork Eel River, Van Duzen River, and Lower Eel River using knotless nylon nets. In addition to sampling smaller size classes of pikeminnow in shallow water, seines may be deployed for active sampling, where snorkelers herd fish out of deeper water into the nets. Seines will also be used to capture juvenile coho salmon and steelhead for acoustic tagging.

Active gillnetting will be conducted in the mainstems of the South Fork Eel River, Van Duzen River, and Lower Eel River during time periods to avoid salmonids. As with other methods, prior to conducting gillnetting, each site will be snorkeled to ensure the absence of non-target species. Gillnets will never be left unattended in the water; gillnets will be actively tended and constantly inspected to ensure no harm is done to salmonids or other non-target species. At some sites, two gillnets will be actively maneuvered toward each other by divers to capture fleeing pikeminnow.

Spearfishing and hook and line sampling will be conducted in the South Fork Eel River, Van Duzen River, and Lower Eel River. Only divers with extensive experience distinguishing pikeminnow from native fish will be used. Hook-and-line sampling will rely on using only barbless hooks and any juvenile steelhead or other non-target species captured will be released immediately.

The following activities in the South Fork Eel River will occur annually:

Feb 1–Jun 1: Daily for up to 2 weeks—downstream migrant trapping, seining
 April 1–October 1: Opportunistically—seining, electrofishing
 April 1–October 31: Daily—resistance board weir; Biweekly—spearfishing, seining
 April 1–September 30: Biweekly—active gillnetting, hook-and-line, snorkeling
 July 1–September 30: Weekly—boat electrofishing
 June 15–August 31: Biweekly—spearfishing, seining, active gillnetting, hook- and-line, snorkeling

The annual sum of take requested across the various components of this effort in the South Fork Eel River are as follows: (1) non-lethal capture (backpack electrofishing, beach seining, or fyke net) and release of up to 1,000 juvenile SONCC coho salmon, 1,000 juvenile CC Chinook salmon, and 1,000 juvenile NC steelhead; (2) non-lethal capture (backpack electrofishing, beach seining, or fyke net) and release of up to 300 juvenile SONCC coho salmon

and 300 juvenile NC steelhead for the purpose of applying acoustic tags and collecting tissue samples by fin clip; (3) non-lethal capture (backpack electrofishing, beach seining, or fyke net) and release of up to 100 juvenile SONCC coho salmon and 100 juvenile NC steelhead for the purpose of applying acoustic tags, collecting tissue samples by fin clip and muscle biopsy; (4) non-lethal capture, tissue sampling, and release of up to 220 adult NC steelhead captured while operating the resistance board weir; (6) non-lethal observation of up to 400 adult NC steelhead on camera or sonar while operating the resistance board weir; (7) non-lethal observation of up to 30 juvenile NC steelhead during snorkel and diving surveys; and (8) non-lethal capture and release of up to 16 juvenile NC steelhead while boat electrofishing, beach seining, active gillnetting, and hook-and-line methods. The potential annual unintentional lethal take of SONCC coho salmon, CC Chinook salmon and NC steelhead expected to result from the proposed research and enhancement activities in the South Fork Eel River is up to 12 juvenile SONCC coho salmon, 4 juvenile CC Chinook salmon, 17 juvenile NC steelhead, and one adult NC steelhead.

The following activities will occur in the Van Duzen River annually:

July 1–October 31: Biweekly—spearfishing, seining, active gillnetting, hook- and-line, snorkeling

The annual sum of take requested across the various components of this effort in the Van Duzen River are as follows: (1) non-lethal observation of up to 750 juvenile NC steelhead during snorkel and diving surveys; (2) non-lethal capture and release of up to 35 juvenile NC steelhead while beach seining, active gillnetting, and hook-and-line methods. The potential annual unintentional lethal NC steelhead take expected to result from the proposed enhancement activities in the Van Duzen River is up to 3 juvenile NC steelhead.

The following activities will occur in the Lower Eel River annually:

June 15–August 31: Biweekly—spearfishing, seining, active gillnetting, hook-and-line, snorkeling

The annual sum of take requested across the various components of this effort in the Lower Eel River are as follows: (1) non-lethal observation of up to 100 juvenile SONCC coho salmon, 750 juvenile CC Chinook salmon, and 750 juvenile NC steelhead during snorkel and diving surveys; (2) non-lethal capture and release of up to 3 juvenile SONCC coho salmon, 3

juvenile CC Chinook salmon, and 35 juvenile NC steelhead while beach seining, active gillnetting, and hook-and-line methods. The potential annual unintentional lethal SONCC coho salmon, CC Chinook salmon, and NC steelhead take expected to result from the proposed enhancement activities in the Lower Eel River is up to 3 juvenile SONCC coho salmon, 3 juvenile CC Chinook salmon, and 3 juvenile NC steelhead.

This proposed scientific research and enhancement effort is expected to enhance survival and support recovery within the SONCC ESU of coho salmon, CC ESU of Chinook salmon, and the NC DPS of steelhead and is consistent with recommendations and objectives outlined in NMFS' Southern Oregon/Northern California Coast ESU Coho Salmon Recovery Plan and Coastal Multispecies Recovery Plan. See the Permit 22270-2R application for greater details on the various components of this scientific research and enhancement effort including the specific scientific methods proposed and take allotments requested for each.

Dated: January 12, 2023.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2023-00915 Filed 1-18-23; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XC688]

Endangered Species; File No: 26645

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

ACTION: Notice; issuance of a permit.

SUMMARY: Notice is hereby given that NMFS has issued an Incidental Take Permit (ITP) (No. 26645) to the Arnold Irrigation District, Central Oregon Irrigation District, Lone Pine Irrigation District, North Unit Irrigation District, Ochoco Irrigation District, Swalley Irrigation District, Three Sisters Irrigation District, Tumalo Irrigation District, and the City of Prineville (hereafter applicants), pursuant to the Endangered Species Act (ESA) of 1973, as amended, for the incidental take of Middle Columbia River (MCR) steelhead (*Oncorhynchus mykiss*), listed threatened under the ESA, and the nonessential experimental population of

steelhead (NEP) occurring upstream of the Round Butte Dam and Deschutes River sockeye salmon (*Oncorhynchus nerka*) which are not currently listed under the ESA (hereafter, covered species). Incidental take is associated with the otherwise lawful water management activities including the storage, release, diversion, and return of irrigation water by the eight irrigation districts and groundwater withdrawals, effluent discharges, and surface water diversions by the City of Prineville. The permit is issued for a duration of 28 years.

ADDRESSES: The record of decision, findings, biological opinion and other related documents are available on the NMFS West Coast Region website at <https://www.fisheries.noaa.gov/west-coast/habitat-conservation/habitat-conservation-plans-west-coast>. The draft and final environmental impact statement and public comments are available on the U.S. Fish and Wildlife Service website at <https://www.fws.gov/library/collections/deschutes-hcp>.

FOR FURTHER INFORMATION CONTACT: Scott Carlon (phone: 971-322-7436 or email: scott.carlon@noaa.gov or Celeste Stout (phone: 301-427-8436 or email: cleste.stout@noaa.gov).

SUPPLEMENTARY INFORMATION:

Background

On August 30, 2019, NMFS received an application for an ESA section 10(a)(1)(B) incidental take permit for activities pertaining to irrigation and municipal water management in the Deschutes River basin, Oregon. Included with the application was the draft Deschutes Basin Habitat Conservation Plan (HCP) collectively developed by eight irrigation districts (Arnold, Central Oregon, Lone Pine, North Unit, Ochoco, Swalley, Three Sisters, and Tumalo Irrigation Districts) and the City of Prineville. Activities covered under the HCP would occur in Klamath, Deschutes, Jefferson, Crook, Wasco, and Sherman Counties, Oregon. The applicants also applied with the U.S. Fish and Wildlife Service (USFWS) for incidental take of bull trout (*Salvelinus confluentus*) and Oregon spotted frog (*Rana pretiosa*).

Issuing an ESA section 10(a)(1)(B) permit constitutes a Federal action requiring compliance with the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) as implemented by 40 CFR parts 1500-1508 and NOAA Administrative Order 216-6A, Compliance with the NEPA (2016). For this action, USFWS is the lead agency under NEPA and NMFS is a cooperating agency. As the lead agency, the USFWS

published a notice of availability (NOA) of a draft environmental impact statement (EIS) in the **Federal Register** on October 4, 2019 (84 FR 53164), and published a NOA of the Final EIS with the USFWS on November 6, 2020 (85 FR 71086). USFWS received numerous comments on the Draft EIS, which were considered by both USFWS and NMFS. These comments were addressed as changes to the Final EIS. All alternatives were described in detail, evaluated, and analyzed in the Draft and Final EIS. NMFS found that issuing the ITP would have a significant impact on the quality of the environment and adopted the USFWS' EIS through its own NEPA process (40 CFR 1506.3). NMFS determined that the EIS considered a range of reasonable alternatives and fully evaluated the direct, indirect, and cumulative impacts likely to result from the authorization of ITPs issued by both the NMFS and the US Fish and Wildlife Service for this HCP.

All eight irrigation districts are quasi-municipal corporations formed and operated according to Oregon State law to distribute water to irrigators (patrons) within designated geographic boundaries and in accordance with the individual water rights held by those patrons. The City of Prineville operates City-owned infrastructure and provides essential services—including public safety, municipal water supply, and sewage treatment—for more than 9,000 residents. The applicants determined that continued operation of irrigation and essential services requires incidental take permits to address unavoidable take of the covered species.

Conservation Plan

Section 10 of the ESA requires an applicant to submit an adequate conservation plan. The applicants proposed a conservation program to avoid, minimize, and mitigate the impacts of taking MCR steelhead, the NEP of steelhead, and sockeye salmon (covered species). The activities covered by the HCP cause changes in surface water hydrology that alter the quantity and quality of aquatic habitats for listed species. The covered activities modify the timing and magnitude of flow in the Deschutes River and a number of its tributaries through the storage, release, diversion, and return of irrigation water. In most cases, the hydrologic changes resulting from irrigation activities have adverse impacts on aquatic habitats for the covered species. When flows are reduced, the total area of usable habitat for aquatic species generally decreases and water temperatures typically increase to the extent that habitat quality is negatively impacted. These

adverse effects on listed species can result in direct harm or injury of individuals of the covered species, and through changes in habitat that interfere with the essential life activities of the species. Both types of effects are addressed in the HCP conservation measures.

The HCP addresses the adverse effects of the covered activities on the covered species by reducing or eliminating those effects to the maximum extent practicable, and by mitigating effects that cannot be eliminated altogether. To address the adverse effects, the HCP's conservation measures modify irrigation activities that reduce instream flow. As a result, with implementation of the HCP, flows in the affected reaches will be higher than they were historically (over the last 50+ years) in the winter, and the duration of high summer water temperatures will be reduced.

The conservation strategy consists of a series of conservation measures to reduce and mitigate (*i.e.*, offset) the adverse effects of covered activities that can result in the take of the covered species. Proposed conservation measures include actions that would change the timing and volume of water released from covered reservoirs and streamflow in covered rivers and creeks by (1) establishing a minimum instream flow in the Deschutes River below Crane Prairie Dam; (2) increasing fall and winter Deschutes River flows based on a schedule of flow increases, thus improving rearing and migratory habitat for covered species in the middle and lower Deschutes River; (3) limiting irrigation season flows (summer flow cap) in years 8 through 28 of the ITP; (4) supplementing releases of uncontracted storage from Prineville Reservoir on the Crooked River; (5) providing conservation funds for the Crooked River, Whychus Creek, and Upper Deschutes River; and (6) providing other conservation measures to modify operation and maintenance of water facilities to enhance flows on the Deschutes River, Crescent Creek, Little Deschutes River, Whychus Creek, Crooked River, Ochoco Creek, and McKay Creek. The conservation strategy also provides an adaptive management and monitoring program to ensure that it is achieving the intended benefits to the covered species.

Criteria for Issuing Permit 26645

Issuance criteria for this permit are described in ESA section 10(a)(2)(B) and its implementing regulations (50 CFR 222.307(c)(2)). According to the ESA, NMFS shall issue the requested incidental take permit, if NMFS finds that the following criteria are met:

- (i) The taking will be incidental;
- (ii) The applicant will, to the maximum extent practicable, minimize and mitigate the impacts of such taking;
- (iii) The applicant will ensure that adequate funding for the plan will be provided;
- (iv) The taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild; and
- (v) The measures, if any, required under subparagraph (A)(iv) will be met, and NMFS has received such other assurances as it may require that the plan will be implemented.

NMFS found that the applicants met the criteria for the issuance of an incidental take permit, and as such, NMFS issued the incidental take permit to the applicants for the incidental take of the covered species.

Authority

Section 9 of the ESA and Federal regulations prohibits the "taking" of a species listed as endangered or threatened. The ESA defines "take" to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. NMFS may issue permits, under limited circumstances to take listed species when take is incidental to, and not the purpose of, otherwise lawful activities. Section 10(a)(1)(B) of the ESA provides for authorizing incidental take of listed species by non-Federal entities. The regulations for issuing incidental take permits for threatened and endangered species are promulgated at 50 CFR 222.307.

Dated: January 12, 2023.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2023-00902 Filed 1-18-23; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; International Dolphin Conservation Program

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of

1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on August 31, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: International Dolphin Conservation Program.

OMB Control Number: 0648-0387.

Form Number(s): None.

Type of Request: Regular submission, extension of a currently approved information collection, without change.

Number of Respondents: 518.

Average Hours per Response: 35 minutes for a vessel permit application; 10 minutes for an operator permit application, a notification of vessel arrival or departure, a change in permit operator, a notification of a net modification or a monthly tuna storage removal report; 30 minutes for a request for a waiver to transit the ETP without a permit (and subsequent radio reporting) or for a special report documenting the origin of tuna (if requested by the NOAA Administrator); 10 hours for an experimental fishing operation waiver; 15 minutes for a request for a Dolphin Mortality Limit; 35 minutes for written notification to request active status for a small tuna purse seine vessel; 5 minutes for written notification to request inactive status for a small tuna purse seine vessel or for written notification of the intent to transfer a tuna purse seine vessel to foreign registry and flag; 60 minutes for a tuna tracking form or for a monthly tuna receiving report; 30 minutes for IMO application or exemption request; 30 minutes for chain of custody recordkeeping reporting requirement.

Total Annual Burden Hours: 277.

Needs and Uses: This request is for extension, without change, of a current information collection.

National Oceanic and Atmospheric Administration (NOAA) collects information to implement the International Dolphin Conservation Program Act (Act). The Act allows entry of yellowfin tuna into the United States (U.S.), under specific conditions, from nations in the International Dolphin Conservation Program that would otherwise be under embargo. The Act also allows U.S. fishing vessels to participate in the yellowfin tuna fishery

in the eastern tropical Pacific Ocean (ETP) on terms equivalent with the vessels of other nations. NOAA collects information to allow tracking and verification of “dolphin-safe” and “non-dolphin safe” tuna products from catch through the U.S. market.

The regulations implementing the Act are at 50 CFR parts 216 and 300. The recordkeeping and reporting requirements at 50 CFR parts 216 and 300 form the basis for this collection of information. This collection includes permit applications, notifications, tuna tracking forms, reports, and certifications that provide information on vessel characteristics and operations in the ETP, the origin of tuna and tuna products, chain of custody recordkeeping requirements and certain other information necessary to implement the Act.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: Annually, monthly, as requested, or as needed.

Respondent's Obligation: Mandatory.

Legal Authority: The International Dolphin Conservation Program Act, with regulations implementing the Act at 50 CFR parts 216 and 300. The recordkeeping and reporting requirements at 50 CFR parts 216 and 300 form the basis for this collection of information.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0387.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2023–00983 Filed 1–18–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2022–0032]

Expanding Opportunities To Appear Before the Patent Trial and Appeal Board

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Request for comments; extension of written comment period.

SUMMARY: The United States Patent and Trademark Office (Office or USPTO) published a request for comments in the **Federal Register** on October 18, 2022, seeking comments from the public on the requirements to practice before the Patent Trial and Appeal Board (PTAB). Through this notice, the Office is extending the period for written public comments until January 31, 2023.

DATES: *Comment Deadline:* Written comments must be received by January 31, 2023.

ADDRESSES: For reasons of government efficiency, comments must be submitted through the Federal eRulemaking Portal at www.regulations.gov. To submit comments via the portal, enter docket number PTO–P–2022–0032 on the homepage and click “Search.” The site will provide a search results page listing all documents associated with this docket. Find a reference to this request for comments and click on the “Comment Now!” icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format (PDF) or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included. Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of and access to comments is not feasible due to a lack of access to a computer and/or the internet, please contact the Office using the contact information below for special instructions on how to submit comments by other means.

FOR FURTHER INFORMATION CONTACT: Michael Tierney, Vice Chief Administrative Patent Judge; Scott Moore, Acting Vice Chief Administrative Patent Judge; and/or Jamie Wisz, Lead Administrative Patent Judge; at 571–272–9797.

SUPPLEMENTARY INFORMATION: On October 18, 2022, the USPTO published a **Federal Register** Notice announcing that the Office seeks public input on whether revisions should be made to the criteria for appearing as counsel and/or lead counsel in PTAB proceedings under the Leahy-Smith America Invents Act. The request for comments also sought public input on whether the USPTO should make changes or improvements to training and development programs, such as the PTAB’s Legal Experience and Advancement Program, to increase opportunities for practitioners who wish to appear before the PTAB. 87 FR 63047. The notice requested that written public comments be submitted on or before January 17, 2023.

Through this notice, the USPTO is extending the period for written public comments until January 31, 2023, to give interested members of the public additional time to submit comments. Previously submitted written comments do not need to be resubmitted. Any comments received after the close of the previous deadline of January 17, 2023, and the publication date of this notice will be treated as timely and given full consideration.

All other information and instructions to commenters provided in the October 18, 2022, notice remain unchanged.

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2023–00947 Filed 1–18–23; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2022–0027]

Expanding Admission Criteria for Registration To Practice in Patent Cases Before the United States Patent and Trademark Office

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Request for comments; extension of written comment period.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) published a request for comments in the **Federal Register** on October 18, 2022, seeking comments from the public on the scientific and technical requirements to practice in patent matters before the USPTO. Through this notice, the Office is extending the

period for written public comments until January 31, 2023.

DATES: Comment Deadline: Written comments must be received by January 31, 2023.

ADDRESSES: For reasons of Government efficiency, comments must be submitted through the Federal eRulemaking Portal at www.regulations.gov. To submit comments via the portal, enter docket number PTO-P-2022-0027 on the homepage and click "Search." The site will provide a search results page listing all documents associated with this docket. Find a reference to this request for comments and click on the "Comment Now!" icon, complete the required fields, and enter or attach your comments. Attachments to electronic comments will be accepted in ADOBE® portable document format (PDF) or MICROSOFT WORD® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of comments is not feasible due to a lack of access to a computer and/or the internet, please contact the Office using the contact information below for special instructions on how to submit comments by other means.

Anonymous submissions: The Office will accept anonymous submissions. Enter "N/A" in the required fields if you wish to remain anonymous.

FOR FURTHER INFORMATION CONTACT: Will Covey, Deputy General Counsel and Director, Office of Enrollment and Discipline, at 571-272-4097 or oed@uspto.gov.

SUPPLEMENTARY INFORMATION: On October 18, 2022, the USPTO published a **Federal Register** Notice announcing that the Office seeks input on whether it should revise the scientific and technical criteria for admission to practice in patent matters. 87 FR 63044. The request for comments sought public input on whether to require the USPTO to periodically review certain applicant degrees on a predetermined timeframe, and whether to make certain modifications to the accreditation requirement for computer science degrees. The request for comments also sought input on whether the creation of a separate design patent practitioner bar would be beneficial to the public and the Office, whether to add clarifying instructions to the General Requirements Bulletin for Admission to the Examination for Registration to Practice in Patent Cases before the

United States Patent and Trademark Office for limited recognition applicants, and whether the Office should make any additional updates to the scientific and technical requirements for admission to practice in patent matters. The notice requested that written public comments be submitted on or before January 17, 2023.

Through this notice, the USPTO is extending the period for written public comments until January 31, 2023, to give interested members of the public additional time to submit comments. Previously submitted written comments do not need to be resubmitted. Any comments received after the close of the previous deadline of January 17, 2023, and the publication date of this notice will be treated as timely and given full consideration.

All other information and instructions to commenters provided in the October 18, 2022 notice remain unchanged.

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2023-00945 Filed 1-18-23; 8:45 am]

BILLING CODE 3510-16-P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Renew Collection 3038-0013: Position Limits

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission ("CFTC" or "Commission") is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act ("PRA"), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments on collections of information related to the Commission's position limits rule.

DATES: Comments must be submitted on or before March 20, 2023.

ADDRESSES: You may submit comments, identified by "Position Limits," or "OMB Control No. 3038-0013," by any of the following methods:

- The Agency's website, at <http://comments.cftc.gov>. Follow the

instructions for submitting comments through the website.

- **Mail:** Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

- **Hand Delivery/Courier:** Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to www.cftc.gov.

FOR FURTHER INFORMATION CONTACT: Steven A. Haidar, Assistant Chief Counsel, Division of Market Oversight, (202) 418-5611, email: shaidar@cftc.gov, or Grey Tanzi, Assistant Chief Counsel, Division of Market Oversight, (312) 596-0635, email: gtanzi@cftc.gov.

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.*, Federal agencies must obtain approval from the Office of Management and Budget ("OMB") for each collection of information they conduct or sponsor. "Collection of Information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing this notice of the proposed collection of information listed below. 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.¹

Title: Position Limits (OMB Control No. 3038-0013). This is a request for extension of a currently approved information collection.

Abstract: Commodity Exchange Act ("CEA") section 4a directs the Commission to establish limits on speculative positions, as the Commission determines to be necessary, to prevent the harms caused by excessive speculation. This Position Limits (OMB Control No. 3038-0013) collection of information includes collections of information required under both the Final Rule and the

¹ 44 U.S.C. 3512, 5 CFR 1320.5(b)(2)(i) and 1320.5(b)(3)(vi).

Aggregation Rule (as each is defined below).

In 2021, the Commission issued a final rule on position limits that implemented CEA section 4a and established the Commission's new position limits regime found in part 150 of the Commission's Regulations ("Final Rule").² The Final Rule, among other things, includes: new and amended Federal spot-month limits for the 25 core referenced futures contracts; (2) amended Federal non-spot limits for the nine legacy agricultural contracts subject to existing Federal position limits; (3) amended rules governing exchange-set limit levels and grants of exemptions therefrom; (4) an amended process for requesting certain spread exemptions and non-enumerated bona fide hedge recognitions for purposes of Federal position limits directly from the Commission; (5) a new streamlined process for recognizing non-enumerated bona fide hedge positions from Federal limit requirements; and (6) amendments to part 19 of the Commission's Regulations and related provisions that eliminated certain reporting obligations that require traders to submit a Form 204 and parts I and II of Form 304.

Separately, in 2016 the Commission issued a final rule amending Commission Regulation 150.4, which sets forth requirements regarding the aggregation of positions subject to federal position limits (the "Aggregation Rule").³ Among other things, Regulation 150.4 includes standards for the aggregation of accounts and procedures for seeking an exemption from position aggregation requirements under the Commission's federal position limits.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

² See "Position Limits for Derivatives," 86 FR 3236 (January 24, 2021).

³ See "Aggregation of Positions," 81 FR 91454 (December 16, 2016). The position aggregation requirements set forth in Regulation 150.4 are the subject of no-action letter 22-09 and have been the subject of similar no-action letters since the rule's effective date. As such, as of the date of this notice, market participants do not submit the reports set forth in Regulation 150.4. Accordingly, all collections of informations and related burden estimates under Regulation 150.4 are hypothetical.

- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and

- Ways to minimize the burden of 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.

You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.⁴

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from <http://www.cftc.gov> that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

Burden Statement: The respondent burden for this collection is estimated to be as follows:

Currently Affected Entities: Designated Contract Markets and market participants.

Estimated Number of Respondents: 776.

Estimated Average Burden Hours per Respondent: 15.14 hours.

Estimated Total Annual Burden on Respondents: 11,748 hours.

Frequency of Collection: As needed.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: January 13, 2023.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2023-00923 Filed 1-18-23; 8:45 am]

BILLING CODE 6351-01-P

⁴ 17 CFR 145.9.

DEPARTMENT OF EDUCATION

[Docket No.: ED-2023-SCC-0017]

Agency Information Collection Activities; Comment Request; Evaluation of Full-Service Community Schools: Early Implementation Data Collection

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a new information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before March 20, 2023.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2023-SCC-0017. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the [regulations.gov](http://www.regulations.gov) site is not available to the public for any reason, the Department will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W203, Washington, DC 20202-8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Erica Johnson, 202-245-7676.

SUPPLEMENTARY INFORMATION: The Department, 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. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department 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: Evaluation of Full-Service Community Schools: Early Implementation Data Collection.

OMB Control Number: 1850-NEW.

Type of Review: A new ICR.

Respondents/Affected Public: State, local, and Tribal governments.

Total Estimated Number of Annual Responses: 14.

Total Estimated Number of Annual Burden Hours: 4.

Abstract: The Full-Service Community Schools program seeks to improve student outcomes by helping schools expand and enrich learning opportunities, provide integrated student support services, strengthen family and community engagement, and adopt collaborative leadership practices that include families and community organizations. Congress has invested \$180 million in Full-Service Community Schools grants and mandated an evaluation of the program.

This package requests approval to conduct a survey of Full-Service Community Schools 2022 grantees. These data will be used to study the early implementation of the Full-Service Community Schools program.

Dated: January 13, 2023.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2023-00939 Filed 1-18-23; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2023-SCC-0006]

Agency Information Collection Activities; Comment Request; Visual Representations for Proportional Reasoning: Impacts of a Teacher Professional Development Program for Multilingual Learners and Other Students

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a new information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before March 20, 2023.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2023-SCC-0006. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the www.regulations.gov site is not available to the public for any reason, the Department will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W203, Washington, DC 20202-8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Janelle Sands, 202-245-6786.

SUPPLEMENTARY INFORMATION: The Department, 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. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department 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: Visual Representations for Proportional Reasoning: Impacts of a Teacher Professional Development Program for Multilingual Learners and Other Students.

OMB Control Number: 1850-NEW.

Type of Review: A new ICR.

Respondents/Affected Public: Individuals and households; State, local, and Tribal governments.

Total Estimated Number of Annual Responses: 36,784.

Total Estimated Number of Annual Burden Hours: 11,281.

Abstract: This submission is a request for approval of data collection activities that will be used to support the Northeast and Islands Regional Educational Laboratory (REL) Visual Representations for Proportional Reasoning: Impacts of a Teacher Professional Development Program for Multilingual Learners and Other Students. The study is being funded by the Institute of Education Sciences (IES) U.S. Department of Education and is being implemented by Education Development Center (EDC) and its subcontractor, American Institutes for Research (AIR). This submission requests approval to recruit schools for the study, and administer measures to teachers and students.

This study aims to contribute to the evidence base on professional development associated with improved student outcomes for multilingual learners (MLLs) in mathematics. The Visual Access to Mathematics Professional Development (VAM PD) leverages recent and rigorous evidence on the importance of visual representations (VRs) and integrates

language and content to support MLLs in proportional reasoning. Proportional reasoning content is a major emphasis in grade 7 math content standards in most U.S. states, and is fundamental to success in subsequent mathematics coursework. Prior research has demonstrated positive impacts of the Visual Access to Mathematics Professional Development (VAM PD) on teacher outcomes (DePiper, et al., 2021b, Louie et al., 2022, DePiper et al., 2019 & DePiper, et al., 2021a). This study will fill the gap in information about how VAM PD impacts student outcomes. In the current study, we will collect pre- and post-data from both teachers and students to examine what impact the VAM PD has on student learning. Teachers in participating schools will be assigned randomly to either a treatment or control group. Both groups will complete (1) a measure of mathematical content knowledge, (2) a measure of teacher ability to analyze student work, and (3) a brief survey/questionnaire about instructional practices in fall 2023 and again in spring 2024. Students taught by teachers in both conditions will complete (1) a measure of mathematical content knowledge, (2) three items related to VRs, and (3) a survey regarding attitudes toward mathematics. Data collected will be summarized and analyzed using multilevel modeling to understand the efficacy of the VAM PD on both teacher and student level outcomes.

Dated: January 12, 2023.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2023-00897 Filed 1-18-23; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Idaho Cleanup Project

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a virtual open meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Idaho Cleanup Project (ICP). The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, February 16, 2023; 9 a.m.–3 p.m. MT.

The opportunities for public comment are at 11 a.m. and 1 p.m. MT.

These times are subject to change; please contact the ICP Citizens Advisory Board (CAB) Administrator (below) for confirmation of times prior to the meeting.

ADDRESSES: This virtual meeting will be open to the public via Zoom. To attend virtually, please contact Jordan Davies, ICP CAB Administrator, by email jdavies@northwindgrp.com or phone (720) 775-7522, no later than 5 p.m. MT on Tuesday, February 14, 2023.

FOR FURTHER INFORMATION CONTACT: Jordan Davies, ICP CAB Administrator, by phone (720) 775-7522 or email jdavies@northwindgrp.com or visit the Board's internet homepage at <https://energy.gov/em/icpcab>.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE-EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda (agenda topics may change up to the day of the meeting; please contact Jordan Davies for the most current agenda):

1. Recent Public Outreach
2. Program Presentations
3. DOE Presentation
4. EM SSAB Meeting Update

Public Participation: The virtual meeting is open to the public via Zoom. To sign-up for public comment, please contact the ICP CAB Administrator (above) no later than 5 p.m. MT on Tuesday, February 14, 2023. In addition to participation in the live public comment sessions identified above, written statements may be filed with the Board either five days before or five days after the meeting by sending them to the ICP CAB Administrator at the aforementioned email address. Written public comment received prior to the meeting will be read into the record. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Jordan Davies, ICP CAB Administrator, phone (720) 775-7522 or email jdavies@northwindgrp.com. Minutes will also be available at the following website: <https://www.energy.gov/em/icpcab/listings/cab-meetings>.

Signed in Washington, DC, on January 13, 2023.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2023-00938 Filed 1-18-23; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Notice of request for comments.

SUMMARY: The Department of Energy (DOE) invites public comment on a proposed collection of information that DOE is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995.

DATES: Comments regarding this proposed information collection must be received on or before February 21, 2023. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at (202) 881-8588.

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

FOR FURTHER INFORMATION CONTACT: Scott Whiteford, Director, Office of Asset Management, 950 L'Enfant Plaza, Washington, DC 20585, (202) 287-1563, or by email at scott.whiteford@hq.doe.gov.

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

or other forms of information technology.

This information collection request contains:

(1) *OMB No.*: 1910–1000.

(2) *Information Collection Request Titled*: Personal Property.

(3) *Type of Review*: Renewal.

(4) *Purpose*: The data collected is used by Department of Energy (DOE) leadership to exercise oversight and control over management of Government furnished personal property in the hands of DOE's management and operating (M&O) contractors and Federal Acquisition Regulation (FAR) contractors. The contractor management oversight and control function cover the ways in which DOE contractors provide goods and services for DOE organizations and activities in accordance with the terms of their contracts; the applicable statutory, regulatory, and mission support requirements of the Department; and regulations in the functional areas covered by this package.

(5) *Annual Estimated Number of Respondents*: 284.

(6) *Annual Estimated Number of Total Responses*: 284.

(7) *Annual Estimated Number of Burden Hours*: 1,730.

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden*: \$230,090.

Statutory Authority: The basic authority for these collections is the statute establishing the Department of Energy ("Department of Energy Organization Act", Pub. L. 95–91, August 4, 1977) which vests the Secretary of Energy with the executive direction and management functions, authority, and responsibilities for the Department, including contract management.

Signing Authority

This document of the Department of Energy was signed on January 5, 2023, by Scott L. Whiteford, Director, Office of Asset Management, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 13, 2023.

Treana V. Garrett,

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

[FR Doc. 2023–00966 Filed 1–18–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Nevada

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an in-person/virtual hybrid open meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Nevada. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, February 15, 2023; 4:00 p.m.–8:00 p.m. PT.

The opportunity for public comment is at 4:10 p.m. PT.

This time is subject to change; please contact the Nevada Site Specific Advisory Board (NSSAB) Administrator (below) for confirmation of time prior to the meeting.

ADDRESSES: This meeting will be open to the public in-person at the Molasky Corporate Center (address below) or virtually via Microsoft Teams. To attend virtually, please contact Barbara Ulmer, NSSAB Administrator, by email nssab@emcbc.doe.gov or phone (702) 523–0894, no later than 4:00 p.m. PT on Monday, February 13, 2023.

Molasky Corporate Center, 15th Floor Conference Room, 100 North City Parkway, Las Vegas, NV 89106.

Attendees should check the website listed below for any meeting format changes due to COVID–19 protocols.

FOR FURTHER INFORMATION CONTACT: Barbara Ulmer, NSSAB Administrator, by phone: (702) 523–0894 or email: nssab@emcbc.doe.gov or visit the Board's internet homepage at www.nnss.gov/NSSAB/.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

1. Fiscal Year 2025 Prioritization (Work Plan Item #2)
2. Development of Round Robin Presentation for the EM SSAB National Chairs Meeting

Public Participation: The in-person/online virtual hybrid meeting is open to the public either in-person at the Molasky Corporate Center or via Microsoft Teams. To sign-up for public comment, please contact the NSSAB Administrator (above) no later than 4:00 p.m. PT on Monday, February 13, 2023. In addition to participation in the live public comment session identified above, written statements may be filed with the Board either before or within seven days after the meeting by sending them to the NSSAB Administrator at the aforementioned email address. Written public comment received prior to the meeting will be read into the record. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments can do so in 2-minute segments for the 15 minutes allotted for public comments.

Minutes: Minutes will be available by writing or calling Barbara Ulmer, NSSAB Administrator, U.S. Department of Energy, EM Nevada Program, 100 North City Parkway, Suite 1750, Las Vegas, NV 89106; Phone: (702) 523–0894. Minutes will also be available at the following website: http://www.nnss.gov/nssab/pages/MM_FY23.html.

Signed in Washington, DC, on January 13, 2023.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2023–00936 Filed 1–18–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Proposed Agency Information Collection

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

ACTION: Submission for Office of Management and Budget (OMB) review; comment request.

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

DATES: Comments regarding this proposed information collection must be received on or before 11:59 p.m. ET on March 20, 2023. If you anticipate difficulty in submitting comments within that period, contact the person

listed in **FURTHER INFORMATION CONTACT** as soon as possible.

ADDRESSES: Written comments may be sent by email to hydroelectricincentives@hq.doe.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Madden Sciubba, madden.sciubba@hq.doe.gov, (240) 798-1195.

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

This information collection request contains: (1) *OMB No.:* "New"; (2) *Information Collection Request Title:* Hydroelectric Incentive Programs; (3) *Type of Request:* New; (4) *Purpose:* GDO proposes to collect, annually applications and required supporting documents from applicants as required to receive payments for hydroelectric incentive programs ("Section 242" Hydroelectric Production Incentives, under 42 U.S.C. 15881; "Section 243" Hydroelectric Efficiency Improvement Incentives, under 42 U.S.C. 15882; and "Section 247" Maintaining and Enhancing Hydroelectricity Incentives, under 42 U.S.C. 15883); (5) *Annual Estimated Number of Respondents:* 200; (6) *Annual Estimated Number of Total Responses:* 200; (7) *Annual Estimated Number of Burden Hours:* 8 hours for each applicant, (1,600 total hours); (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* \$512 per applicant, annually (\$102,400 in total); (9) *Respondents/affected entities:* businesses and other for-profits; not-for-profits; State, Local or Tribal Governments; Federal Government.

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

Signing Authority

This document of the Department of Energy was signed on January 12, 2023, by Maria Duaime Robinson, Director of the Grid Deployment Office. That

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

Signed in Washington, DC, on January 13, 2023.

Treana V. Garrett,

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

[FR Doc. 2023-00967 Filed 1-18-23; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC23-4-000]

Commission Information Collection Activities (FERC-73) Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC Form No. 73, (Oil Pipeline Service Life Data).

DATES: Comments on the collection of information are due March 20, 2023.

ADDRESSES: You may submit your comments (identified by Docket No. IC23-4-000) by one of the following methods:

Electronic filing through <https://www.ferc.gov>, is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.

- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:

- *Mail via U.S. Postal Service Only:*

Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

- *Hand (Including Courier) Delivery:* Deliver to: Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: <https://www.ferc.gov>. For user assistance, contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at (866) 208-3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at <https://www.ferc.gov>.

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at DataClearance@FERC.gov, telephone at (202) 502-8663.

SUPPLEMENTARY INFORMATION:

Title: FERC Form No. 73, Oil Pipeline Service Life Data.

OMB Control No.: 1902-0019.

Type of Request: Three-year extension of the FERC Form No. 73 information collection requirements with no changes to the current reporting requirements.

Abstract: The Commission collects FERC Form No. 73 information as part of its authority under the Interstate Commerce Act, 49 U.S.C. 60501, *et al.* FERC Form No. 73 contains necessary information for the review of oil pipeline companies' proposed depreciation rates, as regulated entities are required to provide service life data illustrating the remaining physical life of an oil pipeline's properties. This is used to calculate the company's cost of service and its transportation rates to access customers. The Commission implements these filing reviews under the purview of 18 CFR part 357.3, *FERC Form No. 73, Oil Pipeline Data for Depreciation Analysis*, and 18 CFR part 347.

Parts 357.3 and 347 require an oil pipeline company to submit information under FERC Form No. 73 when: (1) requesting approval for new or changed depreciation rates of an oil pipeline; or (2) being directed by the Commission to file the service life data during an investigation of its book depreciation rates.

Type of Respondent: Oil pipeline companies.

*Estimate of Annual Burden:*¹ The Commission estimates the annual public

¹ "Burden" is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

reporting burden for the information collection as below:

FERC FORM NO. 73, OIL PIPELINE SERVICE LIFE DATA

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ²	Total annual burden & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Oil Pipelines Undergoing Investigation or Review.	22	1	22	40 hrs.; \$3,640	880 hrs.; \$80,080.	\$3,640

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: January 12, 2023.

Kimberly D. Bose,
Secretary.

[FR Doc. 2023-00952 Filed 1-18-23; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14971-001]

Lock+™ Hydro Friends Fund XVIII, LLC; Notice of Surrender of Preliminary Permit

Take notice that Lock+™ Hydro Friends Fund XVIII, LLC, permittee for the proposed Union City Dam Hydropower Project, has requested that its preliminary permit be terminated. The permit was issued on January 13, 2020 and would have expired on December 31, 2023.¹ The project would have been located at the U.S. Army Corps of Engineers' (Corps) Union City Dam on French Creek in Erie County, Pennsylvania.

The preliminary permit for Project No. 14971 will remain in effect until the

close of business, February 13, 2023. But, if the Commission is closed on this day, then the permit remains in effect until the close of business on the next day in which the Commission is open.² New applications for this site may not be submitted until after the permit surrender is effective.

Dated: January 12, 2023.

Kimberly D. Bose,
Secretary.

[FR Doc. 2023-00956 Filed 1-18-23; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2587-066]

Northern States Power Company; Notice of Application Tendered for Filing With The Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2587-066.

c. *Date Filed:* December 30, 2022.

d. *Applicant:* Northern States Power Company.

e. *Name of Project:* Superior Falls Hydroelectric Project (Superior Falls Project).

f. *Location:* The Superior Falls Project is located on the Montreal River in Iron County, Wisconsin and Gogebic County, Michigan.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)-825(r).

h. *Applicant Contact:* Matt Miller, Hydro License Consultant, Northern States Power Company, 1414 West Hamilton Avenue, P.O. Box 8, Eau

Claire, Wisconsin 54702-0008, (715) 737-1353 or email at matthew.i.miller@xcelenergy.com.

i. *FERC Contact:* Lee Emery at (202) 502-8379 or email at lee.emery@ferc.gov.

j. *Cooperating Agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. See, 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* February 28, 2023.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at <https://ferconline.ferc.gov/FEROnline.aspx>. For assistance, please contact FERC Online Support at FEROnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, you may submit a paper copy. 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.

² "The Commission staff estimates the average cost in salary and benefits for the average respondent based on the Commission's 2022 average cost for salary plus benefits at \$91/hour.

¹ 170 FERC ¶ 62,017 (2020).

² 18 CFR 385.2007(a)(2) (2022).

Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Superior Falls Hydroelectric Project (P-2587-066).

m. This application is not ready for environmental analysis at this time.

n. *The existing Superior Falls Project consists of:* (1) a reservoir with a surface area of 16.3-acres with a storage capacity of 78.2 acre-feet; (2) a 240-foot-long, 28.5-foot-high dam; (3) a 1,697-foot-long, 7-foot diameter conduit; (4) a 28-foot-diameter by 28-foot-high surge tank; (5) two 207-foot-long by 54-inch-diameter penstocks extending from the surge tank to the powerhouse; (6) a powerhouse containing two turbine-

generator units each rated at 825 kilowatts with a combined plant capacity of 1.65 megawatts; (7) a 200-foot-long above ground transmission line; and (8) appurtenant facilities.

The Superior Falls Project is operated in a run-of-river mode with an estimated average annual energy production of 11,436 megawatt-hours, based on a five-year period ending in 2021. Northern States Power Company proposes to continue operating the project as a run-of-river facility and does not propose any new construction to the project.

o. A copy of the application can be viewed on the Commission's website at <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 on March 13, 2020. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (866) 208-3676 or (202) 502-8659 (TTY).

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. *Procedural Schedule:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Milestone	Target date
Issue Deficiency Letter (if necessary)	March 2023.
Request Additional Information (if necessary)	April 2023.
Issue Scoping Document 1 for comments	September 2023.
Issue Scoping Document 2 (if necessary)	December 2023.

q. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: January 12, 2023.

Kimberly D. Bose,
Secretary.

[FR Doc. 2023-00951 Filed 1-18-23; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2610-012]

Northern States Power Company; Notice of Application Tendered for Filing With The Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent License.

b. *Project No.:* 2610-012.

c. *Date Filed:* December 30, 2022.

d. *Applicant:* Northern States Power Company.

e. *Name of Project:* Saxon Falls Hydroelectric Project (Saxon Falls Project).

f. *Location:* The Saxon Falls Project is located on the Montreal River in Iron County, Wisconsin and Gogebic County, Michigan.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)-825(r).

h. *Applicant Contact:* Matt Miller, Hydro License Consultant, Northern States Power Company, 1414 West Hamilton Avenue, P.O. Box 8, Eau Claire, Wisconsin 54702-0008, (715) 737-1353 or email at matthew.i.miller@xcelenergy.com.

i. *FERC Contact:* Lee Emery at (202) 502-8379 or email at lee.emery@ferc.gov.

j. *Cooperating Agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. See, 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in

order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* February 28, 2023.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at <https://ferconline.ferc.gov/ferconline.aspx>. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, you may submit a paper copy. 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. All filings must clearly identify the project name and docket number on the first page: Saxon Falls Hydroelectric Project (P-2610-012).

m. This application is not ready for environmental analysis at this time.

n. *The Saxon Falls Project consists of:* (1) a reservoir with a surface area of 65.5 acres with a storage capacity of 524 acre-feet; (2) a 440-foot-long, 40-foot-high dam; (3) a 1,670-foot-long, 6-foot diameter conduit; (4) a 23.5-foot-diameter by 59.5-foot-high surge tank; (5) two 156-foot-long by 56-inch-diameter penstocks extending from the surge tank to the powerhouse; (6) a powerhouse containing two turbine-generator units each rated at 750 kilowatts with a combined plant capacity of 1.5 megawatts; (7) a 0.25-mile-long above ground transmission line; and (8) appurtenant facilities.

The Saxon Falls Project is operated in a run-of-river mode with an estimated average annual energy production of 10,015 megawatt-hours, based on a five-year period ending in 2021. Northern States Power Company proposes to continue operating the project as a run-of-river facility and does not propose any new construction to the project.

o. A copy of the application can be viewed on the Commission's website at <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 on March 13, 2020. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (866) 208-3676 or (202) 502-8659 (TTY).

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. *Procedural Schedule:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Milestone	Target date
Issue Deficiency Letter (if necessary)	March 2023.
Request Additional Information (if necessary)	April 2023.
Issue Scoping Document 1 for comments	September 2023.
Issue Scoping Document 2 (if necessary)	December 2023.

q. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: January 12, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023-00950 Filed 1-18-23; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 5944-024]

Moretown Hydroelectric, LLC; Notice of Waiver Period for Water Quality Certification Application

On December 20, 2022, Moretown Hydroelectric, LLC submitted to the Federal Energy Regulatory Commission (Commission) evidence of the date on which the certifying agency received the certification request for a Clean Water Act section 401(a)(1) water quality certification filed with the Vermont Department of Environmental Conservation, in conjunction with the above captioned project. Pursuant to 40 CFR 121.6 and section [4.34(b)(5), 5.23(b), 153.4, or 157.22] of the Commission's regulations,¹ we hereby notify the Vermont Department of

Environmental Conservation of the following:

Date of Receipt of the Certification Request: December 16, 2022.

Reasonable Period of Time to Act on the Certification Request: One year (December 16, 2023).

If the Vermont Department of Environmental Conservation fails or refuses to act on the water quality certification request on or before the above date, then the agency certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: January 11, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023-00892 Filed 1-18-23; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15-1434-006.
Applicants: ISO New England Inc., Emera Maine.

Description: Compliance filing: ISO New England Inc. submits tariff filing per 35: Versant Power; Docket No. ER15-1434 Revised Joint offer of Settlement to be effective N/A.

Filed Date: 1/12/23.

Accession Number: 20230112-5000.
Comment Date: 5 p.m. ET 2/2/23.

Docket Numbers: ER20-2119-002.
Applicants: ISO New England Inc., Versant Power.

Description: Compliance filing: ISO New England Inc. submits tariff filing per 35: Versant Power; Docket No. ER20-2119 Revised Joint Offer of Settlement to be effective N/A.

Filed Date: 1/12/23.
Accession Number: 20230112-5001.
Comment Date: 5 p.m. ET 2/2/23.

Docket Numbers: ER23-226-001.
Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: Deficiency Response—Fourth Amended and Restated WDJAs to be effective 12/28/2022.

Filed Date: 1/11/23.
Accession Number: 20230111-5072.
Comment Date: 5 p.m. ET 1/25/23.

Docket Numbers: ER23-446-001.
Applicants: Duke Energy Indiana, LLC.

Description: Tariff Amendment: DEI-Request to Defer Action on Construction Agreement to be effective 12/31/9998.

Filed Date: 1/12/23.
Accession Number: 20230112-5071.
Comment Date: 5 p.m. ET 2/2/23.

Docket Numbers: ER23-817-000.
Applicants: WPL Bear Creek Solar, LLC.

Description: Tariff Amendment: WPL Bear Creek Solar Cancellation of MBR Tariff to be effective 1/11/2023.

Filed Date: 1/11/23.
Accession Number: 20230111-5126.

¹ 18 CFR [4.34(b)(5)/5.23(b)/153.4/157.22].

Comment Date: 5 p.m. ET 2/1/23.
Docket Numbers: ER23–818–000.
Applicants: WPL Crawfish River Solar, LLC.
Description: Tariff Amendment: WPL Crawfish River Solar Notice of Cancel MBR Tariff to be effective 1/11/2023.
Filed Date: 1/11/23.
Accession Number: 20230111–5128.
Comment Date: 5 p.m. ET 2/1/23.
Docket Numbers: ER23–819–000.
Applicants: WPL North Rock Solar, LLC.
Description: Tariff Amendment: WPL North Rock Solar Notice of Cancel MBR Tariff to be effective 1/11/2023.
Filed Date: 1/11/23.
Accession Number: 20230111–5129.
Comment Date: 5 p.m. ET 2/1/23.
Docket Numbers: ER23–820–000.
Applicants: WPL Wood County Solar, LLC.
Description: Tariff Amendment: WPL Wood County Solar, LLC Notice of Cancel MBR Tariff to be effective 1/11/2023.
Filed Date: 1/11/23.
Accession Number: 20230111–5131.
Comment Date: 5 p.m. ET 2/1/23.
Docket Numbers: ER23–821–000.
Applicants: New York State Reliability Council, L.L.C.
Description: Informational Filing of the Revised Installed Capacity Requirement of the New York Control Area by the New York State Reliability Council, L.L.C.
Filed Date: 12/22/22.
Accession Number: 20221222–5340.
Comment Date: 5 p.m. ET 1/18/23.
Docket Numbers: ER23–822–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2023–01–12_SA 3339 Termination of MidAmerican-Contrail Wind Project E&P (J611) to be effective 1/13/2023.
Filed Date: 1/12/23.
Accession Number: 20230112–5017.
Comment Date: 5 p.m. ET 2/2/23.
Docket Numbers: ER23–823–000.
Applicants: EnerSmart Chula Vista BESS LLC.
Description: § 205(d) Rate Filing: Request to Make Capacity Sales at Market-Based Rates to be effective 3/14/2023.
Filed Date: 1/12/23.
Accession Number: 20230112–5022.
Comment Date: 5 p.m. ET 2/2/23.
Docket Numbers: ER23–824–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to ISA, Service Agreement No. 5999; Queue No. AC2–012 to be effective 3/10/2021.

Filed Date: 1/12/23.
Accession Number: 20230112–5087.
Comment Date: 5 p.m. ET 2/2/23.
Docket Numbers: ER23–825–000.
Applicants: Appalachian Power Company.
Description: § 205(d) Rate Filing: OATT—Revise Attachment K, AEP Texas Inc. Compliance with PUCT Project 53169 to be effective 12/31/9998.
Filed Date: 1/12/23.
Accession Number: 20230112–5088.
Comment Date: 5 p.m. ET 2/2/23.
Docket Numbers: ER23–826–000.
Applicants: Northern States Power Company, a Minnesota corporation.
Description: § 205(d) Rate Filing: 2023–1–12 ERPC Nighthawk CIAC 716–NSP to be effective 3/13/2023.
Filed Date: 1/12/23.
Accession Number: 20230112–5114.
Comment Date: 5 p.m. ET 2/2/23.
Docket Numbers: ER23–827–000.
Applicants: Michigan Electric Transmission Company, LLC.
Description: § 205(d) Rate Filing: Filing of Certificate of Concurrence to be effective 3/13/2023.
Filed Date: 1/12/23.
Accession Number: 20230112–5115.
Comment Date: 5 p.m. ET 2/2/23.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercensearch.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: January 12, 2023.

Kimberly D. Bose,
 Secretary.

[FR Doc. 2023–00953 Filed 1–18–23; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2011–0901; FRL–10588–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Prevention of Significant Deterioration and Nonattainment New Source Review (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Prevention of Significant Deterioration and Nonattainment New Source Review (EPA ICR Number 1230.34, OMB Control Number 2060–0003), 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 January 31, 2023. Public comments were previously requested via the **Federal Register** on April 8, 2022, during a 60-day comment period. This notice allows for 30 days for public comments.

DATES: Comments may be submitted on or before February 21, 2023.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–HQ–OAR–2011–0901, online using www.regulations.gov (our preferred method), or by email to a-and-r-docket@epa.gov. 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: Ben Garwood, Air Quality Policy Division, Office of Air Quality Planning and Standards, C504–03, U.S. Environmental Protection Agency, Research Triangle Park, NC 27709; telephone number: (919) 541–1358; fax

number: (919) 541-4028; email address: garwood.ben@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through January 31, 2023. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on April 8, 2022 during a 60-day comment period (87 FR 20855). This notice allows for an additional 30 days for public comments. Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Abstract: This ICR is for activities related to the implementation of the EPA's New Source Review (NSR) program for the time period between February 1, 2023, and January 31, 2025. Title I, part C of the Clean Air Act (CAA or the Act), Prevention of Significant Deterioration, and part D, Plan Requirements for Nonattainment Areas, require all states to adopt preconstruction review programs for new or modified stationary sources of air pollution. The provisions of section 110 of the Act include a requirement for states to have a preconstruction review program to manage the emissions from the construction and modification of any stationary source of air pollution to assure that the National Ambient Air Quality Standards are achieved and maintained. Tribes may choose to develop implementation plans to address these requirements.

Implementing regulations for these three programs are promulgated at 40 CFR 49.101 through 49.105; 40 CFR 49.151 through 49.173; 40 CFR 51.160 through 51.166; 40 CFR part 51, appendix S; and 40 CFR 52.21 and 52.24. In order to receive a construction permit for a major new source or major modification, the applicant must conduct the necessary research, perform the appropriate analyses, and prepare the permit application with documentation to demonstrate that their project meets all applicable statutory and regulatory NSR requirements. Specific activities and requirements are

listed and described in the ICR Supporting Statement.

State, local, tribal, or federal reviewing authorities review permit applications and provide for public review of proposed projects and issue permits based on their consideration of all technical factors and public input. The EPA, more broadly, reviews a fraction of the total applications and audits the state and local programs for their effectiveness. Consequently, information prepared and submitted by sources is essential for sources to receive permits, and for federal, state, tribal, and local environmental agencies to adequately review the permit applications and thereby properly administer and manage the NSR programs.

Information that is collected is handled according to the EPA's policies set forth in title 40, chapter 1, part 2, subpart B—Confidentiality of Business Information (see 40 CFR part 2). See also section 114(c) of the Act.

Form numbers: 5900-246, 5900-247, 5900-248, 5900-340, 5900-341, 5900-342, 5900-343, 5900-344, 5900-367, 5900-368, 5900-369, 5900-370, 5900-371, 5900-372, 5900-390, 5900-391, and 6700-06.

Respondents/affected entities: Those which must apply for and obtain a preconstruction permit under part C or D or section 110(a)(2)(C) of title I of the Act. In addition, state, local, and tribal reviewing authorities that must review permit applications and issue permits are affected entities.

Respondent's obligation to respond: Mandatory [see 40 CFR part 49, subpart C; 40 CFR part 51, subpart I; 40 CFR part 52, subpart A; 40 CFR part 124, subparts A and C].

Estimated number of respondents: 30,359 (total); 30,236 industrial facilities and 123 state, local, and tribal reviewing authorities.

Frequency of response: On occasion, as necessary.

Total estimated burden: 2,970,503 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$242,352,032 (per year). This includes \$3,772,240 annually in outsourced start-up costs for preconstruction monitoring.

Changes in estimates: There is no change in the hours in the total estimated respondent burden compared with the ICR currently approved by OMB because the estimated number of permits of each type has not changed. There is a slight increase in estimated

costs as labor costs have been updated from 2016 to 2019 labor rates.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2023-00969 Filed 1-18-23; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OA-2019-0292; FRL-10585-01-OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Survey To Improve Economic Analysis of Surface Water Quality Changes (New)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), "Survey to Improve Economic Analysis of Surface Water Quality Changes" (EPA ICR Number 2588.01, OMB Control Number 2090-NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request for approval of a new collection. Public comments were previously requested via the **Federal Register** on September 29, 2021, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before February 21, 2023.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA-HQ-OA-2019-0292 online using www.regulations.gov (our preferred method), by email to docket_oms@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

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

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

FOR FURTHER INFORMATION CONTACT:

Chris Moore, AO/OP/NCEE, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202-566-2348; fax number: 202-566-2448; email address: moore.chris@epa.gov.

SUPPLEMENTARY INFORMATION: This is a request for approval of a new collection. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on September 29, 2021, during a 60-day comment period (86 FR 53960). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA’s public docket, visit <http://www.epa.gov/dockets>.

Abstract: Researchers and analysts in EPA’s Office of Research and Development (ORD), Office of Water (OW), and National Center for Environmental Economics (NCEE) are collaborating to improve EPA’s ability to perform benefit cost analysis on changes in surface water quality (lakes, rivers, and streams). We are requesting approval to conduct a survey that will provide data critical to that effort. A number of non-market valuation methods can be used to estimate the economic benefits of improving environmental quality, but they often require more time and resources than federal agencies have to complete the regulatory impact analysis. Benefit transfer can provide reasonably accurate estimates of economic benefits under certain conditions with fewer resources and far less time. Federal agencies rely on benefit transfer often when analyzing the economic impacts of environmental regulation. In conducting benefit cost analyses of surface water regulations, however, it has become apparent that there is a lack of data on some features of policy analysis that have forced analysts to make assumptions about the relationships between a number of factors. This information collection is

necessary to provide insight on those relationships and improve the EPA’s and other federal agencies’ ability to perform benefit transfer in regulatory analysis.

Analysts in the Office of Policy, the Office of Water, and the Office of Research and Development have begun work on an integrated hydrological and economic model that will be capable of estimating benefits for a wide range of surface water regulations. The data collected with this survey will inform that effort. Analysts elsewhere in the EPA and other federal agencies may also be able to use the results of this study to improve benefit transfer in other applications. The survey will be administered electronically to a probability-based internet panel. An internet-based survey mode provides several advantages in efficiency and accuracy over other collection modes. It is also necessary to meet several of our research objectives described in the ICR Supporting Statement. Participation in the survey will be voluntary and the identity of the participants will be kept confidential.

Form numbers: EPA Form 5800-078, *A Survey on Water Quality in Rivers, Lakes, and Streams*.

Respondents/affected entities: Eligible respondents for this survey will be U.S. civilian, non-institutionalized individuals, age 18 years and older.

Respondent’s obligation to respond: Voluntary.

Estimated number of respondents: 6120 (total).

Frequency of response: One-time collection.

Total estimated burden: 2,040 hours.

Total estimated cost: \$637,122. There are no capital or operation and maintenance costs associated with this collection.

Changes in the estimates: This is a new collection. The survey is a one-time data collection activity.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2023-00972 Filed 1-18-23; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2021-0756; FRL-10116-01-OCSPF]

Availability of New Approach Methodologies in the Endocrine Disruptor Screening Program; Notice of Availability and Opportunity for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on a draft White Paper entitled “Availability of New Approach Methodologies (NAMs) in the Endocrine Disruptor Screening Program (EDSP).” This draft White Paper was developed pursuant to the Federal, Food, Drug and Cosmetic Act (FFDCA), which requires EPA to develop a screening program, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects. This draft White Paper announces that certain NAMs have been validated and may now be accepted by the EPA as alternatives for certain EDSP Tier 1 assays while others are useful for prioritization purposes and for use as other scientifically relevant information, where appropriate, in weight of evidence evaluations.

DATES: Comments must be received on or before March 20, 2023.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2021-0756, 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>.

FOR FURTHER INFORMATION CONTACT: Natalie Bray, Pesticide Reregistration Division (7508M), Office of Pesticide Programs, Environmental Protection Agency; telephone number: (202) 566-2222; email address: bray.natalie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions

regarding the applicability of this action to a particular entity, contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI information to EPA through [regulations.gov](https://www.epa.gov/regulations) or email. Clearly mark the part or all of the information that you claim to be 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. *Multimedia submissions.* 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. The 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).

3. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/comments.html>. Please note that once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket.

II. Executive Summary

A. What is the Agency's authority for taking this action?

Section 408(p)(1) of the Federal, Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 408, requires EPA to “develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effects as [EPA] may designate.”

B. What action is the Agency taking?

The Agency is releasing the draft document entitled “Availability of New Approach Methodologies (NAMs) in the Endocrine Disruptor Screening Program (EDSP)” [herein called the draft “White Paper”]. This draft White Paper announces that certain NAMs have been validated and may now be accepted by the EPA as alternatives for certain EDSP

Tier 1 assays while others are useful for prioritization purposes and for use as other scientifically relevant information, where appropriate, in weight of evidence evaluations. The draft White Paper provides further details concerning when specified NAMs may be used.

In 1998, pursuant to FFDCA section 408(p)(1), EPA introduced the EDSP including the use of a two-tiered screening framework consisting of a battery of *in vitro* and *in vivo* assays (63 FR 42852, August 11, 1998 (FRL–6021–3) and 63 FR 71542, December 28, 1998 (FRL–6052–9)). The purpose of Tier 1 screening is to identify chemicals that have potential biological activity (“bioactivity”) in the estrogen, androgen or thyroid hormone pathways using a battery of assays. For more than a decade at the EPA, research efforts have focused on the development and evaluation of high-throughput *in vitro* assays and *in silico* methods as NAMs, including databases and computational models, for use as alternatives to the current suite of assays in the EDSP Tier 1 battery to accelerate the pace of screening, add efficiencies, decrease costs, and reduce animal testing.

EPA has determined that the Estrogen Receptor (ER) pathway model based on the full 18-assay ToxCast/Tox21 battery may be used as an alternative to performing certain EDSP Tier 1 screening assays: ER binding *in vitro* assay (OCSPP 890.1250), ER transcriptional activation *in vitro* assay (ERTA; OCSPP 890.1300), and the *in vivo* Uterotrophic assay (rat) (OCSPP 890.1600). EPA has further determined that the Androgen Receptor (AR) pathway model based on the full 11-assay ToxCast/Tox21 battery may be used as an alternative for the AR binding *in vitro* assay (OCSPP 890.1150). The data from these NAMs will be evaluated on a chemical-by-chemical basis (each assay evaluated independently).

The following models and assays are not yet accepted by the EDSP as alternatives *per se* for Tier 1 screening assays, but may be used for priority setting for EDSP Tier 1 screening or for consideration for use as other scientifically relevant information, where appropriate in weight of evidence evaluations:

(1) ER and AR pathway models using assay subsets (also referred to as reduced or minimal assay data sets); (2) *In Silico* Qualitative Structure Activity Relationship Consensus Models for ER and AR (<https://ntp.niehs.nih.gov/whattwestudy/niceatm/comptox/ct-opera/opera.html>); (3) Integration of Bioactivity and Exposure (Integrated

Bioactivity Exposure Ratio), which compares an estimated external dose threshold for a biological effect, based on an internal dose (*i.e.*, plasma concentration) derived from bioactivity data (e.g., ER and AR pathway model outputs), with estimates of exposure; and, (4) The Sequence Alignment to Predict Across Species Susceptibility (SeqAPASS) tool for interspecies extrapolation.

EPA requests the public provide comment on the clarity and completeness of the draft document. Given the strengths and uncertainties of these methods, EPA also requests the public provide comment on the draft conclusions that certain NAMs have been validated and may now be accepted by the EPA as alternatives for certain EDSP Tier 1 assays while others are useful for prioritization purposes and for consideration for use as other scientifically relevant information.

Included in the docket for this action are two documents that respond to comments on related subject matter. One document responds to comments received in response to a notice issued in the **Federal Register** of June 19, 2015 (80 FR 35350 (FRL–9928–69), see also docket ID No. EPA–HQ–OPP–2015–0305) requesting comment on EPA’s document titled “Endocrine Disruptor Screening Program: Use of High Throughput Assays and Computational Tools.” The other document contains EPA’s responses to comments regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) Meeting from November 28–30, 2017 (82 FR 26097, June 6, 2017 (FRL–9962–79) and 82 FR 36137, August 3, 2017 (FRL–9965–61), see also docket ID No. EPA–HQ–OPP–2017–0214). EPA is including these documents in the docket for this action because they provide useful context on past public input on the EDSP which EPA considered when developing the draft White Paper. EPA is not requesting public comment on these response to comments documents.

III. Do guidance documents contain binding requirements?

As guidance, the draft White Paper is not binding on the Agency or any outside parties, and the Agency may depart from it where circumstances warrant and without prior notice. While EPA has made every effort to ensure the accuracy of the discussion in the guidance, the obligations of EPA and the regulated community are determined by statutes, regulations, or other legally binding documents. In the event of a conflict between the discussion in the guidance documents and any statute,

regulation, or other legally binding document, the guidance documents will not be controlling.

Authority: 21 U.S.C. 408.

Dated: January 13, 2023.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2023-00940 Filed 1-18-23; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2007-1196; FRL-10485-01-OAR]

Recent Postings of Broadly Applicable Alternative Test Methods

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the broadly applicable alternative test method approval decisions that the Environmental Protection Agency (EPA) made under and in support of New Source Performance Standards (NSPS) and the National Emission Standards for Hazardous Air Pollutants (NESHAP) between January 1, 2022, and December 31, 2022.

FOR FURTHER INFORMATION CONTACT: An electronic copy of each alternative test method approval document is available at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods>. For questions about this notice, contact Mrs. Lula H. Melton, Air Quality Assessment Division, Office of Air Quality Planning and Standards (E143-02), Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541-2910; fax number: (919) 541-0516; email address: melton.lula@epa.gov. For technical questions about individual alternative test method decisions, refer to the contact person identified in the individual approval document(s).

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this notice apply to me?

This notice will be of interest to entities regulated under 40 Code of Federal Regulations (CFR) parts 59, 60, 61, 63 and 65; state, local, and tribal agencies; and the EPA Regional offices responsible for implementation and enforcement of regulations under 40 CFR parts 59, 60, 61, 63, and 65.

B. How can I get copies of this information?

You may access copies of the broadly applicable alternative test method approval documents at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods>.

II. Background

This notice identifies broadly applicable alternative test methods that the EPA approved in 2022 under the NSPS, 40 CFR part 60 and the NESHAP, and 40 CFR part 63 programs. See Table 1 of this notice for the summary of these test methods. Source owners and operators may voluntarily use these broadly applicable alternative test methods in lieu of otherwise required test methods or related testing procedures. Use of these broadly applicable alternative test methods are not intended to and should not change the applicable emission standards.

The Administrator has the authority to approve the use of alternative test methods for compliance with requirements under 40 CFR parts 59, 60, 61, 63, and 65. This authority is found in 40 CFR 60.8(b)(3), 61.13(h)(1)(ii), and 63.7(e)(2)(ii). Additional and similar authority can be found in 40 CFR 59.104(f) and 65.158(a)(2). The criteria for approval and procedures for submission and review of broadly applicable alternative test methods are explained in a previous **Federal Register** notice published at 72 FR 4257 (January 30, 2007) and located at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods>. As explained in this notice, we will announce approvals for broadly applicable alternative test methods at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods> as they are issued and publish an annual notice that summarizes approvals for broadly applicable alternative test methods during the preceding year.

As also explained in the January 30, 2007 notice, our approval decisions involve thorough technical reviews of numerous source-specific requests for alternatives and modifications to test methods and procedures. Based on these reviews, we have often found that these modifications or alternatives would be equally valid and appropriate to apply to other sources within a particular class, category, or subcategory. Consequently, we have concluded that where either a method modification or an alternative method is clearly broadly applicable to a class, category, or subcategory of sources, it is both equitable and efficient to

simultaneously approve its use for all appropriate sources and situations.

Use of approved alternative test methods is not mandatory but rather permissive. Sources are not required to employ such a method but may choose to do so in appropriate circumstances. As specified in 40 CFR 63.7(f)(5), however, a source owner or operator electing to use an alternative method for 40 CFR part 63 standards must continue to use the alternative method until otherwise authorized. Source owners or operators should, therefore, review the specific broadly applicable alternative method approval decision at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods> before electing to employ any alternative method. Source owners or operators choosing to use a broadly applicable alternative should also notify their regulatory agency prior to using the alternative.

III. Approved Alternative Test Methods and Modifications to Test Methods

This notice specifies five broadly applicable alternative test methods that the EPA approved between January 1, 2022, and December 31, 2022. The alternative method decision letter/memo designation numbers, test methods affected, sources allowed to use this alternative, and method modifications or alternative methods allowed are summarized in Table 1 of this notice. A summary of approval documents was previously made available on our Technology Transfer Network between January 1, 2022, and December 31, 2022. For more detailed information, please refer to the complete copies of these approval documents available at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods>.

As also explained in our January 30, 2007 notice, we will revisit approvals of alternative test methods in response to written requests or objections indicating that a particular approved alternative test method either should not be broadly applicable or that its use is not appropriate or should be limited in some way. Any objection to a broadly applicable alternative test method, as well as the resolution of that objection, will be announced at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods> and in a subsequent **Federal Register** notice. If we decide to retract a broadly applicable test method, we will likely consider the need for an appropriate

transition period for users either to request case-by-case approval or to transition to an approved method.

Dated: January 13, 2023.
Richard A. Wayland,
Director, Air Quality Assessment Division.

TABLE 1—APPROVED ALTERNATIVE TEST METHODS AND MODIFICATIONS TO TEST METHODS REFERENCED IN OR PUBLISHED UNDER APPENDICES IN 40 CFR PARTS 60 AND 63 POSTED BETWEEN JANUARY 2022 AND DECEMBER 2022 ^a

Alternative method decision letter/memo No.	As an alternative or modification to . . .	For . . .	You may . . .
ALT-146	ASTM E2779-10—Standard Test Method for Determining Particulate Matter Emissions from Pellet Heaters.	Certification testing of pellet heaters subject to 40 CFR part 60, subpart AAA—Standards of Performance for New Residential Wood Heaters.	Use the modified methodology in the Agency’s memorandum dated February 2, 2022, entitled “Appropriate Calculation of Medium Burn Rate Category in ASTM E-2779 Testing to calculate the Medium Burn Rate Category to conduct certification testing on pellet heaters with the caveats in the Agency’s approval letter dated February 4, 2022.
ALT 147	GRI-GLYCalc software for modeling glycol dehydration unit emissions.	Sources subject to 40 CFR part 63, subpart HH—National Emission Standards for Hazardous Air Pollutants From Oil and Natural Gas Production Facilities.	Use Pro-Max, Version 5.0 or higher for modeling glycol dehydration unit emissions with the provisos specified in the Agency’s approval letter dated March 31, 2022.
ALT 148	Flow test methods specified in 40 CFR 63.565(d)(3)(iii).	Sources subject to 40 CFR part 63, subpart Y—National Emission Standards for Marine Tank Vessel Loading Operations.	Use Method 2B—Exhaust Volume Flow Rate.
ALT 149	SW-846 Method 8270D and SW-846 Method 8015C.	Sources subject to 40 CFR part 63, subpart HHHHHH—Polyvinyl Chloride and Copolymers Production: National Emission Standards for Hazardous Air Pollutants.	Use SW-846 Method 8270E and SW-846 Method 8015D with the provisos specified in the Agency’s approval letter dated July 27, 2022.
ALT 150	Surface Emission Monitoring (SEM) procedures required under the cited sections of the following subparts: 40 CFR 60, Subpart WWW, §§ 60.753(d) and 60.755(c)–(e); 40 CFR 60, Subpart XXX, §§ 60.763(d) and 60.765(c)–(d); 40 CFR 60, Subpart Cf, §§ 60.34f(d) and 60.36f(c)–(e); 40 CFR 62, Subpart OOO, §§ 62.16716(d) and 62.16720; 40 CFR 63, Subpart AAAA, §§ 63.1958(d) and 63.1960(c)–(d).	Sources subject to 40 CFR part 60, subparts WWW, XXX, and Cf (Emission Guidelines), 40 CFR part 62, subpart OOO (Federal Plan), and 40 CFR part 63, subpart AAAA.	Use Other Test Method 51 (OTM-51) with the provisos specified in the Agency’s approval letter dated December 15, 2022.

^aSource owners or operators should review the specific broadly applicable alternative method approval letter at <https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods> before electing to employ any alternative test method.

[FR Doc. 2023-01004 Filed 1-18-23; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2002-0059; FRL-10519-01-OW]

Proposed Information Collection Request; Clean Water State Revolving Fund and Drinking Water State Revolving Fund Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), “Clean Water State Revolving Fund and

Drinking Water State Revolving Fund Programs” (EPA ICR No. 1803.09 OMB Control No. 2040-0185) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, the EPA is soliciting public comments on specific aspects of the proposed information collection as described in the **SUPPLEMENTARY INFORMATION** section. This is a proposed renewal of the ICR, which is currently approved through August 31, 2023, for the Drinking Water State Revolving Fund (DWSRF). This ICR consolidates the DWSRF and Clean Water State Revolving Fund (CWSRF) ICRs (ICR No. 1803.08 and ICR NO. 1391.12, respectively) because they affect the same set of respondents in similar ways. Additional information collection

requirements made necessary by the Bipartisan Infrastructure Law (BIL) are similar for both programs. Therefore, EPA is consolidating the DWSRF and CWSRF ICRs, in addition to updating and renewing them, to provide a more coherent picture of the information components of EPA’s SRF program. An Agency may not conduct or sponsor a collection of information nor is a person required to respond unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before March 20, 2023.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA-HQ-OW-2002-0059, 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.

FOR FURTHER INFORMATION CONTACT:

Bizzy Berg, Drinking Water Infrastructure Development Division, Office of Ground Water and Drinking Water, 4606M, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202-564-7558; email address: Berg.Bizzy@epa.gov.

Mark Mylin, Water Infrastructure Division, Office of Wastewater Management, 4204M, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202-564-0607; email address: Mylin.Mark@epa.gov.

SUPPLEMENTARY INFORMATION:

Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Pursuant to section 3506(c)(2)(A) of the PRA (44 U.S.C. 3501 *et seq.*), EPA is soliciting comments and information to enable it to: (i) 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; (ii) 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; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) 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. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to the Office of

Management and Budget (OMB) for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The information collection activities will occur primarily at the program-level through the State Capitalization Grant Agreement/Intended Use Plan and Annual Report. The information on the Intended Use Plan (IUP) is needed annually to describe how the State intends to use available State Revolving Fund (SRF) funds for the year to meet the objectives of the Clean Water Act (CWA) or Safe Drinking Water Act (SDWA) and to further the goal of protecting public health. The Annual Report is needed to provide detailed information on how the State has met its goals and objectives of the previous one or two fiscal years as stated in the IUP and grant agreement. The CWA and SDWA require this information to ensure the national accountability, adequate public review and comment, fiscal integrity, and consistent management needed to achieve public health and CWA and SDWA compliance objectives.

Title VI of the CWA of 1987 established the Clean Water State Revolving Fund (CWSRF) program, which replaced the Environmental Protection Agency's (EPA) Construction Grants Program. As outlined in 40 CFR part 35, subpart K, State Water Pollution Control Revolving Funds, and EPA guidance, each State and Puerto Rico has its own CWSRF. The 1996 SDWA Amendments created the Drinking Water State Revolving Fund (DWSRF). Much like the CWSRF, each State and Puerto Rico has its own DWSRF, outlined in 40 CFR part 35, subpart L.

A State's CWSRF and DWSRF include funds provided by Federal capitalization grants, repayments from prior assistance agreements, interest that has been repaid to the SRF, and investment income. In some cases, a State SRF secures additional funding through bond proceeds. Each State designs and operates its own revolving fund to provide financial assistance to eligible recipients for water pollution control and drinking water safety activities.

The CWSRF and DWSRF were established as low-interest sources of funding for a wide range of water infrastructure projects and have the flexibility to use options beyond low interest loans. States have the authority to use the SRFs to issue and refinance loans, purchase or guarantee local debt, and purchase bond insurance. States may also set specific terms such as

interest rates and repayment periods. The CWSRF can also issue loan guarantees, and in 2009, Congress authorized States to provide further financial assistance via the CWSRF program in the form of grants, principal forgiveness, and negative interest rate loans. Under the DWSRF, a State may, at its discretion, establish disadvantaged community criteria and offer negative interest rates, principal forgiveness, and/or an extended repayment term.

Congress provides EPA annual appropriations for providing capitalization grants to State SRFs. EPA awards these grants to each State upon the State's submission of a grant application, which includes an IUP. While EPA provides oversight that ensures that States' procedures are consistent with the CWA or SDWA and accompanying regulations, the States have a great deal of autonomy in administering the program and selecting which projects receive funding. Additional information about the CWSRFs and DWSRFs are available at <https://www.epa.gov/cwsrf/learn-about-clean-water-state-revolving-fund-cwsrf> and <https://www.epa.gov/dwsrf/how-drinking-water-state-revolving-fund-works#tab-1>, respectively.

This ICR renews the OMB Number 2040-0185 DWSRF ICR and provides updated estimates of the reporting burden associated with the information collection activities for both DWSRF ICR and CWSRF ICR.

The individual information collections covered under this ICR are briefly described as follows:

(1) Capitalization Grant Agreement/Intended Use Plan

The Capitalization Grant Agreement is the principal instrument by which the State commits to manage its revolving fund program in conformity with the requirements of the CWA or SDWA. The grant agreement contains or incorporates by reference the IUP, application materials, payment schedule, required certifications, Operating Agreement (if used), and other documentation required by the Regional Administrator. Information on how an SRF program intends to use its funds for the upcoming year to meet the objectives of the CWA or SDWA can be found in the IUP. The agreement is a general instrument to legally commit the State and EPA to execute their responsibilities under the CWA or SDWA.

(2) Annual Report

The Annual Report indicates how the State has met its goals and objectives of the past fiscal year as stated in the grant

agreement and, more specifically, in the IUP. The Annual Report provides information on loan recipients, loan amounts, loan terms, project categories of eligible costs, and similar data on other forms of assistance. The Annual Report also describes the extent to which the existing CWSRF or DWSRF financial operating policies, alone or in combination with other State financial assistance programs, will provide for the long-term fiscal health of the SRFs and carry out other key provisions of the CWA or SDWA. Financial information from the Annual Report may be entered into the SRF Data System. The SRF Data System updated and consolidated the Project Benefits Reporting (PBR) System, CWSRF Benefits Reporting (CBR) System, Drinking Water National Information Management System (DWNIMS), and Clean Water National Information Management System (CWNIMS) into a single portal, where data can be collected on State SRF assistance agreements, annual State level SRF program activity, SRF borrower data, and State SRF program agency management data. Through consolidation of system, the SRF Data System can avoid duplication of data questions to State users, more easily ensure data consistency, and more easily use and share data from other EPA Systems.

(3) State Audit

A State must comply with the provisions of the Single Audit Act Amendments of 1996. Best management practices suggest, and the EPA recommends that a State conduct an annual independent audit of its SRF programs. The State Audit must contain an opinion on the financial condition of the SRF programs, a report on its internal controls, and a report on compliance with applicable laws and the CWA or SDWA. Therefore, a State may voluntarily agree to conduct annual independent audits.

(4) Financial and Project Data

To meet the CWA and SDWA objectives of “promoting the efficient use of fund resources” States must enter financial data, including project commitments and disbursements, into the SRF Data System on an annual basis. These data, also available to the public, are used by the EPA to assess compliance with the Program’s mandate to use all funds in an “expeditious and timely” manner and achieve maximum environmental benefits from the Fund. Project level data are collected on a quarterly basis using the SRF Data System to ensure CWA and SDWA eligibility and to highlight the projected

environmental and health benefits from SRF projects.

(5) SRF Public Awareness Requirements

Per EPA Grants Policy Issuance (GPI) 14–02: Enhancing Public Awareness of EPA Assistance Agreements, SRF borrowers must publicize EPA’s involvement in project funding only up to the funding amount in each year’s capitalization grant. The SRFs have various options to meet this requirement.

Though the CWSRF information collection activities closely mirror those of the DWSRF program, there are several key differences. Specifically, the CWA requires the CWSRFs to provide EPA with an Annual Report that documents program activity over the prior year. In addition, the DWSRF program includes several set-aside programs that are funded through the DWSRF capitalization grants. These set-aside programs cover activities that are separate from the funding provided by the DWSRFs for eligible water infrastructure projects. The use of the set-aside funds must be tracked through the various DWSRF information collection activities, including the IUPs and Annual Reports. The CWA does not provide similar set-aside programs for the CWSRFs.

With the exception of the public awareness requirements, the respondents for the information collection activities are the State environmental departments, State departments of health, requirements should not have an impact on small entities since the SRFs have flexibility in determining which borrowers must comply with these requirements.

Form Numbers: None.

Respondents/affected entities: Entities affected by this action are States and local governments.

Respondent’s obligation to respond: Required to obtain or retain a benefit per the Clean Water Act title VI and the Safe Drinking Water Act section 1452.

Estimated number of respondents: 2,836 State and local respondents (total).

Frequency of response: Varies by requirement (*i.e.*, quarterly, semi-annually, annually).

Total estimated burden: 186,518 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$17,688,247.00 (per year), includes \$6,354,600.00 annualized capital or operation & maintenance costs.

Changes in Estimates: The passage of the BIL created five new appropriations for SRF funding: CWSRF General Supplemental Funding, CWSRF

Emerging Contaminants Funding, DWSRF General Supplemental Funding, DWSRF Emerging Contaminants Funding, and DWSRF Lead Service Line Replacement Funding. For both the CWSRF and the DWSRF, the respondent average annual hourly burden increased, as EPA estimates more applications will be submitted due to this increase in funding. Additionally, wages increased for SRF State staff and SRF borrowers, which also increased the average annual costs to respondents. For the DWSRF, the Agency net average annual hourly and cost burden decreased so that the estimates were corrected and better aligned with those of the CWSRF. For the CWSRF, the Agency hourly burden remained the same as the previous CWSRF ICR, while the Agency cost burden increased to reflect an increase in employee wages. The total annual cost of burden estimate for both SRFs is higher than the previous ICR submitted since this ICR covers both the CWSRF and the DWSRF, while the previous ICR only applied to the DWSRF.

Jennifer L. McLain,

Director, Office of Ground Water and Drinking Water.

Andrew D. Sawyers,

Director, Office of Wastewater Management.

[FR Doc. 2023–00894 Filed 1–18–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1241; FR ID 123260]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission’s burden estimate; ways to enhance the quality, utility, and clarity of the

information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid 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 Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before March 20, 2023. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email PRA@fcc.gov and to nicole.ongele@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418-2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-1241.

Title: Connect America Phase II Auction Waiver Post-Selection Review.

Form Number: FCC Form 5625.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 50 respondents; 150 responses.

Estimated Time per Response: 2-4 hours.

Frequency of Response: Annual reporting requirements and one-time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151-154, 214, and 254.

Total Annual Burden: 500 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality:

There are no assurances of confidentiality. However, the Commission intends to keep the information private to the extent permitted by law. Also, respondents may request materials or information submitted to the Commission believed confidential to be withheld from public

inspection under 47 CFR 0.459 of the FCC's rules.

Needs and Uses: On January 26, 2017, the Commission released Connect America Fund; ETC Annual Reports and Certifications, WC Docket Nos. 10-90 and 14-58, Order, FCC 17-2 (New York Auction Order), which granted New York waiver of the Phase II auction program rules, subject to certain conditions. Specifically, the Commission made an amount up to the amount of Connect America Phase II model-based support that Verizon declined in New York—\$170.4 million—available to applicants selected in New York's New NY Broadband Program in accordance with the framework adopted in the New York Auction Order.

This information collection addresses the eligibility requirements that New York winning bidders must meet before the Wireline Competition Bureau (Bureau) will authorize them to receive Connect America Phase II support. For each New York winning bid that includes Connect America-eligible areas, the Commission authorizes Connect America support up to the total reserve prices of all of the Connect America Phase II auction eligible census blocks that are included in the bid, provided that New York has committed, at a minimum, the same dollar amount of New York support to the Connect America-eligible areas in that bid. Before Connect America Phase II support is authorized, the Bureau will closely review the winning bidders to ensure that they have met the eligibility requirements adopted by the Commission and that they are technically and financially qualified to meet the terms and conditions of Connect America support. To aid in collecting this information regarding New York State's winning bidders and the applicants' ability to meet the terms and conditions of Connect America Phase II support in a uniform fashion, parties must complete FCC Form 5625.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023-00962 Filed 1-18-23; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Tuesday, January 24, 2023 at 10:30 a.m. and its continuation at the conclusion of the open meeting on January 26, 2023.

PLACE: 1050 First Street NE, Washington, DC and virtual. (This meeting will be a hybrid meeting.)
STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Compliance matters pursuant to 52 U.S.C. 30109.

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer; Telephone: (202) 694-1220.

(Authority: Government in the Sunshine Act, 5 U.S.C. 552b.)

Vicktorija J. Allen,

Acting Deputy Secretary of the Commission.

[FR Doc. 2023-01107 Filed 1-17-23; 4:15 pm]

BILLING CODE 6715-01-P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

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

Agreement No.: 201398.

Agreement Name: Siem Car Carriers AS/Schuyler Line Navigation Company Space Charter Agreement.

Parties: Schuyler Line Navigation Company, LLC; Siem Car Carriers AS.

Filing Party: Ashley Craig, Venable LLP.

Synopsis: The Agreement authorizes the parties to charter space to each other on an ad hoc basis in all U.S. trades.

Proposed Effective Date: 2/20/2023.

Location: <https://www2.fmc.gov/FMC/Agreements.Web/Public/AgreementHistory/74502>.

Dated: January 13, 2023.

JoAnne O'Bryant,
Program Analyst.

[FR Doc. 2023-00963 Filed 1-18-23; 8:45 am]

BILLING CODE 6730-02-P

FEDERAL MARITIME COMMISSION

Sunshine Act Meetings

TIME AND DATE: January 25, 2023; 10:00 a.m.

PLACE: This meeting will be held at the Federal Maritime Commission at the address below and also streamed live at Federal Maritime Commission's YouTube Channel.

Federal Maritime Commission, 800 North Capitol St NW, 1st Floor Hearing Room, Washington, DC 20573

STATUS: Part of the meeting will be open to the public: held in-person at the Federal Maritime Commission for public attendants and also available to view streamed live on the Federal Maritime Commission's YouTube Channel. The rest of the meeting will be closed to the public.

The hearing will be held on January 25, 2023, at 10:00 a.m. in the Hearing Room of the Federal Maritime Commission and will be open for public observation. If technical issues prevent the Commission from live streaming, the Commission will post a recording of the public portion of the meeting on the Commission's YouTube Channel. Any person wishing to attend the meeting in-person should report to the Federal Maritime Commission with enough time to clear building security procedures. Health and safety protocols for meeting attendees will depend on the COVID-19 Community Transmission Level for Washington DC as determined on Friday, January 20, 2023. Pre-registered attendees will be notified of the required health and safety protocols before the meeting and no later than Tuesday, January 25, 2023. Additional meeting guidance can be found on www.fmc.gov.

MATTERS TO BE CONSIDERED:

PORTIONS OPEN TO THE PUBLIC:

1. Commissioner Bentzel, Update on Maritime Transportation Data Initiative
2. Staff Briefing on Ocean Shipping Reform Act of 2022
3. Staff Briefing, Economic and Competition Update

PORTIONS CLOSED TO THE PUBLIC:

1. Staff Briefing, Economic and Competition Update

CONTACT PERSON FOR MORE INFORMATION:
William Cody, Secretary, (202) 523-5725.

William Cody,
Secretary.

[FR Doc. 2023-01086 Filed 1-17-23; 4:15 pm]

BILLING CODE 6730-02-P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission.

ACTION: Notice and request for comment.

SUMMARY: The Federal Trade Commission (FTC) requests that the Office of Management and Budget (OMB) extend for three years the current Paperwork Reduction Act (PRA) clearance for information collection requirements contained in the Antitrust Improvements Act Rules (HSR Rules) and corresponding Notification and Report Form for Certain Mergers and Acquisitions (Notification and Report Form). That clearance expires on January 31, 2023.

DATES: Comments must be received by February 21, 2023.

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. The reginfo.gov web link is a United States Government website produced by OMB and the General Services Administration (GSA). Under PRA requirements, OMB's Office of Information and Regulatory Affairs (OIRA) reviews Federal information collections.

FOR FURTHER INFORMATION CONTACT:

Robert L. Jones, Assistant Director, Premerger Notification Office, Bureau of Competition, Federal Trade Commission, Room CC-5301, 600 Pennsylvania Avenue NW, Washington, DC 20580, or by telephone to (202) 326-2740.

SUPPLEMENTARY INFORMATION:

Title: HSR Rules and Notification and Report Form, 16 CFR parts 801-803.

OMB Control Number: 3084-0005.

Type of Review: Extension of a currently approved collection.

Likely Respondents: Merging Parties.

Estimated Annual Hours Burden: 262,579 hours [derived from 7,096 non-

index filings × 37 hours/each) + (12 index filings × two hours/each) + (one withdrawn transaction later restarted × three hours)].

Estimated Annual Cost Burden: \$120,786,340, which is derived from \$460/hour × 262,579 hours.

Abstract: Section 7A of the Clayton Act ("Act"), 15 U.S.C. 18a, as amended by the Hart-Scott-Rodino Antitrust Improvements Act of 1976, Public Law 94-435, 90 Stat. 1390, requires all persons contemplating certain mergers or acquisitions to file notification with the Commission and the Assistant Attorney General and to wait a designated period of time before consummating such transactions. Congress empowered the Commission, with the concurrence of the Assistant Attorney General, to require "that the notification . . . be in such form and contain such documentary material and information . . . as is necessary and appropriate" to enable the agencies "to determine whether such acquisitions may, if consummated, violate the antitrust laws." 15 U.S.C. 18a(d). Congress similarly granted rulemaking authority to, among other things, "prescribe such other rules as may be necessary and appropriate to carry out the purposes of this section." *Id.*

Pursuant to that section, the Commission, with the concurrence of the Assistant Attorney General, developed the HSR Rules and the corresponding Notification and Report Form.

On August 26, 2022, the Commission sought comment on the reporting requirements associated with the HSR Rules and corresponding Notification and Report Form. 87 FR 52569. No relevant comments were received. Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.*, the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for those information collection requirements.

Burden Statement

The following burden estimates are primarily based on FTC data concerning the number of HSR filings and FTC staff's informal consultations with leading HSR counsel for outside parties.

Estimated Total Annual Hours

In fiscal year 2022, the FTC received 6,518 non-index filings. Based on an average annual increase in filings of 4.3% in the pre-COVID fiscal years

2017–2019,¹ FTC staff projects an average of 7,096 non-index filings per year for fiscal years 2023–2025, the time period for which PRA clearance will be requested from OMB.² For index filings, FTC staff projects an average of 12 index filings for fiscal years 2023–2025, based on a rough average of 12 such filings per year over fiscal years 2017–2019. Retaining prior assumptions, FTC staff estimates that non-index filings require, on average, approximately 37 hours per filing and that index filings require an average of two hours per filing.³

On rare occasions, a transaction for which the HSR filing is automatically withdrawn during the merger review process (due to the parties' Securities and Exchange Commission filing indicating that the transaction has been terminated) could be subsequently restarted. Based on experience to date, this would occur approximately once every fifteen years, *i.e.*, a historical frequency of 0.067 transactions per year. FTC staff believes that this new filing would require the same work and diligence as any new non-index filing. Assuming, then, an average of 37 hours for one transaction, when applied to a historical frequency of 0.067, this amounts to an annual average of three hours, rounded up, for a withdrawn transaction later restarted.

Thus, the total estimated hours burden is 262,579 hours [(7,096 non-index filings × 37 hours/each) + (12 index filings × two hours/each) + (one withdrawn transaction later restarted × three hours)].

¹ Due to the exceptional volatility in the number of filings in fiscal years 2020 and 2021, data for these years was not included in the estimation of the annual growth rate of filings.

² The number of non-index filings and the projected annual average of non-index filings are updated from the estimates provided in the Commission's August 2022 Notice. See 87 FR 52569, 52570 (2022) (estimating that the FTC would receive 6,580 non-index filings in fiscal year 2022 and projecting an average of 7,160 non-index filings per year for fiscal years 2023–2025).

³ Index filings pertain to certain transactions described in Sections 7A(c)(6) and (c)(8) of the Clayton Act that are subject to the approval of other agencies and are exempt from the requirements of the premerger notification program. Index filings are incorporated into the FTC's currently cleared burden estimates, because the parties to these exempt transactions must file copies of the information submitted to the other agencies with the Commission and the Assistant Attorney General. However, the task of filing a copy of information provided to another agency requires significantly less time than the preparation of a filing for a non-exempt transaction.

Estimated Total Annual Labor Cost

Using the burden hours (262,579) estimated above and applying an estimated average of \$460/hour for executive and/or attorney compensation, FTC staff estimates that the total labor cost associated with the HSR Rules and the Notification and Report Form is approximately \$120,786,340.

Estimated Total Annual Non-Labor Cost

The applicable requirements impose minimal start-up costs, as businesses subject to the HSR Rules generally have or obtain necessary equipment for other business purposes. Staff believes that the above requirements necessitate ongoing, regular training so that covered entities stay current and have a clear understanding of federal mandates, but such training would be subsumed within the ordinary training that employees receive.

Request for Comments

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2023–00891 Filed 1–18–23; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–OH–22–001, Panel A, Occupational Safety and Health Education and Research Centers (ERC); Amended Notice of Closed Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–OH–22–001, Panel A, Occupational Safety and Health Education and Research Centers (ERC); February 21–22, 2023, 12:00 p.m.–5:00 p.m., EST, in the original FRN. The meeting was published in the **Federal Register** on December 9, 2022, Volume 87, Number 236, page 75633. The meeting is being amended to change the Notice of Funding Opportunity (NOFO) number and should read as follows:

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–OH–23–003, Panel A, Occupational Safety and Health Education and Research Centers (ERC).

The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT: Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505; Telephone: (304) 285–5951; Email: MGoldcamp@cdc.gov.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–00899 Filed 1–18–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA—OH—22—001, Panel B, Occupational Safety and Health Education and Research Centers (ERC); Amended Notice of Closed Meeting**

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA—OH—22—001, Panel B, Occupational Safety and Health Education and Research Centers (ERC); February 23–24, 2023, 12 p.m.–5 p.m., EST, in the original FRN. The meeting was published in the **Federal Register** on December 9, 2022, Volume 87, Number 236, page 75632. The meeting is being amended to change the Notice of Funding Opportunity (NOFO) number and should read as follows:

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA—OH—23—003, Panel B, Occupational Safety and Health Education and Research Centers (ERC).

The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT: Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505; Telephone: (304) 285–5951; Email: MGoldcamp@cdc.gov.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–00901 Filed 1–18–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA–2013–N–0403]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Protection of Human Subjects and Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by February 21, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0130. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Protection of Human Subjects; Informed Consent; and Institutional Review Boards—21 CFR Parts 50 and 56

OMB Control Number 0910–0130—Extension

This information collection supports Agency regulations pertaining to the protection of human subjects, informed consent, and responsibilities of institutional review boards (IRBs) as set forth in parts 50 and 56 (21 CFR parts 50 and 56). Parts 50 and 56 apply to all

clinical investigations regulated by FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) and 360j)(g), respectively), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA. The regulations in parts 50 and 56 are intended to protect the rights and safety of subjects involved in such investigations. The regulations also contain the standards for composition, operation, and responsibilities of IRBs that review clinical investigations regulated by FDA.

21 CFR Part 50—Protection of Human Subjects

Provisions in part 50 provide for the protection of human subjects involved in FDA-regulated clinical investigations. With few exceptions, no investigator may involve a human being as a subject in FDA-regulated research unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. Basic elements of informed consent are set forth in § 50.25 (21 CFR 50.25) and include, among other things: (1) a statement of the purpose and duration of a subject’s participation in the research; (2) a description of the procedures to be followed; (3) identification of any experimental procedures; (4) a description of risks, benefits, and appropriate alternative procedures or treatments; (5) a description of extent to which confidentiality of records identifying the subject will be maintained; (6) certain contact information; and (7) a statement that participation is voluntary and may be discontinued at any time. Additional elements set forth in § 50.25 are required in the informed consent as appropriate. Exceptions to these requirements are governed by 21 CFR 50.23, which requires both investigator and physician to certify in writing that necessary elements for exception from general requirements have been satisfied; and § 50.24 (21 CFR 50.24), which covers exception from informed consent requirements for emergency research. In accordance with § 50.27 (21 CFR 50.27) informed consent must be documented, except as provided in § 56.109(c) (21 CFR 56.109(c)), which provides for an IRB to waive documentation of informed consent in certain circumstances.

Informed consent must be documented using a written consent form approved by the IRB and signed and dated by the subject or the subject’s legally authorized representative at the

time of consent. For each clinical investigation reviewed by an IRB, we believe there will typically be one associated written consent form developed by an investigator. In some cases, investigators will seek IRB approval of changes in the research and/or consent form after initial IRB approval. For some multi-institutional clinical investigations, the IRB of each institution involved may separately conduct initial and continuing review of the research, including review of the written consent form to determine whether it is in accordance with § 50.25. However, in cases where a multi-institutional clinical investigation uses a single IRB review process, there may only be one IRB conducting such reviews. Additional safeguards are required for children, as prescribed in subpart D (21 CFR 50.50 through 50.56) of the regulations.

21 CFR Part 56—Institutional Review Boards

The general standards for the composition, operation, and responsibilities of an IRB are set forth in part 56. IRBs serve in an oversight capacity by reviewing, among other things, informed consent documents and protocols for FDA-regulated studies, to make findings required to approve research, and document IRB actions. Part 56 also regulates the administrative activities of IRBs reviewing FDA-regulated research including, among other things, identification of types of IRB records that must be prepared and maintained. Required recordkeeping includes documentation pertaining to written procedures, proposals reviewed, committee membership, meeting minutes, actions taken by the IRB, correspondence, as well as other

functional and operational aspects of the IRB. Finally, the regulations describe administrative actions for noncompliance, including both disqualification of IRBs or IRB parent institutions, as well as reinstatement and alternative and additional actions.

Description of Respondents: Respondents to the information collection are IRBs that review and approve clinical investigations regulated by FDA and clinical investigators of such research who obtain informed consent of human subjects prior to research participation.

In the **Federal Register** of June 24, 2022 (87 FR 37867), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

We estimate the annual burden for the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
56.113; suspension or termination of research	2,520	1	2,520	0.5 (30 minutes)	1,260
56.120(a); IRB response to lesser administration actions for noncompliance.	7	1	7	10	70
56.123; reinstatement of an IRB or an institution	1	1	1	5	5
Total					1,335

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on available data, there are approximately 2,520 IRBs overseeing FDA-regulated clinical research. We have organized the table summarizing estimated annual reporting burden to

list only one requirement per row recognizing that some provisions may also include recordkeeping or third-party disclosure tasks. We believe we have accounted for all burden

cumulatively across the information collection activity tables and invite comments on our estimates.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
50.24; exceptions from informed consent for emergency research.	8	3	24	1	24
50.27; documentation of informed consent	2,520	40	100,800	0.5 (30 minutes)	50,400
56.115; IRB records (documentation of IRB activities)	2,520	14.6	36,792	40	1,471,680
Total					1,522,104

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We characterize activities associated with §§ 50.24 and 50.27 as recordkeeping burden. We assume each of the 2,520 IRBs meets an average of

14.6 times annually and assume 40 hours of person-time per meeting are required to meet the IRB recordkeeping requirements of § 56.115. We also

assume most recordkeeping is completed electronically.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
50.25; elements of informed consent	2,520	40	100,800	0.5 (30 minutes)	50,400

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN¹—Continued

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
56.109(d); written statement about minimal risk research when documentation of informed consent is waived.	2,520	2	5,040	0.5 (30 minutes)	2,520
56.109(e); written notification to approve or disapprove research.	2,520	40	100,800	0.5 (30 minutes)	50,400
56.109(g); IRB written statement about public disclosures to sponsor of emergency research under § 50.24.	8	2	16	1	16
Total	103,336

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We characterize activities associated with §§ 50.25 and 56.109(d) and (e) as disclosure burden. We estimate that eight IRBs per year will receive a request to review emergency research under § 50.24, thus requiring written notification under § 56.109(g) from the IRB to the sponsor. We estimate that it will take an IRB approximately 1 hour to prepare each written statement, for a total of 2 hours per study. The total annual third-party disclosure burden for IRBs to fulfill this requirement is estimated at 16 hours.

Dated: January 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-00974 Filed 1-18-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0084]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Program for Medical Devices (Medical Product Safety Network)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice

solicits comments on information collections associated with the Adverse Event Program for Medical Devices (Medical Program Safety Network (MedSun)).

DATES: Either electronic or written comments on the collection of information must be submitted by March 20, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 20, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a

written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier** (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-0084 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Program for Medical Devices (Medical Product Safety Network)." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information

redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44

U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun))

OMB Control Number 0910-0471—Extension

Section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i) authorizes FDA to require: (1) manufacturers to report medical device-related deaths, serious injuries, and malfunctions and (2) user facilities to report device-related deaths directly to manufacturers and FDA and serious injuries to the manufacturer. Section 213 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) amended section 519(b) of the FD&C Act relating to mandatory reporting by user facilities of

deaths, serious injuries, and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a “. . . subset of user facilities that constitutes a representative profile of user reports” for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the FD&C Act (21 U.S.C. 360i(b)(5)(A)). This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high-quality data on medical devices in clinical use. This system is called MedSun. FDA is seeking OMB clearance to continue to use electronic data collection to obtain information related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities, and for additional questions, which will permit FDA to better understand the cause of reported adverse events. Participation in the program is voluntary and includes approximately 300 facilities. In addition to collecting data on the electronic adverse event report form, MedSun collects additional information from participating sites about reported problems emerging from the MedSun hospitals. This data collection is also voluntary and is collected on the same website as the report information. The burden estimate is based on the number of facilities participating in MedSun (300). FDA estimates an average of 18 reports per site annually. This estimate is based on MedSun working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric intensive care units, the electrophysiology laboratories, and the hospital laboratories.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Adverse event reporting	300	18	5,400	0.5 (30 minutes)	2,700

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: January 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-00926 Filed 1-18-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3657]

Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation Scheme for Conformity Assessment Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the Accreditation Scheme for Conformity Assessment (ASCA) Program.

DATES: Either electronic or written comments on the collection of information must be submitted by March 20, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 20, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments.

Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-3657 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation Scheme for Conformity Assessment Program." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including

the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites

comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Accreditation Scheme for Conformity Assessment Program

OMB Control Number 0910-0889—
Extension

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d(d)) by adding a new subsection (d) entitled "Accreditation Scheme for Conformity Assessment."

Section 514(d) of the FD&C Act required FDA to establish a pilot program under which testing laboratories may be accredited by accreditation bodies meeting criteria specified by FDA to assess the conformance of a device within certain FDA-recognized standards. Determinations by accredited testing laboratories that a device conforms with an eligible standard included as part of the ASCA Program shall be accepted by FDA for the purposes of demonstrating such conformity unless FDA finds that a particular such determination shall not be so accepted.

The statute provides that FDA may review determinations by accredited testing laboratories, including by conducting periodic audits of such determinations or processes of accreditation bodies or testing laboratories.

Following such a review, or if FDA becomes aware of information materially bearing on safety or effectiveness of a device assessed by an accredited testing laboratory, FDA may take additional measures as determined appropriate, including suspension or withdrawal of accreditation of a testing laboratory or a request for additional information regarding a specific device.

FDA issued the final guidance "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program" (<https://www.fda.gov/media/130901/download>) to discuss the goals and

implementation of the voluntary ASCA Pilot Program (hereafter referred to as the ASCA Program in accordance with amendments made to section 514 of the FD&C Act by FDARA, and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV)).

The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Program supports the Agency's continued efforts to use its scientific resources effectively and efficiently to protect and promote public health. FDA believes the voluntary ASCA Program may further encourage international harmonization of medical device regulation because it incorporates elements, where appropriate, from a well-established set of international conformity assessment practices and standards (e.g., ISO/IEC 17000 series). The voluntary ASCA Program does not supplant or alter any other existing statutory or regulatory requirements governing the decision-making process for premarket submissions.

Under the ASCA Program's conformity assessment scheme, recognized accreditation bodies accredit testing laboratories using ASCA program specifications associated with each eligible standard and ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories. ASCA-accredited testing laboratories may conduct testing to determine conformance of a device with at least one of the standards eligible for inclusion in the ASCA Program. When an ASCA-accredited testing laboratory conducts such testing, it may provide a complete test report to the device manufacturer. A device manufacturer who utilizes an ASCA-accredited testing laboratory to perform testing in accordance with the provisions of the ASCA Program can then include a declaration of conformity with supplemental documentation (including a summary test report) as part of a premarket submission to FDA. Testing performed by an ASCA-accredited testing laboratory can be used to support a premarket submission for any device if the testing was conducted using a standard eligible for inclusion in the ASCA Program and in accordance with the ASCA program specifications for that standard.

The ASCA Program includes participation from accreditation bodies, testing laboratories, device manufacturers, and FDA staff. Each of these entities plays a critical role in the ASCA Program to ensure that patients and healthcare providers have timely

and continued access to safe, effective, and high-quality medical devices.

To participate in the ASCA Program, accreditation bodies and testing laboratories apply to FDA to demonstrate that they have the qualifications for their respective roles within the program. An application includes agreement to terms of participation. For example, a participating accreditation body or testing laboratory agrees to attend training, regularly communicate with FDA, and support periodic FDA audits. FDA recognizes qualified applicants as participants. In its recognition, FDA will identify the scope of recognition of specific standards and test methods to which each participant may accredit or test as part of the ASCA Program.

After recognizing a testing laboratory as a participant in the ASCA Program, FDA will generally grant the testing laboratory ASCA Accreditation. During the ASCA Program, FDA generally will accept determinations from ASCA-accredited testing laboratories that a medical device is in conformity with the specified testing to a particular standard and does not intend to review complete test reports from ASCA-accredited testing laboratories in support of a declaration of conformity submitted with a premarket submission except in certain circumstances.

Note that ASCA Accreditation is separate from any accreditation that an accreditation body may provide to a testing laboratory for purposes other than the ASCA Program. FDA's decision to recognize the accreditation for purposes of the ASCA Program is separate and distinct from any independent decision by the accreditation body with respect to a testing laboratory for purposes outside of the ASCA Program.

The ASCA Program does not address specific content for a particular premarket submission. Information collections associated with premarket submissions have been previously approved.

FDA plans to issue draft guidance updates to the three published ASCA Pilot guidance documents¹ to improve

¹ The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program | FDA (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program>). Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program | FDA (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and>).

and streamline the ASCA Program. The guidance updates are being issued to discuss the lessons learned during ASCA’s pilot phase and to also facilitate the transition from a pilot to a

permanent program. As a result of these guidance updates, there is minimal adjustment to the burden estimate. Respondents are accreditation bodies (ABs) and testing laboratories (TLs). In

tables 1 through 3, these abbreviations are used.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours ²
Application by AB for <i>ASCA Recognition</i>	8	1	8	6	48
Request by AB to continue <i>ASCA Recognition</i>	2	1	2	6	12
Request by AB for <i>ASCA Recognition</i> (subsequent to withdrawal).	1	1	1	6	6
Request by AB to expand scope of <i>ASCA Recognition</i> .	1	1	1	6	6
AB annual status report	8	1	8	3	24
AB notification of change	8	1	8	1	8
Application by TL for <i>ASCA Accreditation</i>	150	1	150	4	600
Request by TL to continue <i>ASCA Accreditation</i>	75	1	75	4	300
Request by TL for <i>ASCA Accreditation</i> (subsequent to withdrawal or suspension).	5	1	5	4	20
Request by TL to expand scope of <i>ASCA Accreditation</i> .	75	1	75	4	300
TL annual status report	150	1	150	1.5	225
TL notification of change	5	1	5	1	5
Request for withdrawal or suspension of <i>ASCA Accreditation</i> (TLs) or request for withdrawal of <i>ASCA Recognition</i> (ABs).	6	1	6	0.08 (5 minutes)	1
Pilot feedback questionnaire (ABs and TLs)	158	1	158	0.5 (30 minutes)	79
Total					1,634

¹ Totals have been rounded to the nearest hour.

² There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
AB setup documentation standard operating procedures (SOPs) & training (one-time burden)	3	1	3	25	75
TL setup documentation SOPs & training (one-time burden)	20	1	20	25	500
AB record maintenance	8	1	8	1	8
TL record maintenance	150	1	150	1	150
Total					733

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Request for Accreditation (TLs requesting accreditation from ABs).	150	1	150	0.5 (30 minutes)	75
Review/Acknowledgement of accreditation request (ABs).	8	22	176	40	7,040
Test Reports (TLs)	880	1	880	1	880
Total					7,995

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate of eight ABs is based on the number of International Laboratory Accreditation Cooperation signatories in the U.S. economy. We estimate that approximately 150 testing labs will seek accreditation. Our estimate of Test Reports is based on the number of premarket submissions we expect per year with testing from an ASCA-accredited testing laboratory.

Our estimates for the average burden per response, recordkeeping, and disclosure are based on our experience with the pilot program.

Our estimated burden for the information collection reflects an overall decrease of 3,129 hours and an increase of 94 responses/records. We attribute this adjustment to a decrease in the one-time burden for accreditation bodies and testing laboratories training and SOPs because much of this activity was completed during the pilot. In addition, there is an increase in the annual responses/records because there is an increase in renewal requests (Request by AB to continue *ASCA Recognition* and Request by TL to continue *ASCA Accreditation*) since the pilot program was initiated.

Dated: January 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-00973 Filed 1-18-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Public Health Service Act, and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

DATES: Thursday, February 9, 2023, from 9:30 a.m. to 3 p.m. Eastern Time (ET) and Friday, February 10, 2023, from 9:30 a.m. to 2 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required. Please visit the ACHDNC website for information on registration: <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html> by the deadline of 12 p.m. ET on February 8, 2023. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301-443-0721; or ACHDNC@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel (RUSP), following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.*, policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the February 9-10, 2023, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

(1) Presentation of the final evidence-based review report on the Krabbe disease condition nomination for possible inclusion on the RUSP. Following this report presentation, the ACHDNC expects to vote on whether to

recommend to the Secretary adding Krabbe Disease to the RUSP;

(2) An update by the ACHDNC Prioritization and Capacity workgroup;

(3) A possible presentation from the Center for Disease Control and Prevention's Enhancing Data Driven Disease Detection in Newborns Project;

(4) A potential update on the HRSA-funded Newborn Screening Interoperability Programs;

(5) A presentation on the Blueprint for Change, which outlines an agenda for advancing the system of services for children and youth with special health care needs (see <https://mchb.hrsa.gov/programs-impact/focus-areas/children-youth-special-health-care-needs-cyshcn/blueprint-change>);

(6) Workgroup updates; and

(7) A potential update on the Duchenne muscular dystrophy condition nomination and a potential vote on whether to move it forward to full evidence-based review, which, depending on the strength of the evidence, could lead to a future recommendation to add this condition to the RUSP.

The agenda for this meeting includes a potential vote to recommend a nominated condition (Krabbe Disease) be added by the Secretary to the RUSP. In addition, as noted in the agenda items, the Committee may hold a vote on whether or not to recommend a nominated condition (Duchenne muscular dystrophy) to full evidence-based review, which may lead to a recommendation to add or not add this condition to the RUSP at a future time.

Agenda items are subject to change as priorities dictate. Information about the ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website.

Members of the public also will have the opportunity to provide comments on any or all of the above agenda items. Public participants may request to provide general oral comments and may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Subject to change: members of the public registered to submit oral public comments on Krabbe Disease are tentatively scheduled to provide their statements on Thursday, February 9, 2023. Members of the public registered to provide oral public comments on all other newborn screening related topics are tentatively scheduled to provide their statements on Friday, February 10, 2023. Requests to provide a written statement or make oral comments to the ACHDNC must be submitted via the registration website by 12 p.m. ET on

Thursday, January 26, 2023. Written comments will be shared with the Committee, so that they have an opportunity to consider them prior to the meeting.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023-00964 Filed 1-18-23; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of First Meeting of the 2025 Dietary Guidelines Advisory Committee and Request for Comments

AGENCY: Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS); Food, Nutrition, and Consumer Services (FNCS), U.S. Department of Agriculture (USDA).

ACTION: Notice.

SUMMARY: The U.S. Departments of Health and Human Services and Agriculture announce the first meeting of the newly appointed 2025 Dietary Guidelines Advisory Committee (Committee). This meeting will be open to the public virtually. Additionally, this notice opens a public comment period that will remain open until late 2024, throughout the Committee's deliberations.

DATES: The first meeting will be held February 9–10, 2023. The public comment period opens with the publication of this notice.

ADDRESSES:

(a) The meeting will be accessible online via livestream and recorded for later viewing. Registrants will receive the livestream information prior to the meeting.

(b) You may send comments, identified by Docket OASH–2022–0021, by either of the following methods:

- *Online (preferred method):* Federal eRulemaking Portal: <http://www.regulations.gov>.

- *Mail:* Janet M. de Jesus, MS, RD, HHS/OASH Office of Disease Prevention and Health Promotion (ODPHP), 1101 Wootton Parkway, Suite 420, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket OASH–2022–0021. For detailed instructions on sending comments, see

the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Designated Federal Officer, 2025 Dietary Guidelines Advisory Committee, Janet M. de Jesus, MS, RD; HHS/OASH/ODPHP, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852; Phone: 240–453–8266; Email DietaryGuidelines@hhs.gov. Additional information is available on the internet at www.DietaryGuidelines.gov.

SUPPLEMENTARY INFORMATION:

Authority and Purpose: Under section 301 of Public Law 101–445 (7 U.S.C. 5341, the National Nutrition Monitoring and Related Research Act of 1990, title III), the Secretaries of HHS and USDA are directed to publish the *Dietary Guidelines for Americans (Dietary Guidelines)* jointly at least every five years. The law instructs that this publication shall contain nutritional and dietary information and guidelines for the general public; shall be based on the preponderance of scientific and medical knowledge current at the time of publication; and shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program. The current edition of the *Dietary Guidelines (2020–2025)* provides guidance on the entire lifespan, from birth to older adulthood, including pregnancy and lactation. The *Dietary Guidelines for Americans, 2025–2030* will continue to provide food-based dietary guidance across the entire lifespan to help meet nutrient needs, promote health, and reduce the risk of chronic disease. HHS and USDA appointed the 2025 Dietary Guidelines Advisory Committee (Committee) to conduct an independent scientific review that will help inform the Departments' development of the next edition of the *Dietary Guidelines*. The Committee's review and advice will focus on the scientific questions prioritized by HHS and USDA, with the potential to inform nutrition guidance for Americans across the lifespan. Information on the 2025 Committee membership and the scientific questions will be available at www.DietaryGuidelines.gov.

The 2025 Committee's formation is governed under the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. app), which sets forth standards for the formation and use of advisory committees.

Committee's Task: The work of the Committee will be solely advisory in nature and time limited. The Committee will examine evidence on the scientific questions, using approaches including

systematic reviews, food pattern modeling, and data analysis. The Committee will then develop a scientific report to be submitted to the HHS and USDA Secretaries. The scientific report should describe the Committee's review and conclusions and provide science-based advice and rationale to the Departments based on the preponderance of evidence reviewed. HHS and USDA will consider the Committee's scientific report as they develop the *Dietary Guidelines for Americans, 2025–2030*. The Committee will hold approximately six meetings, open to the public virtually, to review the evidence and discuss recommendations. Future meeting dates, times, and other relevant information will be announced via **Federal Register** notice and at www.DietaryGuidelines.gov. As stipulated in the charter, the Committee will disband after delivery of its final report to the Secretaries of HHS and USDA, or two years from the date the charter was filed, whichever comes first.

Purpose of the Meeting: In accordance with FACA, and to promote transparency of the process, deliberations of the Committee will occur in a public forum. The purpose of this first meeting is to orient the Committee to the *Dietary Guidelines* process and mark the beginning of its work.

Meeting Agenda: The first meeting agenda will include (a) review of operations for the Committee members, (b) overview of the proposed scientific questions identified by the Departments to be examined by the Committee, (c) presentations on the evidence-based approaches for reviewing the scientific evidence, and (d) plans for future Committee work.

Meeting Registration: The meeting is open to the public. The meeting will be accessible online via livestream and recorded for later viewing. Registration is required for the livestream. To register, go to

www.DietaryGuidelines.gov and click on the link for "Meeting Registration." Online registration begins on January 18, 2023 and ends on February 10, 2023. To request a sign language interpreter or other special accommodations, please email dietaryguidelines@hhs.gov by February 5, 2023. All registrants will be asked to provide their name, affiliation, email address, and days attending. After registration, individuals will receive livestream access information via email.

Public Comments and Meeting Documents: Written comments from the public will be accepted throughout the Committee's deliberative process for the next approximately two years.

Opportunities to present oral comments to the Committee will be provided at a future meeting.

- *Online (preferred method):* Follow the instructions for submitting comments at www.regulations.gov. Comments submitted electronically, including attachments, will be posted to Docket OASH–2022–0021.

- *Mail:* Mail/courier to Janet M. de Jesus, MS, RD, HHS/OASH/ODPHP, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852. For written/paper submissions, ODPHP will post your comment, as well as any attachments, to www.regulations.gov.

Meeting materials for each meeting will be accessible at www.DietaryGuidelines.gov. Materials may be requested by email at dietaryguidelines@hhs.gov.

Paul Reed,

Deputy Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

[FR Doc. 2023–00921 Filed 1–18–23; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Annual Update of the HHS Poverty Guidelines

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice provides an update of the Department of Health and Human Services (HHS) poverty guidelines to account for last calendar year’s increase in prices as measured by the Consumer Price Index.

DATES: January 12, 2023 unless an office administering a program using the guidelines specifies a different effective date for that particular program.

ADDRESSES: Office of the Assistant Secretary for Planning and Evaluation, Room 404E, Humphrey Building, Department of Health and Human Services, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: For information about how the guidelines are used or how income is defined in a particular program, contact the federal, state, or local office that is responsible for that program. For information about poverty figures for immigration forms, the Hill-Burton Uncompensated Services Program, and the number of people in poverty, use the specific telephone numbers and addresses given below.

For general questions about the poverty guidelines themselves, contact

Kendall Swenson, Office of the Assistant Secretary for Planning and Evaluation, Room 404E.3, Humphrey Building, Department of Health and Human Services, Washington, DC 20201—telephone: (202) 795–7309—or visit <http://aspe.hhs.gov/poverty/>.

For information about the percentage multiple of the poverty guidelines to be used on immigration forms such as USCIS Form I–864, Affidavit of Support, contact U.S. Citizenship and Immigration Services at 1–800–375–5283. You also may visit <https://www.uscis.gov/i-864>.

For information about the Hill-Burton Uncompensated Services Program (free or reduced-fee health care services at certain hospitals and other facilities for persons meeting eligibility criteria involving the poverty guidelines), visit <https://www.hrsa.gov/get-health-care/affordable/hill-burton/index.html>.

For information about the number of people in poverty, visit the Poverty section of the Census Bureau’s website at <https://www.census.gov/topics/income-poverty/poverty.html> or contact the Census Bureau’s Customer Service Center at 1–800–923–8282 (toll-free) or visit <https://ask.census.gov> for further information.

SUPPLEMENTARY INFORMATION:

Background

Section 673(2) of the Omnibus Budget Reconciliation Act (OBRA) of 1981 (42 U.S.C. 9902(2)) requires the Secretary of the Department of Health and Human Services to update the poverty guidelines at least annually, adjusting them on the basis of the Consumer Price Index for All Urban Consumers (CPI–U). The poverty guidelines are used as an eligibility criterion by Medicaid and a number of other federal programs. The *poverty guidelines* issued here are a simplified version of the *poverty thresholds* that the Census Bureau uses to prepare its estimates of the number of individuals and families in poverty.

As required by law, this update is accomplished by increasing the latest published Census Bureau poverty thresholds by the relevant percentage change in the Consumer Price Index for All Urban Consumers (CPI–U). The guidelines in this 2023 notice reflect the 8.0 percent price increase between calendar years 2021 and 2022. After this inflation adjustment, the guidelines are rounded and adjusted to standardize the differences between family sizes. In rare circumstances, the rounding and standardizing adjustments in the formula result in small decreases in the poverty guidelines for some household sizes even when the inflation factor is

not negative. In cases where the year-to-year change in inflation is not negative and the rounding and standardizing adjustments in the formula result in reductions to the guidelines from the previous year for some household sizes, the guidelines for the affected household sizes are fixed at the prior year’s guidelines. As in prior years, these 2023 guidelines are roughly equal to the poverty thresholds for calendar year 2022 which the Census Bureau expects to publish in final form in September 2023.

The poverty guidelines continue to be derived from the Census Bureau’s current official poverty thresholds; they are not derived from the Census Bureau’s Supplemental Poverty Measure (SPM).

The following guideline figures represent annual income.

2023 POVERTY GUIDELINES FOR THE 48 CONTIGUOUS STATES AND THE DISTRICT OF COLUMBIA

Persons in family/household	Poverty guideline
1	\$14,580
2	19,720
3	24,860
4	30,000
5	35,140
6	40,280
7	45,420
8	50,560

For families/households with more than 8 persons, add \$5,140 for each additional person.

2023 POVERTY GUIDELINES FOR ALASKA

Persons in family/household	Poverty guideline
1	\$18,210
2	24,640
3	31,070
4	37,500
5	43,930
6	50,360
7	56,790
8	63,220

For families/households with more than 8 persons, add \$6,430 for each additional person.

2023 POVERTY GUIDELINES FOR HAWAII

Persons in family/household	Poverty guideline
1	\$16,770
2	22,680
3	28,590
4	34,500

2023 POVERTY GUIDELINES FOR HAWAII—Continued

Persons in family/household	Poverty guideline
5	40,410
6	46,320
7	52,230
8	58,140

For families/households with more than 8 persons, add \$5,910 for each additional person.

Separate poverty guideline figures for Alaska and Hawaii reflect Office of Economic Opportunity administrative practice beginning in the 1966–1970 period. (Note that the Census Bureau poverty thresholds—the version of the poverty measure used for statistical purposes—have never had separate figures for Alaska and Hawaii.) The poverty guidelines are not defined for Puerto Rico or other outlying jurisdictions. In cases in which a federal program using the poverty guidelines serves any of those jurisdictions, the federal office that administers the program is generally responsible for deciding whether to use the contiguous-states-and-DC guidelines for those jurisdictions or to follow some other procedure.

Due to confusing legislative language dating back to 1972, the poverty guidelines sometimes have been mistakenly referred to as the “OMB” (Office of Management and Budget) poverty guidelines or poverty line. In fact, OMB has never issued the guidelines; the guidelines are issued each year by the Department of Health and Human Services. The poverty guidelines may be formally referenced as “the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2).”

Some federal programs use a percentage multiple of the guidelines (for example, 125 percent or 185 percent of the guidelines), as noted in relevant authorizing legislation or program regulations. Non-federal organizations that use the poverty guidelines under their own authority in non-federally-funded activities also may choose to use a percentage multiple of the guidelines.

The poverty guidelines do not make a distinction between farm and non-farm families, or between aged and non-aged units. (Only the Census Bureau poverty thresholds have separate figures for aged and non-aged one-person and two-person units.)

This notice does not provide definitions of such terms as “income” or

“family” as there is considerable variation of these terms among programs that use the poverty guidelines. The legislation or regulations governing each program define these terms and determine how the program applies the poverty guidelines. In cases where legislation or regulations do not establish these definitions, the entity that administers or funds the program is responsible to define such terms as “income” and “family.” Therefore questions such as net or gross income, counted or excluded income, or household size should be directed to the entity that administers or funds the program.

Dated: January 12, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–00885 Filed 1–18–23; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Center for Advancing Translational Sciences; 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 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; SBIR Phase I Topic 023 Contract Review.

Date: February 15, 2023.

Time: 9 a.m. to 1 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892.

Contact Person: Rahat (Rani) Khan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892, (301) 594–7319, kharr2@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: January 13, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–00993 Filed 1–18–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of Dental and Craniofacial Research; 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 Dental and Craniofacial Research Special Emphasis Panel; DSR Member Conflict Applications Meeting.

Date: February 17, 2023.

Time: 11 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aiwu Cheng, Ph.D., MD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Bethesda, MD 20892, 301–594–4859, Aiwu.cheng@nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: January 13, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–00995 Filed 1–18–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; GEMSSTAR.
Date: March 3, 2023.

Time: 10 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ramesh Vemuri, Ph.D., Chief, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C-212, Bethesda, MD 20892, 301-402-7700, rv23r@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 13, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-00992 Filed 1-18-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; 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 Center for Advancing Translational Sciences Special Emphasis Panel; Understudied Proteins Associated with Rare Diseases.

Date: March 7-8, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Alomit Ishai, Ph.D., Scientific Review Officer, Office of Grants Management and Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892, (301) 496-9539, alomit.ishai@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: January 13, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-00991 Filed 1-18-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Data Infrastructure to Understand Disparities.

Date: February 22, 2023.

Time: 9 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ramesh Vemuri, Ph.D., Chief, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C-212, Bethesda, MD 20892, 301-402-7700, rv23r@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 13, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-00994 Filed 1-18-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications, contract proposals and discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; NIEHS Bioinformatics Contract Proposal Review Meeting.

Date: March 7, 2023.

Time: 10:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Varsha Shukla, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, (984) 287-3288, Varsha.shukla@nih.gov.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; NIEHS Research Intensive Short Courses and Educational Opportunities.

Date: April 6, 2023.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Beverly W. Duncan, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, (240) 353-6598, beverly.duncan@nih.gov.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; NIEHS Genetic Diversity in Toxicity Testing: New Approaches in Determining Response Variability From Environmental Exposures.

Date: April 11, 2023.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Science, Research Triangle Park, NC 27709, (984) 287-3340, worth@niehs.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, (HHS)

Dated: January 12, 2023.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-00920 Filed 1-18-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting for the Interdepartmental Serious Mental Illness Coordinating Committee

AGENCY: Substance Abuse and Mental Health Services Administration,

Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services announces a meeting of the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC).

The meeting will provide information on federal efforts related to serious mental illness (SMI) and serious emotional disturbance (SED).

DATES: March 14, 2023, 11 a.m. to 4 p.m. (EDT)/Open.

ADDRESSES: The meeting is open to the public and can be accessed virtually only by accessing: <https://www.zoomgov.com/j/1610294627?pwd=V1FTTEtKRmxORktqNndHMDZhelhxUT09>, or by dialing 646-828-7666, webinar ID: 161 029 4627, passcode: 127155. Agenda with call-in information will be posted on the SAMHSA website prior to the meeting at <https://www.samhsa.gov/about-us/advisory-councils/meetings>.

FOR FURTHER INFORMATION CONTACT: Pamela Foote, ISMICC Designated Federal Officer, SAMHSA, 5600 Fishers Lane, 14E53C, Rockville, MD 20857; telephone: 240-276-1279; email: pamela.foote@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Authority

The ISMICC was established on March 15, 2017, in accordance with section 6031 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to report to the Secretary, Congress, and any other relevant federal department or agency on advances in SMI and SED, research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of SMIs, SEDs, and advances in access to services and supports for adults with SMI or children with SED. In addition, the ISMICC will evaluate the effect federal programs related to SMI and SED have on public health, including public health outcomes such as: (A) rates of suicide, suicide attempts, incidence and prevalence of SMIs, SEDs, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment; (B) increased rates of employment and enrollment in educational and vocational programs; (C) quality of mental and substance use disorders treatment services; or (D) any other criteria determined by the

Secretary. Finally, the ISMICC will make specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with SMI or children with SED. Not later than one (1) year after the date of enactment of the 21st Century Cures Act, and five (5) years after such date of enactment, the ISMICC shall submit a report to Congress and any other relevant federal department or agency.

II. Membership

This ISMICC consists of federal members listed below or their designees, and non-federal public members.

Federal Membership: Members include, The Secretary of Health and Human Services; The Assistant Secretary for Mental Health and Substance Use; The Attorney General; The Secretary of the Department of Veterans Affairs; The Secretary of the Department of Defense; The Secretary of the Department of Housing and Urban Development; The Secretary of the Department of Education; The Secretary of the Department of Labor; The Administrator of the Centers for Medicare and Medicaid Services; the Administrator of the Administration for Community Living, and The Commissioner of the Social Security Administration.

Non-federal Membership: Members include, not less than 14 non-federal public members appointed by the Secretary, representing psychologists, psychiatrists, social workers, peer support specialists, and other providers, patients, family of patients, law enforcement, the judiciary, and leading research, advocacy, or service organizations.

The ISMICC is required to meet at least twice per year.

To attend virtually, submit written or brief oral comments, or request special accommodation for persons with disabilities, contact Pamela Foote. Individuals can also register at <https://snacregister.samhsa.gov/>.

The public comment section will be scheduled at the conclusion of the meeting. Individuals interested in submitting a comment, must notify Pamela Foote on or before February 21, 2023, via email to: Pamela.Foote@samhsa.hhs.gov.

Up to three minutes will be allotted for each approved public comment as time permits. Written comments received in advance of the meeting will be considered for inclusion in the official record of the meeting.

Substantive meeting information and a roster of Committee members is

available at the Committee's website: <https://www.samhsa.gov/about-us/advisory-councils/ismicc>.

Dated: January 12, 2023.

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2023-00916 Filed 1-18-23; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention's (CSAP) Drug Testing Advisory Board (DTAB) will convene via web conference on March 7, 2023, from 10 a.m. EST to 4:30 p.m. EST.

The board will meet in open-session March 7, 2023, from 10 a.m. EST to 2 p.m. EST to discuss the Mandatory Guidelines for Federal Workplace Drug Testing Programs, updates to the Electronic Chain of Custody Form (ECCF), as well as updates from the Department of Transportation, the Nuclear Regulatory Commission, the Department of Defense, and the Food and Drug Administration as well as a presentation by Dr. Svante Vikingsson on Fentanyl and Opioids Pulse Study results.

The board will meet in closed session on March 7, 2023, from 2:15 p.m. EST to 4:30 p.m. EST to discuss issues surrounding cannabinoids pertaining to the effect of the proliferation of various cannabinoid isomers, including Delta-8-THC, on federal workplace drug testing programs, including federal and state responses to cannabinoid drug testing issues of concern, and potential SAMSHA actions. In closed session the board will also review information and proposed actions concerning the Department of Health and Human Services (HHS) Mandatory Guideline internal review and approval process that has not been made public by HHS. Therefore, the March 7, 2023, meeting from 2:15 p.m. to 4:30 p.m. is closed to the public, as determined by the Assistant Secretary for Mental Health and Substance Use, SAMHSA, in accordance with 5 U.S.C. 552b(c)(9)(B) and 5 U.S.C. App. 2, section 10(d).

Meeting registration information can be completed at <https://snacregister.samhsa.gov/>. Web conference and call information will be

sent after completing registration. Meeting information and a roster of DTAB members may be obtained by accessing the SAMHSA Advisory Committees website, <https://www.samhsa.gov/about-us/advisory-councils/meetings>, or by contacting the Designated Federal Officer, Lisa Davis.

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention, Drug Testing Advisory Board.

Dates/Time/Type: March 7, 2023, from 10 a.m. EST to 2 p.m. EST: OPEN; March 7, 2023, from 2:15 p.m. EST to 4:30 p.m. EST: CLOSED.

Place: Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857.

Contact: Lisa S. Davis, M.S., Social Science Analyst, Center for Substance Abuse Prevention, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (240) 276-1440, Email: Lisa.Davis@samhsa.hhs.gov.

Anastasia Marie Donovan,

Public Health Advisor, Division of Workplace Programs.

[FR Doc. 2023-00911 Filed 1-18-23; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R1-ES-2022-0169; ES1114010000-234-FF01E0000]

Candidate Conservation Agreement With Assurances for the Fisher in Oregon; Enhancement of Survival Permit Applications; Hampton and Starker Site Plans

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), received two enhancement of survival permit (permit) applications pursuant to the Endangered Species Act (ESA). If granted, the requested permits would authorize take of the fisher (*Pekania pennanti*), incidental to otherwise lawful activities, if the species becomes federally listed under the ESA. These applications are associated with a template candidate conservation agreement with assurances (CCAA) developed by the Service for the conservation of the fisher. We have also prepared draft environmental action statements documenting our preliminary determination that the permit decisions may be eligible for

categorical exclusion under the National Environmental Policy Act. We provide this notice to open a public comment period and invite comments from all interested parties.

DATES: Submit written comments no later than February 21, 2023.

ADDRESSES:

Obtaining Documents: The applications, application supporting materials, and any comments and other materials that we receive will be available for public inspection at <https://www.regulations.gov> in Docket No. FWS-R1-ES-2022-0169.

Submitting Comments: To submit written comments, please use one of the following methods:

- *Internet:* <https://www.regulations.gov>. Search for and submit comments on Docket No. FWS-R1-2022-0169.
- *U.S. Mail:* Attn: Docket No. FWS-R1-ES-2022-0169; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike, Falls Church, VA 22041-3803.

For more information, see Public Availability of Comments under

SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Frank Weaver, via telephone at 541-957-3471, or via email at Frank.Weaver@fws.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), have received two enhancement of survival permit (permit) applications pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The two applicants are Hampton Lumber (Hampton) and Starker Forest Inc./Starker Properties LLC (Starker).

If granted, either or both of the requested permits would authorize take of the fisher (*Pekania pennanti*) incidental to the applicants' routine forest-related management activities, if the species becomes federally listed under the ESA. Each application includes a proposed individual site plan developed under a template candidate conservation agreement with assurances (CCAA) developed by the Service in 2018 for the conservation of the fisher. The conservation measures in the CCAA are intended to provide a net

conservation benefit to the species. We have also prepared draft environmental action statements (EAS) for our preliminary determinations that each of the two permit decisions is eligible for categorical exclusion under the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*). We provide this notice to open a public comment period and invite comments from all interested parties regarding the documents referenced above.

Background

A CCAA is a voluntary agreement whereby landowners agree to manage their lands to remove or reduce threats to species that may become listed under the ESA (64 FR 32726; June 17, 1999). CCAAs are intended to facilitate the conservation of proposed and candidate species, and species that are likely to become candidates soon, by giving non-Federal property owners incentives to implement conservation measures for declining species. In return for managing their lands to the benefit of the covered species, enrolled landowners receive assurances that additional land, water, or resource use restrictions will not be required if the covered species becomes listed as threatened or endangered under the ESA, so long as the CCAA remains in place and is being fully implemented.

A CCAA serves as the basis for the Service to issue permits to non-Federal participants pursuant to section 10(a)(1)(A) of the ESA. Application requirements and issuance criteria for permits under CCAAs are found in the Code of Regulations (CFR) at 50 CFR 17.22(d) and 17.32(d).

Template CCAA for Fisher

The Service developed a template CCAA for the West Coast distinct population segment (DPS) of the fisher in Oregon. To comply with NEPA, the Service also issued a draft EAS for future issuance of permits under the finalized template. The template CCAA and the draft EAS were both made available for public comment via a **Federal Register** notice (81 FR 15737; March 24, 2016). The template CCAA and EAS were finalized and signed by the Service on June 20, 2018.

The template CCAA established general guidelines and identified minimum conservation measures for potential participants in the CCAA. Interested participants can voluntarily enroll their properties under the CCAA by developing individual site plans prepared in accordance with the provisions of the CCAA and submitting

the site plans part of their permit applications. If granted, the permits authorize incidental take of the fisher with regulatory assurances to qualifying landowners who carry out conservation measures that would benefit the West Coast DPS of the fisher.

Proposed Actions

Starker and Hampton Lumber each submitted their applications on July 20, 2022, and July 21, 2022, respectively, for separate ESA section 10(a)(1)(A) permits under the template CCAA for the fisher for their identified lands in Oregon. Hampton Lumber and Starker are responsible for planning and carrying out forest management activities on their respective lands. Hampton Lumber seeks to enroll its controlled and managed Oregon timberlands in Clatsop, Columbia, Tillamook, Washington, Yamhill, Lincoln, Polk, Marion, and Benton Counties. Hampton Lumber lands total approximately 97,821 acres (ac) in many separate parcels. Starker seeks to enroll its controlled and managed Oregon timberlands in Benton, Lane, Lincoln, Linn, and Polk Counties. Starker lands total approximately 90,432 ac in many separate parcels.

The Hampton Lumber and Starker permits would authorize incidental take of the fisher until June 20, 2048, should it become federally listed and affected by the applicants' routine forest-related management activities on their properties. Fisher are not currently known to occur on the applicants' proposed enrolled lands within the West Coast Fisher DPS, but fisher may occur there in the future through translocation or range expansion.

Each of the two permit applications includes a distinct proposed site plan that describes the lands covered by the permit and the conservation measures required under the template CCAA that will be implemented on covered lands. The primary conservation measures provided in the site plans include:

- Allowing access to covered lands to conduct fisher surveys;
- Protecting fisher dens and their young by limiting disturbance and impacts to denning structures;
- Limiting control of other animals by trapping/nuisance that could pose a risk to the fisher (trapping of fishers is prohibited by State of Oregon law);
- Allowing the potential future translocation of fishers onto enrolled lands; and
- Promoting the development of habitat structures that would support the fisher.

Request for Public Comments

We invite public review and comment on the two permit application packages, including the individual site plans and draft EASs (see **ADDRESSES**). The final template CCAA and EAS that were finalized and signed by the Service on June 20, 2018, are also available for public information. You may submit your comments and materials by one of the methods listed in the **ADDRESSES** section. We request data, comments, new information, or suggestions from the public, other concerned governmental agencies, the scientific community, Tribes, industry, or any other interested party on our proposed Federal action, including on the adequacy of the site plans prepared in accordance with the template CCAA, pursuant to the requirements for permits at 50 CFR parts 13 and 17.

Public Availability of Comments

All comments and materials we receive become part of the public record associated with this action. Before including your address, phone number, email address or other personal identifying information in your comments, 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. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Authority

We provide this notice in accordance with the requirements of section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations (50 CFR 17.22), and the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6).

Nanette Seto,

Acting Deputy Regional Director, Pacific Region 1, U.S. Fish and Wildlife Service.

[FR Doc. 2023–00896 Filed 1–18–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR**Bureau of Land Management**

[L19900000.PO0000.LLHQ320.23X; OMB Control No. 1004–0114]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Recordation of Location Notices and Mining Claims; Payment of Fees

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Land Management (BLM) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before February 21, 2023.

ADDRESSES: Written comments and recommendations for this information collection request (ICR) 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: To request additional information about this Information Collection Request (ICR), contact Sabry Hanna by email at shanna@blm.gov, or by telephone at (571) 458–6644. 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. You may also view the ICR at <http://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the PRA (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we invite the public and other Federal agencies to comment on new, proposed, revised and continuing collections of information. This helps the BLM assess impacts of its information collection requirements and minimize the public’s reporting burden. It also helps the public understand BLM information collection requirements and ensure requested data are provided in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on October 27, 2022, 2022 (87 FR 65099). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again inviting the public and other Federal agencies to comment on the proposed ICR described below. The BLM is especially interested in public comment addressing the following:

(1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of response.

Comments submitted in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The information that is collected under this control number enables the BLM to maintain records of mining claims and sites on Federal lands and enables the BLM to determine which mining claims and sites claimants wish to continue to hold such claims and sites. The BLM collects information under this control number in accordance with The General Mining Law, as amended, the Stock Raising Homestead Act and other statutes. This OMB Control Number is currently scheduled to expire on April 30, 2023. The BLM request that OMB renew this OMB Control Number for an additional three years.

Title of Collection: Recordation of Location Notices and Mining Claims; Payment of Fees (43 CFR 3832–3838).

OMB Control Number: 1004–0114.

Form Numbers: 3830–2, Maintenance Fee Waiver Certification; 3830–3, Notice of Intent to Locate a Lode or Placer Mining Claim(s) and/or a Tunnel Site(s) on Lands Patented under the Stock Raising Homestead Act of 1916, As Amended by the Act of April 16, 1993; and 3830–4, Affidavit of Annual Assessment Work.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Mining claimants.

Total Estimated Number of Annual Respondents: 195,582.

Total Estimated Number of Annual Responses: 195,582.

Estimated Completion Time per Response: Varies from 30 to 60 minutes per response.

Total Estimated Number of Annual Hours: 95,014.

Respondent’s Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion, except Form 3830–2 (which may be filed annually) and annual FLPMA documents (are to be filed annually when required).

Total Estimated Annual Nonhour Burden Cost: \$3,387,355.

An agency may not conduct or sponsor and, notwithstanding any other provision of law, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Darrin King,

Information Collection Clearance Officer.

[FR Doc. 2023–01006 Filed 1–18–23; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR**Office of Natural Resources Revenue**

[Docket No. ONRR–2011–0008; DS63644000 DRT000000.CH7000 234D1113RT; OMB Control Number 1012–0006]

Agency Information Collection Activities: Suspensions Pending Appeal and Bonding

AGENCY: Office of Natural Resources Revenue, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (“PRA”), the Office of Natural Resources Revenue (“ONRR”) is proposing to revise a currently approved information collection to expand its scope to include

the mineral estate underlying Osage County, Oklahoma (“Osage Mineral Estate”). Through this revision, ONRR seeks authority to collect information related to the paperwork requirements under the Bureau of Indian Affairs’ (“BIA”) proposed regulations to post a surety or bond, or demonstrate financial solvency. ONRR uses forms ONRR–4435, ONRR–4436, and ONRR–4437 as part of these information collection requirements.

DATES: Submit written comments on or before March 20, 2023.

ADDRESSES: All comment submissions must (1) reference “OMB Control Number 1012–0006” in the subject line; (2) be sent to ONRR before the close of the comment period listed under **DATES**; and (3) be sent using the following method:

Electronically via the Federal eRulemaking Portal: Please visit <https://www.regulations.gov>. In the Search Box, enter the Docket ID Number for this ICR renewal (“ONRR–2011–0008”) and click “search” to view the publications associated with the docket folder. Locate the document with an open comment period and click the “Comment Now!” button. Follow the prompts to submit your comment prior to the close of the comment period.

Docket: To access the docket folder to view the ICR **Federal Register** publications, go to <https://www.regulations.gov> and search “ONRR–2011–0008” to view renewal notices recently published in the **Federal Register**, publications associated with prior renewals, and applicable public comments received for this ICR. ONRR will make the comments submitted in response to this notice available for public viewing at <https://www.regulations.gov>.

OMB ICR Data: OMB also maintains information on ICR renewals and approvals. You may access this information at <https://www.reginfo.gov/public/do/PRAsearch>. Please use the following instructions: Under the “OMB Control Number” heading enter “1012–0006” and click the “Search” button located at the bottom of the page. To view the ICR renewal or OMB approval status, click on the latest entry (based on the most recent date). On the “View ICR—OIRA Conclusion” page, check the box next to “All” to display all available ICR information provided by OMB.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, please contact Kimberly Werner, Financial Services, ONRR, by telephone at (303) 231–3801 or email to Kimberly.Werner@onrr.gov. Individuals in the United States who are deaf,

deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: Pursuant to the PRA, 44 U.S.C. 3501, *et seq.*, and 5 CFR 1320.5, all information collections, as defined in 5 CFR 1320.3, require approval by OMB. ONRR may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

As part of ONRR’s continuing effort to reduce paperwork and respondent burdens, ONRR is inviting the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information in accordance with the PRA and 5 CFR 1320.8(d)(1). This helps ONRR to assess the impact of its information collection requirements and minimize the public’s reporting burden. It also helps the public understand ONRR’s information collection requirements and provide the requested data in the desired format.

ONRR is especially interested in public comments addressing the following:

- (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) The accuracy of ONRR’s estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;
- (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. ONRR will include or summarize each comment in its request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time.

While you can ask ONRR in your comment to withhold your personal identifying information from public review, ONRR cannot guarantee that it will be able to do so.

Abstract: (a) General Information: The Federal Oil and Gas Royalty Management Act of 1982 (“FOGRMA”) directs the Secretary of the Interior (“Secretary”) to “establish a comprehensive inspection, collection and fiscal and production accounting and auditing system to provide the capability to accurately determine oil and gas royalties, interest, fines, penalties, fees, deposits, and other payments owed, and to collect and account for such amounts in a timely manner.” 30 U.S.C. 1711. ONRR performs these and other mineral revenue management responsibilities for the Secretary. *See* U.S. Department of the Interior Departmental Manual, 112 DM 34.1 (Sept. 9, 2020). FOGRMA and ONRR’s regulations at 30 CFR Chapter XII do not apply to the Osage Mineral Estate.

The Osage Mineral Estate is held in trust by the United States for the benefit of the Osage Nation. *See* Osage Allotment Act of June 28, 1906, Public Law 59–321, § 3, 34 Stat. 539, as amended. BIA’s regulations at 25 CFR part 226 contain requirements specific to the Osage Mineral Estate, and, historically, BIA has performed compliance activities related to those requirements. In conjunction with this ICR, BIA has published a proposed rule in the **Federal Register** on January 13, 2023 (88 FR 2430) that would require a lessee of the Osage Mineral Estate to submit to ONRR certain forms already authorized in this ICR for Federal and non-Osage Indian lands. Accordingly, this ICR revision adds information collections specific to oil and gas royalty and production reporting for the Osage Mineral Estate.

For Federal lands only, Section 4(l), “Stay of Payment Obligation Pending Review,” of the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996 (“RSFA”) requires ONRR to evaluate any person, ordered by the Secretary or a delegated State to pay any obligation (other than an assessment) subject to RSFA, to determine whether that person is entitled to a stay of the order without bond or other surety instrument, pending an administrative or judicial proceeding, based on the financial solvency of that person.

Regulations under 30 CFR part 1243 and proposed regulations under 25 CFR part 226, subpart O, govern the suspension of orders or decisions pending administrative appeal for Federal and Indian leases. For Federal

leases, these regulations allow an appellant to submit information demonstrating financial solvency in lieu of providing a surety. For appellants who are not financially solvent or for appeals involving Indian leases, ONRR requires appellants to post a surety instrument to secure the financial interest of the public and Indian lessors during the entire administrative or judicial appeal process.

BIA has published a proposed rule in the **Federal Register** on January 13, 2023 (88 FR 2430) that would require lessees of the Osage Mineral Estate to submit the forms authorized by this ICR to ONRR. Accordingly, this ICR revision adds information collections specific to posting an ONRR-specified surety instrument under 30 CFR part 1243 subpart B within the time period that ONRR prescribes to secure the financial interest of the Osage Mineral Estate.

This ICR remains unchanged in its application and effect as to all leases previously subject to the information collections described below, which includes all Federal leases onshore and offshore and all Indian leases held in trust by the United States, except for the Osage Mineral Estate.

If ONRR determines that a lessee did not properly report, pay, or both, it may issue orders, notices of noncompliance, and civil penalty notices to compel corrective reporting, payment, or both. Lessees have a right to appeal ONRR's determinations.

(b) Information Collections:

Regulations under 30 CFR part 1243 and proposed regulations under 25 CFR part 226, subpart O, govern the submission of appropriate surety instruments to suspend compliance with an order or decision, and to stay the accrual of civil penalties (if the Office of Hearings and Appeals grants a lessee's petition to stay accrual of civil penalties) pending administrative appeal for Federal and Indian leases. For Federal oil and gas leases, under 30 U.S.C. 1724(l) and its implementing regulations under 30 CFR part 1243, an appellant requesting a suspension without providing a surety must submit information to demonstrate financial solvency. This ICR covers the burden hours associated with submitting financial statements and surety instruments required to stay an ONRR order, decision, or accrual of civil penalties as follows:

(1) Stay of Payment Pending Appeal: Title 30 CFR 1243.1 states that lessees or recipients of ONRR orders may suspend compliance with an order if they appeal under 30 CFR part 1290. Pending appeal, ONRR may suspend the payment requirement if the appellant submits a formal agreement of payment

in the case of default, such as a bond or other surety. For Federal oil and gas leases, the appellant may alternatively demonstrate financial solvency. If the Office of Hearings and Appeals grants a recipient of a notice of noncompliance or civil penalty notice's request to stay the accrual of civil penalties under 30 CFR 1241.55(b)(2) and 1241.63(b)(2), recipient must post a bond or other surety. For Federal oil and gas leases, the appellant may alternatively demonstrate financial solvency.

ONRR accepts the following surety types:

(i) Form ONRR-4435, Administrative Appeal Bond;

(ii) Form ONRR-4436, Letter of Credit;

(iii) Form ONRR-4437, Assignment of Certificate of Deposit;

(iv) Self-bonding (Federal leases only); and

(v) U.S. Treasury Securities.

When an appellant selects one of the surety types and puts it in place, the appellant must maintain the surety until the appeal's resolution. If the appeal is decided in favor of the appellant, ONRR will return the surety to the appellant. If the appeal is decided in favor of ONRR, then ONRR will take action to collect the total amount due or draw down on the surety. ONRR will draw down on a surety if the appellant fails to comply with requirements relating to the amount due, timeframe, or surety submission or resubmission. Whenever ONRR draws down on a surety, it reduces the total amount due, which is defined as the unpaid principal plus the interest accrued to the projected receipt date of the surety payment. Appellants may refer to the Surety Instrument Posting Instructions, available on our website at <http://www.onrr.gov/compliance/appeals.htm>.

(2) Forms and Other Surety Types:

A. Form ONRR-4435, Administrative Appeal Bond: An appellant may file form ONRR-4435, *Administrative Appeal Bond*, which ONRR uses to secure the financial interests of the public and Indian lessors during the entire administrative and judicial appeal processes. Under 30 CFR 1243.4 and proposed regulations at 25 CFR 226.179, an appellant is required to submit its contact and surety amount information on the bond to obtain the benefit of suspension of an obligation to comply with an order. The bond must be issued by a qualified surety company that the U.S. Department of the Treasury approves (see Department of the Treasury Circular No. 570, revised periodically in the **Federal Register**). ONRR's Director, or the delegated bond-approving officer, maintains the bonds in a secure facility. After an appeal's

conclusion, ONRR may release and return the bond to the appellant or collect payment on the bond. If collection is necessary for a remaining balance, ONRR will issue a demand for payment to the surety company with a notice to the appellant. ONRR will also include all interest accrued on the affected receivable.

B. Form ONRR-4436, Letter of Credit:

An appellant may choose to file form ONRR-4436, *Letter of Credit*, with no modifications. Requirements under 30 CFR 1243.4 and proposed regulations at 25 CFR 226.179 continue to apply. ONRR's Director, or the delegated bond-approving officer, maintains the Letter of Credit ("LOC") in a secure facility. The appellant is responsible for verifying that the bank provides a current Fitch rating to ONRR. After the appeal's resolution, ONRR may release and return the LOC to the appellant or collect payment on the LOC. If collection is necessary for a remaining balance, ONRR will issue a demand for payment that includes the principal amount plus the interest assessed on the receivable, to the bank with a notice to the appellant.

C. Form ONRR-4437, Assignment of Certificate of Deposit: An appellant may choose to secure a debt by requesting to use a Certificate of Deposit ("CD") from a bank with the required minimum rating and submitting form ONRR-4437, *Assignment of Certificate of Deposit*. Requirements under 30 CFR 1243.4 and proposed regulations at 25 CFR 226.179 continue to apply. The appellant must file the request with ONRR prior to the invoice due date. ONRR will accept a book-entry CD that explicitly assigns the CD to ONRR's Director. If collection of the CD is necessary for an unpaid balance, ONRR will return unused CD funds to the appellant after total settlement of the appealed issues, including applicable interest charges.

D. Self-Bonding (Federal leases only, not applicable to Indian or the Osage Mineral Estate leases): For Federal oil and gas leases, regulations under 30 CFR 1243.201 provide that no surety instrument is required when a person representing the appellant periodically demonstrates, to the satisfaction of ONRR, that the guarantor or appellant is financially solvent or otherwise able to pay the obligation. The appellant must submit a written request to "self-bond" every time a new appeal is filed. To evaluate the financial solvency and exemption from requirements of appellants to maintain a surety related to an appeal, ONRR requires appellants to submit a consolidated balance sheet, subject to annual audit. In some cases, ONRR also requires copies of the most

recent tax returns (up to three years) filed by the appellant.

In addition, an appellant must annually submit financial statements, subject to audit, to support its net worth. ONRR uses the consolidated balance sheet or business information supplied to evaluate the financial solvency of a lessee, designee, or payor seeking a stay of payment obligation pending review. If the appellant does not have a consolidated balance sheet documenting its net worth, or if it does not meet the \$300 million net worth requirement, ONRR will select a business information or credit reporting service to provide information concerning the appellant's financial solvency. ONRR charges the appellant a \$50 fee each time it reviews data from a business information or credit reporting service. The fee covers ONRR's cost to determine an appellant's financial solvency.

E. U.S. Treasury Securities: An appellant may choose to secure its debts by requesting to use a U.S. Treasury Security ("TS"). The appellant must file the letter of request with ONRR prior to the invoice due date. The TS must be a U.S. Treasury note or bond with maturity equal to or greater than one year. The TS must equal 120 percent of the appealed amount plus 1 year of estimated interest (necessary to protect ONRR against interest rate fluctuations). ONRR only accepts book-entry TS.

Title of Collections: Suspensions Pending Appeal and Bonding.

OMB Control Number: 1012-0006.

Form Numbers: ONRR-4435, ONRR-4436, and ONRR-4437.

Type of Review: Revision to a currently approved collection.

Respondents/Affected Public: Businesses.

Total Estimated Number of Annual Respondents: 107 appellants.

Total Estimated Number of Annual Responses: 107.

Estimated Completion Time per Response: The time per response is 120 mins. The average completion time is calculated by first multiplying the estimated annual burden hours (214 burden hours) by 60 to obtain the total annual burden minutes. Then the total annual burden minutes (12,840) is divided by the estimated annual responses (107).

Total Estimated Number of Annual Burden Hours: 214 hours.

Respondent's Obligation: Mandatory.

Frequency of Collection: Annually and on occasion.

Total Estimated Annual Non-Hour Burden Cost: ONRR identified no "non-hour cost" burden associated with this collection of information.

Estimated Annual Reporting and Recordkeeping "Non-Hour" Cost Burden: There are no additional recordkeeping costs associated with this information collection. However, ONRR estimates 5 appellants per year will pay a \$50 fee to obtain credit data from a business information or credit reporting service, which is a total "non-hour" cost burden of \$250 per year (5 appellants per year \times \$50 = \$250).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the PRA (44 U.S.C. 3501, *et seq.*).

Howard Cantor,

Acting Director, Office of Natural Resources Revenue.

[FR Doc. 2023-01009 Filed 1-18-23; 8:45 am]

BILLING CODE 4335-30-P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM-2023-0008]

Modifications to the Bid Adequacy Procedures for Offshore Oil and Gas Lease Sales

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notification of procedural changes; request for comments.

SUMMARY: The Bureau of Ocean Energy Management (BOEM) announces and invites comments on its intention to change its bid adequacy procedures (BAPs), which ensure the United States receives fair market value (FMV) from Outer Continental Shelf (OCS) oil and gas lease sales. BOEM proposes to discontinue the use of both tract classification and delayed valuation methodology. Instead, BOEM proposes to use a statistical lower bound confidence interval (LBCI), at the 90 percent confidence level, as a measure of bid adequacy. BOEM is also proposing other, minor adjustments to its BAPs to clarify and streamline its processes.

DATES: BOEM must receive your comments by March 6, 2023.

ADDRESSES: You may submit comments by either of the following methods:

- *Regulations.gov web portal:* Navigate to <http://www.regulations.gov> and under the "Search" tab, in the space provided, type in Docket ID: BOEM-2023-0008. Select the document that you would like to comment on and click on the "Comment" button to submit

your comments. You may also view other comments already posted to the docket.

- In written form by mail or other delivery services: Send comments in an envelope labeled "Comments for the proposed revised BAP" and addressed to Mr. Matt Frye, Chief, Resource Evaluation Division, Office of Strategic Resources, Bureau of Ocean Energy Management, 45600 Woodland Road, Sterling, VA 20166-9216.

- For additional information on sending comments, see the "Public Participation and Availability of Comments" heading under the **SUPPLEMENTARY INFORMATION** section of this notice.

The proposed, revised procedures are available for review at: <https://www.boem.gov/oil-gas-energy/energy-economics/lease-sales-and-fair-market-value>. A copy of BOEM's current BAP entitled "Summary of Procedures for Determining Bid Adequacy at Offshore Oil and Gas Lease Sales, Effective March 2016 with Central Gulf of Mexico Sale 241 and Eastern Gulf of Mexico Sale 226" is available on BOEM's website at: <https://www.boem.gov/sites/default/files/oil-and-gas-energy-program/Energy-Economics/Fair-Market-Value/Summary-of-Procedures-For-Determining-Bid-Adequacy.pdf>.

FOR FURTHER INFORMATION CONTACT: Mr. Matt Frye, Chief, Resource Evaluation Division, Office of Strategic Resources, at (703) 787-1514 or email at matt.frye@boem.gov.

SUPPLEMENTARY INFORMATION:

Background and Summary of Changes

In administering the offshore oil and gas leasing program under the OCS Lands Act, the Secretary of the Interior is required to ensure that the Federal Government receives FMV for the lease rights granted and the rights conveyed. To carry out this responsibility since 1983, BOEM (and its predecessor agency) has used a two-phase, post-sale bid evaluation process to assess the adequacy of bids received in Federal offshore oil and gas lease sales. Under its BAP, BOEM reviews all high bids and evaluates all tracts to ensure that FMV is received for each OCS lease issued. The BAP relies on both evidence of market competition and in-house estimates of tract value.

Currently, in phase 1 of the BAP, BOEM reviews all bids for legal sufficiency and anomalies to establish the set of bids to be evaluated for each tract. All tracts receiving legal bids are

then classified¹ as “drainage or development” (DD), “confirmed or wildcat” (CW), or “unknown” if undetermined at this phase. All CW tracts are tested for geologic and economic viability and high bids are accepted for tracts that BOEM determines to be nonviable. A nonviable tract is considered by BOEM not to have the potential capability of being explored, developed, and produced profitably under economic conditions present at the time of the lease sale. The remaining CW tracts are then reviewed under phase 2. All DD and unknown tracts begin at phase 2.

In phase 2 of the BAP, BOEM may use its probabilistic discounted cash flow simulation model to generate up to four measures of bid adequacy to help determine if a tract’s high bid may be accepted. These four measures are: mean range of values (MROV), delayed mean Range of values (DMROV), adjusted delayed values (ADV), and revised arithmetic measure (RAM). The MROV is a single value that represents the maximum cash payment that a bidder can offer for acquiring the tract’s drilling and development property rights and still expect to make a normal rate of return on their investment. The DMROV is intended to allow a determination of whether, in cases where the high bid is below the MROV, leasing revenues consisting of the cash bonus plus royalties or profit shares would be greater if the high bid were to be accepted, rather than rejected and the tract reoffered in the next available sale. BOEM calculates the tract’s MROV and DMROV and designates the lesser of these two measures as the ADV. The RAM represents the average of the highest qualified bid, all other qualified bids that are at least 25 percent of the highest qualified bid, and the MROV. If the high bid is equal to or greater than any of these measures, the Regional Director may accept the highest qualified bid as representative of FMV for the tract.

In October 2019, the Government Accountability Office (GAO) published a report entitled “Offshore Oil and Gas: Opportunities Exist to Better Ensure a Fair Return on Federal Resources” (GAO–19–531). In its report, GAO provided four recommendations to BOEM, including a recommendation to have a third party “examine the extent to which the bureau’s use of delayed

valuations assures the receipt of fair market value, and make changes—such as terminating the use of delayed valuations or amending its model’s assumptions—as appropriate.” In response, BOEM committed to examine its use of delayed valuation and to identify any appropriate changes.

After a 2-year comprehensive technical review of the delayed valuation methodology, BOEM intends to replace the delayed valuation methodology with a statistical lower bound confidence interval (LBCI) at a 90 percent confidence level as a decision criterion for accepting or rejecting qualified high bids on tracts offered in OCS oil and gas lease sales. Following extensive testing of the alternative approaches using both historical and current lease sale tract data and existing BOEM cash flow simulation models, BOEM determined that the LBCI approach would be the most appropriate substitute for the delayed valuation methodology. The LBCI is a statistical concept that captures the lower bound of a range of values encompassing the true unknown mean of the risked present worth² of the resources at the time of the lease sale. The LBCI incorporates the uncertainty of parameters unique to the valuation of each OCS oil and gas lease sale tract. These parameters may include, but are not limited to, subsurface characterization of reservoir properties, cost and timing of the development, and projected revenues. Unlike the delayed valuation methodology, the LBCI approach would not require that BOEM estimate the time delay period between the current OCS oil and gas lease sale and the projected next lease sale. As such, BOEM finds the LBCI to be a better approach going forward.

Additionally, BOEM proposes to discontinue the use of tract classification in the BAP to streamline the bid review process. BOEM has found that this classification process has had minimal impact on its procedural analysis of FMV; since 1997, only approximately 1 percent of tracts have been classified as DD, and the remaining tracts have been classified as CW. The classification process has therefore been of limited utility to BOEM in the existing BAP. Therefore, in the proposed revised BAP, the formal tract classification process would be removed and all tracts receiving legal bids in phase 1 would be passed on to phase 2

unless the tract is determined to be nonviable. In phase 2, BOEM may use its probabilistic discounted cash flow simulation model to generate up to two measures of bid adequacy: LBCI and RAM. A tract’s highest qualified bid would then be compared to the applicable measures of bid adequacy. If that bid is equal to or greater than either of these measures, the Regional Director may accept the highest qualified bid as representative of FMV for the tract.

BOEM is also proposing other minor revisions to its procedures, for example, the removal of the “Definitions” section to streamline the document and ensure clarity.

BOEM intends to assess bids using the revised BAP, once finalized, during lease sales included in the next National OCS Oil and Gas Leasing Program.

Public Participation and Availability of Comments

All comments will be made publicly available in the docket. BOEM will consider all comments before finalizing the revised BAP.

All interested parties can submit written comments to BOEM. BOEM will protect privileged or proprietary information that you submit in accordance with the Freedom of Information Act (FOIA) and OCS Lands Act. To avoid inadvertent release of such information, interested parties should mark all documents and every page containing such information with “Confidential—Contains Proprietary Information.” To the extent a document contains a mix of proprietary and nonproprietary information, interested parties should clearly mark the portions of the document that are proprietary and those that are not. Exemption 4 of FOIA applies to trade secrets and commercial or financial information that you submit that is privileged or confidential.

Please be aware that BOEM’s practice is to make all other comments, including the names and addresses of individuals, available for public inspection. Before including your address, phone number, email address, or other personal identifying information in your comment, please be advised that your entire comment, including your personal identifying information, may be made publicly available at any time. In order for BOEM to consider withholding from disclosure your personal identifying information, you must identify, in a cover letter, any information contained in the submittal of your comments that, if released, would constitute a clearly unwarranted invasion of your personal privacy. You must also briefly describe any possible harmful consequences of the disclosure,

¹ For definitions of BOEM tract classification, please refer to current bid adequacy procedures published on BOEM website: <https://www.boem.gov/sites/default/files/oil-and-gas-energy-program/Energy-Economics/Fair-Market-Value/Summary-of-Procedures-For-Determining-Bid-Adequacy.pdf>.

² Risked present worth is a net present value of the potential oil and gas resources contained in a tract adjusted for the geological risks of not finding hydrocarbons and the uncertainties associated with the development and economic parameters of that tract at the time of the lease sale.

such as embarrassment, injury, or other harm.

Even if BOEM withholds your information in the context of its BAP modification process, your submission is subject to FOIA, and if your submission is requested under FOIA, your information will be withheld only if a determination is made that one of FOIA's exemptions to disclosure applies. Such a determination will be made in accordance with the Department's FOIA regulations and applicable law.

BOEM will make available for public inspection, in their entirety, all comments submitted by organizations and businesses, or by individuals identifying themselves as representatives of organizations or businesses.

Authority: 43 U.S.C. 1331 *et seq.* (Outer Continental Shelf Lands Act, as amended) and 30 CFR part 556.

Amanda Lefton,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2023-00842 Filed 1-18-23; 8:45 am]

BILLING CODE 4340-98-P

INTERNATIONAL TRADE COMMISSION

[USITC SE-23-005]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: January 23, 2023 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205-2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none.
2. Minutes.
3. Ratification List.
4. Commission vote on Inv. Nos. 731-TA-1578-1579 (Final)(Lemon Juice from Brazil and South Africa). The Commission currently is scheduled to complete and file its determinations and views of the Commission on February 2, 2023.

5. Outstanding action jackets: none.

CONTACT PERSON FOR MORE INFORMATION: Tyrell Burch, Management Analyst, 202-205-2595.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: January 17, 2023.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2023-01104 Filed 1-17-23; 4:15 pm]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1281]

Certain Video Security Equipment and Systems, Related Software, Components Thereof, and Products Containing Same; Notice of a Commission Determination To Review in Part a Final Initial Determination Finding a Violation of Section 337; Request for Written Submissions on Issues Under Review and on Remedy, the Public Interest, and Bonding; Extension of Target Date

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part a final initial determination ("FID") issued by the presiding administrative law judge ("ALJ"), finding a violation of section 337 of the Tariff Act of 1930, as amended, in the above-captioned investigation. The Commission requests briefing from the parties on certain issues under review, as indicated in this notice. The Commission also requests written submissions from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding. The Commission has further determined to extend the target date in the above-captioned investigation to March 23, 2023.

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 September 14, 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 Motorola Solutions, Inc. of Chicago, Illinois ("Motorola Solutions"); Avigilon Corporation of British Columbia, Canada; Avigilon Fortress Corporation of British Columbia, Canada; Avigilon Patent Holding 1 Corporation of British Columbia, Canada ("Avigilon Patent Holding"); and Avigilon Technologies Corporation of British Columbia, Canada (collectively, "Complainants"). See 86 FR 51182-83 (Sept. 14, 2021). The complaint 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 video security equipment and systems, related software, components thereof, and products containing same by reason of infringement of certain claims of U.S. Patent Nos. 7,868,912 ("the '912 patent"); 10,726,312 ("the '312 patent"); and 8,508,607 ("the '607 patent") (collectively, "the Asserted Patents"). *Id.* The complaint further alleges that a domestic industry exists. *Id.* The notice of investigation ("NOI") names Verkada Inc. of San Mateo, California as the only respondent. *Id.*

The complaint and NOI were previously amended to reflect the transfer of all right, title, and interest in: (1) the '312 patent from Avigilon Corporation to Motorola Solutions; (2) the '912 patent from Avigilon Fortress Corporation to Motorola Solutions; and (3) the '607 patent from Avigilon Patent Holding to Motorola Solutions. Order No. 7 (Dec. 28, 2021), *unreviewed by* 87 FR 4658-59 (Jan. 28, 2022). The complaint and NOI were further amended to add a new licensee, Avigilon USA Corporation of Dallas, Texas, as an additional complainant. *Id.*

The Commission previously terminated the investigation as to claims 4 and 10-12 of the '312 patent based on Complainants' partial withdrawal of the complaint. Order No. 58 (June 14, 2022), *unreviewed by* Comm'n Notice (June 30, 2022). The Commission also previously terminated the investigation as to claims 6, 15, 25, and 26 of the '607 patent based on Complainants' partial withdrawal of the complaint. Order No. 59 (July 13, 2022), *unreviewed by* Comm'n Notice (Aug. 4, 2022).

On October 24, 2022, the presiding ALJ issued the FID, finding that a

violation of section 337 has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain video security equipment and systems, related software, components thereof, and products containing same that infringe claims 6–11 of the '912 patent. The FID further finds no violation of section 337 with respect to the remaining asserted claims of the '912 patent, or as to the '312 patent or the '607 patent. The FID includes the ALJ's recommended determination on remedy, the public interest, and bonding should the Commission find a violation of section 337.

On November 7, 2022, Complainants filed a contingent petition requesting review of the FID's findings of non-infringement as to asserted claims 1–4, 12–22, 26–28, 30 of the '912 patent, the asserted claims of the '312 patent, and the asserted claims of the '607 patent, as well as Verkada's proposed redesigns. That same day, respondent Verkada filed a combined petition and contingent petition requesting review of the FID's findings that the accused products include an imported "article" that infringes asserted claims 6–11 of the '912 patent, certain accused products infringe asserted claims 6–11 of the '912 patent, and asserted claims 6–11 of the '912 patent are not anticipated or rendered obvious by the prior art. Verkada also seeks contingent review of the FID's findings that the accused products include an imported "article" that infringes claims 24–25, 27–28, 32–33, and 35–36 of the '912 patent; additional non-infringement bases for the asserted claims of the '912 patent; claims 1–4 and 12–36 of the '912 patent are not anticipated or rendered obvious by the asserted prior art; claims 1, 5, 6, 9, 13, and 16 of the '312 patent are not anticipated or rendered obvious by the asserted prior art; additional non-infringement bases for the asserted claims of the '607 patent; and claims 1–4, 7, 10–13, 16, 19–21, and 29 of the '607 patent are not rendered obvious by the asserted prior art. On November 15, 2022, Complainants and Verkada filed their respective responses to the petitions for review.

On November 23, 2022, Complainants and Verkada each filed a submission on the public interest pursuant to Commission Rule 210.50(a)(4) (19 CFR 210.50(a)(4)). No submissions were received in response to the Commission notice seeking public interest submissions. 87 FR 65827–28 (Nov. 1, 2022).

Having reviewed the record of the investigation, including the FID, the

parties' submissions to the ALJ, the petitions for review, and the responses thereto, the Commission has determined to review the FID in part. Specifically, the Commission has determined to review: (1) the FID's findings regarding "subject matter jurisdiction"; (2) the FID's findings that certain accused products infringe claims 6–11 of the '912 patent and finding a violation of section 337 as to those claims; and (3) the FID's finding that asserted claims 6–11 of the '912 patent are not invalid as anticipated or obvious. The Commission has determined not to review any other findings presented in the FID.

The Commission has also determined to extend the target date for completing this investigation to March 23, 2023.

In connection with its review, the Commission requests responses to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

1. Please address whether, under the framework set forth by Commissioner Kearns in his Additional Views in *Certain High-Density Fiber Optic Equipment and Components Thereof*, Inv. No. 337–TA–1194, Comm'n Op. at 98–104 (Aug. 3, 2021), Verkada's imported cameras should be considered "articles that infringe" for purposes of finding a violation of section 337 by Verkada's direct infringement of claims 6–11 of the '912 patent.

2. Regarding claims 6–11 of the '912 patent, given the uncontested claim constructions and differences between claim 1 and claims 6–11, please address whether the existing evidentiary record supports the FID's finding that "Event Detection and Analysis from Video Streams" by Medioni et al., published in the IEEE Transactions on Pattern Analysis and Machine Intelligence, Vol. 23, No. 8 in August 2001 (RX–302) does not disclose either (1) a processor that receives detected/determined attributes over a communications channel, or (2) attributes which are independent of events. Please also address whether the differences between claim 1 and claims 6–11 affect the anticipation analysis, and if so, please explain how.

3. Please provide a status update regarding which of the adjudicated design(s) and/or redesign(s) are currently implemented in the accused products that are being sold or offered for sale by Verkada. In addition, please address whether, if the Commission finds a violation as to only the accused products that the FID finds infringing with respect to claims 6–11 of the '912 patent, a consent order could resolve the parties' remaining issues with respect to that patent.

The parties are invited to brief only these discrete issues for the specific claims identified. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

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 a 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: The parties to the investigation are requested to file written submissions on the issues identified in this notice. 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. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

In their initial submission, Complainants are also requested to identify the remedy sought and Complainants are requested to submit proposed remedial orders for the Commission's consideration. Complainants are 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 January 27, 2023. Reply submissions must be filed no later than the close of business on February 3, 2023. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. No further submissions on any of 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-1281) 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. Any non-party wishing to submit comments containing

confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of 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 January 12, 2023.

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: January 12, 2023.

Katherine M. Hiner,

Acting Secretary to the Commission.

[FR Doc. 2023-00907 Filed 1-18-23; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1270]

Certain Casual Footwear and Packaging Thereof; Notice of Request for Submissions on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on January 9, 2023, the presiding administrative law judge ("ALJ") issued a combined Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond ("RD") in this

investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public only.

FOR FURTHER INFORMATION CONTACT: Carl P. Bretscher, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-2382. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket system ("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, telephone (202) 205-1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States: unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation, specifically: (1) a general exclusion order excluding imports of all infringing products, regardless of the source of the infringing products; (2) a limited exclusion order excluding importation of certain casual footwear and packaging thereof that are sold for importation into the United States or sold in the United States after importation by respondents Hobby Lobby Stores, Inc. ("Hobby Lobby"); Quanzhou ZhengDe Network Corp. d/b/a/Amoji ("Amoji"); and Orly Shoe Corp. ("Orly"); and (3) cease and desist orders directed to respondents Hobby Lobby, Amoji, and Orly. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public are

invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ's RD issued in this investigation on January 9, 2023. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the recommended remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third-party suppliers have the capacity to replace the volume of articles potentially subject to the recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on February 10, 2023.

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 (Mar. 19, 2020). Submissions should refer to the investigation number ("Inv. No. 337-TA-1270") 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. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing and must be served in accordance with Commission Rule 210.4(f)(7)(ii)(A) (19 CFR 210.4(f)(7)(ii)(A)). 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.

This action is taken under the authority of 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: January 13, 2023.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2023-00934 Filed 1-18-23; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-679 and 731-TA-1585 (Final)]

Sodium Nitrite From India; Supplemental Schedule for the Final Phase of Countervailing and Antidumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: January 6, 2023.

FOR FURTHER INFORMATION CONTACT: Peter Stebbins ((202) 205-2039), Office

of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION: Effective April 15, 2022, the Commission established a general schedule for the conduct of the final phase of its countervailing and antidumping duty investigations on sodium nitrite from India and Russia (87 FR 23567, April 20, 2022), following a preliminary determination by the U.S. Department of Commerce ("Commerce") that imports of sodium nitrite from Russia were being subsidized by the government of Russia (87 FR 22504, April 15, 2022). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on April 20, 2022 (87 FR 23567). In light of the restrictions on access to the Commission building due to the COVID-19 pandemic, the Commission conducted its hearing through video conference on June 21, 2022. All persons who requested the opportunity were permitted to participate.

Commerce issued a final affirmative countervailing duty determination with respect to sodium nitrite from Russia (87 FR 38375, June 28, 2022). The Commission subsequently issued its final determination that an industry in the United States was materially injured by reason of imports of sodium nitrite from Russia provided for in subheading 2834.10.10 of the Harmonized Tariff Schedule of the United States ("HTSUS") that have been found by Commerce to be subsidized by the government of Russia (87 FR 51141, August 19, 2022).

Commerce issued a final affirmative antidumping duty determination with respect to imports of sodium nitrite from Russia (87 FR 55781, September 12, 2022). The Commission

subsequently issued its final determination that an industry in the United States was materially injured by reason of imports of sodium nitrite from Russia provided for in subheading 2834.10.10 of the HTSUS that have been found by Commerce to be sold in the United States at less than fair value (87 FR 66323, November 3, 2022).

Commerce issued final affirmative countervailing and antidumping duty determinations with respect to imports of sodium nitrite from India (88 FR 1042, January 6, 2023; and 88 FR 1052, January 6, 2023). Accordingly, the Commission currently is issuing a supplemental schedule for its countervailing and antidumping duty investigations on imports of sodium nitrite from India.

This supplemental schedule is as follows: the deadline for filing supplemental party comments on Commerce's final countervailing and antidumping duty determinations is Wednesday, January 18, 2023. Supplemental party comments may address only Commerce's final countervailing and antidumping duty determinations regarding imports of sodium nitrite from India. These supplemental final comments may not contain new factual information and may not exceed five (5) pages in length. The supplemental staff report in the final phase of the current investigations will be placed in the nonpublic record on Wednesday, February 1, 2023, and a public version will be issued thereafter.

For further information concerning these investigations see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document

Information System (EDIS, <https://edis.usitc.gov>.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: January 13, 2023.

Jessica Mullan,

Acting Supervisory Attorney.

[FR Doc. 2023-00984 Filed 1-18-23; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Second Amendment to Consent Decree Under the Resource Conservation and Recovery Act

On January 11, 2022, the Department of Justice lodged a proposed second amendment to a consent decree with the United States District Court for the Southern District of Texas in the lawsuit entitled *United States v. Formosa Plastics Corporation, Texas, et al.*, Civil Action No. 09-00061.

Under the original 2010 consent decree, Formosa Plastics Corporation, Texas, Formosa Hydrocarbons, Inc. (now Formosa Hydrocarbons Company, Inc.) (collectively "FPC TX"), and Formosa Plastics Corporation, Louisiana (collectively "Defendants") agreed to undertake numerous measures to come into compliance with various environmental statutes and regulations at their facilities in Point Comfort, Texas, and Baton Rouge, Louisiana. The Defendants still are in the process of complying with the 2010 Decree and the 2013 First Amendment to the Consent Decree. Under the 2010 consent decree, Defendant FPC TX is required to manage and dispose of its wastewater treatment system sludge as a listed hazardous waste under the Resource Conservation and Recovery Act, 42 U.S.C. 6901 *et seq.* ("RCRA"), because the company treats a RCRA listed hazardous waste (recovered groundwater from its contaminated groundwater treatment system) in its wastewater system. Under the proposed Second Amendment, FPC TX will cease treating the recovered groundwater onsite, and instead send the recovered wastewater offsite to a RCRA permitted hazardous waste treatment, storage, and disposal facility. Accordingly, the RCRA hazardous waste listing will no longer carry through to the wastewater sludge.

In doing so, FPC TX will eliminate the wastewater sludge hazardous waste stream. FPC TX also will clean the wastewater treatment system to eliminate hazardous waste residue.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States v. Formosa Plastics Corporation, Texas, et al.*, D.J. Ref. No. 90-5-2-1-08995. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	pubcomment-ees.enrd@usdoj.gov
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

During the public comment period, the proposed second amendment may be examined and downloaded at this Justice Department website: <https://www.justice.gov/enrd/consent-decrees>. We will provide a paper copy of the proposed amendments upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Please enclose a check or money order for \$ 2.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Thomas Carroll,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2023-00960 Filed 1-18-23; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request, Reemployment Services and Eligibility Assessments (RESEA) Program Implementation Study, Reinstatement

AGENCY: Office of the Assistant Secretary for Policy, Chief Evaluation Office, Department of Labor.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents is properly assessed. Currently, the Department of Labor is soliciting comments concerning the collection of data about the Reemployment Services and Eligibility Assessments (RESEA) Program Implementation Study. A copy of the proposed Information Collection Request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before March 20, 2023.

ADDRESSES: You may submit comments by either one of the following methods: *Email:* ChiefEvaluationOffice@dol.gov; *Mail or Courier:* Megan Lizik, Chief Evaluation Office, OASP, U.S. Department of Labor, Room S-2312, 200 Constitution Avenue NW, Washington, DC 20210. *Instructions:* Please submit one copy of your comments by only one method. All submissions received must include the agency name and OMB Control Number identified above for this information collection. Comments, including any personal information provided, become a matter of public record. They will also be summarized and/or included in the request for OMB approval of the information collection request.

FOR FURTHER INFORMATION CONTACT: Megan Lizik by email at ChiefEvaluationOffice@dol.gov or by phone at (202)430-1255.

SUPPLEMENTARY INFORMATION:

I. Background: DOL funds RESEA programs across all 50 states, DC, Puerto Rico, and the Virgin Islands. States and territories use these funds to address the reemployment services needs of Unemployment Insurance (UI) claimants and to prevent and detect UI improper payments (Unemployment Insurance Program Letter 8-18). The Bipartisan Budget Act of 2018 (Pub. L. 115-123) included amendments to the Social Security Act (SSA) that create a permanent authorization for the RESEA program. The permanently authorized RESEA program in Section 306 of the SSA provides for a phased implementation of new program requirements over several years, one of which is to “establish and expand the use of evidence-based interventions” in states’ RESEA programs. To help meet this requirement and build evidence about RESEA, DOL is conducting an implementation study that will provide an understanding of current RESEA programs and program components being implemented in the field. As part of this implementation study, DOL will conduct a web-based survey of all RESEA grantees nationwide. This **Federal Register** Notice provides the opportunity to comment on a new proposed information collection activity that will be used for the implementation study.

- *Web-based survey instrument.* The evaluation team will conduct a survey of all states and territories operating RESEA programs to systematically gather up-to-date information about RESEA program operations not available in existing documents. This includes detail on how reemployment services are provided, interactions with federal workforce programs, how eligibility

assessment and enforcement are carried out, types of reemployment services provided, and exploratory information about evaluation activities.

II. Desired Focus of Comments:

Currently, the Department of Labor is soliciting comments concerning the above data collection for the Evaluation to Advance Reemployment Services and Eligibility Assessments Program Evidence. DOL is particularly interested in comments that do the following:

- evaluate whether the proposed collection of information is necessary for the proper performance functions of the agency, including whether the information will have practical utility;
- evaluate the accuracy of the agency’s burden estimate of the proposed information collection, including the validity of the methodology and assumptions;
- 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—for example, permitting electronic submissions of responses.

III. Current Actions: At this time, the Department of Labor is requesting clearance for for the survey protocol to be administered with all RESEA grantees nationwide.

Type of Review: New information collection request.

OMB Control Number: 1290-0029.

Affected Public: State RESEA program administrators.

Comments submitted in response to this request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

ESTIMATED ANNUAL BURDEN HOURS

Type of instrument	Number of respondents ^a	Number of responses per respondent	Total No. of responses	Average burden time per response (hours)	Estimated burden hours
Web-based survey instrument for State RESEA administrators	^b 18	1	18	2	36
Total	18	1	18	2	36

^a We are seeking a clearance period of three years.

^b Assumes approximately 1 survey participant from each of approximately 53 state and territory RESEA programs over the three-year clearance period.

Scott Gibbons,

Acting Chief Evaluation Officer, U.S.
Department of Labor.

[FR Doc. 2023-00917 Filed 1-18-23; 8:45 am]

BILLING CODE 4510-HX-P

LEGAL SERVICES CORPORATION

Notice of Availability of Calendar Year 2023 Competitive Grant Funds for the Technology Initiative Grant Program

AGENCY: Legal Services Corporation.

ACTION: Notice.

SUMMARY: The Legal Services Corporation (LSC) issues this Notice describing the conditions for submitting a pre-application for 2023 Technology Initiative Grants (TIGs), and for applying under TIG categories that do not require pre-applications. Pre-applications must be submitted electronically via LSC's unified grants management system, GrantEase.

DATES: The deadline to submit a Pre-Application is 11:59 p.m. Eastern Standard Time on Friday, March 10, 2023.

FOR FURTHER INFORMATION CONTACT: David Bonebrake, Program Counsel for Technology, Office of Program Performance, Legal Services Corporation, 3333 K Street NW, Washington, DC 20007; (202) 295-1547 or dbonebrake@lsc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Since 2000, Congress has provided an annual appropriation to LSC to award special funding for client self-help and information technology projects. LSC's Technology Initiative Grant (TIG) program funds technology tools that help achieve LSC's goal of increasing the quantity and quality of legal services available to eligible persons. Projects funded under the TIG program develop, test, and replicate innovative technologies that can enable grant recipients and state justice communities to improve low-income persons' access to high-quality legal assistance through an integrated and well-managed technology system. The TIG program also supports effective technology planning and management at LSC-funded organizations through the use of targeted assessment grants focused on improvements to technology systems and information security.

II. Funding Opportunity Information

A. Eligible Applicants

To be eligible for Technology Initiative Grants, applicants must be

current grantees of LSC Basic Field-General, Basic Field-Migrant, or Basic Field-Native American grants. In addition, applicants must receive basic field funding of at least a one-year term, be up to date on reporting on any existing TIG-funded projects, and not have had a previous TIG terminated in the past three years for reporting or other performance issues.

B. Technology Initiative Grant Purpose and Key Goals

Since LSC's TIG program was established in 2000, LSC has made over 859 grants totaling over \$81 million. This grant program encourages organizations to use technology in innovative ways to:

1. Effectively and efficiently provide high-quality legal assistance to low-income persons and to promote access to the judicial system through legal information, advice, and representation.
2. Improve service delivery, quality of legal work, and management and administration of grantees.
3. Develop, test, and replicate innovative strategies that can enable grantees and state justice communities to improve clients' access to high-quality legal assistance.

C. Funding Categories

1. General Technology Initiative Grants

Projects in this category (1) implement new or innovative approaches for using technology in legal services delivery; (2) enhance the effectiveness and efficiency of existing technologies so that they may be better used to increase the quality and quantity of services to clients; or (3) replicate, adapt, or provide added value to the work of prior technology projects. This includes, but is not limited to, the implementation and improvement of tested methodologies and technologies from previous TIG projects. We also encourage replication of proven technologies from non-LSC funded legal aid organizations as well as sectors outside the legal aid community. (Applicants seeking continuation funding for their own existing TIG initiatives may wish to apply under the new Adoption, Expansion and Enhancement Grants category discussed below.)

LSC recommends a minimum amount for funding requests in this category of \$40,000, but projects with lower budgets will be considered. There is no maximum amount for TIG funding requests that are within the total appropriation for TIG. All applicants in this category must submit a pre-application according to the process and requirements outlined in this notice.

2. Technology Improvement Projects

LSC recognizes that grantees need sufficient technology infrastructure in place before they can take on a more innovative TIG project, and this grant category is for applicants that need to improve their basic technology infrastructure or their information security posture. The maximum funding amount for this category is \$35,000.

Technology Improvement Projects do not require a pre-application. LSC will open the application system and provide guidance for this project category by April 10, 2023. The application deadline for Technology Improvement Projects is May 19, 2023.

3. Adoption, Expansion, and Enhancement Grants

In 2023, LSC is piloting a new category, called Adoption, Expansion, and Enhancement Grants, to provide continuation funding for those TIG projects that have moved beyond the proof-of-concept phase and demonstrated excellent results. This funding will allow successful TIG grantees to further build upon a specific project and its technologies, ensure that their TIG-funded work is effectively integrated into the service delivery system, and complete the project activities necessary to ensure the initiative's long-term success.

Adoption, Expansion, and Enhancement Grants are available to current Technology Initiative Grant (TIG) recipients and to recipients of recently completed TIG projects. (Applicants seeking to enhance a non-TIG initiative or replicate another organization's project should apply under the General category.) There is not a pre-application for these proposals, but LSC encourages all prospective applicants to meet with their regional TIG program manager to discuss whether an Adoption, Expansion, and Enhancement grant may be a good fit. Applicants should be able to clearly demonstrate that their project was successful and that they have a reasonable plan for building on that success.

LSC recommends a minimum amount for funding requests in this category of \$40,000, but projects with lower budgets will be considered. There is no maximum amount for TIG funding requests that are within the total appropriation for TIG.

Adoption, Expansion, and Enhancement Grants do not require a pre-application. LSC will open the application system and provide guidance for this project category by April 10, 2023, and the application deadline is May 19, 2023.

D. Available Funds for 2023 Grants

A total of \$5 million is available for 2023 TIG awards. LSC will not designate fixed or estimated amounts for the three different funding categories and will make grant awards for the three categories within the total amount of funding available.

E. Grant Terms

Applicants to the Technology Initiative Grant (TIG) program may propose grant terms between 12 and 36 months for general category projects and between 12 and 18 months for technology improvement projects. For the new Adoption, Expansion, and Enhancement category, the grant term is set at 24 months. The grant term for all TIGs is expected to commence on November 1, 2023.

III. Grant Application Process

A. Technology Initiative Grant Application Process

The Technology Initiative Grant (TIG) application process will be administered in LSC's unified grants management system, GrantEase. Applicants in the General TIG category must first submit a pre-application to LSC in GrantEase by March 10, 2023, at 11:59 p.m. ET, to be considered for a grant. After review by LSC staff, LSC's president decides which applicants will be asked to submit a full application. Applicants will be notified of approval to submit a full application by late-April 2023. Full applications are due to LSC in the GrantEase system on June 2, 2023, at 11:59 p.m. ET. Once received, full applications will undergo a rigorous review by LSC staff. LSC's president makes the final decisions on funding for the Technology Initiative Grant program.

As noted above, applicants applying for Technology Improvement Project funding or in the new Adoption, Expansion, and Enhancement category are not required to submit pre-applications. LSC will launch the online application system for these categories by April 10, 2023, and set a submission deadline of May 19, 2023, at 11:59 p.m. ET. LSC follows a similar review process for applications in these categories, which includes LSC staff conducting a rigorous review of all proposals and the LSC president making final funding decisions.

B. Late or Incomplete Applications

LSC may consider a request to submit a pre-application after the deadline, but only if the applicant has submitted an email to techgrants@lsc.gov explaining

the circumstances that caused the delay prior to the pre-application deadline. Communication with LSC staff, including assigned program liaisons, is not a substitute for sending a formal request and explanation to techgrants@lsc.gov. At its discretion, LSC may consider incomplete applications. LSC will determine whether it will consider late or incomplete applications on a case-by-case basis.

C. Multiple Pre-Applications

Applicants may submit multiple pre-applications. If applying for multiple grants that require pre-applications, applicants should submit separate pre-applications for each funding request.

D. Additional Information and Guidelines

Additional guidance and instructions on the pre-application and application processes for Technology Initiative Grants will be available and regularly updated at <https://www.lsc.gov/grants/technology-initiative-grant-program>.

(Authority: 42 U.S.C. 2996g(e))

Dated: January 12, 2023.

Stefanie Davis,

Senior Associate General Counsel.

[FR Doc. 2023-00910 Filed 1-18-23; 8:45 am]

BILLING CODE 7050-01-P

POSTAL REGULATORY COMMISSION

[Docket No. T2023-1; Order No. 6412]

Income Tax Review

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is recognizing a recent Postal Service filing concerning the calculation of the assumed Federal income tax on competitive products income for Fiscal Year 2022. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 14, 2023.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT:

David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Notice of Commission Action
- III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3634 and 39 CFR 3060.40 *et seq.*, the Postal Service filed its calculation of the assumed Federal income tax on Competitive products income for Fiscal Year (FY) 2022.¹ The calculation details the FY 2022 Competitive product revenue and expenses, the Competitive products net income before tax, and the assumed Federal income tax on that net income.

II. Notice of Commission Action

In accordance with 39 CFR 3060.42, the Commission establishes Docket No. T2023-1 to review the calculation of the assumed Federal income tax and supporting documentation.

The Commission invites comments on whether the Postal Service's filing in this docket is consistent with the policies of 39 U.S.C. 3634 and 39 CFR 3060.40 *et seq.* Comments are due no later than April 14, 2023. The Postal Service's filing can be accessed via the Commission's website (<http://www.prc.gov>).

The Commission appoints Jennaca D. Upperman to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. T2023-1 to consider the calculation of the assumed Federal income tax on Competitive products for FY 2022.

2. Pursuant to 39 U.S.C. 505, Jennaca D. Upperman is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than April 14, 2023.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2023-00904 Filed 1-18-23; 8:45 am]

BILLING CODE 7710-FW-P

¹ See Notice of the United States Postal Service of Submission of the Calculation of the FY 2022 Assumed Federal Income Tax on Competitive Products, January 11, 2023.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96649; File No. SR-C2-2023-003]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule

January 12, 2023.

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 January 3, 2023, Cboe C2 Exchange, Inc. (the “Exchange” or “C2”) 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 C2 Exchange, Inc. (the “Exchange” or “C2”) proposes to amend the Exchange’s Fee Schedule (“Fee Schedule”) to reflect adjustments to the Financial Industry Regulatory Authority, Inc. (“FINRA”) General Registration Fees, Fingerprinting Fees, and Continuing Education Fees. 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://markets.cboe.com/us/options/regulation/rule_filings/ctwo/), 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 its Fee Schedule regarding Regulatory Fees to reflect updates to the FINRA Disclosure Processing Fee, Annual System Processing Fee, Fingerprint Processing Fees, and Continuing Education Fees.³ The applicable fees are collected and retained by FINRA via Web CRD⁴ for the registration of associated persons of Exchange Trading Permit Holder (“TPH”) organizations that are not FINRA members (“Non-FINRA members”). The Exchange is merely listing these fees on its Fee Schedule and does not collect or retain the fees.

Specifically, the Exchange proposes to amend: (1) the \$110 fee for the additional processing of each initial or amended Form U-4, Form U-5, Form BD and amendments that include the initial reporting, amendment, certification, or one or more disclosure events or proceedings to \$155; (2) the \$45 FINRA Annual System Processing Fee assessed only during Renewals to \$70;⁵ and (3) the current \$55 per continuing education exam fee to \$18 per exam. These amendments are being made in accordance with a FINRA rule change and a FINRA amendment to its By-Laws to adjust these fees.⁶

The Exchange also proposes to amend the following Fingerprint Fees: (1) the \$29.50 Initial Submission (Electronic) fee to \$31.25;⁷ (2) the \$15 Second Submission (Electronic) Fingerprint Processing Fee to \$20; (3) the \$29.50 Third Submission (Electronic) fee to \$31.25;⁸ (4) the \$44.50 Initial

Submission (Paper) fee to \$41.25;⁹ and (5) the \$44.50 Third Submission (Paper) fee to \$41.25.¹⁰ Specifically, today, the FBI fingerprint charge is \$11.25¹¹ and the FINRA electronic Fingerprint Fee will increase from \$15 to \$20 in 2023.¹² While FINRA did not amend the paper Fingerprint Fee, previously the FBI fee was reduced from \$14.50 to \$11.25.¹³ The paper Fingerprint Fees are not currently reflecting the amount assessed by FINRA. The amendment to the paper Fingerprint Fees will conform these fees with those of FINRA.

The FINRA Web CRD Fees are user-based, and there is no distinction in the cost incurred by FINRA if the user is a FINRA-member itself, associated with a FINRA-member organization, or a Non-FINRA member. Accordingly, the proposed fees mirror those currently assessed by FINRA.¹⁴

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.¹⁵ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁶ 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 facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the

³ See Securities Exchange Act Releases No. 34-90176 (October 14, 2020), 85 FR 66592 (October 20, 2020) (SR-FINRA-2020-032) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Adjust FINRA Fees to Provide Sustainable Funding for FINRA’s Regulatory Mission); and 93928 (January 7, 2022), 87 FR 2193 (January 13, 2022) (SR-FINRA-2021-034) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend Section 4 of Schedule A to the FINRA By-Laws Relating to the Continuing Education Fees).

⁴ FINRA operates Web CRD, the central licensing and registration system for the U.S. securities industry. FINRA uses Web CRD to maintain the qualification, employment, and disciplinary histories of registered associated persons of broker-dealers.

⁵ This fee change will not be effective until January 2, 2024.

⁶ *Supra* note 3.

⁷ This fee includes a \$20.00 FINRA fee and \$11.25 FBI fee. See <https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees>.

⁸ This fee includes a \$20.00 FINRA fee and \$11.25 FBI fee. See <https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees>.

⁹ This fee includes a \$30.00 FINRA fee and a \$11.25 FBI fee. See <https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees>.

¹⁰ This fee includes a \$30.00 FINRA fee and a \$11.25 FBI fee. See <https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees>.

¹¹ See Securities Exchange Act Release No. 34-67247 (June 25, 2012), 77 FR 38866 (June 29, 2012) (SR-FINRA-2012-030) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Sections 4 and 6 of Schedule A to the FINRA By-Laws Regarding Fees Relating to the Central Registration Depository) (“2012 Rule Change”).

¹² *Supra* note 3.

¹³ See 2012 Rule Change at note 11. The FBI does not charge its fee on a second fingerprint transaction when it identifies the first set of fingerprints as illegible for the same individual.

¹⁴ *Supra* note 3.

¹⁵ 15 U.S.C. 78f(b).

¹⁶ 15 U.S.C. 78f(b)(5).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

proposed rule change is consistent with the Section 6(b)(5)¹⁷ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. All similarly situated FINRA-Member organizations are subject to the same fee structure, and all must use the CRD system for registration and disclosure.

The Exchange believes the proposed changes to the FINRA Disclosure Processing Fee, Annual System Processing Fee, Fingerprint Fees, and continuing education fee are reasonable because they are identical to the fee changes adopted by FINRA for use of the Web CRD system for disclosure, registration, and continuing education of associated persons of FINRA Members and their associated persons.¹⁸ The costs are borne by FINRA when a non-FINRA member uses Web CRD for these purposes. Thus, the Exchange's Fee Schedule will reflect the current rates that will be assessed by FINRA as of January 2, 2023 and January 2, 2024, as applicable, for use of Web CRD by any Trading Permit Holders that are not also FINRA members for the additional processing of each initial or amended Form U4, Form U5 or Form BD, (Electronic) Fingerprint Processing, registration, and continuing education. The Exchange believes the proposed fee changes are equitable and not unfairly discriminatory, because the Exchange will not be collecting or retaining these fees, and therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

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 believes that its proposal will not impose an undue burden on competition because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner. The proposal will reflect the fees that will be assessed by FINRA to all market participants (FINRA and non-FINRA members) for these uses of Web CRD.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁹ and paragraph (f) of Rule 19b-4²⁰ 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-C2-2023-003 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-C2-2023-003. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<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-C2-2023-003 and should be submitted on or before February 9, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²¹

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023-00913 Filed 1-18-23; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96644; File No. SR-CBOE-2023-002]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule To Reflect Adjustments to the Financial Industry Regulatory Authority, Inc. General Registration Fees, Fingerprinting Fees, and Continuing Education Fees

January 12, 2023.

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 January 3, 2023, 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

¹⁷ *Id.*

¹⁸ *Supra* note 3.

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b-4(f).

²¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

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 amend the Exchange's Fee Schedule ("Fee Schedule") to reflect adjustments to the Financial Industry Regulatory Authority, Inc. ("FINRA") General Registration Fees, Fingerprinting Fees, and Continuing Education Fees. 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 its Fee Schedule regarding Regulatory Fees to reflect updates to the FINRA Disclosure Processing Fee, Annual System Processing Fee, Fingerprint Processing Fees, and Continuing Education Fees.³ The applicable fees are collected and retained by FINRA via Web CRD⁴ for the registration of

³ See Securities Exchange Act Releases No. 34-90176 (October 14, 2020), 85 FR 66592 (October 20, 2020) (SR-FINRA-2020-032) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Adjust FINRA Fees to Provide Sustainable Funding for FINRA's Regulatory Mission); and 93928 (January 7, 2022), 87 FR 2193 (January 13, 2022) (SR-FINRA-2021-034) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend Section 4 of Schedule A to the FINRA By-Laws Relating to the Continuing Education Fees).

⁴ FINRA operates Web CRD, the central licensing and registration system for the U.S. securities industry. FINRA uses Web CRD to maintain the

associated persons of Exchange Trading Permit Holder ("TPH") organizations that are not FINRA members ("Non-FINRA members"). The Exchange is merely listing these fees on its Fee Schedule and does not collect or retain the fees.

Specifically, the Exchange proposes to amend: (1) the \$110 fee for the additional processing of each initial or amended Form U-4, Form U-5, Form BD and amendments that include the initial reporting, amendment, certification, or one or more disclosure events or proceedings to \$155; (2) the \$45 FINRA Annual System Processing Fee assessed only during Renewals to \$70;⁵ and (3) the current \$55 per continuing education exam fee to \$18 per exam. These amendments are being made in accordance with a FINRA rule change and a FINRA amendment to its By-Laws to adjust these fees.⁶

The Exchange also proposes to amend the following Fingerprint Fees: (1) the \$29.50 Initial Submission (Electronic) fee to \$31.25;⁷ (2) the \$15 Second Submission (Electronic) Fingerprint Processing Fee to \$20; (3) the \$29.50 Third Submission (Electronic) fee to \$31.25;⁸ (4) the \$44.50 Initial Submission (Paper) fee to \$41.25;⁹ and (5) the \$44.50 Third Submission (Paper) fee to \$41.25.¹⁰ Specifically, today, the FBI fingerprint charge is \$11.25¹¹ and the FINRA electronic Fingerprint Fee will increase from \$15 to \$20 in 2023.¹² While FINRA did not amend the paper Fingerprint Fee, previously the FBI fee was reduced from \$14.50 to \$11.25.¹³

qualification, employment, and disciplinary histories of registered associated persons of broker-dealers.

⁵ This fee change will not be effective until January 2, 2024.

⁶ *Supra* note 3.

⁷ This fee includes a \$20.00 FINRA fee and \$11.25 FBI fee. See <https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees>.

⁸ This fee includes a \$20.00 FINRA fee and \$11.25 FBI fee. See <https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees>.

⁹ This fee includes a \$30.00 FINRA fee and a \$11.25 FBI fee. See <https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees>.

¹⁰ This fee includes a \$30.00 FINRA fee and a \$11.25 FBI fee. See <https://www.finra.org/registration-exams-ce/classic-crd/fingerprints/fingerprint-fees>.

¹¹ See Securities Exchange Act Release No. 34-67247 (June 25, 2012), 77 FR 38866 (June 29, 2012) (SR-FINRA-2012-030) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Sections 4 and 6 of Schedule A to the FINRA By-Laws Regarding Fees Relating to the Central Registration Depository) ("2012 Rule Change").

¹² *Supra* note 3.

¹³ See 2012 Rule Change at note 11. The FBI does not charge its fee on a second fingerprint transaction when it identifies the first set of fingerprints as illegible for the same individual.

The paper Fingerprint Fees are not currently reflecting the amount assessed by FINRA. The amendment to the paper Fingerprint Fees will conform these fees with those of FINRA.

The FINRA Web CRD Fees are user-based, and there is no distinction in the cost incurred by FINRA if the user is a FINRA-member itself, associated with a FINRA-member organization, or a Non-FINRA member. Accordingly, the proposed fees mirror those currently assessed by FINRA.¹⁴

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.¹⁵ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁶ 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 facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁷ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. All similarly situated FINRA-Member organizations are subject to the same fee structure, and all must use the CRD system for registration and disclosure.

The Exchange believes the proposed changes to the FINRA Disclosure Processing Fee, Annual System Processing Fee, Fingerprint Fees, and continuing education fee are reasonable because they are identical to the fee changes adopted by FINRA for use of the Web CRD system for disclosure, registration, and continuing education of associated persons of FINRA Members and their associated persons.¹⁸ The costs are borne by FINRA when a non-FINRA member uses Web CRD for these purposes. Thus, the Exchange's Fee Schedule will reflect the current

¹⁴ *Supra* note 3.

¹⁵ 15 U.S.C. 78f(b).

¹⁶ 15 U.S.C. 78f(b)(5).

¹⁷ *Id.*

¹⁸ *Supra* note 3.

rates that will be assessed by FINRA as of January 2, 2023 and January 2, 2024, as applicable, for use of Web CRD by any Trading Permit Holders that are not also FINRA members for the additional processing of each initial or amended Form U4, Form U5 or Form BD, (Electronic) Fingerprint Processing, registration, and continuing education. The Exchange believes the proposed fee changes are equitable and not unfairly discriminatory, because the Exchange will not be collecting or retaining these fees, and therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

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 believes that its proposal will not impose an undue burden on competition because the Exchange will not be collecting or retaining these fees, therefore, the Exchange will not be in a position to apply them in an inequitable or unfairly discriminatory manner. The proposal will reflect the fees that will be assessed by FINRA to all market participants (FINRA and non-FINRA members) for these uses of Web CRD.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁹ and paragraph (f) of Rule 19b-4²⁰ 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.

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b-4(f).

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-2023-002 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-2023-002*. 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-2023-002 and should be submitted on or before February 9, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²¹

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2023-00908 Filed 1-18-23; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96662; File No. SR-CBOE-2023-004]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 5.6 Concerning All-or-None Orders With the Size of One Contract

January 13, 2023.

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 January 5, 2023, 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 and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Text of the Proposed Rule Change

(a) Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") proposes to amend Rule 5.6. The text of the proposed rule change is provided below.

(additions are italicized; deletions are [bracketed])

* * * * *
Rules of Cboe Exchange, Inc.
* * * * *

Rule 5.6. Order Types, Order Instructions, and Times-in-Force

(a)-(b) No change.
(c) Order Instructions. An "Order Instruction" is a processing instruction a User may apply to an order (multiple instructions may apply to a single order), subject to the restrictions set forth in Rule 5.5(c) with respect to orders and bulk messages submitted through bulk ports and any other restrictions set forth in the Rules, when entering it into the System for electronic or open outcry processing and includes:

²¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

All-or-None or AON

An “All-or-None” or “AON” order is an order to be executed in its entirety or not at all. An AON order may be a market or limit order. Users may not designate an AON order as All Sessions or RTH and Curb.

(1)–(6) No change.

(7) *The System disregards an AON instruction on an order with a size of one contract.*

* * * * *

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 5.6. Specifically, the proposed rule change codifies in new subparagraph (7) of the definition of an All-or-None (“AON”) order in Rule 5.6(c) that the System will disregard an AON instruction on an order with a size of one contract. An AON order is an order to be executed in its entirety or not at all.³ Any order for one contract (regardless of whether it has an AON instruction) may only be executed in its entirety or not at all, as the Exchange does not permit executions of partial contracts. Therefore, an AON instruction on such an order is unnecessary. If a market participant submits an order for one contract with an AON instruction, that order would execute in the same manner as an order for one contract without an AON instruction. However, in certain circumstances, the System handles orders with AON instructions differently than non-AON orders. For example, pursuant to Rule 5.32(a)(3),

AON orders are generally last in priority. Such provisions may prevent or delay executions of one-lot orders with AON instructions, despite the fact that they would otherwise execute in the same manner as one-lot orders without AON instructions. The Exchange believes it is appropriate to treat all one-lot orders (which are functionally like AON orders (as they can only execute in their entirety or not at all)) as non-AON orders so such orders that unnecessarily include an AON instruction, including AON orders from customers, do not lose otherwise lose priority.

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.⁴ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁵ 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 facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁶ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed rule change will promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system, because the System will handle and prioritize all one-lot orders, which are functionally like AON orders (as they can only execute in their entirety or not at all), in the same manner. The Exchange believes it is equitable to treat all one-lot AON orders as non-AON orders so such orders do not lose priority despite inclusion of an instruction that has no practical impact on its execution. The Exchange believes the proposed rule change may benefit and protect market

participants that submit one-lot orders with unnecessary AON instructions, as it may improve the priority (and possibly increase execution opportunities) of such orders. Additionally, because the proposed rule change codifies current System behavior, it adds transparency and clarity to the Rules, which ultimately benefits investors.

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 intramarket burden that is not necessary or appropriate in furtherance of the purposes of the Act because it applies to all orders for one contract with AON instructions in the same manner. Additionally, as described above, by disregarding an AON instruction on an order for one contract, the System handles and prioritizes all one-lot orders that may execute in their entirety or not at all (and thus all one-lot orders) in the same manner. The Exchange does not believe that the proposed rule change will impose any intermarket burden that is not necessary or appropriate in furtherance of the purposes of the Act because it only impacts how the System internally handles and prioritizes one-lot orders with AON instructions on the Exchange.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act⁷ and Rule 19b–4(f)(6) thereunder.⁸

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 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

Continued

³ Rule 5.6(c).

⁴ 15 U.S.C. 78f(b).

⁵ 15 U.S.C. 78f(b)(5).

⁶ *Id.*

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)⁹ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The codification of the new System functionality to treat all one-lot AON orders as non-AON orders, so that such orders do not lose priority, may benefit and protect investors sooner with the waiver of the operative delay. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest as the proposed rule change does not raise any new or novel issues. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.¹⁰

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.

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-2023-004 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.

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.

⁹ 17 CFR 240.19b-4(f)(6)(iii).

¹⁰ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

All submissions should refer to File Number SR-CBOE-2023-004. 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-2023-004 and should be submitted on or before February 9, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2023-00989 Filed 1-18-23; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96654; File No. SR-NYSEAMER-2022-53]

Self-Regulatory Organizations; NYSE American LLC; Notice of Withdrawal of Proposed Rule Change To Amend Rule 7.19E Concerning Pre-Trade Risk Controls

January 12, 2023.

On November 17, 2022, NYSE American LLC ("NYSE American") filed with the Securities and Exchange Commission (the "Commission"),

¹¹ 17 CFR 200.30-3(a)(12).

pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act")¹ and Rule 19b-4 thereunder² to add additional pre-trade risk controls to Rule 7.19E. The proposed rule change was published for comment on December 5, 2022.³ On January 10, 2023, NYSE American withdrew the proposed rule change (SR-NYSEAMER-2022-53).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2023-00909 Filed 1-18-23; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34804; 812-15402]

RBB Fund Trust and Element ETFs, LLC

AGENCY: Securities and Exchange Commission ("Commission" or "SEC").
ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 ("Act") for an exemption from section 15(a) of the Act and Rule 18f-2 thereunder, as well as from certain disclosure requirements in rule 20a-1 under the Act, Item 19(a)(3) of Form N-1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934, and sections 6-07(2)(a), (b), and (c) of Regulation S-X ("Disclosure Requirements").

SUMMARY OF APPLICATION: The requested exemption would permit Applicants to enter into and materially amend subadvisory agreements with subadvisers without shareholder approval and would grant relief from the Disclosure Requirements as they relate to fees paid to the subadvisers.

APPLICANTS: RBB Fund Trust, and Element ETFs, LLC.

FILING DATES: The application was filed on November 2, 2022, and amended on December 16, 2022.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 96403 (November 29, 2022), 87 FR 74459 (December 5, 2022). Comments received on the proposal are available on the Commission's website at: <https://www.sec.gov/comments/sr-nyseamer-2022-53/srnyseamer202253.htm>.

⁴ 17 CFR 200.30-3(a)(12).

will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on February 6, 2023, and should be accompanied by proof of service on the Applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0-5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov*. Applicants: Steven Plump, *splump@rbbfund.com*; and Aisha Hunt, *aisha@kelleyhuntlaw.com*.

FOR FURTHER INFORMATION CONTACT: Lisa Ragen, Branch Chief, at (202) 551-6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' amended application, dated December 16, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field on the SEC's EDGAR system. The SEC's EDGAR system may be searched at <https://www.sec.gov/edgar/searchedgar/legacy/companysearch.html>. You may also call the SEC's Public Reference Room at (202) 551-8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Dated: January 12, 2023.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2023-00893 Filed 1-18-23; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96646; File No. SR-C2-2023-002]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule

January 12, 2023.

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 January 3, 2023, Cboe C2 Exchange, Inc. (the "Exchange" or "C2") 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 C2 Exchange, Inc. (the "Exchange" or "C2") is filing with the Securities and Exchange Commission ("Commission") a proposed rule change to amend the fees schedule. 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://markets.cboe.com/us/options/regulation/rule_filings/ctwo/), 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 its fee schedule in connection with its discount program for Bulk BOE Logical Ports, effective January 3, 2023.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 options venues to which market participants may direct their order flow. Based on publicly available information, no single options exchange has more than approximately 18% of the market share and currently the Exchange represents approximately 4% of the market share.³ Thus, in such a low-concentrated and highly competitive market, no single options exchange, including the Exchange, possesses significant pricing power in the execution of option order flow. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange currently offers BOE Bulk Logical Ports ("BOE Bulk Ports"), which provide users with the ability to submit single and bulk order messages to enter, modify, or cancel orders designated as Post Only Orders with a Time-in-Force of Day or GTD with an expiration time on that trading day. Bulk BOE Ports are assessed \$1,500 per port, per month for the first five Bulk BOE Ports and thereafter assessed \$2,500 per port, per month for each additional Bulk BOE Port. Each Bulk BOE Port also incurs the logical port fee indicated in the table above when used to enter up to 30,000,000 orders per trading day per logical port as measured on average in a single month. Each incremental usage of up to 30,000,000 orders per day per Bulk BOE Port will incur an additional logical port fee of

³ See Cboe Global Markets U.S. Options Market Volume Summary by Month (December 27, 2022), available at https://markets.cboe.com/us/options/market_statistics/.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

\$2,500 per month (“incremental usage fees”). The Exchange also offers a discount program for Bulk BOE Ports, which provides an opportunity for Market-Makers to obtain credits on their monthly Bulk BOE Port fees (excluding incremental usage fees).⁴ Currently, under the Bulk BOE Ports discount program, Market-Makers will receive a (i) 30% discount on its monthly Bulk BOE Port fees (excluding incremental usage fees) where a Market-Maker has (1) a Step-Up ADAV⁵ equal to or greater than 0.03% of average OCV⁶ from June 2021 and (2) a “Make Rate” equal to or greater than 97%⁷ or a (ii) 40% discount on its monthly Bulk BOE Logical Port fees, excluding incremental usage fees, where the Market-Maker (1) has a Step-Up ADAV equal to or greater than 0.05% of OCV from June 2021 and (2) has a “Make Rate” equal to or greater than 97%.

The Exchange proposes to amend the current criteria under the Bulk BOE Port discount program required to receive the offered discounts. Particularly, the proposed rule change amends the current criteria in prong one for both the 30% and 40% discounts by changing the base “step-up” month from June 2021 to September 2022.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,⁸ in general, and furthers the objectives of Section 6(b)(4),⁹ in particular, as it is designed to provide for the equitable

allocation of reasonable dues, fees and other charges among its Trading Permit Holders and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5)¹⁰ 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 facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed rule change to amend the Bulk BOE Ports discount program is reasonable, equitable and not unfairly discriminatory. The Exchange believes the proposed rule change to update the baseline month to a month that is closer in time provides for a more relevant measure for “step-up” volume. The Exchange believes the Bulk BOE Port discount program, currently and as amended, is designed to attract liquidity from traditional Market-Makers and encourage Market-Makers to grow their volume. Increased liquidity and enhanced quote streaming from Market Makers generally provide greater trading opportunities and tighter spreads, signaling an additional corresponding increase in order flow from other market participants. This potentially deepens the Exchange’s liquidity pool, provides increased execution incentives and opportunities, offers additional flexibility for all investors to enjoy cost savings, supports the quality of price discovery, promotes market transparency and improves investor protection.

The proposed rule change to amend the Bulk BOE Port discount program, which is offered only to Market Makers, is equitable and not unfairly discriminatory because Market Makers are valuable market participants that provide liquidity in the marketplace and incur costs that other market participants do not incur. For example, Market Makers have a number of obligations, including quoting obligations and fees associated with appointments that other market participants do not have. As noted above, the Exchange also believes that

the discount program, even as amended, provides an incentive for Market Makers to provide more liquidity to the Exchange. Generally, greater liquidity benefits all market participants by providing more trading opportunities and tighter spreads. The Exchange also believes it is reasonable, equitable and not unfairly discriminatory to provide credits to those Market Makers that primarily provide and post liquidity to the Exchange, as the Exchange wants to continue to encourage Market Makers with significant Make Rates to continue to participate on the Exchange and add liquidity. Further, the discount program, even as amended, is intended to mitigate the costs incurred by traditional Market Makers that focus on adding liquidity to the Exchange (as opposed to those that provide and take, or just take). Additionally, while the Exchange has no way of predicting with certainty how many and which Market Makers will satisfy the proposed criteria to receive the discount, the Exchange anticipates at least two Market Makers will satisfy the criteria across the two tiers to receive the applicable discounts. The Exchange does not believe the proposed discount will adversely impact any Market Maker’s pricing. Rather, should a Market Maker not meet the proposed criteria, the Market Maker will merely not receive the proposed discount.

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 the proposed rule change to amend the Bulk BOE Port discount program offered to Market Makers will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because Market Makers are valuable market participants that provide liquidity in the marketplace and incur costs that other market participants do not incur. As described above, Market Makers have a number of obligations, including quoting obligations and fees associated with appointments that other market participants do not have. The proposed change is also equitable and not unfairly discriminatory as it applies uniformly to all Market-Makers. The Exchange does not believe the proposed rule change does will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange

⁴ While BOE Bulk Ports are available to all market participants, they are used primarily by Market Makers or firms that conduct similar business activity.

⁵ “ADAV” means average daily added volume calculated as the number of contracts added per day. ADAV is calculated on a monthly basis, excluding contracts added or removed on any day that the Exchange’s system experiences a disruption that lasts for more than 60 minutes during regular trading hours (“Exchange System Disruption”) and on any day with a scheduled early market close.

⁶ “OCV” (or “OCC Customer Volume” means, the total equity and ETF options volume that clears in the Customer range at the Options Clearing Corporation (“OCC”) for the month for which the fees apply, excluding volume on any day that the Exchange experiences an Exchange System Disruption and on any day with a scheduled early market close.

⁷ The “Make Rate” shall be derived from a Market-Maker’s volume the previous month in all symbols using the following formula: (i) the Market-Maker’s total simple add volume divided by (ii) the Market-Maker’s total simple volume. Trades on the open and complex orders will be excluded from the Make Rate calculation. The Exchange will aggregate the trading activity of separate Market-Maker firms for purposes of the discount tier and make rate calculation if there is at least 75% common ownership between the firms as reflected on each firm’s Form BD, Schedule A.

⁸ 15 U.S.C. 78f.

⁹ 15 U.S.C. 78f(b)(4).

¹⁰ 15 U.S.C. 78f(b)(5).

operates in a highly competitive market. Trading Permit Holders have numerous alternative venues that they may participate on and director their order flow, including 15 other options exchanges and off-exchange venues. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single options exchange has more than 18% of the market share. Therefore, no exchange possesses significant pricing power in the execution of option order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, 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.” The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition v. Securities and Exchange Commission*, the D.C. Circuit stated as follows: “[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’ . . .”. Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹¹ and paragraph (f) of Rule 19b-4¹² 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-C2-2023-002 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-C2-2023-002. 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-C2-2023-002 and should be submitted on or before February 9, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023-00912 Filed 1-18-23; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270-580, OMB Control No. 3235-0642]

Proposed Collection; Comment Request; Extension: Investment Company Interactive Data

Upon Written Request, Copies Available

From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the “Commission”) is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget (“OMB”) for extension and approval.

Certain funds have current requirements to submit to the Commission information included in their registration statements, or information included in or amended by any post-effective amendments to such registration statements, in response to certain form items in structured data language (“Investment Company Interactive Data”). This also includes the requirement for funds to submit interactive data to the Commission for any form of prospectus filed pursuant to 17 CFR 230.497(c) or 17 CFR 230.497(e)

¹¹ 15 U.S.C. 78s(b)(3)(A).

¹² 17 CFR 240.19b-4(f).

¹³ 17 CFR 200.30-3(a)(12).

under the Securities Act of 1933 (“Securities Act”) [15 U.S.C. 77a *et seq.*] that includes information in response to certain form items. This collection of information relates to regulations and forms adopted under the Securities Act, and the Investment Company Act of 1940 (“Investment Company Act”) [15 U.S.C. 80a–1 *et seq.*], that set forth disclosure requirements for funds and other issuers.

On October 26, 2022, the Commission adopted rule and form amendments that require open-end management investment companies (“open-end funds”) to transmit concise and visually engaging annual and semi-annual reports to shareholders that highlight key information that is particularly important for retail investors to assess and monitor their fund investments.¹ The Commission also adopted amendments to Form N–1A, Form N–CSR, and rule 405 of Regulation S–T to require certain new structured data requirements for open-end funds.² Specifically, the final rule and form amendments require open-end funds to tag their shareholder report contents using Inline eXtensible Business Reporting Language or “Inline XBRL.” These requirements will make open-end funds’ shareholder report disclosure more readily available and easily accessible for aggregation, comparison, filtering, and other analysis.

The Commission estimates that the total current annual hour burden associated with the Investment Company Interactive Data requirements is approximately 252,684 hours. Based on estimates of 11,840 open-end funds, each incurring 6 hours on average annually to tag their shareholder reports using Inline XBRL, the Commission estimates that, in the aggregate, funds will incur an additional 71,040 annual burden hours. The Commission therefore estimates that, in the aggregate, Investment Company Interactive Data requirements will result in approximately 323,724 annual burden hours (252,684 currently-estimated annual burden hours + 71,040 additional estimated annual burden hours).

The Commission estimates that the current average cost burden associated with the Investment Company Interactive Data requirements is approximately \$15,449,450 per year.

¹ See Tailored Shareholder Reports for Mutual Funds and Exchange-Traded Funds; Fee Information in Investment Company Advertisements, Investment Company Act Release No. 34731 (Oct. 26, 2022) (“Shareholder Reports Adopting Release”).

² See Shareholder Reports Adopting Release at section II.H.

Based on the estimate of 11,840 open-end funds, each incurring approximately \$50 additional annual external cost associated with tagging their shareholder reports using Inline XBRL, the Commission estimates that, in the aggregate, funds will incur an additional \$592,000 in annual external costs. The Commission therefore estimates that, in the aggregate, Investment Company Interactive Data requirements will result in approximately \$16,041,450 in external costs (\$15,449,450 in currently-estimated external costs + \$592,000 in additional external costs).

Estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms.

The collection of information under the Investment Company Interactive Data requirements is mandatory for all funds. Responses to the disclosure requirements will not be kept confidential. 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.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission’s estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by March 20, 2023.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: PRA_Mailbox@sec.gov.

Dated: January 13, 2023.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2023–00986 Filed 1–18–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34807; File No. 812–15297]

Prospect Capital Management L.P. and Prospect Floating Rate and Alternative Income Fund, Inc.

January 13, 2023.

AGENCY: Securities and Exchange Commission (“Commission” or “SEC”).

ACTION: Notice.

Notice of application for an order under section 6(c) of the Investment Company Act of 1940 (the “Act”) granting an exemption from section 23(a)(1) of the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end management investment companies and business development companies (as defined under section 2(a)(48) of the Act) to pay investment advisory fees (as described in the application) in shares of their common stock.

APPLICANTS: Prospect Capital Management L.P. and Prospect Floating Rate and Alternative Income Fund, Inc.

FILING DATES: The application was filed on January 1, 2022 and amended on September 14, 2022 and December 13, 2022.

HEARING OR NOTIFICATION OF HEARING:

An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC’s Secretary at Secretarys-Office@sec.gov and serving the applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on February 7, 2023, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission’s Secretary at Secretarys-Office@sec.gov.

ADDRESSES: The Commission: Secretarys-Office@sec.gov. Applicants: Russell Winger, Prospect Floating Rate and Alternative Income Fund, Inc., 10 East 40th Street, 42nd Floor, New

York, NY 10016; Steven B. Boehm, Esq., and Cynthia R. Beyea, Esq., Eversheds Sutherland (US) LLP, 700 6th Street NW, Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT:

Christopher D. Carlson, Senior Counsel, or Trace W. Rakestraw, Branch Chief, at (202) 551-6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For applicants' representations, legal analysis, and conditions, please refer to applicants' second amended and restated application, dated December 13, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at <http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html>. You may also call the SEC's Public Reference Room at (202) 551-8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023-00971 Filed 1-18-23; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96645; File No. SR-CboeEDGX-2023-002]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

January 12, 2023.

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 January 3, 2023, Cboe EDGX Exchange, Inc. (the "Exchange" or "EDGX") 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 EDGX Exchange, Inc. (the "Exchange" or "EDGX Options") proposes to amend its Fee Schedule. 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://markets.cboe.com/us/options/regulation/rule_filings/edgx/), 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 its Fee Schedule to amend three Market Maker Volume Tiers and increase the Market Maker Add Liquidity Fee, effective January 3, 2023.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 options venues to which market participants may direct their order flow. Based on publicly available information, no single options exchange has more than 18% of the market share and currently the Exchange represents only approximately 6% of the market share.³ Thus, in such a low-concentrated and highly competitive market, no single options exchange, including the Exchange, possesses significant pricing power in the execution of option order flow. The Exchange believes that the

ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange's Fees Schedule sets forth standard rebates and rates applied per contract. For example, the Exchange assesses a standard fee of \$0.20 per contract for Market Maker orders that add liquidity in both Penny and Non-Penny Securities and \$0.23 per contract for Market Maker orders that remove liquidity in both Penny and Non-Penny securities. The Fee Codes and Associated Fees section of the Fees Schedule also provide for certain fee codes associated with certain order types and market participants that provide for various other fees or rebates. Additionally, the Fee Schedule offers tiered pricing which provides Members⁴ opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing, which provides Members with opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

For example, pursuant to Footnote 2 of the Fees Schedule, the Exchange currently offers eight [sic] Market Maker Volume Tiers which provide reduced fees between \$0.01 and \$0.17 per contract for qualifying Market Makers orders that yield fee code PM or NM where a Member meets the respective tiers' volume thresholds.⁵ The Exchange proposes to amend the reduced fees that correspond to Market Maker Volume Tiers 4, 5 and 6. Currently, Market Maker Volume Tier 4 provides a reduced fee of \$0.07 per contract for a Member's qualifying orders (*i.e.*, yielding fee code PM or NM) if a Member has an ADV⁶ in Customer

⁴ See Exchange Rule 1.5(n).

⁵ See Cboe EDGX U.S. Options Exchange Fees Schedule, Footnote 2, Market Maker Volume Tiers.

⁶ "ADV" means average daily volume calculated as the number of contracts added or removed, combined, per day. ADV is calculated on a monthly

Continued

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Cboe Global Markets U.S. Options Market Monthly Volume Summary (December 27, 2022), available at https://markets.cboe.com/us/options/market_statistics/.

orders greater than or equal to 0.50% of average OCV⁷; Market Maker Volume Tier 5 provides a reduced fee of \$0.03 per contract for a Member's qualifying orders (*i.e.*, yielding fee code PM or NM) if a Member has an ADV in Customer orders greater than or equal to 0.95% of average OCV; and Market Maker Volume Tier 6 provides a reduced fee of \$0.01 per contract for a Member's qualifying orders (*i.e.*, yielding fee code PM or NM) if a Member has an ADV in Customer orders greater than or equal to 1.45% of average OCV. The Exchange proposes to increase each of the offered reduced fees for each of these tiers by \$0.01 per contract. More specifically, the Exchange proposes to increase the reduced fees as follows: under Tier 4 from \$0.07 per contract to \$0.08 per contract; under Tier 5 from \$0.03 per contract to \$0.04 per contract; and under Tier 6 from \$0.01 per contract to \$0.02 per contract. The Exchange also proposes to amend the criteria under Tier 5.⁸ Particularly, the Exchange proposes to require that Members have an ADV in Market Maker orders of greater than or equal to 1.20% (instead of 0.95%) of average OCV.

The Exchange lastly proposes to increase the standard fee for Market Maker orders that remove liquidity in both Penny and Non-Penny Securities (*i.e.*, yield fee codes PT and NT, respectively) from \$0.23 per contract to \$0.024 per contract.

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.⁹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁰ 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

basis. See Cboe EDGX Options Exchange Fee Schedule.

⁷ "OCV" means the total equity and ETF options volume that clears in the Customer range at the Options Clearing Corporation ("OCC") for the month for which the fees apply, excluding volume on any day that the Exchange experiences an Exchange System Disruption and on any day with a scheduled early market close. See Cboe EDGX Options Exchange Fee Schedule.

⁸ In connection with the proposed fee changes, the Exchange also proposes to update the corresponding listed fees of "\$0.07", "\$0.03" and "\$0.01" for fee codes PM and NM in the Standard Rates table to the proposed new rates of "\$0.08", "\$0.04" and "\$0.02", respectively.

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹¹ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As described above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. Additionally, the Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges,¹² including the Exchange,¹³ and are reasonable, equitable and non-discriminatory because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Competing exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange.

The Exchange believes that increasing the reduced fees offered under Market Maker Volume Tiers 4, 5 and 6 under Footnote 2 are reasonable because Members are still eligible to receive reduced fees for meeting the corresponding criteria, albeit at less of a discount than before. While Market Maker Volume Tiers 4, 5 and 6 will provide a lower fee reduction than that currently offered and while the proposed change to the criteria under Tier 5 will make it more difficult to attain, the Exchange still believes that the changes are reasonable as the tiers, even as amended, will continue to incentivize Members to send additional Market Maker orders to the Exchange. An overall increase in activity would deepen the Exchange's liquidity pool,

¹¹ *Id.*

¹² See EDGX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

¹³ See BZX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

offers additional cost savings, support the quality of price discovery, promote market transparency and improve market quality, for all investors. Moreover, the Exchange is not required to maintain these tiers nor provide reduced fees. The Exchange believes the proposed changes to the reduced fees offered under these tiers still remain commensurate with the corresponding criteria under the respective tiers, including the proposed change to the criteria under Tier 5. Further, Members still have other opportunities to obtain reduced fees that are not being modified such as via Market Maker Volume Tiers 1 through 3.¹⁴

The Exchange believes the proposed change is also equitable and not unfairly discriminatory because it applies uniformly to all Members. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether these proposed changes would definitely result in any Members qualifying for Tiers 4, 5 and 6. While the Exchange has no way of predicting with certainty how the proposed changes will impact Member activity, based on trading activity from the prior months, the Exchange anticipates that at least 3 Members will achieve Tier 4, 1 Member will achieve Tier 5, and 1 Member will achieve Tier 6. The Exchange also believes that the proposed changes will not adversely impact any Member's ability to otherwise qualify for reduced fees or enhanced rebates offered under other tiers.

The Exchange believes the proposed change to increase the standard fee for Market Maker orders that remove liquidity in both Penny and Non-Penny Securities (*i.e.*, yield fee codes PT and NT, respectively) is reasonable because it is a modest increase and is still in line with (and in fact lower than) fees assessed for similar transactions at other exchanges.¹⁵ The Exchange believes the proposed change is equitable and not unfairly discriminatory because it applies uniformly to all Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose

¹⁴ See Cboe EDGX Options Fees Schedule, Footnote 2.

¹⁵ See, e.g., NYSE Arca Fee Schedule, Transaction Fee for Electronic Executions—Per Contract, which provides Market Makers that remove liquidity are assessed \$0.50 per contract in Penny Issues and \$1.10 per contract in Non-Penny Issues. See also Cboe BZX Options Fees Schedule, which provides Market Makers that remove liquidity are assessed \$0.50 per contract in Penny Program Securities and \$1.10 per contract in Non-Penny Program Securities.

any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In particular, the Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposal to amend the Market Maker Volume Tiers and Market Maker fees for orders that remove liquidity applies to all Members. All Members will continue to have an opportunity to receive reduced fees under various tiers, including Market Maker Volume Tiers 1 through 6, which tiers are generally designed to increase the competitiveness of EDGX and attract order flow and incentivize participants to increase their participation on the Exchange, providing for additional execution opportunities for market participants and improved price transparency. Greater overall order flow, trading opportunities, and pricing transparency benefit all market participants on the Exchange by enhancing market quality and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem.

The Exchange also believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues they may participate on and direct their order flow, including 15 other options exchanges. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single options exchange has more than 18% of the market share. Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchanges if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, 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.” The

fact that this market is competitive has also long been recognized by the courts. *In NetCoalition v. Securities and Exchange Commission*, the D.C. Circuit stated as follows: “[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’ . . .”. Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁶ and paragraph (f) of Rule 19b-4¹⁷ 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-CboeEDGX-2023-002 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-CboeEDGX-2023-002. 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. 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-CboeEDGX-2023-002, and should be submitted on or before February 9, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2023-00906 Filed 1-18-23; 8:45 am]

BILLING CODE 8011-01-P

¹⁶ 15 U.S.C. 78s(b)(3)(A).

¹⁷ 17 CFR 240.19b-4(f).

¹⁸ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96666; File No. SR-Phlx-2023-01]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Schedule of Fees and Credits at Equity 7, Section 3

January 13, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on January 3, 2023, Nasdaq PHLX LLC (“Phlx” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange’s schedule of fees and credits at Equity 7, Section 3. 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

The purpose of the proposed rule change is to amend the Exchange’s schedule of fees and credits at Equity 7,

Section 3. First, the Exchange proposes to remove a \$0.0029 per share executed fee for member organizations that remove liquidity from the Exchange. Second, the Exchange proposes to remove several credits for displayed Quotes/Orders, including credits of \$0.0035, \$0.0034, and \$0.0032 per share executed. Third, the Exchange proposes to add a new credit for displayed Quotes/Orders of \$0.0032 per share executed.

Discontinued Fee To Remove Liquidity

The Exchange proposes to amend its pricing schedule, at Equity 7, Section 3, to remove a current \$0.0029 per share executed fee for a member organization that removes liquidity from the Exchange to the extent that the member organization: (i) adds a daily average of at least 2 million shares of liquidity in all securities from the Exchange during the month; (ii) increases its average daily volume added to the Exchange by 50% or more during the month relative to the month of January 2022; (iii) increases its average daily volume added to and removed from the Exchange by 100% or more during the month relative to the month of January 2022; and (iv) adds and removes a daily average of at least 10 million shares of liquidity in all securities from the Exchange during the month. Currently, the \$0.0029 per share executed fee represents a discount relative to the fee of \$0.0030 per share executed for all other orders that do not meet the criteria to qualify for the \$0.0029 per share executed fee. Therefore, the effect of removing the \$0.0029 per share executed fee is that all orders that remove liquidity from the Exchange would be subject to the \$0.0030 per share executed fee. The Exchange proposes to make a conforming change to the existing \$0.0030 per share executed fee to reflect the fact that, going forward, it will apply to all orders that remove liquidity from the Exchange. The Exchange has limited resources available to it to offer its members market-improving incentives, and it allocates those limited resources to those segments of the market where it perceives the need to be greatest and/or where it determines that the incentive is likely to achieve its intended objective. The Exchange proposes to discontinue the \$0.0029 per share executed fee because it has not induced members to grow materially the extent to which they add liquidity to the Exchange over time.

Discontinued Rebates To Add Displayed Liquidity

The Exchange proposes to remove the following credits presently offered to member organizations that add displayed liquidity to the Exchange: (1) \$0.0035 per share executed for Quotes/Orders entered by a member organization that provides 0.10% or more of total Consolidated Volume during the month; (2) \$0.0034 per share executed for Quotes/Orders entered by a member organization that provides 0.05% or more of total Consolidated Volume during the month and removes 0.02% of total Consolidated Volume during the month; and (3) \$0.0032 per share executed for Quotes/Orders entered by a member organization that: (i) provides a daily average of at least 2 million shares of liquidity in all securities on the Exchange during the month; and (ii) increases its average daily volume of Quotes/Orders added to the Exchange by 75% or more during the month relative to the month of March 2022. The Exchange offers these credits as a means of improving market quality by providing its members with an incentive to increase liquidity on the Exchange. The Exchange has limited resources available to it to offer its members market-improving incentives, and it allocates those limited resources to those segments of the market where it perceives the need to be greatest and/or where it determines that the incentive is likely to achieve its intended objective. Accordingly, the Exchange proposes to eliminate the credits noted above.

New Rebate To Add Displayed Liquidity

The Exchange proposes to establish a new credit that will reward a member organization with a credit of \$0.0032 per share executed for Quotes/Orders that provides 0.05% or more of total Consolidated Volume during the month. The proposed new credit will provide an incentive to member organizations to add liquidity to the Exchange. To the extent that the proposed new credit succeeds in increasing liquidity on the Exchange, the Exchange hopes that additional liquidity will improve the quality of the market and help to grow it over time.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,³ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,⁴ in particular, in that it provides for the equitable allocation of

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78f(b).

⁴ 15 U.S.C. 78f(b)(4) and (5).

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 Exchange's proposed changes to its schedule of credits are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for equity securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition v. Securities and Exchange Commission*, the D.C. Circuit stated as follows: "[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'. . . ."⁵

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."⁶

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for equity security transaction services. The Exchange is only one of several equity venues to which market participants may direct their order flow. Competing equity exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based upon members achieving certain volume thresholds.

Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

The Exchange believes it is reasonable, equitable, and not unfairly discriminatory to eliminate the \$0.0029 per share executed fee for member organizations that remove liquidity from the Exchange and make conforming changes to the fee schedule. The fee has not been successful in inducing members to grow materially the extent to which they add liquidity to the Exchange over time. The Exchange has limited resources to allocate to incentives and it must, from time to time, reallocate those resources to maximize their net impact on the Exchange, market quality, and participants.

It is also reasonable, equitable, and not unfairly discriminatory for the Exchange to streamline its schedule of credits for adding displayed liquidity to the Exchange, including removing three credits and adding a new credit. These adjustments will better align incentives with the Exchange's needs. Again, the Exchange has limited resources to devote to incentive programs, and it is appropriate for the Exchange to reallocate these incentives periodically in a manner that best achieves the Exchange's overall mix of objectives.

Those participants that are dissatisfied with the proposed changes to the Exchange's schedule of fees and credits are free to shift their order flow to competing venues that provide more generous incentives or less stringent qualifying criteria.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange does not believe that its proposals will place any category of Exchange participant at a competitive disadvantage.

The Exchange intends for its proposed changes to its fees and credits to reallocate its limited resources more efficiently and to align them with the Exchange's overall mix of objectives. The Exchange notes that its members are free to trade on other venues to the extent they believe that these proposals

are not attractive. As one can observe by looking at any market share chart, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes.

Intermarket Competition

In terms of inter-market competition, 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 credits and fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own credits and fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which credit or fee changes in this market may impose any burden on competition is extremely limited. The proposals are reflective of this competition.

Even as one of the largest U.S. equities exchanges by volume, the Exchange has less than 20% market share, which in most markets could hardly be categorized as having enough market power to burden competition. Moreover, as noted above, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes. This is in addition to free flow of order flow to and among off-exchange venues, which comprises upwards of 50% of industry volume.

In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

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.

⁵ *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782-83 (December 9, 2008) (SR-NYSEArca-2006-21)).

⁶ Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) ("Regulation NMS Adopting Release").

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act⁷ and paragraph (f) of Rule 19b-4 thereunder.⁸ 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.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-Phlx-2023-01 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-2023-01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and

copying at the principal office of the Exchange. 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-2023-01 and should be submitted on or before February 9, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023-00987 Filed 1-18-23; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2022-0139]

Hours of Service of Drivers: Application for Exemption; Ronnie Brown III

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition; denial of application for exemption.

SUMMARY: FMCSA announces its decision to deny the application from Ronnie Brown III requesting an exemption from five provisions of the Federal hours of service (HOS) regulations and the electronic logging device (ELD) regulations. FMCSA analyzed the application and public comments and determined that the exemption would not achieve a level of safety that is equivalent to, or greater than, the level that 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 or richard.clemente@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view comments, go to www.regulations.gov, insert the docket number "FMCSA-2022-0139" in the keyword box, and click "Search." Next,

sort the results by "Posted (Newer-Older)," choose the first notice listed, and click "View Related Comments."

To view documents mentioned in this notice as being available in the docket, go to www.regulations.gov, insert the docket number "FMCSA-2022-0139" in the keyword box, click "Search," and chose the document to review.

If you do not have access to the internet, you may view the docket by visiting Dockets Operations 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., ET, 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. Background

Current Regulatory Requirements

To reduce the possibility of driver fatigue, FMCSA's HOS regulations in 49 CFR part 395 place limits on the amount of time drivers of commercial motor vehicles (CMVs) may drive. The HOS regulations in 49 CFR 395.3(a)(1) prohibit an individual from driving again after 11 hours driving or 14 hours on duty until they have been off duty for a minimum of 10 consecutive hours, or

⁷ 15 U.S.C. 78s(b)(3)(A).

⁸ 17 CFR 240.19b-4(f).

⁹ 17 CFR 200.30-3(a)(12).

the equivalent of at least 10 consecutive hours off duty. Under 49 CFR 395.3(a)(2)—commonly referred to as the 14-hour “driving window”—a driver has 14 consecutive hours in which to drive up to 11 hours after being off duty for 10 or more consecutive hours. Section 395.3(b)(1) prohibits drivers for a motor carrier that does not operate CMVs every day of the week from driving a CMV after being on duty for 60 hours during any 7 consecutive days, and section 395.3(b)(2) prohibits drivers for a motor carrier that operates CMVs every day of the week from driving a CMV after being on duty for 70 hours in any 8 consecutive days. The ELD regulations in 49 CFR part 395, subpart B, specify minimum performance and design standards and requirements for the mandatory use of these devices by drivers currently required to prepare HOS records of duty status.

Applicant's Request

Ronnie Brown III requests a five-year exemption from 49 CFR 395.3(a)(1), section 395.3(a)(3)(i), section 395.3(a)(2), section 395.3(b)(1) and (2), and the ELD regulations in 49 CFR part 395 subpart B. The applicant is a CMV operator who drives for Gray Transportation in Waterloo, Iowa, and has been driving for 15 years. The requested exemption is solely for Mr. Brown. The applicant states that the HOS regulations create “safety concerns” because they do not always coincide with his natural sleep patterns and are a “one size fits all set of rules.” He further adds that he “can safely drive . . . no matter the amount of sleep [he] get[s] or the length of drive time.”

IV. Method To Ensure an Equivalent or Greater Level of Safety

The applicant believes that his level of safety under the exemption, if granted, would be better than he could achieve by complying with the HOS and ELD regulations because he will receive the proper rest needed when he needs it. He states that he can safely drive and knows when he is tired and does not push beyond his limits of safety, regardless of the amount of sleep he gets or the length of drive time. He states that he always maintains a safe distance from other vehicles, has an excellent driving record, and has never been involved in a preventable crash.

V. Public Comments

On August 19, 2022, FMCSA published Mr. Brown's application and requested public comment [87 FR 51189]. The Agency received 1,223 comments, nearly all filed by individual drivers and owner-operators. Of that

total, 587 comments supported the request, 119 opposed it, and another 515 commenters offered no position either for or against the request, but instead submitted general comments on the HOS and ELD regulations. Joint comments in opposition to the exemption were filed by the Truck Safety Coalition, Citizens for Reliable and Safe Highways (CRASH), and Parents Against Tired Truckers (PATT). The AFL-CIO/Transportation Trades Division (TTD) also opposed the exemption request. The Truck Safety Coalition stated: “[we] strongly request this inadequately justified exemption to HOS and ELD requirements be denied in full. Large truck crash fatalities continue to increase at an alarming pace, and it is incumbent on the Department of Transportation and FMCSA to take every measure possible to reverse this trend and affirm life safety as its top priority by denying the request.” The AFL-CIO/TTD urged FMCSA to reject the request, stating, “While we are sensitive to the needs of drivers, it is simply irresponsible to address concerns with HOS and ELD regulations by wholesale exempting particular individuals from these important safeguards.”

Other general “themes” from those who opposed the request included that: (1) there is no data provided for an equivalent level of safety; (2) HOS rules do save lives and are there for everyone's safety; (3) this request cannot be granted for individuals; (4) if the Agency granted this exemption for one individual, then FMCSA must grant it for everyone; and (5) drivers can utilize the provision in 49 CFR 392.3 if they feel ill or fatigued. Many of the commenters said that if the exemption were granted, they and numerous others would apply for a similar exemption. Others provided general comments requesting changes to many facets of the HOS and ELD regulations.

VI. FMCSA Safety Analysis and Decision

FMCSA evaluated Mr. Brown's application and the public comments and denies the exemption request. Mr. Brown failed to establish that he would maintain a level of safety equivalent to, or greater than, the level achieved without the exemption. The Agency established and enforces the HOS regulations to keep fatigued drivers off the public roadways. Research studies demonstrate that long work hours reduce sleep and harm driver health and that crash risk increases with work hours. The HOS regulations impose limits on when and how long an individual may drive to ensure that

drivers stay awake and alert and to reduce the possibility of cumulative fatigue. The Agency agrees with commenters that if it exempts one individual from the HOS regulations, it could open the door for a huge number of similar exemption requests. Such a result would be inconsistent with a primary goal of the HOS regulations.

For the above reasons, FMCSA denies Ronnie Brown's exemption application.

Robin Hutcherson,
Administrator.

[FR Doc. 2023-00975 Filed 1-18-23; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD 2023-0010]

Request for Comments on the Approval of a Previously Approved Information Collection: Requirements for Eligibility of U.S.-Flag Vessels of 100 Feet or Greater in Registered Length to Obtain a Fishery Endorsement

AGENCY: Maritime Administration, DOT.
ACTION: 60-Day Federal Register notice.

SUMMARY: The Maritime Administration (MARAD) invites public comments on our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information collection OMB 2133-0530 (Requirements for Eligibility of U.S.-Flag Vessels of 100 Feet or Greater in Registered Length to Obtain a Fishery Endorsement) is necessary for MARAD to determine if a particular vessel is owned and controlled by United States citizens and is eligible to receive a fishery endorsement to its documentation. A minor change request to include privacy act statements for the collection of personally identifiable information will be added to the affidavits for this collection. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Comments must be submitted on or before March 20, 2023.

ADDRESSES: You may submit comments identified by Docket No. MARAD-2019-0156 through one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Search using the above DOT docket number and follow the online instructions for submitting comments.

- *Fax:* 1-202-493-2251.

• *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Comments are invited on: (a) whether the proposed collection of information is necessary for the Department’s performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB’s clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Michael C. Pucci, (202) 366-5167, Division of Maritime Programs, Maritime Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, Email: *michael.pucci@dot.gov*.

SUPPLEMENTARY INFORMATION:

Title: Requirements for Eligibility of U.S.-Flag Vessels of 100 Feet or Greater in Registered Length to Obtain a Fishery Endorsement.

OMB Control Number: 2133-0530.

Type of Request: Renewal of a previously approved information collection.

Abstract: In accordance with the American Fisheries Act of 1998, owners of vessels of 100 feet or greater who wish to obtain a fishery endorsement are required to file an Affidavit of United States Citizenship with the Maritime Administration (MARAD). The information collected will be used by MARAD to determine if a vessel is owned and controlled by citizens of the United States in accordance with the requirements of the American Fisheries Act (AFA) of 1998 and, therefore, is eligible to be documented with a fishery endorsement to its documentation.

Respondents: Certain vessel owners, vessel operators, financial institutions, and professional trusts.

Affected Public: Vessel owners, charterers, mortgagees, mortgage trustees and managers of vessels of 100 feet or greater who seek a fishery endorsement for the vessel.

Estimated Number of Respondents: 500.

Estimated Number of Responses: 500.
Annual Estimated Total Annual Burden Hours: 2,950.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administrator.
Gabriel Chavez,
Secretary, Maritime Administration.
[FR Doc. 2023-00914 Filed 1-18-23; 8:45 am]
BILLING CODE 4910-81-P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Capital Magnet Fund; 2023 Funding Round.

Funding Opportunities: Capital Magnet Fund; 2023 Funding Round.

Funding Opportunity Title: Notice of Funds Availability (NOFA) inviting Applications for the fiscal year (FY) 2023 Funding Round of the Capital Magnet Fund (CMF) and waiver of the requirement to verify tenant income annually for CMF Recipients who used their CMF Awards to finance or support rental housing Projects with an Affordability Period covering the dates of April 1, 2020 through December 31, 2021.

Announcement Type: Announcement of funding opportunity.

Funding Opportunity Number: CDFI-2023-CMF.

Catalog of Federal Domestic Assistance (CFDA) Number: 21.011.

Dates:

TABLE 1—FY 2023 CAPITAL MAGNET FUND FUNDING ROUND CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline	Time (eastern time—ET)	Submission method
Last day to create an Awards Management Information System (AMIS) Account (if Applicant doesn't have one).	February 23, 2023.	11:59 p.m. ET.	Electronically via Awards Management Information System (AMIS).
Last day to enter or update the Employer Identification Number (EIN) and Unique Entity Identifier (UEI) numbers in AMIS (all Applicants).	February 23, 2023.	11:59 p.m. ET.	Electronically via AMIS.
Last day to submit SF-424 Mandatory Form (Application for Federal Assistance).	February 23, 2023.	11:59 p.m. ET.	Electronically via <i>Grants.gov</i> .
<i>For Applicants using a Consortium Approach only:</i> Applicants are asked to submit a Service Request in AMIS notifying the CMF Program of the organization's intent to apply as a Consortium Member using the Consortium Approach.	February 23, 2023.	11:59 p.m. ET.	Submit Service Request via AMIS using "Capital Magnet Fund" for the program.
Last day to contact Capital Magnet Fund Staff	March 17, 2023.	5:00 p.m. ET	Submit Service Request via AMIS using "Capital Magnet Fund" for the program; call CDFI Fund Helpdesk: 202-653-0421; or email <i>cmf@cdfi.treas.gov</i> .
Last day to contact CDFI Fund with questions about Compliance or CDFI Certification.	March 17, 2023.	5:00 p.m. ET	Submit Service Request via AMIS using "Compliance and Reporting" or "Certification"; call CCME Helpdesk: 202-653-0423; or email <i>ccme@cdfi.treas.gov</i> .
Last day to contact AMIS-IT Help Desk (regarding AMIS technical problems only).	March 21, 2023.	5:00 p.m. ET	Submit Service Request via AMIS using "Technical Issues" for the program; call AMIS Helpdesk: 202-630-0422; or email <i>amis@cdfi.treas.gov</i> .
Last day to submit CMF Application and Required Attachments.	March 21, 2023.	11:59 p.m. ET.	Electronically via AMIS.

Executive Summary: The Capital Magnet Fund (CMF) is administered by the Community Development Financial Institutions Fund (CDFI Fund). Through the CMF, the CDFI Fund provides financial assistance grants to certified Community Development Financial Institutions (CDFIs) and to qualified Nonprofit Organizations that have the development or management of affordable housing as one of their principal purposes. All Awards provided through this Notice of Funds Availability (NOFA) are subject to funding availability.

I. Program Description

A. Authorizing Statute and Regulation: The CMF was established through the Housing and Economic Recovery Act of 2008 (HERA), which added section 1339 to the Federal Housing Enterprises Financial Safety and Soundness Act of 1992. For a complete understanding of the program, the CDFI Fund encourages Applicants to review the CMF Interim Rule (12 CFR part 1807) as amended February 8, 2016 (the CMF Interim Rule); this NOFA; the CDFI Fund's environmental quality regulation (12 CFR part 1815); the CMF funding application (referred to hereafter as the "Application," meaning the application submitted in response to this NOFA); and the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 1000), which is the Department of the Treasury's codification of the Office of Management and Budget (OMB) government-wide framework for grants management at 2 CFR part 200 (Uniform Administrative Requirements or UAR). Each capitalized term used in this NOFA, but not defined herein, shall have the respective meanings assigned to them in the CMF Interim Rule, the Application, or the Uniform Administrative Requirements. Details regarding Application content requirements are found in the Application and related materials at www.cdfifund.gov/cmfi.

B. History: The CDFI Fund was established by the Riegle Community Development Banking and Financial Institutions Act of 1994 to promote economic revitalization and community development through investment in and assistance to CDFIs. The CMF made its first Awards in FY 2010, with subsequent funding rounds beginning in FY 2016 and occurring annually thereafter. To date, more than \$1.07 billion has been awarded under the CMF Program.

C. Programmatic Changes from the Prior Round NOFA:

1. Ability to apply using a Consortium Approach: Under this NOFA, Applicants will be able to apply for a CMF Award as individual members of a Consortium. See Section I.D.2 and Section I.D.3 for definitions. Additional details on applying for and performing as a Consortium member as it relates to a CMF Award are provided throughout this NOFA.

2. Expansion of the High Opportunity Area (HOA) Definition: In addition to the HOA criteria established by the Federal Housing Finance Agency's Duty to Serve Rule, this NOFA includes Expanded CMF HOA Criteria developed by the CDFI Fund. See Section I.D.6 of this NOFA for additional details.

D. Definitions:

1. Areas of Economic Distress: Areas of Economic Distress are census tracts: (a) where at least 20% of households that are Very Low-Income (50% of AMI or below) spend more than half of their income on housing; or (b) that are designated Qualified Opportunity Zones under 26 U.S.C § 1400Z-1; or (c) that are Low-Income Housing Tax Credit Qualified Census Tracts; or (d) where greater than 20% of households have incomes below the poverty rate and the rental vacancy rate is at least 10%; or (e) where greater than 20% of the households have incomes below the poverty rate and the homeownership vacancy rate is at least 10%; or (f) are Underserved Rural Areas as defined in the CMF Interim Rule. The CDFI Fund will publish a dataset on its website indicating which census tracts are designated as Areas of Economic Distress for the FY 2023 CMF Funding Round.

2. Consortium: A Consortium is comprised of a group of at least two, and no more than five, eligible, and unaffiliated CDFIs or nonprofit affordable housing developers/managers, applying for a CMF Award under this NOFA. The purpose of the Consortium must be to finance and support Affordable Housing, and Economic Development Activities, if applicable.

3. Consortium Approach: The Consortium Approach is the manner in which members of a Consortium apply for a CMF Award under this NOFA, wherein member Applications are evaluated both individually and as a Consortium.

4. Entity Approach: The Entity Approach is the manner in which the Applicant will be using the CMF Award. There are two types of Entity Approaches: (a) financing entities and (b) affordable housing developers/managers. Each Applicant will be required to specify which type of Entity

Approach it will be using prior to starting the Application.

A financing entity is an entity whose predominant business activity is the provision of arm's length transactions and services to independent, unrelated parties, each acting in its own best interest. Such transactions support and promote affordable housing and/or community development through the provision of financial products that serve low-income communities, individuals, or families in underserved markets or communities.

An affordable housing developer/manager is a Nonprofit Organization whose primary mission is the construction, development, redevelopment, preservation, or management of affordable housing. The affordable housing developer/manager may own the housing that it develops; may own it in part, such as a limited partnership; may sell the Homeownership or rental housing it develops once completed; or may sell but continue to manage the housing if rental housing.

5. High Opportunity Areas (HOA):

(A) Standard HOA Criteria: Shall mean the definition of High Opportunity Area (HOA) found in the Federal Housing Finance Agency's Duty to Serve Rule (12 CFR 1282.1), effective as of the date of the publication of this NOFA. This term is defined as: (a) An area designated by the Department of Housing and Urban Development (HUD) as a "Difficult Development Area" during any year covered by an Enterprise's Underserved Markets Plan (Plan) or in the year prior to a Plan's effective date, whose poverty rate falls below 10% (for Metropolitan areas) or below 15% (for Non-Metropolitan areas); or (b) an area designated by a state or local Qualified Allocation Plan (QAP) as a high opportunity area whose poverty rate falls below 10% (for Metropolitan areas) or 15% (for Non-Metropolitan areas). The CDFI Fund will publish a dataset on its website indicating which census tracts are designated as High Opportunity Areas for the FY 2023 CMF Funding Round.

(B) Expanded CMF HOA Criteria: The CMF Program will accept an expanded definition of High Opportunity Area for areas that do not meet the Federal Housing Finance Agency definition, but instead meet a set of Expanded CMF HOA Criteria demonstrating the designated area(s) provide access to a combination of at least three of the following four criteria: (1) high-quality youth (K-12) education opportunities; (2) employment opportunities; (3) transportation opportunities; and/or (4) financial service opportunities. For a

Project to qualify as being in a High Opportunity Area under the Expanded CMF HOA Criteria definition, the location of the Project must meet at least three of the four Expanded CMF HOA Criteria, and cannot be located in a Food Desert as identified by the U.S. Department of Agriculture (<https://www.ers.usda.gov/data/fooddesert>) as of the publication date of this NOFA in the **Federal Register**.

I. CMF HOA Criteria Definitions: To meet the Expanded CMF HOA definition, the location must meet at least three of the following four CMF HOA Criteria:

(1) *Access to High-Quality Youth (K–12) Education:* To meet the high-quality youth (K–12) education criterion, the CMF-financed/supported rental unit(s) must be: (i) located in an area served by a school that, in any of the three years prior to the date of this NOFA, has been either recognized by the U.S. Department of Education as a National Blue Ribbon School, or has received the highest rating available from its State's education agency; and (ii) available to Families living in CMF-financed/supported rental units.

(2) *Access to Employment:* To meet the access to employment criterion, the CMF-financed/supported rental unit(s) must be located within a one-mile radius of one of the 25 largest employers in the applicable county. The largest employers in the county are measured by number of employees at the location(s) in the applicable county.

(3) *Access to Transportation:* To meet the access to transportation criterion, the CMF-financed/supported rental unit(s) must be within $\frac{1}{4}$ mile of a multi-modal transit station (includes at least two forms of public transit such as metro, light rail, bus, ferry, or trolley) if located in a Metropolitan Area. The CMF-financed/supported rental unit(s) must be within two miles of "Fixed-route Public Transportation" if located in a rural ("Non-Metropolitan") area. "Fixed-route Public Transportation" means year-round, regularly scheduled public transportation that operates at least 5 days per week and provides regular service throughout the day.

(4) *Access to Financial Services:* To meet the access to financial services criterion, the CMF-financed/supported rental unit(s) must be in a census tract with a bank or credit union branch presence (*i.e.*, not simply a standalone ATM).

E. Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 1000): The Uniform Administrative Requirements codify financial, administrative, procurement,

and program management standards that federal award-making agencies must follow. Per the Uniform Administrative Requirements, when evaluating award Applications, awarding agencies must evaluate each Applicant's merits, eligibility, and any risks to the program posed by each Applicant. These requirements are designed to ensure that Applicants for federal assistance receive a fair and consistent review prior to an award decision. This review will assess items such as the Applicant's financial stability, quality of management systems, history of performance, and single audit findings. In addition, the Uniform Administrative Requirements include guidance on audit requirements and other award compliance requirements for award Recipients.

F. Priorities: The purpose of the CMF is to attract private capital for and increase investment in the Development, Preservation, Rehabilitation, or Purchase of Affordable Housing for primarily Extremely Low-Income, Very Low-Income, and Low-Income Families, as well as Economic Development Activities, which, In Conjunction With Affordable Housing Activities, implement a Concerted Strategy to stabilize or revitalize a Low-Income Area or Underserved Rural Area. To pursue these objectives, the CDFI Fund has established the following priorities for the FY 2023 CMF Funding Round: (i) Applications where at least 20% of all rental Affordable Housing units that will be financed and/or supported with FY 2023 CMF Awards are reserved for Very Low-Income Families, and/or at least 20% of all Homeownership Affordable Housing units are reserved for Low-Income Families; (ii) Applications where rental Affordable Housing units located in either Areas of Economic Distress (AED) and/or High Opportunity Areas (HOA) are reserved for Eligible-Income Families; (iii) Applications where Homeownership Affordable Housing units are for (a) Families with incomes above 80% and no greater than 120% of AMI located in an AED, (b) Low-Income Families (up to 80% of the AMI), or (c) a combination of (a) and (b); and (iv) Applications proposing to use the CMF Award to leverage private capital to finance and/or support Affordable Housing Activities and Economic Development Activities. Additionally, the CDFI Fund seeks to fund Applications serving geographically diverse Areas of Economic Distress, including Metropolitan Areas and Underserved Rural Areas. In particular, the priority

for geographic diversity includes funding highly qualified Applications that serve territories not included in the Service Areas of Recipients in the past two CMF rounds FY 2020 and FY 2021: American Samoa, Guam, the Northern Mariana Islands, and the U.S. Virgin Islands.

G. Funding limitations: The CDFI Fund reserves the right to fund, in whole or in part, any, all, or none of the Applications submitted in response to this NOFA.

II. Federal Award Information

A. Funding Availability: The CDFI Fund plans to award up to \$320.6 million in grants for the FY 2023 CMF Funding Round under this NOFA. Eligible organizations of all sizes are encouraged to apply, including new and previous Applicants, past CMF Recipients, and Applicants focused on Homeownership, rental housing, or both. HERA prohibits the CDFI Fund from obligating more than 15% of the aggregate available in CMF Awards to any Applicant, its Subsidiaries, and its Affiliates in the same funding round. In past rounds, the CDFI Fund has provided Awards smaller than the statutory cap. For example, in the last three funding rounds, Awards ranged from \$633,750 to \$12,000,000, with an average Award of \$4.4 million. Given the administrative and compliance responsibilities for Recipients, the CDFI Fund will not accept Applications that request less than \$500,000, and will not provide Awards below \$500,000 to any CMF Award Recipients.

The CDFI Fund reserves the right, in its sole discretion, to provide a CMF Award in an amount other than that which the Applicant requests. However, the Award amount will not exceed the Applicant's Award request as stated in its Application. An Applicant may receive only one Award through the FY 2023 CMF Funding Round. Affiliates of Applicants are not allowed to apply separately.

B. Types of Awards: The CDFI Fund will provide CMF Awards in the form of grants. CMF Awards must be used to support the eligible activities as set forth in 12 CFR 1807.301.

A CMF Award Recipient may not distribute the CMF Award to any Affiliate, Subsidiary, or third-party entity in any manner that would create a Subrecipient relationship (as defined in the Uniform Administrative Requirements) without the CDFI Fund's prior written consent. The Recipient of a CMF Award must retain all obligations related to the Award. This restriction does not prevent a Recipient from loaning or investing directly in an

Affiliate (separate legal entity) or in a specific Project being undertaken by an Affiliate. With the exception of Depository Institution Holding Company Applicants, CMF Awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent.

C. Limitations on using CMF Awards in conjunction with other CDFI Fund Awards/allocations:

1. A CMF Award Recipient may not use its CMF Award for any Project that also receives funding from other CDFI Fund program awards or allocations the Recipient (or any of its Affiliates) has received, except when the CMF Award dollars are used to finance/support a different "phase" of development in the same Project than that financed by other CDFI Fund awards or allocations. The separate phases of development financing are: (i) Predevelopment; (ii) acquisition; (iii) site work (preconstruction); (iv) construction/rehabilitation; (v) permanent financing; or (vi) bridge financing between two or more phases. This restriction does not apply to the Recipient's prior CMF Awards. The Recipient may combine its multiple CMF Awards to provide financing on any Project, including financing the same phase of any Project.

However, the Recipient may not deem the same costs as Eligible Project Costs under multiple CMF Awards and must prorate the unit production performance across its multiple CMF Awards. Recipients using a Consortium Approach (see Section III.E.1) with separate CMF Awards from the FY 2023 CMF Funding Round must use their Awards to finance the same Projects. For these Projects, Eligible Project Costs, unit production, and Leveraged Costs are prorated.

If providing Homeownership assistance, a CMF Award may be used in conjunction with awards/allocations from other CDFI Fund programs only if the Project can be divided into such phases (e.g. construction of for-sale housing) and the CMF Award is used in a different phase from the other CDFI Fund program awards/allocations. However in the case of Homeownership purchase assistance, a CMF Award cannot be used for a Homeownership property that is permanently financed (or supported) by mortgages funded by both the Recipient's (or any of its Affiliates') CMF Award, and an award/Allocation from another CDFI Fund

program, or that of another CMF Recipient.

2. As further set forth in the Assistance Agreement, CMF Recipients shall not count or report as Leveraged Costs pursuant to this NOFA any costs financed and/or supported by a Recipient's awards/allocations from other CDFI Fund programs or awards/allocations from other CMF Recipients, including awards from prior CMF rounds. While a Recipient may combine its CMF Award pursuant to this NOFA with other CMF Awards to finance/support the same Project, each CMF Award must separately meet the program requirements as outlined in the applicable Assistance Agreement and the CMF Interim Rule (12 CFR part 1807).

In all cases, the CMF Award remains subject to the following restriction imposed by the CDFI Bond Guarantee Program: award funds received under any CDFI Fund program cannot be used by any participant of the CDFI Bond Guarantee Program, 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 (all capitalized terms used in this sentence, other than "CMF Award," shall have the meanings ascribed to them in the CDFI Bond Guarantee Program regulations and applicable guidance).

D. Anticipated Start Date and Period of Performance: The CDFI Fund anticipates the period of performance for the FY 2023 CMF Funding Round to begin in 2023. The period of performance for each CMF Award begins on the date the CDFI Fund announces the Recipients of the FY 2023 CMF Funding Round Awards and continues until the end of the ten-year period of affordability for all Projects financed and/or supported with the CMF Award, as set forth at 12 CFR 1807.401(d) and 12 CFR 1807.402, and as further set forth in the Assistance Agreement, during which time the Recipient must meet certain Performance Goals.

E. Eligible Activities: A CMF Award must support or finance activities that attract private capital for and increase investment in: (i) the Development, Preservation, Rehabilitation, or Purchase of Affordable Housing for primarily Low-, Very Low-, and Extremely Low-Income Families; and (ii) Economic Development Activities. CMF Awards may only be used as follows: (i) to provide Loan Loss Reserves; (ii) to capitalize a Revolving

Loan Fund; (iii) to capitalize an Affordable Housing Fund; (iv) to capitalize a fund to support Economic Development Activities; (v) for Risk-Sharing Loans; or (vi) to provide Loan Guarantees. No more than 30% of a CMF Award may be used for Economic Development Activities. The CDFI Fund allows all Recipients to use up to 5% of their CMF Award for Direct Administrative Expenses. The amount available for Direct Administrative Expenses may only be used for direct costs (as defined by the Uniform Administrative Requirements) incurred by the Recipient and related to the financing and/or support of a Project. The CDFI Fund considers the tracking of impacts and outcomes associated with Projects financed and/or supported by a CMF Award to fall under Direct Administrative Expenses. Any portion of the amount available for Direct Administrative Expenses may be used for direct costs related to the effective tracking and evaluation of program or evidence-based outcomes for Projects.

The CDFI Fund recognizes that some CMF Recipients, due to their business model, may need to work with a third-party originator to originate the CMF loans for mortgage financing. The CMF regulations in 12 CFR 1807.104 defines "Purchase" as "to provide direct financing to a Family for purposes of Homeownership." The CDFI Fund hereby clarifies that under the definition of "Purchase," a CMF Recipient may use its CMF Award to purchase CMF eligible loans from a third-party originator within 12 months of origination. The CDFI Fund deems the CMF Recipient's purchase of the CMF eligible loans as "direct" financing under the definition of "Purchase." The CMF Recipient must work with the third-party originator to identify income eligible borrowers and ensure the loans and associated Affordable Housing meet all of the requirements of 12 CFR part 1807.

III. Eligibility Information

A. Eligible Applicants: In order to be eligible to apply for a CMF Award, an Applicant must either be a Certified CDFI or a Nonprofit Organization, as defined in 12 CFR 1807.104. Table 2 indicates the criteria that each category of Applicant must meet in order to be eligible for a CMF Award pursuant to this NOFA. *Note:* A Certified CDFI that is also a Nonprofit Organization only needs to meet the Certified CDFI eligibility criteria described in Table 2, below, in order to be eligible for a CMF Award. Applicants may be members applying under a Consortium Approach comprised of eligible Applicants, but

each Consortium member must separately apply and be individually eligible to receive a CMF Award. separately apply and be individually eligible to receive a CMF Award.

TABLE 2—APPLICANT ELIGIBILITY REQUIREMENTS

Category	Eligibility requirements
Certified CDFI	<ul style="list-style-type: none"> • Has been in existence as a legally formed entity for at least three (3) years prior to the AMIS Application deadline under this NOFA; • Has been determined by the CDFI Fund to meet the CDFI certification requirements set forth in 12 CFR 1805.201 and as verified in the CDFI’s AMIS account as of the publication date of this NOFA in the Federal Register; and • Has not been notified in writing by the CDFI Fund that its certification has been terminated since the publication date of this NOFA. • If a Certified CDFI loses its certification at any point prior to the Award announcement, the Application will be deemed ineligible and no longer be considered by the CDFI Fund. Post-Award, if a CMF Recipient loses its CDFI Certification, its compliance status with respect to the Assistance Agreement will be reviewed by the Office of Compliance Monitoring and Evaluation (OCME) in accordance with the terms of the Assistance Agreement. • In cases where the CDFI Fund has provided a Certified CDFI with written notification that it no longer meets one or more certification standards and it has been given an opportunity to cure, the CDFI Fund will continue to deem this Applicant to be a Certified CDFI until it has received a final determination letter that its certification has been terminated. A Certified CDFI is considered eligible for an Award until a final certification determination has been made, and a final determination letter has been provided to the Applicant by the CDFI Fund. • Has audited financial statements encompassing its two most recent historic fiscal years prior to the publication date of this NOFA.¹ A Regulated Institution that files call reports to its regulator is exempt from this requirement and must attach call reports for its two most recent historic fiscal years in lieu of audited financial statements.
Nonprofit Organization	<ul style="list-style-type: none"> • Has been in existence as a legally formed entity for at least three (3) years prior to the AMIS Application deadline under this NOFA; • Meets the definition of Nonprofit Organization set forth in 12 CFR 1807.104; • Demonstrates, through articles of incorporation, by-laws, or other board-approved documents, that the development or management of affordable housing are among its principal purposes; • Demonstrates by providing an attestation in the Application that at least 33.3% of its total assets are dedicated to the development or management of affordable housing; and • Has audited financial statements encompassing its two most recent historic fiscal years prior to the publication date of this NOFA. A Regulated Institution that files call reports to its regulator is exempt from this requirement and must attach call reports for its two most recent historic fiscal years in lieu of audited financial statements.
Debarment/Do Not Pay Verification.	<ul style="list-style-type: none"> • The CDFI Fund will conduct a debarment check and will not consider an Application submitted by an Applicant if the Applicant (or Affiliate of an Applicant) is delinquent on any federal debt. • The Do Not Pay Business Center was developed to support federal agencies in their efforts to reduce the number of improper payments made through programs funded by the federal government. The Do Not Pay Business Center provides delinquency information to the CDFI Fund to assist with the debarment check.
System for Award Management (SAM).	<ul style="list-style-type: none"> • Each Applicant must have its own active SAM registration in order to submit the required Application materials through <i>Grants.gov</i>. • SAM is a web-based, government-wide application that collects, validates, stores, and disseminates business information about the federal government’s trading partners in support of the contract awards, grants, and electronic payment processes. See <i>SAM.gov</i> for more information. • Applicants that have an active SAM registration have been assigned a UEI. Applicants must also have an EIN number in order to register in <i>SAM.gov</i>. • Applicants must complete registration in <i>SAM.gov</i> in order to be able to complete the <i>Grants.gov</i> registration and submit an SF-424. • The CDFI Fund reserves the right to deem an Application ineligible if the Applicant’s SAM account expires during the Application evaluation period, or is set to expire before December 31, 2023, and the Applicant does not re-activate or renew (as applicable) the account within the deadlines that the CDFI Fund communicates to affected Applicants during the Application evaluation period.
Application type and submission method through <i>Grants.gov</i> and Awards Management Information System (AMIS).	<ul style="list-style-type: none"> • Each Applicant must submit the required Application documents listed in Table 4. • The CDFI Fund will only accept Applications that use the official Application templates provided on the <i>Grants.gov</i> and AMIS websites. Applications submitted with alternative or altered templates will not be considered. • Applicants undergo a two-step process that requires the submission of Application documents by two separate deadlines in two different locations: (1) the SF-424 in <i>Grants.gov</i> and (2) all other Required Application Documents in AMIS. • <i>Grants.gov</i> and the SF-424 Mandatory form: • Applicants must submit the Office of Management and Budget (OMB)-approved Standard Form (SF) 424 Mandatory (Application for Federal Assistance) form in <i>Grants.gov</i>. • All Applicants must register in the <i>Grants.gov</i> system to successfully submit an Application. The <i>Grants.gov</i> registration process can take 30 days or more to complete. The CDFI Fund strongly encourages Applicants to register as early as possible to meet the deadlines in Table 1 and Table 6. • The SF-424 must be submitted in <i>Grants.gov</i> before the other Application materials are submitted in AMIS. Applicants are strongly encouraged to submit their SF-424 as early as possible via the <i>Grants.gov</i> portal.

¹ (A) Applicants with a 6/30 fiscal year end date, or 9/30 fiscal year end date, and a completed FY 2022 audit will treat FY 2022 as their most recent historic fiscal year. (B) Applicants with a 6/30 fiscal

year end date, or a 9/30 fiscal year end date, but without a completed FY 2022 audit will treat FY 2021 as their most recent historic fiscal year. (C) Applicants with a 3/31 fiscal year end date will

treat FY 2022 as their most recent historic fiscal year. (D) Applicants with a 12/31 fiscal year end date will treat FY 2021 as their most recent historic fiscal year.

TABLE 2—APPLICANT ELIGIBILITY REQUIREMENTS—Continued

Category	Eligibility requirements
Employer Identification Number (EIN).	<ul style="list-style-type: none"> • Because the SF–424 is part of the Application, if the SF–424 is not accepted by <i>Grants.gov</i> by the applicable deadline, the Applicant will not be able to submit the AMIS Application. • The SF–424 must be submitted under the FY 2023 CMF Funding Round CMF Funding Opportunity Number. • The CDFI Fund will not extend the SF–424 application deadline for any Applicant that started the <i>Grants.gov</i> registration process on, before, or after the date of the publication of this NOFA, but did not complete it by the deadline, except in the case of a federal government administrative or technological error that directly resulted in precluding an Applicant from submitting the SF–424 by the required deadline. • AMIS: <ul style="list-style-type: none"> • Applicants must submit all other required Application materials in AMIS. • AMIS is the CDFI Fund’s enterprise-wide information technology system that will be used to submit and store organization and Application information with the CDFI Fund. • Applicants are only allowed one Capital Magnet Fund Application submission per funding round in AMIS. • Members of a Consortium must submit every component of the Application separately and independently from other members of the Consortium. • Each Application in AMIS must be signed by an Authorized Representative. The Authorized Representative is an employee or officer of the Applicant, authorized to sign legal documents on behalf of the organization. <i>Consultants working on behalf of the organization may not be designated as Authorized Representatives.</i> • Only an Authorized Representative or Application Point of Contact included in the Application may submit the Application in AMIS. • All Required Application Documents must be submitted in AMIS on or before the deadline specified in Table 1. • The CDFI Fund will not extend the deadline for any Applicant except in the case of a federal government administrative or technological error that directly resulted in precluding an Applicant from submitting the Application in AMIS by the required deadline. • Each Applicant must have a unique EIN assigned by the Internal Revenue Service (IRS). • The CDFI Fund will reject an Application submitted with the EIN of a parent or Affiliate of the Applicant. • The EIN in the Applicant’s AMIS account must match the EIN on the SF–424 submitted through <i>Grants.gov</i> and the EIN in the Applicant’s System for Award Management (SAM) account. The CDFI Fund reserves the right to reject an Application if the EIN in the Applicant’s AMIS account does not match the EIN on the SF–424 and/or its SAM account. • The EIN of the Applicant must be entered into the AMIS organization profile by the applicable deadline in Table 1.
Unique Entity Identifier (UEI)	<ul style="list-style-type: none"> • The transition from the Dun and Bradstreet Universal Numbering System (DUNS) to UEI is a federal, government-wide initiative. • The CDFI Fund will reject an Application submitted with the UEI number of a parent or Affiliate organization of an Applicant. • The UEI number in the Applicant’s AMIS account must match the UEI number in the Applicant’s <i>Grants.gov</i> and SAM accounts. • The CDFI Fund will reject an Application if the UEI number in the Applicant’s AMIS account does not match the UEI number in its <i>Grants.gov</i> and SAM accounts.
AMIS Account	<ul style="list-style-type: none"> • Applicants must enter their UEI number into their AMIS profile on or before the deadline specified in Table 1. • Each Applicant, including each Consortium Member, must register as an organization in AMIS and submit all required Application materials through the AMIS portal. • If the Applicant does not fully register its organization in AMIS by the deadline set forth in Table 1, its Application will be rejected without further consideration. • The Authorized Representative and Application Point of Contact must be included as “users” in the Applicant’s AMIS account. • An Applicant that fails to properly register and update its AMIS account may miss important communications from the CDFI Fund or not be able to successfully submit an Application. • In cases where a federal government administrative or technological error directly resulted in precluding an Applicant from creating an AMIS account by the required deadline, the Applicant must submit a written request for approval to create its AMIS account after the deadline, and include documentation of the error, no later than two business days after the AMIS account creation deadline specified in Tables 1 and 6. The CDFI Fund will not respond to requests for creating an AMIS account after that time. Applicants must submit such request via an AMIS Service Request to the CMF Program with a subject line of “AMIS Account Creation Deadline Extension Request.”
501(c)(4) status	<ul style="list-style-type: none"> • Pursuant to 2 U.S.C. 1611, any 501(c)(4) organization that engages in lobbying activities is not eligible to apply for or receive a CMF Award.
Compliance with Non-discrimination and Equal Opportunity Statutes, Regulations, and Executive Orders.	<ul style="list-style-type: none"> • An Applicant may not be eligible to receive a CMF Award if proceedings were instituted against it in, by, or before any court, governmental agency, or administrative body, and a final determination was made within the time period beginning three years prior to the publication of this NOFA through the execution of the Assistance Agreement, declaring that the Applicant violated any federal civil rights laws or regulations, including: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d et seq.); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); and the Age Discrimination Act of 1975 (42 U.S.C. 6101–6107).
Depository Institution Holding Company Applicant.	<ul style="list-style-type: none"> • If a Depository Institution Holding Company and its Certified CDFI Subsidiary Insured Depository Institution both apply for a CMF Program grant, only the Depository Institution Holding Company will receive an Award, not both. In such instances, the Subsidiary Insured Depository Institution will be deemed ineligible. • The Authorized Representative of the Depository Institution Holding Company Applicant must certify that the information included in the Application represents that of the Subsidiary CDFI Insured Depository Institution, and that the Award will be used to support the Subsidiary CDFI Insured Depository Institution for the eligible activities outlined in the Application.

TABLE 2—APPLICANT ELIGIBILITY REQUIREMENTS—Continued

Category	Eligibility requirements
Regulated Institutions ²	<ul style="list-style-type: none"> To be eligible for an Award, each Regulated Institution Applicant must have a CAMELS/CAMEL composite rating (rating for banks and credit unions, respectively), by its federal regulator of at least “3” or state regulator equivalent. Organizations with CAMELS/CAMEL composite ratings of “4” or “5” will not be eligible for Awards. Organizations with a Prompt Corrective Action directive from its regulator will not be eligible for Awards. In the case of a Depository Institution Holding Company Applicant that intends to carry out the Award through a Subsidiary Insured Depository Institution, the CAMELS/CAMEL rating eligibility requirements noted above apply to both the Depository Institution Holding Company Applicant, as well as the Subsidiary Insured Depository Institution. The CDFI Fund will also evaluate material concerns identified by the Appropriate Federal Banking Agency or Appropriate State Agency in determining eligibility of Regulated Institution Applicants.

Any Applicant that does not meet the criteria in Table 2 is ineligible to apply for a CMF Award under this NOFA. Further, Section III.B describes additional considerations applicable to

prior Recipients and/or allocatees under any CDFI Fund program.
B. Prior Award Recipients: Eligibility determinations in prior funding rounds have no bearing on and do not guarantee eligibility in this round. Prior CMF

Award Recipients and prior award recipients of other CDFI Fund programs will be eligible to apply under this NOFA if they meet the eligibility criteria in Table 2, except as noted in Table 3.

TABLE 3—ELIGIBILITY REQUIREMENTS FOR APPLICANTS WHICH ARE PRIOR AWARD/ALLOCATION RECIPIENTS

Criteria	Description
Pending resolution of default or noncompliance.	<ul style="list-style-type: none"> If an Applicant (or Affiliate of an Applicant) that is a prior recipient or allocatee under any CDFI Fund program: (i) has demonstrated it has been in default or noncompliance with a previous assistance agreement, award agreement, allocation agreement, bond loan agreement, or agreement to guarantee and (ii) the CDFI Fund has yet to make a final determination as to whether the entity is in noncompliance with or default of its previous agreement, the CDFI Fund will consider the Applicant’s Application under this NOFA pending full resolution, in the sole determination of the CDFI Fund, of the default or noncompliance.
Default or Noncompliance status.	<ul style="list-style-type: none"> The CDFI Fund will not consider an Application submitted by an Applicant that is a prior CDFI Fund Recipient or allocatee under any CDFI Fund program if, as of the AMIS Application deadline of this NOFA, is noncompliant or found in default with a previously executed award agreement(s), assistance agreement(s), allocation agreement(s), bond loan agreement(s) or agreement(s) to guarantee and the CDFI Fund has provided written notification that the Applicant is ineligible to apply for or receive any future awards or allocations for a time period specified by the CDFI Fund in writing.

C. Contacting the CDFI Fund: Applicants that are prior Recipients and/or allocatees under any CDFI Fund program are advised to comply with requirements specified in an Assistance Agreement, allocation agreement, bond loan agreement, or agreement to guarantee, and to ensure their Affiliates are in compliance with any agreements. All outstanding reporting and compliance questions should be directed to the Office of Compliance Monitoring and Evaluation help desk by AMIS Service Requests (select “Capital Magnet Fund” for “Program”), via email CCME@cdfi.treas.gov, or by telephone on (202) 653-0423. For general questions, organizations with an AMIS account are strongly encouraged to submit a Service Request in AMIS using “Capital Magnet Fund” for the Service Request program. Members of the public that do not have AMIS accounts can contact Capital Magnet Fund staff via email at CMF@cdfi.treas.gov. The CDFI Fund will not

respond to Applicants’ reporting, compliance, or disbursement related telephone calls or email inquiries that are received after 5:00 p.m. ET on March 17, 2023 until after the Application deadline. The CDFI Fund will respond to technical issues related to AMIS Accounts through 5:00 p.m. ET on March 21, 2023, via AMIS Service Requests, or at AMIS@cdfi.treas.gov, or by telephone at (202) 653-0422.

D. Cost sharing or matching funds requirements: Not applicable.

E. Other Eligibility Criteria:

1. *Consortium Approach:* To be eligible under a Consortium Approach, individual members of a Consortium must submit individual Applications and meet the eligibility criteria defined in Table 2 on a stand-alone basis. If awarded, each Recipient will receive a separate Award, and be required to meet the terms of its individual Assistance Agreement. The CDFI Fund will require Recipients using the Consortium

Approach to enter into a CMF Recipient Consortium Member Agreement, which will specify the binding commitments of each member.

All Consortium members must invest their individual Awards in the same Projects as the other Consortium members. A Consortium does not need to be legally formed in advance of submitting an Application; however, each Consortium member is asked to submit a Service Request in AMIS notifying the CDFI Fund of the organization’s intent to apply under this NOFA as a Consortium member by the required deadline specified in Table 1.

If one or more members indicate an intent to apply under the Consortium Approach, but fail to meet the eligibility criteria in Table 2, or are otherwise not eligible for an Award, the CDFI Fund reserves the right to review the other Applications on a stand-alone basis and not as a Consortium.

² Regulated Institutions include Insured Credit Unions, Insured Depository Institutions, State-Insured Credit Unions, and Depository Institution

Holding Companies, that does not meet the criteria in Table 2 is ineligible to apply for a CMF Award under this NOFA. Further, Section III.B describes

additional considerations applicable to prior Recipients and/or allocatees under any CDFI Fund program.

2. *Affiliates:* As part of the Application review process, the CDFI Fund considers whether Applicants are Affiliates, as defined in 12 CFR 1805.104. If an Applicant and its Affiliate(s) wish to submit an Application, they must do so through one of the Affiliated entities, in one Application; an Applicant and its Affiliates may not submit separate Applications. If Affiliates submit multiple or separate Applications, the CDFI Fund may, at its discretion, reject all such Applications received or select only one of the submitted Applications to be deemed eligible, assuming that Application meets all other eligibility criteria in Section III of this NOFA.

3. *Minimum Leverage Multiplier:* An Applicant will not be eligible to receive a CMF Award if the Applicant fails to demonstrate in the Application that its CMF Award would result in Eligible Project Costs (Leveraged Costs plus those costs funded by the CMF Award) that equal at least 10 times the amount of the CMF Award. Note that no costs attributable to Direct Administrative

Expenses may be considered Eligible Project Costs.

IV. Application and Submission Information

A. *Address to Request Application Package:* Application materials can be found on *Grants.gov* and the CDFI Fund’s website at *www.cdfifund.gov/cmf*. If an Applicant is unable to access *Grants.gov* or the CDFI Fund’s website, an Applicant may request a paper version of any Application material by contacting the CDFI Fund Help Desk by email at *cmf@cdfi.treas.gov* or by phone at (202) 653-0421.

B. *Content and Form of Application Submission:* The CDFI Fund will post to its website, at *www.cdfifund.gov/cmf*, instructions for accessing and submitting an Application. Detailed Application content requirements are found in the Application and related guidance documents.

All Applications must be prepared in English and calculations must be made in U.S. dollars. Table 4 lists the required funding Application documents. Applicants must submit all required

documents for the Application to be deemed complete. Please be aware that an Applicant that fails to submit audited financial statements for its two most recent historic fiscal years will be deemed as not having a complete Application and will be considered ineligible. A Regulated Institution that submits call reports for its two most recent historic fiscal years is exempted from this requirement. The CDFI Fund reserves the right to request and review other pertinent or public information that has not been specifically requested in this NOFA or the Application. Information submitted by the Applicant that the CDFI Fund has not specifically requested will not be reviewed or considered as part of the Application. Information submitted must accurately reflect the Applicant’s activities and/or its Subsidiary Insured Depository Institution, in the case where the Applicant is an Insured Depository Institution Holding Company intending to carry out the activities of the Award through its Subsidiary Insured Depository Institution.

TABLE 4—FUNDING APPLICATION DOCUMENTS

Application document	Submission format	Required?
Standard Form (SF) 424 Mandatory Form	Fillable PDF in <i>Grants.gov</i> .	Required for all Applicants.
CMF Application	AMIS	Required for all Applicants.
Attachments to the Application		
Audited financial statements for the <i>two most recent historic fiscal years</i> . Regulated Institutions may submit call reports in lieu of audited financial statements.	PDF in AMIS	Required for all Applicants.
Any Management Letters, if applicable, related to the audited financial statements for the <i>two most recent historic fiscal years</i> . The Management Letter is prepared by the Applicant’s auditor and provides communication on internal control over financial reporting, compliance, and other matters. ³ If no Management Letter was issued for either of the two most recent historic fiscal years, the Applicant must attach a document explicitly stating such.	PDF in AMIS	Required for all Applicants.
State Charter, Articles of Incorporation, authorizing statute, or other establishing documents designating that the Applicant is a nonprofit or not-for-profit entity under the laws of the organization’s State of formation.	PDF in AMIS	Required only for Applicants that are not Certified CDFIs.
A certification demonstrating tax exempt status from the IRS. Only Applicants that are governmental instrumentalities, and are unable to provide such determination from the IRS and meet all other eligibility requirements, must submit a legal opinion from counsel, in form and substance acceptable to the CDFI Fund, opining that the Applicant is exempt from federal income tax.	PDF in AMIS	Required only for Applicants that are not Certified CDFIs.
Articles of incorporation, by-laws, authorizing statute, or other documents demonstrating that the Applicant has a principal purpose of managing or developing affordable housing.	PDF in AMIS	Required only for Applicants that are not Certified CDFIs.

C. *Application Submission:* The CDFI Fund has a sequential, two-step process that requires the submission of Application documents in separate systems with two separate deadlines.

The SF-424 must be submitted through *Grants.gov* and all other Application documents through the AMIS portal. The CDFI Fund will not accept Applications via email, mail, facsimile,

or other forms of communication, except in extremely rare circumstances that have been pre-approved by the CDFI Fund. The separate Application deadlines for the SF-424 and all other

³ The Management Letter may include suggestions for improving identified weaknesses and deficiencies and/or best practice suggestions for items that may not be considered to be weaknesses or deficiencies. The Management Letter may also

include items that are not required to be disclosed in the annual audited financial statements. The Management Letter is distinct from the auditor’s Opinion Letter, which is required by Generally Accepted Accounting Principles (GAAP).

Management Letters are not required by GAAP and are sometimes provided by the auditor as a separate letter from the audit itself.

Application materials are listed in Tables 1 and 6. Only the Authorized Representative for the Organization or Application Point of Contact designated in AMIS may submit the Application through AMIS.

Applicants are strongly encouraged to submit the SF-424 as early as possible through *Grants.gov* in order to provide sufficient time to resolve any potential submission issues. Applicants should contact *Grants.gov* directly with questions related to the registration or submission process, as the CDFI Fund does not administer the *Grants.gov* system.

The CDFI Fund strongly encourages Applicants to start the *Grants.gov* registration process as soon as possible, as it may take several weeks to complete (refer to the following link: <http://www.grants.gov/web/grants/register.html>). An Applicant that has previously registered with *Grants.gov* must verify that its registration is current and active. If an Applicant has not previously registered with *Grants.gov*, it must first successfully register in *SAM.gov*, as described in Section IV.D below.

D. Unique Entity Identifier (UEI): The UEI has replaced the Dun and Bradstreet Data Universal Numbering System (DUNS) number effective April 4, 2022.

The UEI, generated in the System for Award Management (*SAM.gov*), has become the official identifier for doing business with the federal government. This transition allows the federal government to streamline the entity identification and validation process, making it easier and less burdensome for entities to do business with the federal government. If an entity is registered in *SAM.gov* today, its UEI has already been assigned and is viewable in *SAM.gov*, including inactive registrations. New registrants will be assigned a UEI as part of their *SAM* registration.

E. System for Award Management (SAM): Any entity applying for federal grants or other forms of federal financial assistance through *Grants.gov* must be registered in *SAM* before submitting its Application materials through that platform. When accessing *SAM.gov*, users will be asked to create a *Login.gov* user account (if they don't already have one). Going forward, users will use their *Login.gov* username and password every time when logging into *SAM.gov*. The *SAM* registration process can take four weeks or longer to complete so Applicants are strongly encouraged to begin the registration process upon publication of this NOFA in order to avoid potential Application submission

issues. An original, signed notarized letter identifying the authorized entity administrator for the entity associated with the UEI number is required by *SAM* and must be mailed to the Federal Service Desk. This requirement is applicable to new entities registering in *SAM* or on existing registrations where there is no existing entity administrator. Existing entities with registered entity administrators do not need to submit an annual notarized letter. Applicants that have previously completed the *SAM* registration process must verify that their *SAM* accounts are current and active. Applicants are required to maintain a current and active *SAM* account at all times during which it has an active federal award or an application under consideration for an award by a federal awarding agency.

The CDFI Fund will not consider any Applicant that fails to properly register or activate its *SAM* account and, as a result, is unable to submit the SF-424 in *Grants.gov* or the Application by the applicable Application deadline. Applicants must contact *SAM* directly with questions related to registration or *SAM* account changes, as the CDFI Fund does not maintain this system. For more information about *SAM*, please visit <https://www.sam.gov> or call 866-606-8220.

TABLE 5—*Grants.gov* REGISTRATION TIMELINE SUMMARY

Step	Agency	Estimated minimum time to complete
Obtain an EIN Number	Internal Revenue Service (IRS)	Two Weeks.*
Register in <i>SAM.gov</i>	System for Award Management (SAM). This step will include obtaining a UEI	Four Weeks.*
Register in <i>Grants.gov</i>	<i>Grants.gov</i>	One Week.**

* Applicants are advised that the stated duration are estimates only and represent minimum timeframes. Actual timeframes may take longer. The CDFI Fund will not consider any Applicant that fails to properly register or activate its *SAM* account, has not yet received a UEI number, and/or fails to properly register in *Grants.gov*.

** This estimate assumes an Applicant has a UEI number, an EIN number, and is already registered in *SAM.gov*.

F. Submission Dates and Times: documents related to this CMF Funding

1. **Submission Deadlines:** Table 6 lists Round: the deadlines for submission of the

TABLE 6—FY 2023 CMF FUNDING ROUND DEADLINES FOR APPLICANTS

Document	Deadline	Time—eastern time (ET)	Submission method
SF-424 Mandatory form	February 23, 2023	11:59 p.m. ET ...	Electronically via <i>Grants.gov</i> .
Create AMIS Account (if the Applicant does not already have one)	February 23, 2023	11:59 p.m. ET ..	Electronically via AMIS.
<i>For Consortium Approach Applicants only:</i> Applicants are asked to submit a Service Request in AMIS notifying the CMF Program of the organization's intent to apply as a Consortium Member using the Consortium Approach.	February 23, 2023	11:59 p.m. ET ...	Electronically via AMIS.
CMF Application and Required Attachments	March 21, 2023	11:59 p.m. ET ...	Electronically via AMIS.

2. **Confirmation of Application Submission in *Grants.gov* and AMIS:** Applicants are required to submit the

SF-424 Mandatory Form through the *Grants.gov* system under the FY 2023 CMF Funding Round Capital Magnet

Fund Funding Opportunity Number (listed at the beginning of this NOFA). All other required Application materials

must be submitted through the AMIS website. Application materials submitted through each system are due by the applicable deadline listed in Tables 1 and 6. Applicants must submit the SF-424 by an earlier deadline than that of the other required Application materials in AMIS. If a valid SF-424 is not submitted through *Grants.gov* by the corresponding deadline, the Applicant will not be able to submit the additional Application materials in AMIS, and the Application will be deemed ineligible. Thus, Applicants are strongly encouraged to submit the SF-424 as early as possible in the *Grants.gov* portal, given that potential submission issues may impact the ability to submit a complete Application. Applicants must also ensure that their AMIS account contains the correct EIN and UEI numbers by the deadline listed in Table 1 of this NOFA.

(a) *Grants.gov Submission Information*: Each Applicant will receive an initial email from *Grants.gov* immediately after submitting the SF-424, confirming that the submission has entered the *Grants.gov* system. This email will contain a tracking number for the submitted SF-424. Within 48 hours, the Applicant will receive a second email which will indicate if the submitted SF-424 was either successfully validated or rejected with errors. However, Applicants should not rely on the email notification from *Grants.gov* to confirm that their SF-424 was validated. Applicants are strongly encouraged to use the tracking number provided in the first email to closely monitor the status of their SF-424 by checking *Grants.gov* directly. The Application materials submitted in AMIS are not accepted by the CDFI Fund until *Grants.gov* has validated the SF-424. In the *Grants.gov* Workspace function, please note that the Application package has not been submitted if you have not received a tracking number.

(b) *AMIS Submission Information*: AMIS is a web-based portal where Applicants will directly enter their Application information and add required attachments listed in Table 4. Each Applicant must register as an organization in AMIS in order to submit the required Application materials through this portal. AMIS will verify that the Applicant provided the minimum information required to submit an Application. Applicants are responsible for the quality and accuracy of the information in the Application and in the attachments included in the Application submitted in AMIS. The CDFI Fund strongly encourages the Applicant to allow sufficient time to

confirm the Application content, review the material submitted, and remedy any issues prior to the Application deadline. Applicants can only submit one Application in AMIS. Upon submission, the Application will be locked and cannot be resubmitted, edited, or modified in any way. The CDFI Fund will not unlock or allow multiple AMIS Application submissions.

Prior to submission, each Application in AMIS must be signed by an Authorized Representative. An Authorized Representative is an employee or officer that has the authority to legally bind and make representations on behalf of the Applicant; consultants working on behalf of the Applicant cannot be designated as Authorized Representatives. The Applicant may include consultants as Application point(s) of contact, who will be included on any communication regarding the Application and will be able to submit the Application, but cannot digitally sign the Application. The Authorized Representative and/or Application point(s) of contact must be included as "Contacts" in the Applicant's AMIS account. The Authorized Representative must also be a "user" in AMIS. An Applicant that fails to properly register and update its AMIS account may miss important communications from the CDFI Fund or fail to submit an Application successfully. Only an Authorized Representative for the organization or an Application point of contact can submit the Application in AMIS. After submitting its Application, the Applicant will not be permitted to revise or modify its Application in any way.

(c) *CMF Consortium Member Service Request*: Applicants intending to apply using a Consortium Approach are asked to submit a Service Request in AMIS by February 9, 2023, to notify the CDFI Fund of their intent to apply as part of a Consortium. As part of the Service Request, potential Consortium members are asked to provide the names of the Consortium member organizations, the UEIs of Consortium members, and the amount of funding to be requested by each member. In the event all Consortium members do not submit an Application or a member is otherwise ineligible for an Award, the CDFI Fund reserves the right to review the Applications of the other members on a stand-alone basis and not as a Consortium.

3. *Multiple Application Submissions*: Each Applicant is only permitted to submit one complete Application in AMIS. However, the CDFI Fund does

not administer *Grants.gov*, which does allow for multiple submissions of the SF-424. If an Applicant submits multiple SF-424 Applications in *Grants.gov*, the CDFI Fund will only review the SF-424 Application submitted in *Grants.gov* that is attached to the AMIS Application. Applicants using a Consortium Approach must each separately submit an SF-424.

4. *Late Submission*: The CDFI Fund will not accept an Application if a valid SF-424 is not submitted by *Grants.gov* by the SF-424 deadline. Additionally, the CDFI Fund will not accept an Application if it is not signed by an Authorized Representative and submitted in AMIS by the Application deadline. In either case, the CDFI Fund will not review any material submitted and the Application will be deemed ineligible, except in the case of a federal government administrative or technological error that directly resulted in precluding an Applicant from submitting by the deadline. This exception includes any errors associated with *Grants.gov*, *SAM.gov*, AMIS, or any other applicable government system.

(a) *SF-424 Late Submission*: In cases where a federal government administrative or technological error directly resulted in precluding an Applicant from submitting the SF-424 by the deadline, the Applicant must submit a Service Request in AMIS for acceptance of the late SF-424 submission and include documentation of the error no later than two business days after the SF-424 deadline. The CDFI Fund will not respond to requests for acceptance of late SF-424 submissions after that time period. Applicants must submit late SF-424 submission requests to the CDFI Fund via an AMIS Service Request to the CMF Program with a subject line of "CMF Late SF-424 Submission Request."

(b) *Application Late Submission*: In cases where a federal government administrative or technological error directly resulted in precluding an Applicant from submitting the Application by the deadline, the Applicant must submit a Service Request in AMIS for acceptance of the late Application submission and include documentation of the error no later than two business days after the Application deadline. The CDFI Fund will not respond to requests for acceptance of late Application submissions after that time period. Applicants must submit late Application submission requests to the CDFI Fund via an AMIS Service Request to the CMF Program with a subject line of "CMF Late Application Submission Request."

5. *Intergovernmental Review*: Not Applicable.

6. *Funding Restrictions*: CMF Awards are limited by the following:

(a) A Recipient shall use CMF Award funds only for the eligible activities set forth in 12 CFR 1807.301 and as described in Section II.C and Section II.E of this NOFA and its Assistance Agreement.

(b) A Recipient may not disburse CMF Award funds to an Affiliate, Subsidiary, or any other entity in any manner that would create a Subrecipient relationship (as defined in the Uniform Administrative Requirements) without the CDFI Fund's prior written approval.

(c) CMF Award dollars shall only be paid to the Recipient.

(d) The CDFI Fund, in its sole discretion, may pay CMF Awards in amounts, or under terms and conditions, which are different from those requested by an Applicant. However, the CDFI Fund will not grant an Award in excess of the amount requested by the Applicant.

(e) With the exception of Depository Institution Holding Company Applicants, CMF Awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent.

V. Application Review Information

A. Criteria: All complete and eligible Applications will be reviewed in accordance with the criteria and procedures described in the CMF Interim Rule, this NOFA, the Application guidance, and the Uniform Administrative Requirements. As part of the review process, the CDFI Fund reserves the right to contact the Applicant by telephone, email, mail, or through an on-site visit for the sole purpose of clarifying or confirming Application information at any point during the review process. The CDFI Fund reserves the right to collect such additional information from Applicants as it deems appropriate. If contacted, the Applicant must respond within the time period communicated by the CDFI Fund or its Application may be rejected. For the sake of clarity, specific Application evaluation criteria are described in the context of the overall Application review and selection process described in Section V.B. below.

B. Review and Selection Process:

The CDFI Fund will evaluate each complete and eligible Application using the multi-phase review process

described in this Section. For the first part of the review process, the External Review, the Applications will be grouped into two categories depending on their Entity Approach: (1) financing entities and (2) affordable housing developers/managers. All Applicants will be able to select the Entity Approach under which they are applying. However, all eligibility requirements described in Table 2, as either a Certified CDFI or Nonprofit Organization, must be met. In most cases, CDFIs will select the financing Entity Approach; however, a CDFI that is applying with a strategy to act as an affordable housing developer/manager, and has a track record as an affordable housing developer/manager, may select the affordable housing developer/manager approach. Separately, those Applicants applying using a Consortium Approach will also indicate that they are applying using the Consortium Approach. The Applications of the two Entity Approach classifications, and those using a Consortium Approach, will be evaluated based on the criteria listed in this section. Where appropriate, the CDFI Fund will use different criteria in order to evaluate the financial health, capacity, portfolio performance, and projected activities of the Applicant based on these distinct approaches. These differences are noted in the following sections and the Application Instructions.

1. *External Review and Quantitative Assessment*: All eligible Applications will be evaluated through a Quantitative Assessment and External Review. The Quantitative Assessment evaluates the Applicant's quantitative factors and is performed automatically in AMIS. In the External Review, Applications will be separately scored by two or more external non-federal reviewers who are selected based on criteria that include: a professional background in affordable housing or in community and economic development finance with affordable housing experience. These reviewers must complete the CDFI Fund's conflict of interest process and be approved by the CDFI Fund. Reviewers will be assigned a set number of Applications to review, consisting of either Applicants with a financing Entity Approach, or Applicants with an affordable housing developer/manager approach. The reviewer will provide a score for each of the Applications assessed in accordance with the scoring criteria outlined in Section V.B.2 of this NOFA and the Application materials.

The external reviewer's evaluation, in combination with the quantitative assessment factors, will result in the Application being awarded up to 100

points for each review scorecard. The majority of the score will be based on the external reviewer's evaluation. These points will be distributed across three sections: Business and Leveraging Strategy (40 possible points), Community Impact (35 possible points), and Organizational Capacity (25 possible points). As each Application is evaluated by two external reviewers, the maximum score each Application can receive is 200 points (100 points × 2 Reviewers).

(a) *Business and Leveraging Strategy (40 points)*: In the Business and Leveraging Strategy section, an Applicant will address: (i) the needs of communities and persons in the areas it proposes to serve with a CMF Award and the extent to which the proposed strategy addresses these needs; (ii) the affordable housing, economic development, and financing gaps addressed by its business strategy; (iii) the projected CMF activities and relevant track record; (iv) the role CMF will play in its project financing strategy; (v) its strategy for leveraging private capital with a CMF Award; and (vi) its strategy for leveraging its CMF Award at the Enterprise-level, through reinvestments, and/or at the Project-level (as applicable).

An Applicant will generally score more favorably in the criteria evaluated by the External Review and by the quantitative assessment factors to the extent that it: (i) clearly aligns its proposed CMF Award activities with the affordable housing needs and financing gaps it identifies; (ii) demonstrates that its CMF Award activities will result in more favorable financing rates and terms for Projects; (iii) demonstrates that its projected activities are achievable based on the Applicant's strategy and track record; (iv) describes a process for selecting projects that have a clear need for CMF financing; (v) has a credible pipeline of projects or can demonstrate clear demand for its proposed financial products from borrowers; (vi) has a clear strategy for and track record of leveraging private capital resulting in a higher multiplier of private leverage; (vii) has a clear strategy for attracting capital and demonstrates a track record of leveraging funds at the Enterprise-level, through reinvestments, and/or at the Project-level (as applicable); and (viii) whether the Application is proposing to serve American Samoa, Guam, the Northern Mariana Islands, or the U.S. Virgin Islands.

(b) *Community Impact (35 points)*: In the Community Impact Section, the Applicant will address: (i) the extent to which the Applicant's strategy is likely

to result in the selected Affordable Housing and/or Economic Development Activities impacts and its plan to track relevant outcome metrics; (ii) for rental housing, a) its strategy for and track record of financing and/or supporting rental housing units located in Areas of Economic Distress or High Opportunity Areas; and b) its strategy for and track record of financing rental housing units targeted to Very Low-Income (VLI) Families (50% of AMI or below); (iii) for Homeownership housing, its strategy for and track record of financing Homeownership units targeted to Low-Income (LI) Families (80% of AMI or below) or units located in Areas of Economic Distress targeted to Families with incomes above 80% and no greater than 120% of AMI; (iv) if applicable, its strategy for and track record of financing and/or supporting Economic Development Activities and how the projected activities will align with a Concerted Strategy and will benefit the residents of nearby Affordable Housing; and (v) commitment to and track record of serving Rural Areas.

An Applicant will generally score more favorably in the criteria evaluated by the external reviewer and by the quantitative assessment factors to the extent that it: (i) demonstrates a clear strategy for achieving the selected Affordable Housing and/or Economic Development Activities impacts identified in the Application and it presents a clear and effective plan to track metrics related to relevant outcomes; (ii) if rental housing is proposed, demonstrates a compelling strategy for and track record of financing and/or supporting rental housing units located in Areas of Economic Distress and/or High Opportunity Areas; (iii) if rental housing is proposed, demonstrates a compelling strategy for and track record of financing and/or supporting rental housing units targeted to Very Low-Income (VLI) Families (50% of AMI or below), with the maximum score available to Applications that propose to target at least 45% of units to Very Low-Income Families; (iv) if Homeownership is proposed, demonstrates a compelling strategy for financing and/or supporting up to 100% of CMF Award to Homeownership units either targeted to Low-Income Families (80% of AMI or below) or Homeownership units targeted to Eligible-Income Families (120% of AMI or below) located in Areas of Economic Distress, with the Applicant's track record supporting their ability to execute this strategy; (v) if proposing Economic Development Activities, demonstrates how its

proposed Economic Development Activities fit within a Concerted Strategy and will benefit the residents of the nearby Affordable Housing; and (vi) makes a commitment to invest at least 10% of the CMF Award in Rural Areas and presents a corresponding track record of serving Rural Areas.

(c) *Organizational Capacity (25 points)*: In the Organizational Capacity section, the Applicant will discuss: (i) its management team and key staff; (ii) the roles and responsibilities of those staff in managing the proposed CMF Award; (iii) its past experience managing federal awards; (iv) its financial health; and (v) lending or property portfolio (as applicable).

Applicant(s) will generally score more favorably in the criteria evaluated by the external reviewer and by the quantitative assessment factors to the extent that it demonstrates: (i) strong qualifications of its key personnel with respect to their skills and experience in identifying investments, underwriting or developing similar projects (as applicable), and managing a portfolio of similar activities and ensuring compliance with program requirements; (ii) a strong ability to successfully manage federal awards based on experience managing prior federal awards or administering state or local government awards, foundation grants, or other programs with complex compliance requirements; (iii) strong financial health, including but not limited to strong capitalization, sound operating performance, and strong liquidity; (iv) favorable audit results (e.g. opinion other than unqualified/unmodified) with no negative findings, including lack of a "going concern paragraph", lack of repeat findings of reportable conditions, lack of material weaknesses in internal controls, lack of delinquencies on obligations to investors or lenders, and not having filed for bankruptcy or defaulted on financial obligations; and (v) solid portfolio performance (property portfolio or loan/investment portfolio, as applicable). CMF Program encourages first-time Applicants. Prior CMF Recipients will not receive a scoring advantage solely for having received a prior CMF Award.

(d) *Scoring anomaly*: If, in the case of a particular Application, the reviewers' total External Review scores vary significantly from each other, the CDFI Fund may, in its sole discretion, obtain the evaluation and numeric scoring of an additional reviewer to determine whether the anomalous score should be replaced with the score of the additional reviewer.

2. *Internal Review*: At the conclusion of the External Review phase, the CMF Program Manager will determine the overall number of Applications that will be initially forwarded for Internal Review. Each group of Applications (financing Entity Approach and affordable housing developer/manager approach) will be ranked separately based on their External Review score. The CMF Program Manager may initially forward an amount up to the highest scoring 50% of Applications from the External Review to the Internal Review, as long as the forwarded Applications reflect, within no more than 5% variance, the proportion of financing Entity Approach Applications to affordable housing developer/manager approach Applications in the overall Application Pool. Such Applications will be forwarded for Internal Review in descending order of External Review score. The forwarded Applications will be drawn from the financing Entity Approach and affordable housing developer/manager approach groups in proportion to each group's representation in the overall Application pool. This approach will ensure that the percentage of Applicants with a financing Entity Approach and affordable housing developer/manager approach forwarded to Internal Review reflects the proportion of these entity strategies within the overall Application pool, with no more than 5% variance.

These forwarded Applications will constitute the highly qualified pool. During the Internal Review, CDFI Fund staff will prioritize the Applications in the highly qualified pool for an Award based on the following criteria: (i) final External Review score; (ii) alignment with CMF statutory and policy priorities; (iii) the overall quality of the Applicant's strategy; and (iv) the Applicant's organizational capacity and financial health. The CDFI Fund will not attempt to ensure any specific balance of Applicants with a financing Entity Approach and Applicants with an affordable housing developer/manager approach in the final Award pool.

In assessing the Applicant's organizational capacity, CDFI Fund staff will consider the following factors including, but not limited to, the Applicant's overall organizational and financial capacity, including: (i) its financial strength and ability, and its resources to adapt to changing market conditions and risks; (ii) its organizational strength as demonstrated by good management practices, risk management, and internal controls; (iii) key personnel with relevant experience and capacity; and (iv) relevant

experience and capacity demonstrating ability to meet federal award management standards (including performance with prior CDFI Fund awards). The CDFI Fund will also review OMB-designated repositories of government-wide eligibility qualification and financial integrity information, as part of the assessment of organizational capacity. In the case of an Applicant 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 Recipient is in compliance with current or prior award agreements, as well as to review the results of any Federal Single Audit, and to take such information into consideration before making a CMF Award.

In assessing the Application's alignment with CMF statutory and policy priorities, CDFI Fund staff will consider the following factors including, but not limited to: (i) the likelihood of the Applicant to reach a minimum overall leverage multiplier of 10 times the Award amount or more; (ii) the amount of private capital it will leverage relative to the CMF Award; (iii) if rental housing is proposed, the Applicant's approach, track record, and ability to finance/support a significant portion (up to 45%) of its rental housing for Very Low-Income Families; (iv) if rental housing is proposed, the Applicant's approach, track record, and ability to finance/support a significant portion of rental housing located in Areas of Economic Distress (AED) and/or High Opportunity Areas (HOA) as a percentage of its CMF rental portfolio; (v) if Homeownership is proposed, the Applicant's approach, track record, and ability to successfully finance/support up to 100% of its Homeownership units for (a) Families with incomes in excess of 80% but not greater than 120% of Area Median Income (AMI) located in an Area of Economic Distress (AED); or (b) Low-Income Families (80% AMI or below); or (c) a combination of (a) and (b); and (vi) the number of Affordable Housing units expected to be generated as a result of the Award.

In assessing the quality of the Applicant's strategy, the CDFI Fund staff will consider the following factors, including, but not limited to: (i) the effectiveness and cohesiveness of the Applicant's strategy; (ii) how well the proposed financing activities will help close the financing gaps in their market, including more favorable rates and terms than are currently available in its Service Area; (iii) the Applicant's ability to execute its strategy and support its projections; (iv) how adaptable the

Applicant's strategy is to changing market conditions; (v) the alignment between the proposed activities and strategy and the selected impacts and outcomes; and (vi) for Applicants proposing Economic Development Activities (EDA), the extent the activities are part of a Concerted Strategy, whether activities will benefit Affordable Housing residents, and the track record and capacity of the Applicant to carry out EDA.

In addition to the criteria outlined above, the Applicant's ability to deploy the CMF Award in a timely manner will be a key determinant in funding recommendation. Deployment considerations may include the Applicant's track record of activities compared with projections, the Applicant's progress in committing and/or deploying past CMF Awards, and whether the Applicant received a FY 2022 CDFI/NACA Program award for a similar business strategy as the proposed use of the CMF Award. The CDFI Fund may also consider the number of geographies served when determining funding recommendations.

3. *Scoring of Applicants Using a Consortium Approach:*

Applicants using a Consortium Approach will be evaluated and scored in the following manner:

(a) Applicants will be evaluated as a Consortium and receive the same score on: (i) strategy; (ii) the needs and financing gaps addressed; (iii) track record; (iv) pipeline; (v) impact and metrics; (vi) geographic targets (Areas of Economic Distress and/or High Opportunity Areas); (vii) income targeting; (viii) key personnel; (ix) adaptability and community partnerships; (x) alignment with priorities; (xi) Project selection process; (xii) serving underserved areas; (xiii) resources to adapt to changing market conditions and risks; and (xiv) deployment capacity.

(b) Applicants will be evaluated on a prorated basis and receive an individual score on: (i) Eligible Project Costs; (ii) unit production; and (iii) Leveraged Costs.

(c) Applicants will be evaluated individually and receive an individual score on: (i) previous federal award management; (ii) financial health; (iii) audit findings; (iv) portfolio performance; (v) the likelihood of reaching the minimum leverage multiplier; (vi) organizational strength; (vii) management practices; (viii) the ability to execute the strategy and projected activities; and (ix) commitment to serving Rural Areas. In the event that an Applicant(s) applying using a Consortium Approach does not

sufficiently score to reach the highly qualified pool, the CDFI Fund will evaluate the remaining members of the Consortium using the Consortium Approach, provided there are at least two members remaining in the highly qualified pool. If there is only one member of the Consortium remaining in the highly qualified pool, the Applicant will be evaluated on an individual basis.

4. *Selection:* Once Applications have been internally evaluated and preliminary Award determinations have been made, the Applications will be forwarded to the selecting official(s) for a final Award determination. After preliminary Award determinations are made, the selecting official(s) will review the list of potential Recipients to determine whether the Recipient pool meets the following statutory objectives:

(a) The potential Recipients' proposed Service Areas collectively represent broad geographic coverage throughout the United States; and

(b) The potential Recipients' proposed activities equitably represent both Metropolitan Areas and Rural Areas. For the purposes of the FY 2023 CMF Funding Round, the term Rural Area is defined per 12 CFR 1282.1 (Enterprise Duty To Serve Final Rule) as (i) A census tract outside of a Metropolitan Statistical Area as designated by the Office of Management and Budget; or (ii) A census tract in a Metropolitan Statistical Area as designated by the Office of Management and Budget that is outside of the Metropolitan Statistical Area's Urbanized Areas, as designated by the U.S. Department of Agriculture's (USDA) Rural-Urban Commuting Area (RUCA) Code #1, and outside of tracts with a housing density of over 64 housing units per square mile for USDA's RUCA Code #2.

As Rural Areas data for the Enterprise Duty to Serve Rule is not available for American Samoa, Guam, the Northern Mariana Islands, and the U.S. Virgin Islands; all census tracts in these territories will be deemed as Rural census tracts for Awards issued under this NOFA. The CDFI Fund will publish a dataset indicating which census tracts are designated as Rural Areas for the FY 2023 CMF Funding Round on its website.

In the event the preliminary Recipient pool does not reflect the geographic coverage or representation of Metropolitan and Rural Areas present in the overall Applicant pool, the CDFI Fund reserves the right to modify CMF Award amounts and/or the CMF Recipient pool if deemed necessary to achieve either of these statutory objectives. For the purposes of conducting this analysis, the CDFI Fund

will classify Applications as addressing Rural Areas if they propose to use 20% or more of their Award in Rural Areas, and as addressing Metropolitan Areas if they propose to use less than 20% of their Award in Rural Areas.

In order to evaluate the geographic coverage of the potential CMF Recipient pool, Applicants will be asked to designate one of the following two Service Area types in their Applications: Statewide or Multi-State. These Service Area types are further defined in the Application. Applicants planning to serve communities below the state level (cities, municipalities, counties, or regions) and within one state should designate their Service Area as Statewide. Similarly, an Applicant that is planning to serve communities below the state level, but in more than one state, should designate their Service Area as Multi-State. The smallest Service Area an Applicant can request is one state or U.S. territory; the largest Service Area an Applicant can propose is a 15- state Multi-State Service Area. Applicants should indicate in the narrative portions of their Application if they plan to concentrate their CMF activities in a subset (e.g. a county or a Metropolitan Area) of their broader Service Area. If necessary to achieve proportional activity in Rural Areas and/or broader geographic coverage, the CDFI Fund may award Applications not in the preliminary Recipient pool, including Applications outside of the highly qualified pool, in the order of their Internal Review scoring ranking. During the selection process, the CDFI Fund also reserves the right to modify or place restrictions on the Service Area requested in any Application in order to further these statutory objectives. In the case of Applicants using a Consortium Approach, the Service Area designated by each Consortium member in its Application will be combined with the Service Area of the other members as part of the review process. This ensures all members are serving the same areas and that all members are able to invest in all CMF financed/supported projects of the Consortium.

In cases where the selecting official's award determination varies significantly from the initial CMF Award amount recommended by the CDFI Fund staff review, the CMF Award recommendation will be forwarded to a reviewing official for final determination. The CDFI Fund, in its sole discretion, reserves the right to reject an Application and/or adjust CMF Award amounts as appropriate, based

on information obtained during the review process.

4. Insured Depository Institution Applicants: In the case of Applicants that are Insured Depository Institutions or Insured Credit Unions, the CDFI Fund will consider safety and soundness information from the Appropriate Federal Banking Agency or Appropriate State Agency, as applicable. If the Applicant is a CDFI Depository Institution Holding Company, the CDFI Fund will consider information provided by the Appropriate Federal Banking Agency and Appropriate State Agency about both the CDFI Depository Institution Holding Company and the CDFI Insured Depository Institution that will expend and carry out the Award. If the Appropriate Federal Banking Agency or Appropriate State Agency identifies safety and soundness concerns, the CDFI Fund will assess whether the concerns warrant that the Applicant is incapable of undertaking the activities for which funding has been requested.

5. Right of Rejection: The CDFI Fund reserves the right to reject an Application if information (including administrative errors) comes to the attention of the CDFI Fund that adversely affects an Applicant's eligibility for an Award, adversely affects the CDFI Fund's evaluation or scoring of an Application, or indicates fraud or mismanagement on the Applicant's part, including mismanagement of another federal award. If the CDFI Fund determines that any portion of the Application is incorrect in any material respect, the CDFI Fund reserves the right, in its sole discretion, to reject the Application. The CDFI Fund reserves the right to change its eligibility and evaluation criteria and procedures, if the CDFI Fund deems it appropriate. If said changes materially affect the CDFI Fund's Award decisions, the CDFI Fund will provide information regarding the changes through the CDFI Fund's website. There is no right to appeal the CDFI Fund's Award decisions. The CDFI Fund's Award decisions are final.

6. Anticipated Award Announcement: The CDFI Fund anticipates making CMF Award announcements in calendar year 2023.

VI. Federal Award Administration Information

A. Award Notification: Each successful Applicant will receive notification from the CDFI Fund stating that its Application has been approved for an Award. Each Applicant not

selected for an Award will receive notification and be provided a debriefing document in its AMIS account.

B. Administrative and Policy Requirements Prior to Entering into an Assistance Agreement: The CDFI Fund may, in its discretion and without advance notice to the Recipient, terminate the Award or take other actions as it deems appropriate if, prior to entering into an Assistance Agreement, information (including an administrative error) comes to the CDFI Fund's attention that adversely affects the following: the Recipient's eligibility for an Award; the CDFI Fund's evaluation of the Application; the Recipient's compliance with any requirement listed in the Uniform Requirements; or indications of fraud or mismanagement on the Recipient's part, including mismanagement of another federal award.

If the Recipient's CDFI certification status changes prior to entering into an Assistance Agreement, the CDFI Fund reserves the right, in its sole discretion, to re-evaluate the CMF Award, or modify the Assistance Agreement based on the Recipient's non-CDFI status.

By receiving notification of a CMF Award, the Recipient agrees that, if the CDFI Fund becomes aware of any information (including an administrative error) prior to the Effective Date of the Assistance Agreement that either adversely affects the Recipient's eligibility for an CMF Award, adversely affects the CDFI Fund's evaluation of the Recipient's Application, or indicates fraud or mismanagement on the part of the Recipient, the CDFI Fund may, in its discretion and without advance notice to the Recipient, rescind the notice of award or take other actions as it deems appropriate.

The CDFI Fund reserves the right, in its sole discretion, to rescind an Award if the Recipient fails to return the Assistance Agreement, signed by an Authorized Representative of the Recipient, and/or provide the CDFI Fund with any other requested documentation, within the CDFI Fund's deadlines.

In addition, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the Assistance Agreement and the Award made under this NOFA for any criteria described in Table 7:

TABLE 7—REQUIREMENTS PRIOR TO EXECUTING AN ASSISTANCE AGREEMENT

Requirement	Criteria
Failure to meet reporting requirements.	<ul style="list-style-type: none"> • If an Applicant received a prior award or allocation under any CDFI Fund program and is not current on the reporting requirements set forth in the previously executed assistance, award, allocation, bond loan agreement(s), or agreement to guarantee, as of the date of the notice of award, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Assistance Agreement and/or to delay making a Payment of CMF Award, until said prior Recipient or allocatee is current on the reporting requirements in the previously executed assistance, award, allocation, bond loan agreement(s), or agreement to guarantee. • If such a prior Recipient or allocatee is unable to meet this requirement within the timeframe set by the CDFI Fund, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the notice of award and the CMF Award made under this NOFA. • Please note that automated systems employed by the CDFI Fund for receipt of reports submitted electronically typically acknowledge only a report's receipt; such acknowledgment does not warrant that the report received was complete, nor that it met reporting requirements. If said prior Recipient or allocatee is unable to meet this requirement within the timeframe set by the CDFI Fund, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the notice of award and the CMF Award made under this NOFA.
Failure to maintain CDFI Certification (if applicable) or eligible Nonprofit Organization status (if applicable).	<ul style="list-style-type: none"> • A Recipient must be a Certified CDFI or an eligible Nonprofit Organization, as each is defined in the CMF Interim Rule and this NOFA, prior to entering into an Assistance Agreement. • If, at any time prior to entering into an Assistance Agreement under this NOFA, an Applicant that is a Certified CDFI has submitted reports that demonstrate noncompliance with the requirements for certification to the CDFI Fund, failed to submit an annual certification report as instructed by the CDFI Fund, or demonstrates non-compliance with the requirements for certification through other information obtained by the CDFI Fund, but the CDFI Fund has yet to make a final determination regarding whether or not the entity is Certified, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Assistance Agreement and/or to delay making a Payment of CMF Award, pending full resolution, in the sole determination of the CDFI Fund, of the noncompliance. • If the Applicant is unable to meet this requirement, in the sole determination of the CDFI Fund, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the notice of award and the CMF Award made under this NOFA.
Pending resolution of default or noncompliance.	<ul style="list-style-type: none"> • The CDFI Fund will delay entering into an Assistance Agreement with a Recipient that has pending default or noncompliance issues with any of its previously executed CDFI Fund award(s), allocation(s), bond loan agreement(s), or agreement(s) to guarantee. • If said prior Recipient or allocatee is unable satisfactorily resolve the compliance issues, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the notice of award and the CMF Award made under this NOFA.
Default or Noncompliance status.	<ul style="list-style-type: none"> • If, at any time prior to entering into an Assistance Agreement, the CDFI Fund determines that an Applicant (or an Affiliate of the Applicant) that is a prior CDFI Fund Recipient or allocatee under any CDFI Fund program is noncompliant or found in default with any previously executed award agreement(s), assistance agreement(s), allocation agreement(s), bond loan agreement(s), or agreement(s) to guarantee) and the CDFI Fund has provided written notification that the Applicant is ineligible to apply for or receive any future awards or allocations for a time period specified by the CDFI Fund in writing, the CDFI Fund may, in its sole discretion, delay entering into an Assistance Agreement with Applicant until the Recipient has cured the default or noncompliance by taking actions the CDFI Fund has specified in writing within such specified timeframe. If the Recipient is unable to cure the default or noncompliance within the specified timeframe, the CDFI Fund may modify or rescind all or a portion of the CMF Award made under this NOFA.
Compliance with federal civil rights requirements.	<ul style="list-style-type: none"> • If, within the period starting three years prior to this NOFA and through the date of the Assistance Agreement, the Recipient received a final determination, in any proceeding instituted against the Recipient in, by, or before any court, governmental, or administrative body or agency, declaring that the Recipient violated any federal civil rights laws or regulations, including: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d <i>et seq.</i>); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); and the Age Discrimination Act of 1975 (42 U.S.C. 6101–6107), the CDFI Fund may terminate and rescind the Assistance Agreement and the Award made under this NOFA.
Debarment/Do Not Pay	<ul style="list-style-type: none"> • The Do Not Pay Business Center was developed to support federal agencies in their efforts to reduce the number of improper payments made through programs funded by the federal government. The Do Not Pay Business Center provides delinquency information to the CDFI Fund to assist with the debarment check. • The CDFI Fund reserves the right, in its sole discretion, to rescind an Award if the Recipient (or Affiliate of Recipient) is identified as being delinquent on any federal debt in the Do Not Pay database.
Safety and soundness	<ul style="list-style-type: none"> • If it is determined that the Recipient is or will be incapable of meeting its CMF Award obligations, the CDFI Fund will deem the Recipient to be ineligible or require it to improve safety and soundness conditions prior to entering into an Assistance Agreement.

C. Assistance Agreement: Each Applicant that is selected to receive an Award under this NOFA must enter into an Assistance Agreement with the CDFI Fund in order to become a Recipient and receive Payment. Each CMF Award under this NOFA generally will have a period of performance that begins with the announcement date of the Award

and continues until the end of the period of affordability, as set forth at 12 CFR 1807.401(d) and 12 CFR 1807.402, and as further set forth in the Assistance Agreement.

1. The Assistance Agreement will set forth certain required terms and conditions of the CMF Award, which will include, but not be limited to:

- (a) The amount of the Award;

- (b) The approved uses of the Award;

- (c) The approved Service Area in which the Award may be used. Applicants selected for a CMF Award will be allowed to use up to 15% of the Award amount outside of their approved Service Area at their discretion. Moreover, they will be able to reinvest Program Income from the

CMF Award anywhere in the United States, including the U.S. territories.

(d) Performance goals and measures;

(e) Reinvestment requirements for Program Income; and

(f) Reporting requirements for all Recipients.

2. Prior to executing the Assistance Agreement, the CDFI Fund may, in its discretion, allow Recipients to request changes to the Service Area of the Award and certain performance goals and measures. The CDFI Fund, in its sole determination, may approve or reject these requested changes or propose other modifications, including a reduction in the Award amount. The CDFI Fund will only approve performance goals and measures or Service Area changes if it determines that such requested changes do not undermine the competitive process upon which the CMF Award determination was made. The CDFI Fund may also, in its discretion, provide Recipients the opportunity to add states to their Service Area in order to serve states not already covered in the Award pool and to further HERA's goal that the CMF serve geographically diverse areas of every state. The CDFI Fund may also, in its discretion, provide Recipients the opportunity to add states to its approved Service Area in order to serve geographies for which: (i) the President issued a "major disaster declaration," and (ii) the major disaster declaration makes such geographies eligible for both "individual and public assistance." The major disaster declaration must be made after the publication date of this NOFA and prior to the execution of the Recipient's Assistance Agreement. In these cases, the CDFI Fund may allow a Recipient to exceed the maximum 15 state Service Area, if applicable. Any modifications agreed upon prior to the execution of the Assistance Agreement will become a condition of the Award. Recipients may utilize up to 15% of their Award to undertake Activities outside of their Service Area at their discretion.

3. The Assistance Agreement shall provide that, prior to any determination by the CDFI Fund that a Recipient has failed to comply substantially with the Act, the CMF Interim Rule, or the environmental quality regulations, the CDFI Fund shall provide the Recipient with reasonable notice and opportunity to be heard. If the Recipient fails to comply substantially with the Assistance Agreement, the CDFI Fund may:

(a) Require changes in the performance goals set forth in the Assistance Agreement;

(b) Reduce or terminate the CMF Award; or

(c) Require repayment of any CMF Award that has been distributed to the Recipient.

4. The Assistance Agreement shall also provide that, if the CDFI Fund determines noncompliance with the terms and conditions of the Assistance Agreement on the part of the Recipient, the CDFI Fund may:

(a) Bar the Recipient from reapplying for any assistance from the CDFI Fund; or

(b) Take such other actions as the CDFI Fund deems appropriate or as set forth in the Assistance Agreement.

5. In addition to entering into an Assistance Agreement, each Applicant selected to receive a CMF Award must furnish to the CDFI Fund a certificate of good standing from the jurisdiction in which it was formed. The CDFI Fund may, in its sole discretion or in lieu of a certificate of good standing, also require the Applicant to furnish an opinion from its legal counsel, the content of which may be further specified in the Assistance Agreement, and which, among other matters, opines that:

(a) The Recipient is duly formed and in good standing in the jurisdiction in which it was formed and the jurisdiction(s) in which it transacts business;

(b) The Recipient has the authority to enter into the Assistance Agreement and undertake the activities that are specified therein;

(c) The Recipient has no pending or threatened litigation that would materially affect its ability to enter into and carry out the activities specified in the Assistance Agreement;

(d) The Recipient is not in default of its articles of incorporation or formation, bylaws or operating agreements, other organizational or establishing documents, or any agreements with the federal government;

(e) The CMF affordability restrictions that are required to be imposed by deed restrictions, covenants running with the land, or other CDFI Fund approved mechanisms are recordable and enforceable under the laws of the State and locality where the Recipient will undertake its CMF activities;

(f) If applicable, the Recipient is exempt from federal income taxation pursuant to the Internal Revenue Code of 1986; and

(g) If applicable, the Recipient is designated as a nonprofit or not for profit entity under the laws of the organization's State of formation.

As a condition of closing on the Assistance Agreement, the CDFI Fund will require a CMF Recipient Consortium Member Agreement to specify the binding commitments of each member awarded under a Consortium Approach.

6. *Closing and Payment of the Award:* Pursuant to the Assistance Agreement, there will be an initial closing at which point the Assistance Agreement and related documents will be properly executed and delivered, and a Payment of the CMF Award is made. Recipients of CMF Awards will have the option to choose Payment of the Award in a Lump Sum Payment or, in two payments, an Initial Payment and Subsequent Payment, each no more than one year apart, as set forth in the Assistance Agreement. If the Applicant elects to receive the Award in two Payments, they must specify an Initial Payment amount in the Application. The CDFI Fund reserves the right to adjust the Initial Payment amount based on the total Award amount so that no payment is less than \$500,000. For example, if awarded \$950,000 and the Initial Payment amount requested in the Application was \$500,000, per the rule above, the CDFI Fund would disburse a single \$950,000 Lump Sum Payment to the Recipient, pursuant to the Assistance Agreement.

The Payment option election will affect the required date of Commitment of the Award, but will not affect or change any other performance goal(s) or requirement(s) set forth in the Assistance Agreement, including the requirement that all Projects must achieve Project Completion within five years of the Effective Date of the Assistance Agreement. The Lump Sum Payment⁴ or Initial Payment⁵ must be committed for use two years after the Effective Date of the Assistance Agreement. The Subsequent Payment⁶ must be committed three years after the Effective Date of the Assistance Agreement.

Following the initial closing of the Assistance Agreement, for those Recipients who opted for and qualify for two Payments, there will be a subsequent closing involving the additional Award payment. In addition to the Assistance Agreement, any documentation that is related to the subsequent closing and payment shall

⁴ "Lump Sum Payment" shall mean one single payment which comprises the entire CMF Award.

⁵ "Initial Payment" shall mean the first Payment from the CDFI Fund to the Recipient at Closing.

⁶ "Subsequent Payment" shall mean a second Payment representing the balance of the CMF Award in the case where a Recipient exercises its option to receive the CMF Award in two Payments.

be properly executed and delivered in a timely manner by the Recipient to the CDFI Fund.

D. 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. If applicable, the CDFI Fund may inform Applicants that they do not need to provide certain Application information otherwise required.

Pursuant to the Paperwork Reduction Act, the Capital Magnet Fund Application has been assigned the following control number: 1559-0036.

E. Reporting: The CDFI Fund will require each Recipient that receives a CMF Award through this NOFA to account for and report to the CDFI Fund on the use of the CMF Award. This will require Recipients to establish administrative controls, subject to the UAR and other applicable OMB guidance. The CDFI Fund will collect information from each such Recipient

on its use of the CMF Award annually, following Payment, and more often if deemed appropriate by the CDFI Fund in its sole discretion. The CDFI Fund will provide guidance to Recipients outlining the format and content of the information required to be provided to describe how the Award funds were used.

The CDFI Fund may collect information from each Recipient including, but not limited to, an annual report with the components listed in Table 8:

TABLE 8—REPORTING REQUIREMENTS *

Criteria	Description
Single Audit (if applicable) ...	A non-profit Recipient must complete an annual Single Audit pursuant to the Uniform Requirements (2 CFR 200.501) if it expends \$750,000 or more in federal awards in its fiscal year, or such other dollar threshold established by OMB pursuant to 2 CFR 200.501. If a Single Audit is required, it must be submitted electronically to the Federal Audit Clearinghouse (FAC) (see 2 CFR Subpart F—Audit Requirements in the Uniform Requirements) and optionally through AMIS.
Financial Statement Audit	For-profit and nonprofit Recipients must submit a Financial Statement Audit (FSA) report in AMIS, along with the Recipient's statement of financial condition audited or reviewed by an independent certified public accountant.
Performance Report	The Recipient must submit a performance report not less than annually, which is a progress report on the Recipient's use of the CMF Award towards meeting its performance goals, Affordable Housing outcomes, and the Recipient's overall performance. The CMF Performance Report covers the Announcement Date through the Investment Period for the CMF Award and the ten-year Affordability Period for each Project. The Investment Period shall mean the period beginning with the Effective Date of the Assistance Agreement and ending no earlier than the fifth year anniversary of the Effective Date, or as otherwise established in the Assistance Agreement. The Affordability Period shall mean, for each Project, the period beginning on the date when the Project is placed into service and consisting of the full ten consecutive years thereafter, or as otherwise established in the Assistance Agreement. If the Recipient fails to meet a performance goal or reporting requirements, it must submit an explanation of non-compliance via AMIS.
Environmental Review	The Recipient shall submit the Environmental Review Notification Report each time the Recipient identifies a new proposed CMF Project for which (i) a categorical exclusion does not apply and/or (ii) the Recipient determines that the proposed Project does involve actions that normally require an Environmental Impact Statement, as described in 12 CFR part 1815. The Environmental Review Notification Report must be submitted to the CDFI Fund no later than one hundred eighty (180) days prior to the date that the funds are Committed to a Project.

* Personally Identifiable Information (PII) is information, which if lost, compromised, or disclosed without authorization, could result in substantial harm, embarrassment, inconvenience, or unfairness to an individual. Although Applicants are required to enter addresses of homes and other properties in AMIS, Applicants should *not* include the following PII for the individuals who received the financial products or services in AMIS or in the supporting documentation (*i.e.* name of the individual, Social Security Number, driver's license or state identification number, passport number, Alien Registration Number, etc.). This information should be redacted from all supporting documentation (if applicable).

Each Recipient is responsible for the timely and complete submission of the annual reporting documents. The CDFI Fund will use such information to monitor each Recipient's compliance with the requirements set forth in the Assistance Agreement and to assess the impact of the CMF Award. The CDFI Fund reserves the right, in its sole discretion, to modify these reporting requirements if it determines it to be appropriate and necessary; however, such reporting requirements will be modified only after notice to Recipients.

F. Financial Management and Accounting: The CDFI Fund will require Recipients to maintain financial management and accounting systems that comply with federal statutes, regulations, and the terms and conditions of the CMF Award. These systems must be sufficient to permit the

preparation of reports required by general and program specific terms and conditions, including the tracing of funds to a level of expenditures adequate to establish that such funds have been used in accordance with the federal statutes, regulations, and the terms and conditions of the CMF Award.

The cost principles used by Recipients must be consistent with federal cost principles, must support the accumulation of costs as required by the principles, and must provide for adequate documentation to support costs charged to the CMF Award. In addition, the CDFI Fund will require Recipients to: maintain effective internal controls; comply with applicable statutes and regulations, the Assistance Agreement, and related guidance; evaluate and monitor

compliance; take action when not in compliance; and safeguard personally identifiable information.

VII. Agency Contacts

A. Availability: The CDFI Fund will respond to questions and provide support concerning this NOFA and the Application between the hours of 9:00 a.m. and 5:00 p.m. ET, starting on the date of the publication of this NOFA until the close of business on the second business day preceding the Application deadline. The CDFI Fund will not respond to questions or provide support concerning the Application that are received after 5:00 p.m. ET on said date, until after the Application deadline. CDFI Fund IT support will be available until 5:00 p.m. ET on date of the Application deadline. 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/cmfi>. The CDFI Fund

will post on its website responses to questions of general applicability regarding the CMF.

B. The CDFI Fund's Contact Information is Listed in Table 9:

TABLE 9—CONTACT INFORMATION

Type of question	Preferred method	Telephone number (not toll free)	Email addresses
CMF Program and Application Questions	Submit a Service Request in AMIS	202-653-0421	cmfi@cdfi.treas.gov .
CDFI Certification	Submit a Service Request in AMIS	202-653-0423	ccme@cdfi.treas.gov .
Compliance Monitoring and Evaluation	Submit a Service Request in AMIS	202-653-0423	ccme@cdfi.treas.gov .
Information Technology Support	Submit a Service Request in AMIS	202-653-0422	AMIS@cdfi.treas.gov .

The preferred method of contact is to submit a Service Request within AMIS. For a CMF Application question, select "Capital Magnet Fund" for the program. For a CDFI Certification question, select "Certification." For a Compliance question, select "Compliance & Reporting." For Information Technology, select "Technical Issues." Failure to select the appropriate program for the Service Request could result in delays in responding to your question.

C. Communication with the CDFI Fund: The CDFI Fund will use AMIS to communicate with Applicants and Recipients, using the contact information maintained in their respective AMIS accounts. Therefore, the Recipient and any Subsidiaries, signatories, and Affiliates must maintain accurate contact information (including contact persons and Authorized Representatives, email addresses, fax numbers, phone numbers, and office addresses) in its AMIS account(s). For more information about AMIS please see the Help documents posted at <https://amis.cdfifund.gov/s/Training>.

D. 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 Equal Employment Opportunity 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 Equal Employment Opportunity, 1500 Pennsylvania Ave. NW, Washington, DC 20220 or (202) 622-1160 (not a toll-free number).

E. 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, and the environment; and those prohibiting discrimination.

VIII. Other Information

The CMF regulations are set forth in 12 CFR part 1807. 12 CFR 1807.105 provides the CDFI Fund the ability to waive any part of the regulations for good cause: "The CDFI Fund may waive any requirement of this part that is not required by law upon a determination of good cause. Each such waiver shall be in writing and supported by a statement of the facts and the grounds forming the basis of the waiver. For a waiver in an individual case, the CDFI Fund must determine that application of the requirement to be waived would adversely affect the achievement of the purposes of the Act. For waivers of general applicability, the CDFI Fund will publish notification of granted waivers in the **Federal Register**." Pursuant to this requirement, the CDFI Fund is publishing notification in this NOFA that it hereby waives the requirements set forth in 12 CFR 1807.401(f) for all CMF Recipients who used their CMF Awards to finance or support rental housing Projects with an Affordability Period covering the dates of April 1, 2020 through December 31, 2021. Thus, if a CMF Recipient's Affordability Period covers the timeframe of April 1, 2020 through December 31, 2021, the requirement to verify the tenant's income annually in such timeframe is hereby waived.

A. Statement of Facts: The CMF Interim Rule requires CMF Recipients to annually re-examine tenant income. 12 CFR 1807.401(f) requires that each year during the period of affordability, the tenant's income must be re-examined. The tenant income examination and verification is ultimately the

responsibility of the CMF Recipient. Annual income includes income from all household members. CMF Recipients must require the Project owner to obtain information on rents and occupancy of Affordable Housing financed or assisted with a CMF Award in order to demonstrate compliance with 12 CFR 1807.401(f). On March 13, 2020, the President of the United States issued an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.*, in response to the ongoing COVID-19 pandemic. On February 18, 2022, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), the President continued the national emergency declared in Proclamation 994 concerning COVID-19 pandemic to be in effect beyond March 1, 2022. On January 31, 2020, Secretary of Health and Human Services issued a determination that as a result of the confirmed cases of 2019 Novel Coronavirus, a public health emergency exists and has existed since January 27, 2020, nationwide ("HHS Determination"). On October 13, 2022, the HHS Determination was renewed to state that a public health emergency exists and has existed since January 27, 2020, nationwide, due to the continued consequences of COVID-19. In response, several federal agencies issued notices announcing certain statutory suspensions and regulatory waivers to alleviate the burden on program participants and stakeholders affected by the COVID-19 pandemic.

B. Grounds for Waiver: The CDFI Fund determined that Recipients experienced difficulty in carrying out annual tenant income recertification during the COVID-19 pandemic. Further, other federal agencies provided temporary relief from federal program criteria similar to those required by CMF Recipients. To illustrate, the Internal Revenue Service issued Notice 2021-12 granting relief for owners of low-income buildings from the requirement to perform income recertifications under 26 CFR 1.42-

5(c)(1)(iii) from April 1, 2020, to September 30, 2021. Similarly, the U.S. Department of Housing and Urban Development issued a memorandum on September 27, 2021, updating its memorandum, *Revision, Extension and Update of April 2020 Memorandum Availability of Waivers and Suspensions of the HOME Program Requirements in Response to COVID-19 Pandemic* issued on December 4, 2020, extending the waiver to perform onsite inspections of HOME-assisted rental housing and annual re-inspections of units assisted with HOME Tenant-Based Rental Assistance from September 30, 2021, to December 31, 2021. The CDFI Fund has determined that to provide relief to CMF Recipients during the height of the COVID-19 pandemic, and to align CMF regulatory requirements with other federal programs, temporary relief related to annual tenant income determination for this period is warranted.

For the above stated reasons, the CDFI Fund is issuing a general waiver herein of 12 CFR 1807.401(f) in cases where the CMF Award Recipient did not undertake or complete annual tenant income examination and verification during the period of affordability for the applicable dates in response to the COVID-19 pandemic. This is to provide maximum administrative flexibility and better assist low-and very low-income households as they deal with the effects of the COVID-19 pandemic.

This waiver extends relief for the period beginning April 1, 2020, and ending December 31, 2021. As of January 1, 2022, the CMF Award Recipient shall have recommenced tenant income re-certification on an annual basis in compliance with 12 CFR 1807.401(f).

Authority: Pub. L. 110-289, 12 U.S.C. 4701, 12 CFR part 1805, 12 CFR part 1807, 12 CFR part 1815, 12 U.S.C. 4502.

Jodie L. Harris,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2023-00932 Filed 1-18-23; 8:45 am]

BILLING CODE 4810-05-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Superfund Chemical Substance Tax; Request To Modify List of Taxable Substances; Filing of Petition for 4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of filing and request for comments.

SUMMARY: This notice of filing announces that a petition has been filed pursuant to Revenue Procedure 2022-26, 2022-29 I.R.B. 90, requesting that 4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer be added to the list of taxable substances under section 4672(a) of the Internal Revenue Code ("Code"). This notice of filing also requests comments on the petition. This notice of filing is not a determination that the list of taxable substances is modified.

DATES: Written comments and requests for a public hearing must be received on or before March 20, 2023.

ADDRESSES: Commenters are encouraged to submit public comments or requests for a public hearing relating to this petition electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> (indicate public docket number IRS-2022-0038 or 4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer) by following the online instructions for submitting comments. Comments cannot be edited or withdrawn once submitted to the Federal eRulemaking Portal. Alternatively, comments and requests for a public hearing may be mailed to: Internal Revenue Service, Attn: CC:PA:LPD:PR (Notice of Filing for 4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer), Room 5203, P.O. Box 7604, Ben Franklin Station, Washington DC 20044. All comments received are part of the public record and subject to public disclosure. All comments received will be posted without change to www.regulations.gov, including any personal information provided. You should submit only information that you wish to make publicly available. If a public hearing is scheduled, notice of the time and place for the hearing will be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Please contact Amanda F. Dunlap, (202) 317-6855 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

(a) *Overview.* The petition requesting the addition of 4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer to the list of taxable substances under section 4672(a) of the Code is based on weight and contains the information detailed in paragraph (b) of this document. The information is provided for public notice and comment pursuant to section 9 of Rev. Proc. 2022-26. The publication of petition content in this notice of filing does not constitute Department of

the Treasury or Internal Revenue Service confirmation of the accuracy of the information published.

(b) *Petition Content.*

(1) *Substance name:* 4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer.

According to the petition, these are the chemical names of 4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer: Bisphenol A Epoxy Resin.

(2) *Petitioner:* Westlake Epoxy Inc., an exporter of 4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer.

(3) *Proposed Classification Numbers:* HTSUS number: 3907.30.0000.

Schedule B number: 3907.30.0000.

CAS number: 25068-38-6.

(4) *Petition Filing Date:* December 20, 2022.

Petition filing date for purposes of section 11.02 of Rev. Proc. 2022-26: July 1, 2022.

(5) *Brief Description of the Petition:*

According to the petition, 4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer is a Bisphenol A Epoxy Resin and is used for Epoxide Resin. 4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer is derived from the taxable chemicals benzene, propylene, chlorine, and sodium hydroxide and produced predominantly from epichlorohydrin and bisphenol-A via a two-step glycidation reaction sequence. Taxable chemicals comprise 92.98 percent of the final product.

(6) *Process Identified in Petition as Predominant Method of Production of Substance:* 4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer is derived from the taxable chemicals benzene, propylene, chlorine, and sodium hydroxide, and is produced predominantly from epichlorohydrin and bisphenol-A via a two-step glycidation reaction sequence. Epichlorohydrin is typically produced via an addition reaction of chlorine to propylene that yields allyl chloride and subsequently dichlorohydrin isomers, followed by a dehydrochlorination step in the presence of sodium hydroxide to yield epichlorohydrin. Bisphenol A is typically produced from the reaction of benzene and propylene that yields phenol and acetone. Under acidic conditions and with an appropriate catalyst, two units of phenol can react with one unit of acetone to yield Bisphenol A. With available epichlorohydrin and Bisphenol A, 4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer can be obtained through a two-step glycidation

reaction sequence where epichlorohydrin is added to Bisphenol A (deprotonated with sodium hydroxide) and then water, sodium hydroxide, and sodium chloride are removed in a dehydrochlorination step.

(7) *Stoichiometric Material Consumption Equation, Based on Process Identified as Predominant Method of Production:*

2 C₆H₆ (benzene) + 4 C₃H₆ (propylene) + 4 Cl₂ (chlorine) + 6 NaOH (sodium hydroxide) + 2 O₂ (oxygen) → (CH₃)₂C(C₆H₄OC₃H₅O)₂ (4,4'-Isopropylidenediphenol-Epichlorohydrin Copolymer) + CH₃COCH₃ (acetone) + 2 HCl (hydrogen chloride) + 6 NaCl (sodium chloride) + 5 H₂O (water)

(8) *Rate of Tax Calculated by Petitioner Based on Petitioner's Conversion Factors for Taxable Chemicals Used in Production of Substance:*

Rate of Tax: \$14.13 per ton.

Conversion Factors:

0.46 for benzene

0.49 for propylene

0.83 for chlorine

0.71 for sodium hydroxide

(9) *Public Docket Number:* IRS-2022-0038.

Stephanie Bland,

Branch Chief (Passthroughs and Special Industries), IRS Office of Chief Counsel.

[FR Doc. 2023-00948 Filed 1-18-23; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request Concerning Extraterritorial Income Exclusion

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning extraterritorial income exclusion.

DATES: Written comments should be received on or before March 20, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue

Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to pra.comments@irs.gov.

Include OMB control number 1545-1722 or comments concerning extraterritorial income exclusion.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the form should be directed to Kerry Dennis at (202) 317-5751, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at Kerry.L.Dennis@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Extraterritorial Income Exclusion.

OMB Number: 1545-1722.

Form Number: 8873.

Abstract: The FSC and Extraterritorial Income Exclusion Act of 2000 added section 114 to the Internal Revenue Code. Section 114 provides for an exclusion from gross income for certain transactions occurring after September 30, 2000, with respect to foreign trading gross receipts. Form 8873 is used to compute the amount of extraterritorial income excluded from gross income for the tax year.

Current Actions: There are no changes to the form or burden.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 100.

Estimated Time per Respondent: 25 hours, 27 minutes.

Estimated Total Annual Burden Hours: 2,545 hours.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 12, 2023.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2023-00919 Filed 1-18-23; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 14767

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Consent to Disclose Tax Compliance Check.

DATES: Written comments should be received on or before March 20, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to pra.comments@irs.gov. Include "OMB Number 1545-1856-Consent to Disclose Tax Compliance Check" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of this collection should be directed to Martha R. Brinson, at (202) 317-5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at Martha.R.Brinson@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Consent to Disclose Tax Compliance Check.

OMB Number: 1545-1856.

Form Number: Form 14767.

Abstract: Form 14767 is used to authorize the Internal Revenue Service (IRS) to prepare a tax compliance report that discloses confidential tax information to a third-party appointee for Federal employment.

Current Actions: Form 13362 was used by Personnel Offices for external applicants to allow IRS to disclose tax-related information to the Office of Personnel Management for suitability determinations. This form has been obsolete and replaced by Form 14767.

Type of Review: Revision of a currently approved collection.

Affected Public: Federal Government.

Estimated Number of Respondents: 46,000.

Estimated Time per Respondent: 10 mins.

Estimated Total Annual Burden Hours: 7,664.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 11, 2023.

Martha R. Brinson,

Tax Analyst.

[FR Doc. 2023-00946 Filed 1-18-23; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request Concerning Information Return of Nontaxable Energy Grants or Subsidized Energy Financing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning information returns with respect to energy grants and financing.

DATES: Written comments should be received on or before March 20, 2023 to be assured of consideration

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to pra.comments@irs.gov. Include OMB control number 1545-0232 or comments concerning Information Returns with Respect to Energy Grants and Financing.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis at (202) 317-5751, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at Kerry.L.Dennis@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Information Returns with Respect to Energy Grants and Financing.

OMB Number: 1545-0232.

Form Number: 6497.

Abstract: Section 6050D of the Internal Code requires an information return to be made by any person who administers a Federal, state, or local program providing nontaxable grants or subsidized energy financing. Form 6497 is used for making the information

return. The IRS uses the information from the form to ensure that recipients have not claimed tax credits or other benefits with respect to the grants or subsidized financing.

Current Actions: There are no changes to the burden.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations, and not-for-profit institutions.

Estimated Number of Respondents: 250.

Estimated Time per Respondent: 3 hours, 14 minutes.

Estimated Total Annual Burden Hours: 810 hours.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 12, 2023.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2023-00918 Filed 1-18-23; 8:45 am]

BILLING CODE 4830-01-P



FEDERAL REGISTER

Vol. 88

Thursday,

No. 12

January 19, 2023

Part II

Federal Trade Commission

16 CFR Part 910

Non-Compete Clause Rule; Proposed Rule

FEDERAL TRADE COMMISSION**16 CFR Part 910**

RIN 3084-AB74

Non-Compete Clause Rule**AGENCY:** Federal Trade Commission.**ACTION:** Notice of proposed rulemaking.

SUMMARY: Pursuant to Sections 5 and 6(g) of the Federal Trade Commission Act, the Federal Trade Commission (“Commission”) is proposing the Non-Compete Clause Rule. The proposed rule would, among other things, provide that it is an unfair method of competition for an employer to enter into or attempt to enter into a non-compete clause with a worker; to maintain with a worker a non-compete clause; or, under certain circumstances, to represent to a worker that the worker is subject to a non-compete clause.

DATES: Comments must be received on or before March 20, 2023.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write “Non-Compete Clause Rulemaking, Matter No. P201200” on your comment, and file your comment online at <https://www.regulations.gov>, by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex C), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Shannon Lane (202-876-5651), Attorney, Office of Policy Planning, Federal Trade Commission.

SUPPLEMENTARY INFORMATION:**I. Overview of the Proposed Rule**

A non-compete clause is a contractual term between an employer and a worker that typically blocks the worker from working for a competing employer, or starting a competing business, within a certain geographic area and period of time after the worker’s employment ends. Non-compete clauses limit competition by their express terms. As a result, non-compete clauses have always been considered proper subjects for scrutiny under the nation’s antitrust laws.¹ In addition, non-compete clauses

between employers and workers are traditionally subject to more exacting review under state common law than other contractual terms, due, in part, to concerns about unequal bargaining power between employers and workers and the fact that non-compete clauses limit a worker’s ability to practice their trade.²

In recent decades, important research has shed light on how the use of non-compete clauses by employers affects competition. Changes in state laws governing non-compete clauses have provided several natural experiments that have allowed researchers to study the impact of non-compete clauses on competition. This research has shown the use of non-compete clauses by employers has negatively affected competition in labor markets, resulting in reduced wages for workers across the labor force—including workers not bound by non-compete clauses.³ This research has also shown that, by suppressing labor mobility, non-compete clauses have negatively affected competition in product and service markets in several ways.⁴

In this rulemaking, the Commission seeks to ensure competition policy is aligned with the current economic evidence about the consequences of non-compete clauses. In the Commission’s view, the existing legal frameworks governing non-compete clauses—formed decades ago, without the benefit of this evidence—allow serious anticompetitive harm to labor, product, and service markets to go unchecked.

Section 5 of the Federal Trade Commission Act (“FTC Act”) declares “unfair methods of competition” to be unlawful.⁵ Section 5 further directs the Commission “to prevent persons, partnerships, or corporations . . . from using unfair methods of competition in or affecting commerce.”⁶ Section 6(g) of the FTC Act authorizes the Commission to “make rules and regulations for the purpose of carrying out the provisions of” the FTC Act, including the Act’s

recurring” use of non-compete clauses); *Newburger, Loeb & Co., Inc. v. Gross*, 563 F.2d 1057, 1082 (2d Cir. 1977) (“Although such issues have not often been raised in the federal courts, employee agreements not to compete are proper subjects for scrutiny under section 1 of the Sherman Act. When a company interferes with free competition for one of its former employee’s services, the market’s ability to achieve the most economically efficient allocation of labor is impaired. Moreover, employee-noncompetition clauses can tie up industry expertise and experience and thereby forestall new entry.”) (internal citation omitted).

² See *infra* Part II.C.

³ See *infra* Part II.B.1.

⁴ See *infra* Part II.B.2.

⁵ 15 U.S.C. 45(a)(1).

⁶ 15 U.S.C. 45(a)(2).

prohibition of unfair methods of competition.⁷

Pursuant to Sections 5 and 6(g) of the FTC Act, the Commission proposes the Non-Compete Clause Rule. The proposed rule would provide it is an unfair method of competition—and therefore a violation of Section 5—for an employer to enter into or attempt to enter into a non-compete clause with a worker; maintain with a worker a non-compete clause; or, under certain circumstances, represent to a worker that the worker is subject to a non-compete clause.⁸

The proposed rule would define the term “non-compete clause” as a contractual term between an employer and a worker that prevents the worker from seeking or accepting employment with a person, or operating a business, after the conclusion of the worker’s employment with the employer.⁹ The proposed rule would also clarify that whether a contractual provision is a non-compete clause would depend not on what the provision is called, but how the provision functions. As the Commission explains below, the definition of non-compete clause would generally not include other types of restrictive employment covenants—such as non-disclosure agreements (“NDAs”) and client or customer non-solicitation agreements—because these covenants generally do not prevent a worker from seeking or accepting employment with a person or operating a business after the conclusion of the worker’s employment with the employer. However, under the proposed definition of “non-compete clause,” such covenants would be considered non-compete clauses where they are so unusually broad in scope that they function as such.¹⁰

The proposed rule would define “employer” as a person—as the term “person” is defined in 15 U.S.C. 57b-1(a)(6)—that hires or contracts with a worker to work for the person.¹¹ The proposed rule would define “worker” as a natural person who works, whether paid or unpaid, for an employer. The proposed rule would clarify that the term “worker” includes an employee, individual classified as an independent contractor, extern, intern, volunteer, apprentice, or sole proprietor who

⁷ 15 U.S.C. 46(g).

⁸ See proposed § 910.2(a). For ease of reference, this NPRM employs the term “use of non-compete clauses” as a shorthand to refer to the conduct that the proposed rule would provide is an unfair method of competition.

⁹ See proposed § 910.1(b)(1).

¹⁰ See *infra* Part V (in the section-by-section analysis for proposed § 910.1(b)).

¹¹ See proposed § 910.1(c).

¹ See, e.g., *U.S. v. Am. Tobacco Co.*, 221 U.S. 106, 181-83 (1911) (holding several tobacco companies violated Sections 1 and 2 of the Sherman Act due to the collective effect of six of the companies’ practices, one of which was the “constantly

provides a service to a client or customer.¹²

In addition to prohibiting employers from entering into non-compete clauses with workers starting on the rule's compliance date, the proposed rule would require employers to rescind existing non-compete clauses no later than the rule's compliance date.¹³ The proposed rule would also require an employer rescinding a non-compete clause to provide notice to the worker that the worker's non-compete clause is no longer in effect.¹⁴ To facilitate compliance, the proposed rule would (1) include model language that would satisfy this notice requirement¹⁵ and (2) establish a safe harbor whereby an employer would satisfy the rule's requirement to rescind existing non-compete clauses where it provides the worker with a notice that complies with this notice requirement.¹⁶

The proposed rule would include a limited exception for non-compete clauses between the seller and buyer of a business.¹⁷ This exception would only be available where the party restricted by the non-compete clause is an owner, member, or partner holding at least a 25% ownership interest in a business entity.¹⁸ The proposed regulatory text would clarify that non-compete clauses covered by this exception would remain subject to federal antitrust law as well as all other applicable law.

The proposed rule would establish an effective date of 60 days, and a compliance date of 180 days, after publication of a final rule in the **Federal Register**.¹⁹

In this notice of proposed rulemaking ("NPRM"), the Commission describes and seeks comment on several alternatives to the proposed rule, including whether non-compete clauses between employers and senior executives should be subject to a different standard than non-compete clauses with other workers.²⁰ The Commission also assesses the benefits and costs of the proposed rule, the impact of the proposed rule on small businesses, and compliance costs related to the proposed rule's notice requirement.²¹

The Commission seeks comment on all aspects of this NPRM. Comments

must be received on or before March 20, 2023.²²

II. Factual Background

A. What are non-compete clauses?

A non-compete clause is a contractual term between an employer and a worker that prevents the worker from seeking or accepting employment with a person, or operating a business, after the conclusion of the worker's employment with the employer.²³ A typical non-compete clause blocks the worker from working for a competing employer, or starting a competing business, within a certain geographic area and period of time after their employment ends. A non-compete clause may be part of the worker's employment contract or may be contained in a standalone contract. Employers and workers may enter into non-compete clauses at the start of, during, or at the end of a worker's employment.

If a worker violates a non-compete clause, the employer may sue the worker for breach of contract. An employer may be able to obtain a preliminary injunction ordering the worker, for the duration of the lawsuit, to stop the conduct that allegedly violates the non-compete clause. If the employer wins the lawsuit, the employer may be able to obtain a permanent injunction ordering the worker to stop the conduct that violates the non-compete clause; a payment of monetary damages from the worker; or both.²⁴ Where workers are subject to arbitration clauses,²⁵ the employer may seek to enforce the non-compete clause through arbitration.

The below examples of non-compete clauses from recent news reports, legal settlements, and court opinions are illustrative.

²² Pursuant to Section 22(d)(4) of the FTC Act, 15 U.S.C. 57b-3(d)(4), this NPRM was not included in the Commission's Spring 2022 Regulatory Agenda because the Commission first considered it after the publication deadline for the Regulatory Agenda.

²³ See proposed § 910.1(b). The term "non-compete clause" has also been used to describe agreements between one or more business not to compete against one another, see, e.g., *Lumber Liquidators, Inc. v. Cabinets To Go, LLC*, 415 F. Supp. 3d 703, 709 (E.D. Va. 2009), as well as certain kinds of moonlighting during a worker's employment, see, e.g., *In the Matter of the Investigation by Barbara D. Underwood, Att'y Gen. of the State of N.Y. of WeWork Companies, Inc.*, Assurance of Discontinuance No. 18-101 (Sept. 18, 2018) at Exhibit B. As underscored above, however, this proposed rule focuses only on post-employment restraints that employers impose on workers.

²⁴ Donald J. Aspelund & Joan E. Beckner, *Employee Noncompetition Law* § 8:2, § 8:22 (Aug. 2021).

²⁵ See, e.g., Alexander J.S. Colvin, Econ. Pol'y Inst., Report, *The Growing Use of Mandatory Arbitration* (Apr. 6, 2018).

- A contractual term between a security guard firm and its security guards requiring that, for two years following the conclusion of the security guards' employment with the firm, the security guard may not "[a]ccept employment with or be employed by" a competing business "within a one hundred (100) mile radius" of the security guard's primary jobsite with the firm and stating that the security guards may not "[a]ssist, aid or in any manner whatsoever help any firm, corporation, partnership or other business to compete with" the firm. The non-compete clause also contains a "liquidated damages" clause requiring the security guard to pay the firm \$100,000 as a penalty for any conduct that contravenes the agreement.²⁶

- A contractual term between a glass container manufacturing company and its workers typically requiring that, for two years following the conclusion of the worker's employment with the company, the worker may not directly or indirectly "perform or provide the same or substantially similar services" to those the worker performed for the company to any business in the U.S., Canada, or Mexico that is "involved with or that supports the sale, design, development, manufacture, or production of glass containers" in competition with the company.²⁷

- A contractual term between a sandwich shop chain and its workers stating that, for two years after the worker leaves their job, the worker may not perform services for "any business which derives more than ten percent (10%) of its revenue from selling submarine, hero-type, deli-style, pita and/or wrapped or rolled sandwiches" located within three miles of any of the chain's more than 2,000 locations in the United States.²⁸

- A contractual term between a steelmaker and one of its executives prohibiting the executive from working for "any business engaged directly or indirectly in competition with" the steelmaker anywhere in the world for

²⁶ Fed. Trade Comm'n, Complaint, *In re Prudential Sec., Inc. et al.*, Matter No. 221 0026 at ¶ 12-¶ 13 (December 28, 2022).

²⁷ Fed. Trade Comm'n, Complaint, *In re Ardagh Group S.A. et al.*, Matter No. 211 0182 at ¶ 9 (December 28, 2022).

²⁸ Dave Jamieson, *Jimmy John's Makes Low-Wage Workers Sign 'Oppressive' Noncompete Agreements*, HuffPost (Oct. 13, 2014). The company agreed to remove the non-compete clause in 2016 as part of a settlement. Office of the Att'y Gen. of the State of N.Y., Press Release, *A.G. Schneiderman Announces Settlement With Jimmy John's To Stop Including Non-Compete Agreements In Hiring Packets* (June 22, 2016).

¹² See proposed § 910.1(f).

¹³ See proposed § 910.2(b)(1).

¹⁴ See proposed § 910.2(b)(2)(A).

¹⁵ See proposed § 910.2(b)(2)(C).

¹⁶ See proposed § 910.2(b)(3).

¹⁷ See proposed § 910.3.

¹⁸ See proposed §§ 910.3 and 910.1(e).

¹⁹ See proposed § 910.5.

²⁰ See *infra* Part VI.

²¹ See *infra* Parts VII-IX.

one year following the termination of the executive's employment.²⁹

- A contractual term between an office supply company and one of its sales representatives stating that, for two years after the sales representative's last day of employment, the sales representative is prohibited from "engag[ing] directly or indirectly, either personally or as an employee, associate, partner, or otherwise, or by means of any corporation or other legal entity, or otherwise, in any business in competition with Employer," within a 100-mile radius of the sales representative's employment location.³⁰

- A contractual term between a nationwide payday lender and its workers stating that, for one year after the worker leaves their job, they are prohibited from performing any "consumer lending services or money transmission services" for any entity that provides such services, or to "sell products or services that are competitive with or similar to the products or services of the Company," within a 15-mile radius of any of the payday lender's 1,000 locations in the United States.³¹

- A contractual term between an online retailer and its warehouse workers prohibiting the workers, for 18 months after leaving their job, from "directly or indirectly . . . engag[ing] or support[ing] the development, manufacture, marketing, or sale of any product or service that competes or is intended to compete with any product or service sold, offered, or otherwise provided by" the retailer—or that is "intended to be sold, offered, or otherwise provided by [the retailer] in the future"—that the worker "worked on or supported" or about which the worker obtained or received confidential information.³²

- A contractual term between a medical services firm and an ophthalmologist stating that, for two years after the termination of the ophthalmologist's employment with the firm, the ophthalmologist shall not engage in the practice of medicine in

two Idaho counties unless the ophthalmologist pays the firm a "practice fee" of either \$250,000 or \$500,000, depending on when the ophthalmologist's employment ends.³³

In addition to non-compete clauses, other types of contractual provisions restrict what a worker may do after they leave their job. These other types of provisions include, among others:

- Non-disclosure agreements (NDAs)—also known as "confidentiality agreements"—which prohibit the worker from disclosing or using certain information;
- Client or customer non-solicitation agreements, which prohibit the worker from soliciting former clients or customers of the employer (referred to in this NPRM as "non-solicitation agreements");³⁴

- No-business agreements, which prohibit the worker from doing business with former clients or customers of the employer, whether or not solicited by the worker;

- No-recruit agreements, which prohibit the worker from recruiting or hiring the employer's workers;

- Liquidated damages provisions, which require the worker to pay the employer a sum of money if the worker engages in certain conduct; and
- Training-repayment agreements (TRAs), a type of liquidated damages provision in which the worker agrees to pay the employer for the employer's training expenses if the worker leaves their job before a certain date.³⁵

These other types of restrictive employment covenants can sometimes be so broad in scope that they serve as *de facto* non-compete clauses.³⁶

In addition to restricting what workers may do after they leave their jobs, employers have also entered into agreements with other employers in which they agree not to compete for one another's workers. These include no-poach agreements, in which employers agree not to solicit or hire one another's workers, and wage-fixing agreements, in

which employers agree to limit wages or salaries (or other terms of compensation).³⁷

The Commission seeks comment on its description in this Part II.A of non-compete clauses. The Commission also encourages workers, employers, and other members of the public to submit comments describing their experiences with non-compete clauses.

B. Evidence Relating to the Effects of Non-Compete Clauses on Competition

Non-compete clauses have presented challenging legal issues for centuries.³⁸ But only in the last two decades has empirical evidence emerged to help regulators and the general public understand how non-compete clauses affect competition in labor markets and product and service markets.

In the early 2000s, researchers began to shed new light on the impacts of non-compete clauses on innovation and productivity. As this new body of research was evolving, news reports revealed non-compete clauses were being imposed even on low-wage workers.³⁹ These reports surprised many observers, who had assumed only highly skilled workers were subject to non-compete clauses.⁴⁰ Researchers responded by applying the tools of economic research to better understand how employers were using non-compete clauses and how they were affecting competition.

1. Labor Markets

The empirical research on how non-compete clauses affect competition shows that the use of non-compete clauses in the aggregate is interfering with competitive conditions in labor markets.

Labor markets function by matching workers and employers. Workers offer their skills and time to employers. In return, employers offer pay, benefits, and job satisfaction.⁴¹ In a well-functioning labor market, a worker who is seeking a better job—more pay, better hours, better working conditions, more enjoyable work, or whatever the worker may be seeking—can enter the labor market by looking for work. Employers who have positions available compete for the worker's services. The worker's

²⁹ *AK Steel Corp. v. ArcelorMittal USA, LLC*, 55 N.E.3d 1152, 1156 (Ohio Ct. App. 2016).

³⁰ *Osborne v. Brown & Saenger, Inc.*, 904 N.W.2d 34, 36 (N.D. 2017).

³¹ *People of the State of Ill. v. Check Into Cash of Ill., LLC*, Complaint, 2017–CH–14224 (Ill. Circuit Ct. Oct. 25, 2017), ¶ 29, ¶ 70, https://illinoisattorneygeneral.gov/pressroom/2017_10/Check_Into_Cash-Complaint.pdf.

³² Spencer Woodman, Exclusive: Amazon makes even temporary warehouse workers sign 18-month non-compete clauses, *The Verge* (Mar. 26, 2015). The company removed the non-compete clause following the media coverage. Josh Lowensohn, *Amazon does an about-face on controversial warehouse worker non-compete contracts*, *The Verge* (Mar. 27, 2015).

³³ *Intermountain Eye & Laser Ctrs. P.L.L.C. v. Miller*, 127 P.3d 121, 123 (Idaho 2005).

³⁴ The term "non-solicitation agreement" can also refer to a type of agreement between employers not to solicit one another's employees. In this NPRM, however, the term refers only to contractual provisions between employers and workers prohibiting the worker from soliciting clients or customers of the employer.

³⁵ See, e.g., Norman D. Bishara, Kenneth J. Martin, and Randall S. Thomas, *An Empirical Analysis of Non-Competition Clauses and Other Restrictive Post-Employment Covenants*, 68 *Vand. L. Rev.* 1, 13 (2015); Uniform Law Comm'n, *Uniform Restrictive Employment Agreement Act*, Draft For Approval (2021) at § 2.

³⁶ See, e.g., *Wegmann v. London*, 648 F.2d 1072, 1073 (5th Cir. 1981); *Brown v. TGS Mgmt. Co., LLC*, 57 Cal. App. 5th 303, 306, 319 (Cal. Ct. App. 2020).

³⁷ Fed. Trade Comm'n & U.S. Dep't of Justice Antitrust Division, *Antitrust Guidance for Human Resource Professionals* (Oct. 2016) at 3.

³⁸ See *infra* Part II.C.

³⁹ See, e.g., Jamieson, *supra* note 28.

⁴⁰ See, e.g., Alan B. Kreuger & Eric A. Posner, *The Hamilton Project, Policy Proposal 2018–05, A Proposal for Protecting Low-Income Workers from Monopsony and Collusion* (February 2018) at 7.

⁴¹ See, e.g., Dep't of the Treasury, *Report, The State of Labor Market Competition* (March 7, 2022) at 3.

current employer may also compete with these prospective employers by seeking to retain the worker—for example, by offering to raise the worker's pay or promote the worker. Ultimately, the worker chooses the job that best meets their objectives. In general, the more jobs available—*i.e.*, the more options the worker has—the stronger the match the worker will find.

Just as employers compete for workers in a well-functioning labor market, workers compete for jobs. An employer who needs a worker will make it known that the employer has a position available. Workers who learn of the opening will apply for the job. From among the workers who apply, the employer will choose the worker that best meets the employer's needs—in general, the worker most likely to be the most productive. In general, the more workers who are available—*i.e.*, the more options the employer has—the stronger the match the employer will find.

Through these processes—employers competing for workers, workers competing for jobs, and employers and workers matching with one another—competition in the labor market leads to higher earnings for workers, greater productivity for employers, and better economic conditions.

In a perfectly competitive labor market, if a job that a worker would prefer more—for example, because it has higher pay or is in a better location—were to become available, the worker could switch to it quickly and easily. Due to this ease of switching, in a perfectly competitive labor market, workers would easily match to the optimal job for them. If a worker were to find themselves in a job where the combination of their happiness and productivity is less than in some other job, they would simply switch jobs, making themselves better off.

However, this perfectly competitive labor market exists only in theory. In practice, labor markets deviate substantially from perfect competition. Non-compete clauses, in particular, impair competition in labor markets by restricting a worker's ability to change jobs. If a worker is bound by a non-compete clause, and the worker wants a better job, the non-compete clause will prevent the worker from accepting a new job that is within the scope of the non-compete clause. These are often the most natural alternative employment options for a worker: jobs in the same geographic area and in the worker's field of expertise. For example, a non-compete clause might prevent a nurse in Cleveland from working in the health care field in Northeast Ohio, or a

software engineer in Orlando from working for another technology company in Central Florida. The result is less competition among employers for the worker's services and less competition among workers for available jobs. Since the worker is prevented from taking these jobs, the worker may decide not to enter the labor market at all. Or the worker may enter the labor market but take a job in which they are less productive, such as a job outside their field.

Non-compete clauses affect competition in labor markets through their use in the aggregate. The effect of an individual worker's non-compete clause on competition in a particular labor market may be marginal or may be impossible to discern statistically. However, the use of a large number of non-compete clauses across a labor market markedly affects the opportunities of all workers in that market, not just those with non-compete clauses. By making it more difficult for many workers in a labor market to switch to new jobs, non-compete clauses inhibit optimal matches from being made between employers and workers across the labor force. As a result, where non-compete clauses are prevalent in a market, workers are more likely to remain in jobs that are less optimal with respect to the worker's ability to maximize their productive capacity. This materially reduces wages for workers—not only for workers who are subject to non-compete clauses, but for other workers in a labor market as well, since jobs that would otherwise be better matches for an unconstrained worker are filled by workers subject to non-compete clauses.

a. Estimates of Non-Compete Clause Use

Based on the available evidence, the Commission estimates that approximately one in five American workers—or approximately 30 million workers—is bound by a non-compete clause.

A 2014 survey of workers by Evan Starr, JJ Prescott, and Norman Bishara, which resulted in 11,505 responses, found 18% of respondents work under a non-compete clause and 38% of respondents have worked under one at some point in their lives.⁴² Among the

⁴² Evan P. Starr, James J. Prescott, & Norman D. Bishara, *Noncompete Agreements in the U.S. Labor Force*, 64 J.L. & Econ. 53, 53 (2021). A survey of workers conducted in 2017 by *Payscale.com* reached similar results. This survey estimated that 24.2% of workers are subject to a non-compete clause. Natarajan Balasubramanian, Evan Starr, & Shotaro Yamaguchi, *Bundling Employment Restrictions and Value Appropriation from Employees* 35 (2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3814403. This survey also

found that non-compete clause use discussed here, this study has the broadest and likely the most representative coverage of the U.S. labor force.⁴³ Starr, Prescott, and Bishara also found that, among workers without a bachelor's degree, 14% of respondents reported working under a non-compete clause at the time surveyed and 35% reported having worked under one at some point in their lives.⁴⁴ For workers earning less than \$40,000 per year, 13% of respondents work under a non-compete clause and 33% worked under one at some point in their lives.⁴⁵ Furthermore, this survey shows 53% of workers who are covered by non-compete clauses are hourly workers.⁴⁶

Starr, Prescott, and Bishara also found, in states where non-compete clauses are unenforceable, workers are covered by non-compete clauses at approximately the same rate as workers in other states.⁴⁷ This suggests employers maintain non-compete clauses even where they likely cannot enforce them.

Other estimates of non-compete clause use cover subsets of the U.S. labor force. One study, a 2021 study by Rothstein and Starr, is based on National Longitudinal Survey of Youth (NLSY) data.⁴⁸ The NLSY consists of a nationally representative sample of 8,984 men and women born from 1980–84 and living in the United States at the time of the initial survey in 1997.⁴⁹ The survey is an often-used labor survey conducted by the Bureau of Labor Statistics, rather than a one-off survey

found that non-compete clauses are often used together with other restrictive employment covenants, including non-disclosure, non-recruitment, and non-solicitation covenants. *Id.* at 17 (reporting that respondents that had a non-compete clause reported having all three of the other restrictive employment covenants 74.7% of the time). However, a key limitation of the *Payscale.com* survey is that it is a convenience sample of individuals who visited *Payscale.com* during the time period of the survey and is therefore unlikely to be fully representative of the U.S. working population. *Id.* at 13. While weighting based on demographics helps, it does not fully mitigate this concern.

⁴³ The final survey sample contained 11,505 responses, representing individuals from nearly every demographic in the labor force. *Id.* at 58.

⁴⁴ *Id.* at 63.

⁴⁵ *Id.*

⁴⁶ Michael Lipsitz & Evan Starr, *Low-Wage Workers and the Enforceability of Noncompete Agreements*, 68 Mgmt. Sci. 143, 144 (2021) (analyzing data from the Starr, Prescott, & Bishara survey).

⁴⁷ Starr, Prescott, & Bishara, *supra* note 42 at 81.

⁴⁸ Donna S. Rothstein & Evan Starr, *Mobility Restrictions, Bargaining, and Wages: Evidence from the National Longitudinal Survey of Youth 1997* (2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3974897.

⁴⁹ U.S. Bureau of Labor Statistics, *NLSY97 Data Overview*, <https://www.bls.gov/nls/nlsy97.htm>.

directed solely at calculating the prevalence of non-compete clauses. Using this data, Rothstein and Starr estimate the prevalence of non-compete clauses to be 18%, which is comparable to the number estimated by Starr, Prescott, and Bishara.⁵⁰

Finally, four occupations have been studied individually: executives, physicians, hair stylists, and electrical and electronics engineers. Both Shi (2021) and Kini et al. (2021) estimate prevalence of non-compete clauses for executives. Shi (2021) finds the proportion of executives working under a non-compete clause rose from “57% in the early 1990s to 67% in the mid-2010s.”⁵¹ Kini et al. (2021) find that 62% of CEOs worked under a non-compete clause between 1992 and 2014.⁵² Lavetti et al. (2020) find 45% of physicians worked under a non-compete clause in 2007.⁵³ In a survey of independent hair salon owners, Johnson and Lipsitz (2021) find 30% of hair stylists worked under a non-compete clause in 2015.⁵⁴ Finally, in a survey of electrical and electronic engineers, Marx (2011) finds that 43% of respondents signed a non-compete clause.⁵⁵

Some observers have stated that the use of non-compete clauses by employers appears to have increased over time.⁵⁶ However, there is no consistent data available on the prevalence of non-compete clauses over time.

While many workers are bound by non-compete clauses, many workers do not know whether their non-compete clause is legally enforceable or not. As part of their 2014 survey, Starr et al.

asked surveyed individuals “Are noncompetes enforceable in your state?” Of the respondents, 37% indicated that they did not know whether or not their non-compete clause was enforceable.⁵⁷ Additionally, 11% of individuals were misinformed: they believed that non-compete clauses were enforceable in their state when they were not, or they believed that non-compete clauses were not enforceable when they were.⁵⁸

Starr et al. also find that only 10.1% of workers with non-compete clauses report bargaining over it.⁵⁹ Additionally, only 7.9% report consulting a lawyer, and only 11.4% of respondents thought that they still would have been hired if they had refused to sign the non-compete clause.⁶⁰ Marx finds that only 30.5% of electrical engineers who signed non-compete clauses were asked to sign prior to accepting their job offer, and 47% of non-compete clause signers were asked to sign on or after their first day of work.⁶¹

b. Earnings—Effects on Workers Across the Labor Force

By inhibiting optimal matches from being made between employers and workers across the labor force, non-compete clauses reduce the earnings of workers. Several studies have found that increased enforceability of non-compete clauses reduces workers’ earnings across the labor market generally and for specific types of workers.

Each of the studies described below analyzes the effects of non-compete clause enforceability on earnings. While different studies have defined enforceability of non-compete clauses in slightly different ways, each uses enforceability as a proxy for the chance that a given non-compete clause will be enforced.⁶²

These studies use “natural experiments” resulting from changes in state law to assess how changes in the enforceability of non-compete clauses affect workers’ earnings. The use of a natural experiment allows for the

inference of causal effects, since the likelihood that other variables are driving the outcomes is minimal.

First, a study conducted by Matthew Johnson, Kurt Lavetti, and Michael Lipsitz finds that decreasing non-compete clause enforceability from the approximate enforceability level of the fifth-strictest state to that of the fifth-most-lax state would increase workers’ earnings by 3–4%.⁶³ Johnson, Lavetti, and Lipsitz also estimate that a nationwide ban on non-compete clauses would increase average earnings by 3.3–13.9%.⁶⁴ The authors also find that non-compete clauses limit the ability of workers to leverage favorable labor markets to receive greater pay: when non-compete clauses are more enforceable, workers’ earnings are less responsive to low unemployment rates (which workers may typically leverage to negotiate pay raises).⁶⁵

The second study of the effects of non-compete clause enforceability on earnings, conducted by Evan Starr, estimates that if a state that does not enforce non-compete clauses shifted its policy to that of the state with an average level of enforceability, earnings would fall by about 4%.⁶⁶ Unlike many of the other studies described here, this study does not use a change in enforceability of non-compete clauses to analyze the impact of enforceability. Rather, it examines the differential impact of enforceability on workers in occupations which use non-compete clauses at a high rate versus workers in occupations which use non-compete clauses at a low rate. While the Commission believes that this research design may be less informative with respect to the proposed rule than designs which examine changes in enforceability, the study’s estimated effects are in line with the rest of the literature.

The third study, conducted by Michael Lipsitz and Evan Starr, estimates that when Oregon stopped enforcing non-compete clauses for workers who are paid hourly, their wages increased by 2–3%, relative to workers in states which did not experience legal changes. The study also found a greater effect (4.6%) on workers

⁵⁰ Rothstein & Starr, *supra* note 48 at 7.

⁵¹ Liyan Shi, *Optimal Regulation of Noncompete Contracts* 27 (2022), https://static1.squarespace.com/static/59e19b282278e7ca5b9ff84f/t/626659ff73adb2959bd4371/1650874624095/noncompete_shi.pdf.

⁵² Omesh Kini, Ryan Williams, & Sirui Yin, *CEO Noncompete Agreements, Job Risk, and Compensation*, 34 Rev. Fin. Stud. 4701, 4707 (2021).

⁵³ Kurt Lavetti, Carol Simon, & William D. White, *The Impacts of Restricting Mobility of Skilled Service Workers Evidence from Physicians*, 55 J. Hum. Res. 1025, 1042 (2020).

⁵⁴ Matthew S. Johnson & Michael Lipsitz, *Why Are Low-Wage Workers Signing Noncompete Agreements?*, 57 J. Hum. Res. 689, 700 (2022).

⁵⁵ Matt Marx, *The Firm Strikes Back: Non-Compete Agreements and the Mobility of Technical Professionals*, 76 Am. Socio. Rev. 695, 702 (2011). Calculated as 92.60% who signed a non-compete clause of the 46.80% who were asked to sign a non-compete clause.

⁵⁶ See, e.g., Rachel Arnow-Richman, *Cubewrap Contracts and Worker Mobility: The Dilution of Employee Bargaining Power via Standard Form Noncompetes*, 2006 Mich. St. L. Rev. 963, 981 n.59; John W. Lettieri, American Enterprise Institute, Policy Brief, *A Better Bargain: How Noncompete Reform Can Benefit Workers and Boost Economic Dynamism* (December 2020) at 2.

⁵⁷ J.J. Prescott & Evan Starr, *Subjective Beliefs About Contract Enforceability* 10 (2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3873638.

⁵⁸ *Id.* at 11.

⁵⁹ Starr, Prescott, & Bishara, *supra* note 42, at 72.

⁶⁰ *Id.*

⁶¹ Marx (2011), *supra* note 55 at 706. Forty-seven percent is calculated as the sum of 24.43% and 22.86%, the respective percentage of requests that were made on the first day or after the first day at the company.

⁶² All the studies described below rely on twelve concepts of enforceability based on Malsberger’s “Non-Compete Clauses: A State-by-State Survey” and Kini et al. supplemented with data from Beck, Reed, and Riden LLP’s state-by-state survey of non-compete clauses.

⁶³ Matthew S. Johnson, Kurt Lavetti, & Michael Lipsitz, *The Labor Market Effects of Legal Restrictions on Worker Mobility* 2 (2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3455381.

⁶⁴ *Id.*

⁶⁵ *Id.* at 36.

⁶⁶ Evan Starr, *Consider This: Training, Wages, and the Enforceability of Non-Compete Clauses*, 72 LLR. Rev. 783, 799 (2019).

in occupations that used non-compete clauses at a relatively high rate.⁶⁷

The fourth study, conducted by Natarajan Balasubramanian, Jin Woo Chang, Mariko Sakakibara, Jagadeesh Sivadasan, and Evan Starr, found that when Hawaii stopped enforcing non-compete clauses for high-tech workers, earnings of new hires increased by about 4%.⁶⁸

The fifth and sixth studies both show that enforceable non-compete clauses reduce earnings for executives. One study, by Mark Garmaise, finds that decreased enforceability of non-compete clauses increases executives' earnings by 12.7%.⁶⁹ Another study, by Omesh Kini, Ryan Williams, and David Yin, finds that decreased enforceability of non-compete clauses led to lower earnings for CEOs when use of non-compete clauses is held constant. However, the study also finds use of non-compete clauses decreases when non-compete clause enforceability decreases. When that relationship is taken into account, decreased enforceability results in greater earnings for CEOs. For example, if the state which enforces non-compete clauses most strictly (Florida) hypothetically moved to a policy of non-enforcement, then a CEO who had a non-compete clause prior to the policy change would experience an estimated 11.4% increase in their earnings, assuming their non-compete clause was dropped.⁷⁰

Among the studies listed above, Johnson, Lavetti, and Lipsitz likely has the broadest coverage. The study spans the years 1991 to 2014, examines workers across the labor force, and uses all known common law and statutory changes in non-compete clause enforceability to arrive at its estimates. The study by Starr also covers the entire labor force, from 1996 to 2008. However, the Starr study is only able to compare effects for occupations that use non-compete clauses at a high rate to those that use them at a low rate. The next two studies cover just one legal

change, and only a subset of the labor force: hourly workers in Oregon, in the case of Lipsitz and Starr, and high-tech workers in Hawaii, in the case of Balasubramanian et al. Finally, while the studies conducted by Garmaise and Kini et al. examine multiple legal changes, they focus solely on executives.

One limitation of studies of enforceability alone—*i.e.*, studies which do not consider the use of non-compete clauses—is that it is difficult to disentangle the effects of increased enforceability on workers who are subject to non-compete clauses and workers who are not subject to non-compete clauses. In other words, since effects are observed across the labor force (or some subset of it), they include both effects on workers with and without non-compete clauses. However, due to the research cited in the next subsection—indicating non-compete clauses reduce earnings for workers who are *not* subject to non-compete clauses—the Commission believes it is reasonable to conclude based on contextual evidence that the labor-force-wide effects described in the studies above include effects on both workers with and without non-compete clauses.

Three additional studies examine the association between non-compete clause use—rather than enforceability—and earnings. Using the 2014 survey described in Part II.B.1.a, Starr et al. find that the use of non-compete clauses is associated with 6.6% higher earnings in the model including the most control variables among those they observe.⁷¹ Using the *Payscale.com* data, Balasubramanian et al. find that while non-compete clause use is associated with 2.1–8.2% greater earnings (compared with individuals with no post-contractual restrictions), this positive association is due to non-compete clauses often being bundled with non-disclosure agreements. Compared with individuals only using non-disclosure agreements, use of non-compete clauses is associated with a 3.0–7.3% decrease in earnings, though the authors do not disentangle this effect from the effects of use of non-solicitation and non-recruitment provisions.⁷² Finally, Lavetti et al. find that use of non-compete clauses among physicians is associated with greater earnings (by 14%) and greater earnings growth.⁷³ (The Commission notes, however, this study does not consider

how changes in non-compete clause enforceability affect physicians' earnings. As described below in the cost-benefit analysis for the proposed rule, the Commission estimates the proposed rule may increase physicians' earnings, though the study does not allow for a precise calculation.⁷⁴)

However, the Commission does not believe that studies examining the association between non-compete clause use—rather than enforceability—and earnings are sufficiently probative of the effects of non-compete clauses on earnings. The Commission's concern is that non-compete clause use and earnings may both be determined by one or more confounding factors. It may be the case, for example, that employers who rely most on trade secrets both pay more and use non-compete clauses at a high rate (which would not necessarily be captured by the control variables observed in studies of non-compete clause use). This means these studies do not necessarily inform how restricting the use of non-compete clauses through a rule would impact earnings. This methodological limitation contrasts with studies examining enforceability of non-compete clauses, in which changes in enforceability are “natural experiments” that allow for the inference of causal effects, since the likelihood that other variables are driving the outcomes is minimal. A “natural experiment” refers to some kind of change in the real world that allows researchers to study the impact of the change on an outcome. In a natural experiment, the change is effectively random, uninfluenced by other factors which could have simultaneously affected the outcome. In such situations, it is therefore most likely the change itself caused any impact that is observed on the outcomes.

The belief that studies of non-compete clause use do not reflect causal estimates is shared by the authors of at least one of the studies of non-compete clause use. As noted in Starr et al., “Our analysis of the relationships between noncompete use and labor market outcomes . . . is best taken as descriptive and should not be interpreted causally.”⁷⁵ As a result, the Commission gives these studies minimal weight. The study of physicians conducted by Lavetti et al. partially mitigates this concern by comparing earnings effects in high-versus low-enforceability states, though this analysis compares only California and Illinois, meaning that it is

⁶⁷ Lipsitz & Starr, *supra* note 46 at 143.

⁶⁸ Natarajan Balasubramanian, Jin Woo Chang, Mariko Sakakibara, Jagadeesh Sivadasan, & Evan Starr, *Locked In? The Enforceability of Non-Compete Clauses and the Careers of High-Tech Workers*, 57 J. Hum. Res. S349, S349 (2022).

⁶⁹ Mark J. Garmaise, *Ties that Truly Bind: Noncompetition Agreements, Executive Compensation, and Firm Investment*, 27 J.L., Econ., & Org. 376, 403 (2011). The reduction in earnings is calculated as $e^{-1.3575 \times 0.1} - 1$, where -1.3575 is taken from Table 4.

⁷⁰ Kini, Williams, & Yin, *supra* note 52 at 4731. The 11.4% increase is calculated as $e^X - 1$, where X is calculated as 9 times the coefficient on CEO Noncompete \times HQ Enforce (0.047), where 9 is the enforceability index in Florida, plus the coefficient on CEO Noncompete (-0.144), plus 9 times the coefficient on HQ Enforce (-0.043).

⁷¹ Starr, Prescott, & Bishara, *supra* note 42 at 75.

⁷² Balasubramanian, Starr, & Yamaguchi, *supra* note 42 at 40. The percentage range is calculated as $e^{-0.030} - 1$ and $e^{-0.076} - 1$, respectively.

⁷³ Lavetti, Simon, & White, *supra* note 53 at 1051. The increase in earnings is calculated as $e^{0.131} - 1$.

⁷⁴ See *infra* Part VII.B.1.a.ii.

⁷⁵ Starr, Prescott, & Bishara, *supra* note 42 at 73.

impossible to disentangle underlying differences in those two states from the effects of non-compete clause enforceability.

c. Earnings—Effects on Workers Not Covered by Non-Compete Clauses

As described above, non-compete clauses negatively affect competition in labor markets, thereby inhibiting optimal matches from being made between employers and workers across the labor force. As a result, non-compete clauses reduce earnings not only for workers who are subject to non-compete clauses, but also for workers who are not subject to non-compete clauses.

Two studies show non-compete clauses reduce earnings for workers who are not subject to non-compete clauses. The first study, a 2019 study of the external effects of non-compete clauses conducted by Evan Starr, Justin Frake, and Rajshree Agarwal, analyzed workers without non-compete clauses who worked in states and industries in which non-compete clauses were used at a high rate.⁷⁶ They find that, when the use of non-compete clauses in a given state and industry combination increases by 10%, the earnings of workers who do not have non-compete clauses, but who work in that same state and industry, go down by about 6.12% more when that state has an average enforceability level, compared with a state which does not enforce non-compete clauses.⁷⁷ In effect, this study finds when the use of non-compete clauses by employers increases, that drives down wages for workers who do not have non-compete clauses but who work in the same state and industry. This study also finds this effect is stronger where non-compete clauses are more enforceable.

The Commission notes that, similar to some of the studies described above, this study relies on use of non-compete clauses, as well as cross-sectional differences in enforceability of non-compete clauses, to arrive at their conclusions. While this approach calls into question the causal relationship outlined in the study, the authors employ tests to increase confidence in the causal interpretation; however, the tests rely on what data the authors have available, and therefore cannot rule out explanations outside of the scope of their data. This study also analyzes the effect of non-compete clause use for certain workers on workers in a different firm, meaning that factors

simultaneously driving non-compete clause use and outcomes within a certain firm will not break the causal chain identified in the study.

Starr, Frake, and Agarwal show the reduction in earnings (and mobility, discussed below) is due to a reduction in the rate of the arrival of job offers. Individuals in state/industry combinations which use non-compete clauses at a high rate do not receive job offers as frequently as individuals in state/industry combinations where non-compete clauses are not frequently used.⁷⁸ The authors also demonstrate decreased mobility and earnings are *not* due to increased job satisfaction (*i.e.*, if workers are more satisfied with their jobs, they may be less likely to change jobs, and more likely to accept lower pay).⁷⁹ Finally, they show that decreased mobility and earnings are not because workers are searching for jobs less frequently, suggesting that job openings and firm behavior matter more to the underlying mechanism.⁸⁰

The second study, conducted by Johnson, Lavetti, and Lipsitz, isolates the impact of a state's enforceability policy on workers not directly affected by that policy to demonstrate non-compete clauses affect not just the workers subject to those non-compete clauses, but the broader labor market as well. In particular, the study finds that increases in non-compete clause enforceability in one state have negative impacts on workers' earnings in bordering states, and the effects are nearly as large as the effects in the state in which enforceability changed. Johnson, Lavetti, and Lipsitz estimate that the impact on earnings of a law change in one state on workers just across that state's border is 87% as great as for workers in the state in which the law was changed (the effect tapers off as the distance to the bordering state increases).⁸¹ When a law change in one state decreases workers' earnings in that state by 4%, that would therefore mean that workers just across the border (*i.e.*, workers who share a commuting zone—a delineation of a local economy⁸²—but who live in another state) would experience decreased earnings of 3.5%. The authors conclude that, since the workers across the border are not

directly affected by the law change (*i.e.*, contracts that they have signed do not become more or less enforceable), this effect must be due to changes in the local labor market.⁸³

d. Earnings—Distributional Effects

There is evidence that non-compete clauses increase racial and gender wage gaps by disproportionately reducing the wages of women and non-white workers. This may be, for example, because firms use the monopsony power which results from use of non-compete clauses as a means by which to wage discriminate. The study by Johnson, Lavetti, and Lipsitz finds that while earnings of white men would increase by about 3.2% if a state's enforceability moved from the fifth-strictest to the fifth most lax, the comparable earnings increase for workers in other demographic groups would be 3.7–7.7%, depending on the characteristics of the group (though it is not clear from the study whether or not the differences are statistically significant).⁸⁴ The authors estimate that banning non-compete clauses nationwide would close racial and gender wage gaps by 3.6–9.1%.⁸⁵

e. Job Creation

While non-compete clauses may theoretically incentivize firms to create jobs by increasing the value associated with any given worker covered by a non-compete clause, the evidence is inconclusive. One study, by Gerald Carlino, estimates the job creation rate at startups increased by 7.8% when Michigan increased non-compete clause enforceability.⁸⁶ However, the job creation rate calculated in this study is the ratio of jobs created by startups to overall employment in the state; therefore, the job creation rate at startups may rise either because the number of jobs created by startups rose, or because employment overall fell. The study does not investigate which of these two factors drives the increase in the job creation rate at startups.

Another study finds that several increases in non-compete clause enforceability were associated with a 1.4% increase in average per-firm employment at new firms (though not necessarily total employment).⁸⁷ In this

⁷⁶ *Id.* at 10.

⁷⁹ *Id.* at 13.

⁸⁰ *Id.*

⁸¹ Johnson, Lavetti, & Lipsitz, *supra* note 63 at 51. Eighty seven percent is calculated as the coefficient on the donor state NCA score (–.181) divided by the coefficient on own state NCA score (–.207).

⁸² See U.S. Econ. Rsch. Serv., *Commuting Zones and Labor Market Areas*, <https://www.ers.usda.gov/data-products/commuting-zones-and-labor-market-areas/>.

⁸³ Johnson, Lavetti, & Lipsitz, *supra* note 63 at 30.

⁸⁴ *Id.* at 38.

⁸⁵ *Id.*

⁸⁶ Gerald A. Carlino, *Do Non-Compete Covenants Influence State Startup Activity? Evidence from the Michigan Experiment* at 16 (Fed. Reserve Bank of Phila. Working Paper 21–26, 2021).

⁸⁷ Evan Starr, Natarajan Balasubramanian, & Mariko Sakakibara, *Screening Spinouts? How Noncompete Enforceability Affects the Creation*,

⁷⁶ Evan Starr, Justin Frake, & Rajshree Agarwal, *Mobility Constraint Externalities*, 30 *Org. Sci.* 961, 6 (2019).

⁷⁷ *Id.* at 11.

study, the authors attribute the increase in average employment to a change in the composition of newly founded firms. The increases in non-compete clause enforceability prevented the entry of relatively small startups which would otherwise have existed. Therefore, the firms which entered in spite of increases in non-compete clause enforceability had more workers on average: this increased the average job creation rate at new firms, because the average entering firm was relatively larger. However, if the mechanism identified by the authors is correct, increases in enforceability generate fewer total jobs, because the same number of large firms may enter (regardless of non-compete clause enforceability), but fewer small firms enter.

A similar mechanism may explain the results in both studies above. If that is indeed the case, then an increase in average per-firm employment among startups is not a positive effect of non-compete clause enforceability: instead, it could actually represent a negative effect, since non-compete clauses prevent small firms from existing in the first place, and overall job creation may decrease. The Commission therefore believes, with respect to job creation rates, the evidence is inconclusive.

2. Product and Service Markets

In addition to analyzing how non-compete clauses affect competition in labor markets, researchers have also analyzed whether non-compete clauses affect competition in markets for products and services. The available evidence indicates the use of non-compete clauses interferes with competitive conditions in product and service markets as well.

The adverse effects of non-compete clauses on product and service markets likely result from reduced voluntary labor mobility. Non-compete clauses directly impede voluntary labor mobility by restricting workers subject to non-compete clauses from moving to new jobs covered by their non-compete clause. Since non-compete clauses prevent some job openings from occurring (by keeping workers in their jobs), they also prevent workers who are not subject to non-compete clauses from finding new jobs (since the new jobs are already occupied by workers with non-compete clauses).

Influenced by Ronald Gilson's research positing that high-tech clusters in California may have been aided by increased labor mobility because non-

compete clauses are generally unenforceable in that state,⁸⁸ many studies have examined how non-compete clauses affect labor mobility. Even literature primarily focused on other outcomes has examined labor mobility as a secondary outcome. Across the board, all studies have found decreased rates of mobility, measured by job separations, hiring rates, job-to-job mobility, implicit mobility defined by job tenure, and within- and between-industry mobility. We briefly describe each of these studies in turn.

A 2006 study conducted by Fallick, Fleischman, and Rebitzer supported Gilson's hypothesis by showing that labor mobility in information technology industries in metropolitan statistical areas (MSAs) in California was 56% higher than in comparison MSAs outside California. They note, however, the estimates may not be fully (or at all) attributable to non-compete clause enforceability. Although the Commission therefore does not find this particular study to be sufficiently probative of the relationship between non-compete clauses and labor mobility, its qualitative findings are in line with the rest of the literature.⁸⁹

To estimate the impacts of non-compete clause enforceability in a fashion that may more plausibly attribute causality to the relationship, in 2009, Marx, Strumsky, and Fleming examined the impact on labor mobility of Michigan's switch to enforcing non-compete clauses. They found that Michigan's increase in enforceability led to an 8.1% decline in the mobility of inventors.⁹⁰

In 2011, Mark Garmaise examined how a suite of changes in non-compete clause enforceability affected labor mobility. Garmaise found executives made within-industry job changes 47% more often, between-industry job changes 25% more often (though this result was not statistically significant), and any job change 35% more often when non-compete clauses were less enforceable.⁹¹

A 2019 study by Jessica Jeffers uses several legal changes to analyze the impact of non-compete clauses on workers' mobility, finding that

decreases in non-compete clause enforceability were associated with an 8.6% increase in departure rates of workers, and a 15.4% increase in within-industry departure rates of workers.⁹²

Evan Starr's 2019 study comparing workers in occupations which use non-compete clauses at a high versus low rate found that a state moving from mean enforceability to no enforceability would cause a decrease in employee tenure for workers in high-use occupations of 8.2%, compared with those in low-use occupations. Here, tenure serves as a proxy for mobility, since tenure is the absence of prior mobility.⁹³

Returning to an examination of executives, Liyan Shi's 2020 paper qualitatively confirmed Garmaise's results, showing that executives with enforceable non-compete clauses were 1.8 percentage points less likely to separate from their employers, compared with executives without enforceable non-compete clauses.⁹⁴

Starr, Prescott, and Bishara's 2020 study found that having a non-compete clause was associated with a 35% decrease in the likelihood a worker would leave for a competitor.⁹⁵ However, they also found enforceability does not impact this prediction, in contrast with prior studies. Digging deeper into the mechanism, they find that what matters is the worker's belief about the likelihood their employer would seek to enforce a non-compete clause in court. Workers who did not believe employers would enforce non-compete clauses in court were more likely to report they would be willing to leave for a competitor.⁹⁶ This result confirms the need to ensure that workers are aware of the proposed rule, though it suffers from the same limitations as do previously discussed studies of the impacts of non-compete clause use, rather than enforceability: that studies of use are not causally interpretable, since they may conflate the effects of factors which cause use for the effects of use itself.

Two recent studies examined subgroups of the population affected by

⁸⁸ Ronald J. Gilson, *The Legal Infrastructure of High Technology Industrial Districts: Silicon Valley, Route 128, and Non-Compete Clauses*, 74 N.Y.U. L. Rev. 575 (1999).

⁸⁹ Bruce Fallick, Charles A. Fleischman, & James B. Rebitzer, *Job-Hopping in Silicon Valley: Some Evidence Concerning the Microfoundations of a High-Technology Cluster*, 88 Rev. Econ. & Statistics 472, 477 (2006).

⁹⁰ Matt Marx, Deborah Strumsky, & Lee Fleming, *Mobility, Skills, and the Michigan Non-Compete Experiment*, 55 Mgmt. Sci. 875, 884 (2009).

⁹¹ Garmaise, *supra* note 69 at 398.

⁹² Jessica Jeffers, *The Impact of Restricting Labor Mobility on Corporate Investment and Entrepreneurship* 22 (2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3040393.

⁹³ Starr, *supra* note 66 at 798. The value is calculated as $8.2\% = 0.56/6.46$, where 0.56 is the reported impact on tenure and 6.46 is mean tenure in the sample.

⁹⁴ Shi, *supra* note 51 at 26.

⁹⁵ Evan Starr, J.J. Prescott, & Norm Bishara, *The Behavioral Effects of (Unenforceable) Contracts*, 36 J.L., Econ., & Org. 633, 652 (2020).

⁹⁶ *Id.* at 664.

state law changes. Balasubramanian et al., in 2022, focused on high-tech workers whose non-compete clauses were banned in Hawaii, and Lipsitz and Starr, in 2022, focused on hourly workers whose non-compete clauses were banned in Oregon. The former found that the ban increased mobility by 12.5% in the high-tech sector,⁹⁷ while the latter found that mobility of hourly workers increased by 17.3%.⁹⁸

Finally, a 2022 study by Johnson, Lavetti, and Lipsitz examined the impact on labor mobility of all legal changes after 1991 across the entire labor force. They found moving from the enforceability level of the fifth strictest state to that of the fifth most lax state causes a 6.0% increase in job-to-job mobility in industries using non-compete clauses at a high rate.⁹⁹ Furthermore, they found when a state changes its non-compete clause enforceability in that fashion, workers in neighboring states experience 4.8% increases in mobility as measured by job separations, and 3.9% increases as measured by hiring rates, though neither result was statistically significant.¹⁰⁰

As described below in Part IV.A.1.a.ii, the Commission does not view reduced labor mobility from non-compete clauses—in and of itself—as evidence non-compete clauses negatively affect competition in product and service markets. Instead, reduced labor mobility is best understood as the primary driver of effects in product and service markets that the Commission is concerned about. These effects are described below.

a. Consumer Prices and Concentration

There is evidence that non-compete clauses increase consumer prices and concentration in the health care sector. There is also evidence non-compete clauses increase industrial concentration more broadly. Non-compete clauses may have these effects by inhibiting entrepreneurial ventures (which could otherwise enhance competition in goods and service markets) or by foreclosing competitors' access to talented workers.

One study, by Naomi Hausman and Kurt Lavetti, finds increased concentration, as measured by the Herfindahl-Hirschman Index (HHI), at the firm level¹⁰¹ and increased final

goods prices¹⁰² as the enforceability of non-compete clauses increases. Hausman and Lavetti's study focuses on physician markets, showing that while non-compete clauses allow physician practices to allocate clients more efficiently across physicians, this comes at the cost of greater concentration and prices for consumers. Generally, greater concentration may or may not lead to greater prices in all situations and may arise for reasons which simultaneously cause higher prices (indicating, therefore, a noncausal relationship between concentration and prices). In this case, the authors claim that researching the direct link between changes in law governing non-compete clauses and changes in concentration allows them to identify a causal chain starting with greater enforceability of non-compete clauses, which leads to greater concentration, and higher consumer prices.

While there is no additional direct evidence on the link between non-compete clauses and consumer prices, another study, by Michael Lipsitz and Mark Tremblay, shows increased enforceability of non-compete clauses at the state level increases concentration, as measured by an employment-based HHI.¹⁰³ Lipsitz and Tremblay theorize non-compete clauses inhibit entrepreneurial ventures which could otherwise enhance competition in goods and service markets, and show that the potential for harm is greatest in exactly those industries in which non-compete clauses are likely to be used at the highest rate.¹⁰⁴ If the general causal link governing the relationship between enforceability of non-compete clauses, concentration, and consumer prices acts similarly to that identified in the study by Hausman and Lavetti, then it is plausible that increases in concentration identified by Lipsitz and Tremblay would lead to higher prices in a broader set of industries.

In many settings, it is also theoretically plausible that increases in worker earnings from restricting non-compete clauses may increase consumer prices by raising firms' costs (though there is countervailing evidence,

especially in goods manufacturing¹⁰⁵). However, we are not aware of empirical evidence that this occurs, and there are also countervailing forces—such as the impacts on concentration described above and positive impacts on innovation¹⁰⁶—that would tend to decrease consumer prices. Additionally, the greater wages observed for workers where non-compete clauses are less enforceable may be due to better worker-firm matching, which could simultaneously increase wages and increase productivity, which could lead to lower prices.

In addition, the only study of how non-compete clauses affect prices—the Hausman and Lavetti study described above—finds decreased non-compete clause enforceability decreases prices in the healthcare market, rather than increasing them. The study notes that, in theory, changes in non-compete clause enforceability could impact physicians' earnings, which could subsequently pass through to prices in healthcare markets. However, the authors show that, where prices decrease due to decreased non-compete clause enforceability, labor cost pass-through is not driving price decreases. As the authors note, if price decreases associated with non-compete clause enforceability decreases were due to pass-through of decreases in physicians' earnings, then the most labor-intensive procedures would likely experience the greatest price decreases when enforceability decreased. However, they find the opposite: there is little to no effect on prices for the most labor-intensive procedures, in contrast with procedures which use relatively less labor. As the authors explain, this shows that decreases in healthcare prices associated with decreases in non-compete clause enforceability are not due to pass-through of lower labor costs.¹⁰⁷

b. Foreclosing Competitors' Ability To Access Talent

There is evidence that non-compete clauses foreclose the ability of competitors to access talent by effectively forcing future employers to buy out workers from their non-compete clauses if they want to hire them. Firms must either make inefficiently high payments to buy workers out of non-compete clauses with a former employer, which leads to deadweight economic loss, or forego the payment—

level (where an establishment is a physical location, and a firm is a company which may own multiple establishments). For the purposes of consumer outcomes such as a price or product quality, the relevant measure of concentration is at the firm level, since firms are unlikely to compete against themselves on price or quality.

¹⁰² *Id.* at 280.

¹⁰³ Michael Lipsitz & Mark Tremblay, *Noncompete Agreements and the Welfare of Consumers* 6 (2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3975864.

¹⁰⁴ *Id.* at 3.

¹⁰⁵ Sebastian Heise, Fatih Karahan, & Ayşegül Şahin *The Missing Inflation Puzzle: The Role of the Wage-Price Pass-Through*, 54 *J. Money, Credit & Banking* 7 (2022).

¹⁰⁶ See *infra* Part II.B.2.d.

¹⁰⁷ Hausman & Lavetti, *supra* note 101 at 278.

⁹⁷ Balasubramanian et al., *supra* note 68 at S351.

⁹⁸ Lipsitz & Starr, *supra* note 46 at 157.

⁹⁹ Johnson, Lavetti, & Lipsitz, *supra* note 63 at 21.

¹⁰⁰ *Id.* at 76.

¹⁰¹ Naomi Hausman & Kurt Lavetti, *Physician Practice Organization and Negotiated Prices: Evidence from State Law Changes*, 13 *a.m. Econ. J. Applied Econ.* 258, 284 (2021). Note that Hausman and Lavetti find decreased HHI at the establishment

and, consequently, the access to the talent the firm seeks. Whatever choice a firm makes, its economic outcomes in the market are harmed, relative to a scenario in which no workers are bound by non-compete clauses.

Liyun Shi studies this effect in a 2022 paper. This paper finds non-compete clauses are used to ensure that potential new employers of executives make a buyout payment to the executive's current employer.¹⁰⁸ Such a mechanism could be tempered by the ability of a labor market to provide viable alternative workers for new or competing businesses. However, when a particular type of labor is somewhat scarce, when on-the-job experience matters significantly, or when frictions prevent workers from moving to new jobs, there is no way for the market to fill the gap created by non-compete clauses. By studying CEOs, who are difficult to replace and relatively scarce, Shi's paper shows that non-compete clauses foreclose the ability of competitors to access talent by effectively forcing them to make inefficiently high buyout payments. Shi ultimately concludes that "imposing a complete ban on non-compete clauses would be close to implementing the social optimum."¹⁰⁹

c. New Business Formation

The weight of the evidence indicates non-compete clauses likely have a negative impact on new business formation. Three studies show that non-compete clauses and increased enforceability of non-compete clauses reduce entrepreneurship, new business formation, or both. A fourth study also finds that non-compete clauses reduce the rate at which men and women found new startups, though the result is not statistically significant for men. A fifth study finds mixed effects which likely support the theory that non-compete clauses reduce new business formation, and a sixth study finds no effect.

New business formation may refer to entrepreneurs creating new businesses from scratch or to businesses being spun off from existing businesses. New business formation increases competition first by bringing new ideas to market, and second, by forcing incumbent firms to respond to new firms' ideas instead of stagnating. New businesses disproportionately create new jobs and are, as a group, more resilient to economic downturns.¹¹⁰

Recent evidence that new business formation is trending downward has led to concerns that productivity and technological innovation are not as strong as they would have been had new business formation remained at higher levels.¹¹¹ Non-compete clauses restrain new business formation by preventing workers subject to non-compete clauses from starting their own businesses. In addition, firms are more willing to enter markets in which they know there are potential sources of skilled and experienced labor, unhampered by non-compete clauses.

Three studies show that non-compete clauses and increased enforceability of non-compete clauses reduce entrepreneurship and new business formation. First, Sampsa Samila and Olav Sorenson, in a 2011 study, examined the differential impacts of venture capital on business formation, patenting, and employment growth. They found when non-compete clauses are more enforceable, rates of entrepreneurship, patenting, and employment growth slow. They find that a 1% increase in venture capital funding increased the number of new firms by 0.8% when non-compete clauses were enforceable, and by 2.3% when non-compete clauses were not enforceable.¹¹² Similarly, a 1% increase in the rate of venture capital funding increased employment by 0.6% when non-compete clauses were enforceable, versus 2.5% where non-compete clauses were not enforceable.¹¹³

The second study, conducted by Jessica Jeffers in 2019, uses several state law changes to show a decline in new firm entry when non-compete clauses are more enforceable. When non-compete clause enforceability is made stricter (based on the relatively meaningful changes examined in her study), the entry rate of new firms decreased by 10% in the technology sector and the professional, scientific, and technical services sector.¹¹⁴

The third study, conducted by Evan Starr, Natarajan Balasubramanian, and Mariko Sakakibara in 2018, finds that the rate of within-industry spinouts (WSOs) decreases by 0.13 percentage points (against a mean of 0.4%) when non-compete clause enforceability

increases by one standard deviation.¹¹⁵ The study's measured impact on the entry rate of non-WSOs (*i.e.*, spinoffs into other industries) is statistically indistinguishable from zero (0.07 percentage point increase associated with a one standard deviation increase in enforceability).¹¹⁶ WSOs have been shown to be highly successful, on average, when compared with typical entrepreneurial ventures.¹¹⁷ By reducing intra-industry spinoff activity, non-compete clauses prevent entrepreneurial activity that is likely to be highly successful.

The fourth study, published by Matt Marx in 2021, examines the impact of several changes in non-compete clause enforceability between 1991 and 2014.¹¹⁸ Marx finds that, when non-compete clauses are more enforceable, men are 46% less likely to found a rival startup after leaving their employer (though this result is statistically insignificant), that women are 69% less likely to do so, and that the difference in the effect of non-compete clause enforceability on founding rates between men and women is statistically significant.¹¹⁹ This study therefore supports both the theory that non-compete clauses inhibit new business formation and that non-compete clauses tend to have more negative impacts for women than for men.

A fifth study finds mixed effects of non-compete clause enforceability on the entry of businesses into the State of Florida. Hyo Kang and Lee Fleming, in a 2020 study, examine a legal change in Florida which made non-compete clauses more enforceable. This study finds that larger businesses entered the state more frequently (by 8.5%), but smaller businesses entered less frequently (by 5.6%) following the change.¹²⁰ Similarly, Kang and Fleming found that employment at large businesses rose by 15.8% following the change, while employment at smaller businesses effectively did not change.¹²¹

¹¹⁵ Starr, Balasubramanian, & Sakakibara, *supra* note 87 at 561.

¹¹⁶ *Id.* at 561.

¹¹⁷ For reviews of the literature, *see, e.g.*, Steven Klepper, *Spinoffs: A Review and Synthesis*, 6 *European Mgmt. Rev.* 159–71 (2009) and April Franco, *Employee Entrepreneurship: Recent Research and Future Directions*, in *Handbook of Entrepreneurship Research* (2005) 81–96.

¹¹⁸ Matt Marx, *Employee Non-compete Agreements, Gender, and Entrepreneurship*, *Org. Sci.* (Online ahead of print) (2021).

¹¹⁹ *Id.* at 9.

¹²⁰ Hyo Kang & Lee Fleming, *Non-Competes, Business Dynamism, and Concentration: Evidence From a Florida Case Study*, 29 *J. Econ. & Mgmt. Strategy* 663, 673 (2020).

¹²¹ *Id.* at 674. The value is calculated as 15.8% = $e^{0.1468} - 1$.

¹¹¹ *See, e.g.*, Cong. Budget Off., *Federal Policies in Response to Declining Entrepreneurship* (December 2020).

¹¹² Sampsa Samila & Olav Sorenson, *Noncompete Covenants: Incentives to Innovate or Impediments to Growth*, 57 *Mgmt. Sci.* 425, 432 (2011). The values are calculated as $0.8\% = e^{0.00755} - 1$ and $2.3\% = e^{0.00755+0.0155} - 1$, respectively.

¹¹³ *Id.* at 433. The values are calculated as $0.6\% = e^{0.00562} - 1$ and $2.3\% = e^{0.00562+0.0192} - 1$, respectively.

¹¹⁴ Jeffers, *supra* note 92 at 32.

¹⁰⁸ Shi, *supra* note 51.

¹⁰⁹ *Id.* at 35.

¹¹⁰ *See, e.g.*, *The Importance of Young Firms for Economic Growth*, Policy Brief, Ewing Marion Kauffman Foundation (Sept. 24, 2015).

In the Commission's view, however, the results of this study do not necessarily show how non-compete clauses affect new business formation. This study does not examine new business formation specifically; instead, it assesses the number of "business entries" into the state. As the authors acknowledge, many of these business entries are not new businesses being formed in Florida (*i.e.*, startups), but existing businesses that are moving to the state.¹²² Because startups are almost never large businesses, the authors' finding that larger businesses entered the state more frequently is much more likely to reflect businesses moving to the state, rather than new businesses being formed in the state. (While a business's relocation to Florida may benefit Florida, it is not net beneficial from a national perspective, since the business is simply moving from somewhere else.) The authors' finding that increased non-compete clause enforceability decreased the entry of smaller businesses is more likely to reflect an effect of non-compete clause enforceability on new business formation, since smaller businesses are relatively more likely than larger businesses to be startups.

A sixth study finds no effect of non-compete clauses on new business formation. A 2021 study by Gerald Carlino analyzes the impact of a legal change in Michigan that allowed the courts to enforce non-compete clauses. This study finds no significant impact on new business formation.¹²³

d. Innovation

The weight of the evidence indicates non-compete clauses decrease innovation. Innovation may directly improve economic outcomes by increasing product quality or decreasing prices, or may promote competition because successful new products and services force competing firms to improve their own products and services. Non-compete clauses affect innovation by reducing the movement of workers between firms, which decreases knowledge flow between firms. Non-compete clauses also prevent workers from starting businesses in which they can pursue innovative new ideas.

One study shows increased enforceability of non-compete clauses decreases the value of patenting, using a variety of legal changes. Another study shows that increased non-compete clause enforceability decreases the rate at which venture capital funding

increases patenting. Finally, using a legal change in Michigan which increased enforceability, one study shows there were mixed effects on patenting in terms of both quantity and quality, but mechanical patenting (a large part of patenting in Michigan) increased.

The first study, a 2021 study by Zhaozhao He, finds the value of patents, relative to the assets of the firm, increase by about 31% when non-compete clause enforceability decreases.¹²⁴ In contrast to the other two studies of innovation, the study uses the value of patents, rather than the number of patents, to mitigate concerns that patenting activity may not represent innovation, but rather substitutions of protections (in other words, that when non-compete clauses are made less enforceable, firms may use patents instead of non-compete clauses to seek to protect sensitive information).¹²⁵ The study also analyzes the impact of several legal changes to non-compete clause enforceability, which means that the results may be most broadly applicable.

The second study, by Samila and Sorensen, found that, when non-compete clauses are enforceable, venture capital induced less patenting, by 6.6 percentage points.¹²⁶ However, as explained above, the authors note patenting may or may not reflect the true level of innovation, as firms may use patenting as a substitute for non-compete clauses where they seek to protect sensitive information.¹²⁷ The final study of innovation, a 2021 study by Gerald Carlino, examined how patenting activity in Michigan was affected by an increase in non-compete enforceability. The study finds that mechanical patenting increased following the law change, but drug patenting fell, and the quality of computer patents fell (as measured by citations).¹²⁸ The increase in mechanical patenting appears to have primarily occurred approximately 14 years after non-compete clause enforceability changed, however, suggesting some other mechanism may have led to the increase in patenting activity.¹²⁹ We place relatively greater weight on studies focused on multiple legal changes to non-compete clause

enforceability (such as the above referenced study by He), in which factors unrelated to the legal changes at issue are less likely to drive the results. The Carlino study also does not discuss whether patenting activity is an appropriate measure of innovation, though the other two studies suggest that it may be an unreliable measure at best. The study by Samila and Sorensen examines the enforceability of non-compete clauses across all states but does not consider changes in enforceability: they are therefore unable to rule out that their results could be due to underlying differences in the states rather than non-compete clause enforceability.

The Commission therefore places greatest weight on the study by He, which suggests innovation is largely harmed by non-compete clause enforceability. Though the results from Carlino countervail this finding, those results are subject to criticism (as is the corroborating evidence found in Samila and Sorensen).

Two additional studies address firm strategies related to innovation. The first, by Raffaele Conti, uses two changes in non-compete clause enforceability (in Texas and Florida), and indicates that firms engage in riskier strategies with respect to research and development when non-compete clause enforceability is greater.¹³⁰ Riskier research and development strategies lead to more breakthrough innovations, but also lead to more failures, leaving the net impact unclear. The paper does not quantify the total impact on innovation.

The second, by Fenglong Xiao, found increases in non-compete clause enforceability led to increases in exploitative innovation (*i.e.*, innovation which stays within the bounds of the innovating firm's existing competences), and decreases in exploratory innovation (*i.e.*, innovation which moves outside those bounds) in medical devices.¹³¹ Overall, this leads to an increase in the quantity of innovation as measured by the introduction of new medical devices. This increase in quantity, however, is the net result of an increase in exploitative innovation and a decrease in explorative innovation, where the latter is the mode of innovation which the empirical

¹²⁴ Zhaozhao He, *Motivating Inventors: Non-Competes, Innovation Value and Efficiency* 21 (2021), <https://ssrn.com/abstract=3846964>. Thirty one percent is calculated as $e^{0.272} - 1$.

¹²⁵ *Id.* at 17.

¹²⁶ Samila & Sorensen, *supra* note 112 at 432. The value is calculated as $6.6\% = e^{0.0208+0.0630} - e^{0.0208}$.

¹²⁷ *Id.*

¹²⁸ Carlino, *supra* note 86 at 40.

¹²⁹ *Id.* at 48.

¹³⁰ Raffaele Conti, *Do Non-Competition Agreements Lead Firms to Pursue Riskier R&D Strategies?*, 35 *Strategic Mgmt. J.* 1230 (2014).

¹³¹ Fenglong Xiao, *Non-Competes and Innovation: Evidence from Medical Devices*, 51 *Rsch. Pol'y* 1 (2022).

¹²² *Id.* at 668.

¹²³ Carlino, *supra* note 86 at 36.

literature has found to be associated with high growth firms.¹³²

While these two additional studies bring nuance to the changes in the types of innovation pursued by firms when non-compete clause enforceability changes, neither undermines the weight of the evidence described above: that increased non-compete clause enforceability broadly diminishes the rate of innovation.

e. Training and Other Investment

There is evidence that non-compete clauses increase employee training and other forms of investment. Four studies have examined investment outcomes: two examine the effects of non-compete clause enforceability on investment (both of which find positive impacts on investment), while two examine the relationship between non-compete clause use and investment (only one of which finds positive impacts on investment).

Of the two studies that examine the effects of non-compete clause enforceability on investment, one looks at employee training, and one looks at firm capital expenditures (e.g., investment in physical assets, such as machines). The first study, a 2020 study by Evan Starr, finds that moving from mean non-compete clause enforceability to no non-compete clause enforceability would decrease the number of workers receiving training by 14.7% in occupations that use non-compete clauses at a high rate (relative to a control group of occupations that use non-compete clauses at a low rate).¹³³ The study further finds changes in training are primarily due to changes in firm-sponsored, rather than employee-sponsored, training.¹³⁴ Firm-sponsored training is the type of training non-compete clauses are often theorized to protect, as the firm may be unwilling to make an unprotected investment.

The second study, a 2021 study by Jessica Jeffers, finds knowledge-intensive firms invest 32% less in capital equipment following decreases in the enforceability of non-compete clauses.¹³⁵ While firms may invest in capital equipment for many different reasons, Jeffers examines this outcome (as opposed to labor-focused outcomes) to avoid looking at research and development expenditure as a whole, which is in large part composed of labor

expenses. This allows the study to isolate the effects of non-compete clause enforceability on investment from other effects of non-compete clauses, such as reduced worker earnings. Jeffers finds that there are likely two mechanisms driving these effects: first, that firms may be more likely to invest in capital when they train their workers because worker training and capital expenditure are complementary (i.e., the return on investment in capital equipment is greater when workers are more highly trained); and second, that non-compete clauses reduce competition, and firms' returns to capital expenditure are greater when competition is lower, incentivizing firms to invest more in capital.¹³⁶

The first study that examines the impact of non-compete clause use on investment is a 2021 study by Starr et. al. using their 2014 survey of non-compete clause use. They find no statistically significant impact on either training or the sharing of trade secrets (after inclusion of control variables) but cannot examine other investment outcomes.¹³⁷ The second study, a 2021 study by Johnson and Lipsitz, examines investment in the hair salon industry. It finds that firms that use non-compete clauses train their employees at a higher rate and invest in customer attraction through the use of digital coupons (on so-called "deal sites") to attract customers at a higher rate, both by 11 percentage points.¹³⁸ However, the authors of both studies caution that these results do not necessarily represent a causal relationship.¹³⁹ In each study, the use of non-compete clauses and the decision to invest may be jointly determined by other characteristics of the firms, labor markets, or product markets. For this reason, the Commission places relatively minimal weight on these studies in terms of how they inform the relationship between the proposed rule and future potential firm investment.

Overall, the additional incentive to invest (in assets like physical capital, human capital, or customer attraction, or in the sharing of trade secrets and confidential commercial information) is the primary justification for use of non-compete clauses. Any investment which is lost due to the inability of firms to use non-compete clauses would likely represent the greatest cost of the proposed rule. Indeed, one study, by Kenneth Younge and Matt Marx, finds

that the value of publicly traded firms increased by 9% due to an increase in non-compete clause enforceability.¹⁴⁰ However, they attribute this increase to the value of retaining employees, which comes with the negative effects to parties other than the firm (employees, competitors, and consumers) described in this Part II.B. In particular, if benefits to the firm arise primarily from reductions in labor costs, then the increase in the value of firms is in part a transfer from workers to firms, and is therefore not necessarily a procompetitive benefit of non-compete clauses. However, the authors do not explore the extent to which increases in firm value arise from decreases in labor costs. The authors additionally note that since the time frame used in the study is short, "there may be deleterious effects of non-competes in the long run" which are absent in their findings.¹⁴¹

The Commission requests comment on all aspects of its description, in this Part II.B, of the empirical evidence relating to non-compete clauses and their effects on competition. In particular, the Commission seeks submissions of additional data that could inform the Commission's understanding of these effects.

C. Current Law Governing Non-Compete Clauses

The states have always placed a variety of restrictions on the ability of employers to enforce non-compete clauses. These restrictions are based on public policy concerns American courts—and English courts before them—have recognized for centuries. For example, in the English opinion *Mitchel v. Reynolds* (1711), which provided the foundation for the American common law on non-compete clauses,¹⁴² the court expressed concerns that workers were vulnerable to exploitation under non-compete clauses and these clauses threatened workers' ability to practice their trades and earn a living.¹⁴³

Today, while the enforceability of non-compete clauses varies between

¹⁴⁰ Kenneth A. Younge & Matt Marx, *The value of employee retention: evidence from a natural experiment*, 25 J. Econ. & Mgmt. Strategy 652 (2016).

¹⁴¹ *Id.* at 674.

¹⁴² Harlan Blake, *Employment Agreements Not to Compete*, 73 Harv. L. Rev. 625, 630–31 (1960).

¹⁴³ *Mitchel v. Reynolds*, 1 P. Wms. 181, 190 (Q.B. 1711) (expressing concern that non-compete clauses threaten "the loss of [the worker's] livelihood, and the subsistence of his family," and also "the great abuses these voluntary restraints are liable to," for example, "from masters, who are apt to give their apprentices much vexation" by using "many indirect practices to procure such bonds from them, lest they should prejudice them in their custom, when they come to set up for themselves.").

¹³² Alessandra Colombelli, Jackie Krafft & Francesco Quattraro, *High-Growth Firms and Technical Knowledge: Do Gazelles Follow Exploration or Exploitation Strategies?*, 23.1 Industrial and Corporate Change 262 (2014).

¹³³ Starr, *supra* note 66 at 796–97.

¹³⁴ *Id.* at 797.

¹³⁵ Jeffers, *supra* note 92 at 28.

¹³⁶ *Id.* at 29.

¹³⁷ Starr, Prescott, & Bishara, *supra* note 42 at 76.

¹³⁸ Johnson & Lipsitz, *supra* note 54 at 711.

¹³⁹ Starr, Prescott, & Bishara, *supra* note 42 at 73; Johnson & Lipsitz, *supra* note 54 at 711.

states, all fifty states restrict non-compete clauses between employers and workers to some degree.¹⁴⁴ Non-compete clauses between employers and workers are generally subject to greater scrutiny under state common law than other employment terms, due to “the employee’s disadvantageous bargaining position at the time of contracting and hardship at the time of enforcement.”¹⁴⁵ For these reasons, state courts often characterize non-compete clauses as “disfavored.”¹⁴⁶

In addition to state common law, non-compete clauses have always been considered proper subjects for scrutiny under the nation’s antitrust laws.¹⁴⁷

1. State Law on Non-Compete Clauses

The question of whether or under what conditions an employer can enforce a particular non-compete clause depends on the applicable state law. Three states—California, North Dakota, and Oklahoma—have adopted statutes rendering non-compete clauses void for nearly all workers.¹⁴⁸ Among the 47 states where non-compete clauses may be enforced under certain circumstances, 11 states and the District

of Columbia have enacted statutes making non-compete clauses void or unenforceable—or have banned employers from entering into non-compete clauses—based on the worker’s earnings or a similar factor.¹⁴⁹ In addition, the majority of these 47 states have statutory provisions that ban or limit the enforceability of non-compete clauses for workers in certain specified occupations. In most states, those limits apply to just one or two occupations (most commonly, physicians).¹⁵⁰

States have been particularly active in restricting non-compete clauses in recent years. Of the twelve state statutes

¹⁴⁹ Colorado, Colo. Rev. Stat. Ann. sec. 8–2–113(2)(a)–(b), as amended by H.B. 22–1317 (effective Aug. 10, 2022) (non-compete clauses are void except where they apply to a “highly compensated worker,” currently defined as a worker earning at least \$101,250 annually, *see* Colo. Code Regs. sec. 1103–14.1.2); District of Columbia, DC Code sec. 32–581.02(a)(1) (effective Oct. 1, 2022) (where the employee’s compensation is less than \$150,000, or less than \$250,000 if the employee is a medical specialist, employers may not require or request that the employee sign an agreement or comply with a workplace policy that includes a non-compete clause); Illinois, 820 Ill. Comp. Stat. 90/10(a) (effective Jan. 1, 2017) (no employer shall enter into a non-compete clause unless the worker’s actual or expected earnings exceed \$75,000/year); Maine, Me. Rev. Stat. Ann. tit. 26, sec. 599–A(3) (effective Sep. 19, 2019) (an employer may not require or permit an employee earning wages at or below 400% of the federal poverty level to enter into a non-compete clause with the employer); Maryland, Md. Code Ann., Lab. & Empl. sec. 3–716(a)(1)(i) (effective Oct. 1, 2019) (non-compete clauses are void where an employee earns equal to or less than \$15 per hour or \$31,200 per year); Massachusetts, Mass. Gen. Laws Ann. ch. 149, sec. 24L(c) (effective Jan. 14, 2021) (non-compete clauses shall not be enforceable against workers classified as nonexempt under the Fair Labor Standards Act (“FLSA”)); Nevada, Nev. Rev. Stat. sec. 613.195(3) (effective Oct. 1, 2021) (non-compete clauses may not apply to hourly workers); New Hampshire, N.H. Rev. Stat. Ann. sec. 275:70–a(II) (effective Sept. 8, 2019) (employers shall not require a worker who earns an hourly rate less than or equal to 200% of the federal minimum wage to enter into a non-compete clause, and non-compete clauses with such workers are void and unenforceable); Oregon, Or. Rev. Stat. sec. 653.295(1)(e) (effective Jan. 1, 2022) (non-compete clauses are void and unenforceable except where the worker’s annualized gross salary and commissions at the time of the worker’s termination exceed \$100,533); Rhode Island, R.I. Gen. Laws sec. 28–59–3(a)(1) (effective Jan. 15, 2020) (non-compete clauses shall not be enforceable against workers classified as nonexempt under the FLSA); Virginia, Va. Code Ann. sec. 40.1–28.7:8(B) (effective July 1, 2020) (no employer shall enter into, enforce, or threaten to enforce a non-compete clause with an employee whose average weekly earnings are less than the Commonwealth’s average weekly wage); Washington, Wash. Rev. Code Ann. sec. 49.62.020(1)(b) and 49.62.030(1) (effective Jan. 1, 2020) (non-compete clause is void and unenforceable unless worker’s annualized earnings exceed \$100,000 for employees and \$250,000 for independent contractors, to be adjusted for inflation).

¹⁵⁰ *See* Russell Beck, Beck Reed Riden LLP, *Employee Noncompetes: A State-by-State Survey* (August 17, 2022), (hereinafter “Beck Reed Riden Chart”).

restricting non-compete clauses based on a worker’s earnings or a similar factor (including the DC statute), eleven were enacted in the past ten years.¹⁵¹ States have also recently passed legislation limiting the use of non-compete clauses for certain occupations.¹⁵² Other recent state legislation has imposed additional requirements on employers that use non-compete clauses. For example, Oregon, Maine, Massachusetts, New Hampshire, and Washington have enacted laws requiring employers to provide prior notice that a non-compete clause will be required as a condition of employment.¹⁵³ Massachusetts and Oregon have enacted “garden leave” provisions, which require employers to compensate workers during the post-employment period in which the workers are bound by the non-compete clause.¹⁵⁴ Washington limited the permissible duration of non-compete clauses to 18 months,¹⁵⁵ and Massachusetts and Oregon limited it to one year.¹⁵⁶

For workers not covered by these statutory restrictions, the question of whether or under what conditions a non-compete clause may be enforced against them depends on state common law.

In the 47 states where at least some non-compete clauses may be enforced, courts use a reasonableness inquiry to determine whether to enforce a non-compete clause, in addition to whatever statutory limits they are bound to apply. While the precise language of the test differs from state to state, states typically use a test similar to the test in the Restatement (Second) of Contracts:

A promise to refrain from competition that imposes a restraint that is ancillary

¹⁵¹ *See supra* note 149.

¹⁵² *See, e.g.*, Connecticut, Conn. Gen. Stat. Ann. sec. 20–681 (effective June 26, 2019) (home health care workers); Florida, Fla. Stat. Ann. sec. 542.336 (effective June 25, 2019) (certain physicians in certain counties); Hawaii, Haw. Rev. Stat. sec. 480–4(d) (effective July 1, 2015) (technology workers); Indiana, Ind. Code sec. 25–22.5–5.5–2 (effective July 1, 2020) (physicians); Utah, Utah Code Ann. sec. 34–51–201 (effective May 18, 2018) (broadcasting employees).

¹⁵³ Oregon, Or. Rev. Stat. sec. 653.295(1)(a)(A) (effective Jan. 1, 2008); Maine, Me. Rev. Stat. Ann. tit. 26, sec. 599–A(4) (effective Sep. 19, 2019); Massachusetts, Mass. Gen. Laws Ann. ch. 149, sec. 24L(b)(i) (effective Jan. 14, 2021); New Hampshire, N.H. Rev. Stat. Ann. sec. 275:70 (effective July 28, 2014); Washington, Wash. Rev. Code Ann. sec. 49.62.020(1)(a)(i) (effective Jan. 1, 2020).

¹⁵⁴ Massachusetts, Mass. Gen. Laws Ann. ch. 149, sec. 24L(b)(vii) (effective Jan. 14, 2021); Oregon, Or. Rev. Stat. sec. 653.295(7) (effective Jan. 1, 2022).

¹⁵⁵ Washington, Wash. Rev. Code Ann. sec. 49.62.020(2) (effective Jan. 1, 2020).

¹⁵⁶ Massachusetts, Mass. Gen. Laws Ann. ch. 149, sec. 24L(b)(iv) (effective Jan. 14, 2021); Oregon, Or. Rev. Stat. sec. 653.295(3) (effective Jan. 1, 2022).

¹⁴⁴ Cynthia Estlund, *Between Rights and Contract: Arbitration Agreements and Non-Compete Covenants as a Hybrid Form of Employment Law*, 155 U. Pa. L. Rev. 379, 391 (2006).

¹⁴⁵ *Id.* *See also* Restatement (Second) of Contracts sec. 188, cmt. g (1981) (“Postemployment restraints are scrutinized with particular care because they are often the product of unequal bargaining power and because the employee is likely to give scant attention to the hardship he may later suffer through loss of his livelihood.”).

¹⁴⁶ *See, e.g.*, *Navarre Chevrolet, Inc. v. Begnaud*, 205 So. 3d 973, 975 (La. Ct. App. 3d 2016); *Eastman Kodak Co. v. Carmosino*, 77 A.D.3d 1434, 1435 (N.Y. App. Div. 4th 2010); *Access Organics, Inc. v. Hernandez*, 175 P.3d 899, 904 (Mont. 2008); *Bybee v. Isaac*, 178 P.3d 616, 621 (Idaho 2008); *Softchoice, Inc. v. Schmidt*, 763 NW2d 660, 666 (Minn. Ct. App. 2009).

¹⁴⁷ *See, e.g.*, *Am. Tobacco Co.*, 221 U.S. at 181–83 (holding several tobacco companies violated Sections 1 and 2 of the Sherman Act due to the collective effect of six of the companies’ practices, one of which was the “constantly recurring” use of non-compete clauses); *Newburger, Loeb & Co., Inc.*, 563 F.2d at 1082 (“Although such issues have not often been raised in the federal courts, employee agreements not to compete are proper subjects for scrutiny under section 1 of the Sherman Act. When a company interferes with free competition for one of its former employee’s services, the market’s ability to achieve the most economically efficient allocation of labor is impaired. Moreover, employee-noncompetition clauses can tie up industry expertise and experience and thereby forestall new entry.”) (internal citation omitted).

¹⁴⁸ *See* Cal. Bus. & Prof. Code sec. 16600; N.D. Cent. Code sec. 9–08–06; Okla. Stat. Ann. tit. 15, sec. 219A. While California law permits non-compete clauses if they are necessary to protect an employer’s trade secrets, *see Muggill v. Reuben H. Donnelley Corp.*, 62 Cal. 2d 239, 242 (Cal. 1965), the scope of this exception is unclear. In a recent case, the California Supreme Court declined to address the issue. *Edwards v. Arthur Andersen LLP*, 189 P.3d 285, 289 n.4 (Cal. 2008).

to an otherwise valid transaction or relationship is unreasonably in restraint of trade if (a) the restraint is greater than is needed to protect the promisee's legitimate interest, or (b) the promisee's need is outweighed by the hardship to the promisor and the likely injury to the public.¹⁵⁷

The first basis on which a non-compete clause can be found unreasonable is where the restraint is greater than needed to protect the employer's legitimate interest. Nearly all states recognize the protection of an employer's trade secrets as a legitimate interest.¹⁵⁸ Some states also recognize an interest in protecting confidential information that is not a trade secret.¹⁵⁹ Some states also recognize an interest in protecting the employer's investment in training, although many of these states define the interest as protecting specialized training.¹⁶⁰ A few states recognize an interest in preventing a worker who provides "unique" services from working for a competitor.¹⁶¹ Courts do not recognize protection from ordinary competition as a legitimate business interest.¹⁶²

If the employer can demonstrate a legitimate interest, the employer must then show the non-compete clause is tailored to that interest. This analysis typically considers whether the non-compete clause prohibits a greater scope of activity than necessary to protect the employer's legitimate interests;¹⁶³ covers a geographic area more extensive than necessary to protect those interests;¹⁶⁴ or lasts longer than needed to protect those interests.¹⁶⁵

The second basis under which a non-compete clause can be found unreasonable is where the employer's need for the non-compete clause is outweighed by the hardship to the

worker and the likely injury to the public. When assessing the "hardship to the worker" prong, courts typically consider whether the non-compete clause would be unreasonable in light of the worker's personal circumstances. For example, courts have invalidated non-compete clauses where they would destroy a worker's sole means of support.¹⁶⁶

When assessing the "likely injury to the public" prong, the factor most frequently considered by courts is whether enforcing the non-compete clause against the worker would deprive the community of essential goods and services.¹⁶⁷ Because these cases arise in the context of individual litigation, courts focus the "likely injury to the public" inquiry on the loss of the individual worker's services and not on the aggregate effects of non-compete clauses on competition in the relevant market.

State law also differs with respect to the steps courts take when they conclude that a non-compete clause is unenforceable as drafted. The majority of states have adopted the "reformation" or "equitable reform" doctrine, which allows courts to revise the text of an unenforceable non-compete clause to make it enforceable.¹⁶⁸ Some states have adopted the "blue pencil" doctrine, under which courts may remove any defective provisions and may enforce the non-compete clause if the remaining provisions constitute a valid non-compete clause.¹⁶⁹ A few states have adopted the "red pencil" doctrine, under which courts declare an entire non-compete clause void if one or more of its provisions are found to be defective.¹⁷⁰

As noted above, the general language of the test for whether a non-compete clause is reasonable is fairly consistent from state to state. However, the specifics of non-compete clause law differ from state to state. For example, states vary in how narrowly or broadly they define legitimate interests for using a non-compete clause and the extent to which courts are permitted to modify an unenforceable non-compete clause to

render it enforceable. As a result, among the 47 states where non-compete clauses may be enforced, variation exists with respect to the enforceability of non-compete clauses.¹⁷¹

Because the enforceability of non-compete clauses varies from state to state, the question of which state's law applies in a legal dispute between an employer and a worker can determine the outcome of the case. Non-compete clauses often contain choice-of-law provisions designating a particular state's law for resolution of any future dispute.¹⁷² Some non-compete clauses include forum-selection provisions specifying the court and location where any dispute will be heard.¹⁷³ The default rule under conflict-of-laws principles is that the court honors the parties' choice of law, meaning the burden is typically on the worker to argue that the law of a different forum should apply.¹⁷⁴

In addition, there is significant variation in how courts apply choice of law rules in disputes over non-compete clauses.¹⁷⁵ As a result, it can be difficult for employers and workers to predict how disputes over choice of law will be resolved.¹⁷⁶ Additionally—aside from the question of which state's law should apply—employers and workers may be uncertain about whether the non-compete clause is enforceable under the state's law. Furthermore, state non-compete law may change; as described above in Part II.C.1, there have been many changes in state non-compete law in recent years. The result is that employers and workers may face considerable uncertainty as to whether

¹⁵⁷ Restatement (Second) of Contracts sec. 188 (1981).

¹⁵⁸ See, e.g., *Reed, Roberts Assocs. v. Strauman*, 40 N.Y.2d 303, 308–09 (N.Y. 1976); see Beck Reed Riden Chart, *supra* note 150 (listing each state's approach).

¹⁵⁹ See, e.g., *Proudfoot Consulting Co. v. Gordon*, 576 F.3d 1223, 1233–34 (11th Cir. 2009); see Beck Reed Riden Chart, *supra* note 150 (listing each state's approach).

¹⁶⁰ See, e.g., *IDMWORKS LLC v. Pophaly*, 192 F. Supp. 3d 1335, 1342 (S.D. Fla. 2016); see Beck Reed Riden Chart, *supra* note 150 (listing each state's approach).

¹⁶¹ See, e.g., *Ticor Title Ins. v. Cohen*, 173 F.3d 63, 70 (2d Cir. 1999); see Beck Reed Riden Chart, *supra* note 150 (listing each state's approach).

¹⁶² See, e.g., *Valley Med. Specialists v. Farber*, 982 P.2d 1277, 1281 (Ariz. 1999).

¹⁶³ See, e.g., *Diversified Hum. Res. Grp., Inc. v. Levinson-Polakoff*, 752 SW2d 8, 11 (Tex. Ct. App. 1988).

¹⁶⁴ See, e.g., *Orkin Exterm. Co., Inc. v. Girardeau*, 301 So. 2d 38, 39 (Fla. Ct. App. 1st 1974).

¹⁶⁵ See, e.g., *Jorgensen v. Coppedge*, 181 P.3d 450, 454 (Idaho 2008).

¹⁶⁶ See, e.g., *Chavers v. Copy Prods. Co. of Mobile*, 519 So. 2d 942, 945 (Ala. 1988).

¹⁶⁷ See, e.g., *Dick v. Geist*, 693 P.2d 1133, 1136–37 (Idaho Ct. App. 1985).

¹⁶⁸ See, e.g., *Butler v. Arrow Mirror & Glass, Inc.*, 51 SW3d 787, 794 (Tex. Ct. App. 2001). See also Beck Reed Riden Chart, *supra* note 150 (listing each state's approach).

¹⁶⁹ See, e.g., *Compass Bank v. Hartley*, 430 F. Supp. 2d 973, 980 (D. Ariz. 2006). See also Beck Reed Riden Chart, *supra* note 150 (listing each state's approach).

¹⁷⁰ See, e.g., *Hassler v. Circle C Res.*, 505 P.3d 169, 178 (Wyo. 2022). See also Beck Reed Riden Chart, *supra* note 150 (listing each state's approach).

¹⁷¹ Norman D. Bishara, *Fifty Ways to Leave Your Employer: Relative Enforcement of Non-Compete Clauses, Trends, and Implications for Employee Mobility Policy*, 13 U. Pa. J. Bus. L. 751, 778–79 (2011).

¹⁷² Gillian Lester & Elizabeth Ryan, *Choice of Law and Employee Restrictive Covenants: An American Perspective*, 31 Comp. Lab. & Pol'y J. 389, 396–402 (2010).

¹⁷³ *Id.* at 402–04.

¹⁷⁴ Lester & Ryan, *supra* note 172 at 394. Cf. Cal. Lab. Code § 925(a) (stating that employers shall not require an employee who primarily resides and works in California, as a condition of employment, to agree to a provision that would either (1) require the employee to adjudicate outside of California a claim arising in California or (2) deprive the employee of the substantive protection of California law with respect to a controversy arising in California).

¹⁷⁵ *Id.*

¹⁷⁶ *Id.* at 394–95 (“The state of the law is perhaps characterized more by inconsistency than anything else, so much so that commentators lament the ‘disarray’ and ‘mish-mash’ of the law, and criticize courts for their ‘post-hoc rationalizing of intuitions’ or their use of a ‘hodgepodge of factors, often with insignificant explanation of how they decide what weight to give each.’”) (internal citations omitted).

a particular non-compete clause may be enforced.

Workers may also be subject to arbitration clauses, which require that legal disputes with the employer—including disputes related to non-compete clauses—be resolved through binding arbitration rather than in court. Where such clauses are valid, the Federal Arbitration Act requires that courts enforce them.¹⁷⁷

Most state courts apply different rules to non-compete clauses when they are entered into between the seller and buyer of a business, compared with non-compete clauses that arise solely out of the employment relationship.¹⁷⁸ The three states in which non-compete clauses are void in nearly all instances—California, North Dakota, and Oklahoma—permit enforcement when non-compete clauses are entered into between the seller and buyer of a business.¹⁷⁹ In most of the other states, non-compete clauses between the seller and buyer of a business are either exempted from the state’s non-compete clause statute, subject to a more lenient test under the statute, or subject to more lenient standard under the state’s case law.¹⁸⁰ Courts cite several different reasons for why they accord different treatment to non-compete clauses between the seller and buyer of a business. These reasons include the relatively equal bargaining power of both parties in the context of a business sale, relative to the employer-worker context, where there is more likely to be unequal bargaining power; the need to protect the buyer’s right to the goodwill for which it has paid; and the fact that the proceeds from the sale will ensure that the seller of the business will not experience undue hardship.¹⁸¹

2. Non-Compete Clauses and Antitrust Law

Non-compete clauses are “contract[s] . . . in restraint of trade.” Therefore,

¹⁷⁷ See, e.g., *Nitro-Lift Techs. v. Howard*, 568 U.S. 17, 21–22 (2012).

¹⁷⁸ Based on a review of the state cases in Malsberger (2017), *supra* note 62 and Fenwick & West LLC, *Summary of Non-Compete Clauses: A Global Perspective*, https://assets.fenwick.com/legacy/FenwickDocuments/RS_Summary-of-Covenants.pdf.

¹⁷⁹ Cal. Bus. & Prof. Code sec. 16601; N.D. Cent. Code sec. 9–08–06; Okla. Stat. Ann. tit. 15, sec. 218.

¹⁸⁰ See, e.g., Colo. Rev. Stat. Ann. sec. 8–2–113(3)(c) (statutory exemption); Ga. Code Ann. sec. 13–8–57(d) (more lenient statutory test); *Jiffy Lube Int’l, Inc. v. Weiss Bros., Inc.*, 834 F. Supp. 683, 691 (D.N.J. 1993) (more lenient standard under case law).

¹⁸¹ See, e.g., *Woodward v. Cadillac Overall Supply Co.*, 240 NW 2d 710, 715 (Mich. 1976) (bargaining power); *Bybee*, 178 P.3d at 622 (Idaho 2008) (goodwill); *Centorr-Vacuum Indus., Inc. v. Lavoie*, 609 A.2d 1213, 1215 (N.H. 1992) (undue hardship).

they are subject to Section 1 of the Sherman Act.¹⁸² The Commission has identified 17 cases in cases in which private plaintiffs or the federal government have challenged a non-compete clause between an employer and a worker under either Section 1 or an analogous provision in a state antitrust statute.¹⁸³ (Three of these 17 cases concerned non-compete clauses between the seller and buyer of a business,¹⁸⁴ and two of these 17 cases were brought under state antitrust statutes.¹⁸⁵)

In two of these 17 cases, the parties challenging the non-compete clause were successful to some degree. In the early antitrust case of *United States v. American Tobacco Co.*, the Supreme Court held that several tobacco companies violated both Section 1 and Section 2 of the Sherman Act because of the collective effect of six of the companies’ practices, one of which was the “constantly recurring” use of non-compete clauses.¹⁸⁶ This is the only case the Commission has identified in which a court analyzed the collective, rather than isolated, use of non-compete clauses.

More recently, a federal district court denied a motion to dismiss a plaintiff’s

¹⁸² See, e.g., *Newburger, Loeb & Co., Inc.*, 563 F.2d at 1082.

¹⁸³ *U.S. v. Am. Tobacco Co.*, 221 U.S. 106 (1911); *Alders v. AFA Corp. of Fla.*, 353 F. Supp. 654 (S.D. Fla. 1973) (non-compete clause between seller and buyer of a business); *Bradford v. N.Y. Times Co.*, 501 F.2d 51 (2d Cir. 1974); *Golden v. Kentile Floors, Inc.*, 512 F.2d 838 (5th Cir. 1975); *U.S. v. Empire Gas Corp.*, 537 F.2d 296 (8th Cir. 1976); *Newburger, Loeb & Co., Inc. v. Gross*, 563 F.2d 1057 (2d Cir. 1977); *Lektro-Vend Corp. v. Vendo Co.*, 660 F.2d 255 (7th Cir. 1981) (non-compete clause between seller and buyer of a business); *Aydin Corp. v. Loral Corp.*, 718 F.2d 897 (9th Cir. 1983); *Consultants & Designers, Inc. v. Butler Serv. Grp., Inc.*, 720 F.2d 1553 (11th Cir. 1983); *Caremark Homecare, Inc. v. New England Critical Care, Inc.*, 700 F. Supp. 1033 (D. Minn. 1988); *GTE Data Servs., Inc. v. Elec. Data Sys. Corp.*, 717 F. Supp. 1487 (M.D. Fla. 1989); *DeSantis v. Wackenhut Corp.*, 793 SW2d 670 (Tex. 1990) (state antitrust law case); *Borg-Warner Protective Servs. Corp. v. Guardsmark, Inc.*, 946 F. Supp. 495 (E.D. Ky. 1996); *Caudill v. Lancaster Bingo Co., Inc.*, 2005 WL 2738930 (S.D. Ohio Oct. 24, 2005); *Dallas South Mill, Inc. v. Kaolin Mushroom Farms, Inc.*, 2007 WL 9712116 (N.D. Tex. Feb. 23, 2007); *Cole v. Champion Enters., Inc.*, 496 F. Supp. 2d 613 (M.D.N.C. 2007) (non-compete clause between seller and buyer of a business) (state antitrust law case); *Signature MD, Inc. v. MDVIP, Inc.*, 2015 WL 3988959 (C.D. Cal. Apr. 21, 2015). There are also several opinions addressing whether non-compete clauses between businesses violate Section 1. Courts generally apply a less restrictive legal standard to non-compete clauses between businesses. See, e.g., *Lumber Liquidators, Inc.*, 415 F. Supp. 3d at 715–16.

¹⁸⁴ *Alders*, 353 F. Supp. 654; *Lektro-Vend*, 660 F.2d 255; *Cole*, 496 F. Supp. 2d 613.

¹⁸⁵ *DeSantis*, 793 SW2d 670; *Cole*, 496 F. Supp. 2d 613.

¹⁸⁶ *Am. Tobacco Co.*, 221 U.S. at 181–83. Section 2 of the Sherman Act, 15 U.S.C. 2, prohibits monopolization or attempted monopolization.

claim that a non-compete clause between a concierge medicine firm and physicians violated Section 1. The court held that while the reasonableness of the non-compete clause ultimately would be a factual determination, the plaintiff stated a valid claim under Section 1 where it alleged the firm “includes post-contract non-compete clauses with an unreasonably large liquidated damage provision in its employment contracts,” in addition to other practices.¹⁸⁷

In the other 15 Sherman Act cases, the challenge to the individual non-compete clause was unsuccessful. These claims failed for three main reasons. First, in several of these cases, the parties challenging the non-compete clause argued solely that the non-compete clause they were challenging would be *per se* unlawful under Section 1. Courts rejected these arguments, reasoning that non-compete clauses may serve legitimate business interests in some instances¹⁸⁸ and that courts have had insufficient experience with non-compete clauses to warrant a *per se* categorization under Section 1.¹⁸⁹

The second main reason these challenges have been unsuccessful is that, in the vast majority of these 15 cases, the party challenging the non-compete clause did not allege the non-compete clause adversely affected competition, which is an essential element of a Section 1 claim in rule of reason cases.¹⁹⁰ In only one case did the plaintiff appear to allege facts related to anticompetitive effect beyond the effect on the person bound by the non-compete clause. In that case, the court dismissed the plaintiff’s claim because the plaintiff did not sufficiently allege “the amount of competition foreclosed by defendant.”¹⁹¹

Third, courts have also rejected challenges to non-compete clauses based on reasoning that a corporation is not capable of conspiring with its employees as a matter of law.¹⁹²

Plaintiffs have also challenged non-compete clauses between employers and workers under Section 2 of the Sherman Act, which prohibits monopolization or attempted monopolization.¹⁹³ The Commission is not aware of a case in which a Section 2 claim relating to an

¹⁸⁷ *Signature MD, Inc.*, 2015 WL 3988959 at *7.

¹⁸⁸ See, e.g., *Lektro-Vend*, 660 F.2d at 265.

¹⁸⁹ See, e.g., *Aydin*, 718 F.2d at 900.

¹⁹⁰ See, e.g., *Ohio v. Am. Express Co.*, — U.S.—, 138 S. Ct. 2274, 2284 (2018).

¹⁹¹ *GTE Data Servs.*, 717 F. Supp. at 1492.

¹⁹² See, e.g., *Borg-Warner*, 946 F. Supp. 499; *Dallas South Mill*, 2007 WL 9712116 at *3.

¹⁹³ 15 U.S.C. 2. See, e.g., *BRFHH Shreveport, LLC v. Willis Knighton Med. Ctr.*, 176 F. Supp. 3d 606, 616–26 (W.D. La. 2016).

employer's use of a non-compete clause has been successful.

3. Federal and State Enforcement Activity Related to Non-Compete Clauses

In recent years, state attorneys general in Illinois, New York, and Washington have sued companies for unlawfully using non-compete clauses. As of January 2020, state attorneys general have publicly announced settlements with seven companies regarding the use of non-compete clauses.¹⁹⁴ In February 2022, the Antitrust Division filed a statement of interest in a state non-compete clause case brought by private plaintiffs.¹⁹⁵

The Antitrust Division and the Commission have also taken steps in recent years to address other types of contractual provisions that restrict competition in labor markets. The Antitrust Division has brought civil enforcement actions under Section 1 against several technology companies for entering into no-poach agreements with competitors. These enforcement actions ended with consent judgments against the companies.¹⁹⁶ In addition, the Antitrust Division has brought criminal charges for wage-fixing and no-poach agreements against companies and individuals.¹⁹⁷ The Commission too has brought civil enforcement actions against companies related to competition for employment, which ended in consent judgments against the

companies.¹⁹⁸ In addition, the attorney general of the State of Washington has entered into settlement agreements with over 200 companies in which the companies have agreed to stop using no-poach clauses.¹⁹⁹

The Commission seeks comment on all aspects of its description, in this Part II.C, of the law currently governing non-compete clauses. The Commission specifically seeks comment on the extent to which employers use choice-of-law provisions to evade the laws of states where non-compete clauses are relatively less enforceable. The Commission also seeks comment on the extent to which a uniform federal standard for non-compete clauses would promote certainty for employers and workers.

D. The Commission's Work on Non-Compete Clauses

This rulemaking represents the culmination of several years of activity by the Commission related to non-compete clauses and their effects on competition. This activity has included extensive public outreach and fact-gathering related to non-compete clauses, other restrictive employment covenants that may harm competition, and competition in labor markets generally. The Commission has also analyzed non-compete clauses in connection with its enforcement, research, and merger review work.

The Commission first began focusing on non-compete clauses in the mid-2010s, as a growing body of empirical research raised concerns about the anticompetitive effects of non-compete clauses. In 2018 and 2019, the Commission held several "Hearings on Competition and Consumer Protection in the 21st Century."²⁰⁰ The Commission invited public comment on a wide range of topics, including "the use of non-competition agreements and the conditions under which their use may be inconsistent with the antitrust laws."²⁰¹ Participants addressed non-compete clauses at two of the hearings.²⁰²

¹⁹⁴ See Antitrust Guidance for Human Resource Professionals, *supra* note 37 at 4 (citing cases).

¹⁹⁵ Office of the Att'y Gen. of the State of Wash., Press Release, *AG Report: Ferguson's Initiative Ends No-Poach Practices Nationally at 237 Corporate Franchise Chains* (June 16, 2020).

¹⁹⁶ Fed. Trade Comm'n, *Hearings on Competition and Consumer Protection in the 21st Century*, <https://www.ftc.gov/enforcement-policy/hearings-competition-consumer-protection>.

¹⁹⁷ Fed. Trade Comm'n, Notice, *Hearings on Competition and Consumer Protection in the 21st Century*, 83 FR 38307, 38309 (Aug. 6, 2018).

¹⁹⁸ Fed. Trade Comm'n, Transcript, *Competition and Consumer Protection in the 21st Century* (Oct. 16, 2018), <https://www.ftc.gov/system/files/>

Also in 2019, the Open Markets Institute, 19 labor and public interest organizations, and 46 individual advocates and scholars petitioned the Commission to initiate a rulemaking to prohibit non-compete clauses.²⁰³

As evidence mounted regarding the anticompetitive effects of non-compete clauses, the Commission's focus on this issue increased. On January 9, 2020, the Commission held a public workshop on non-compete clauses. At the workshop, speakers and panelists addressed topics including statutory and judicial treatment of non-compete clauses; the Commission's authority to address non-compete clauses; the economic literature regarding the effects of non-compete clauses; and whether the Commission should initiate a rulemaking on non-compete clauses.²⁰⁴ In connection with the workshop, the Commission sought public comment on a wide range of topics related to a potential rulemaking on non-compete clauses. The Commission received 328 comments addressing these topics from researchers, advocates for workers, employers, trade associations, attorneys, members of Congress, state and local officials, unions, other organizations, and individual members of the public.²⁰⁵

In addition, on August 5, 2021, the Commission issued a solicitation for public comment on contract terms that may harm competition, including "non-compete clauses that prevent workers from seeking employment with other firms." The Commission received 280 comments on this solicitation from a wide range of stakeholders.²⁰⁶ On December 6–7, 2021, the Commission and the Antitrust Division held a workshop entitled "Making Competition Work: Promoting Competition in Labor Markets." The Commission sought

documents/public_events/1413712/ftc_hearings_session_3_transcript_day_2_10-16-18_1.pdf; Fed. Trade Comm'n, Transcript, *Competition and Consumer Protection in the 21st Century* (June 12, 2019), https://www.ftc.gov/system/files/documents/public_events/1519667/ftc_hearings_session_14_transcript_6-12-19_0.pdf.

²⁰³ Open Markets Inst. et al., *Petition for Rulemaking to Prohibit Worker Non-Compete Clauses* (March 20, 2019).

²⁰⁴ Fed. Trade Comm'n, *Non-Competes in the Workplace: Examining Antitrust and Consumer Protection Issues*, <https://www.ftc.gov/news-events/events/2020/01/non-compete-clauses-workplace-examining-antitrust-consumer-protection-issues>.

²⁰⁵ Fed. Trade Comm'n, Docket FTC–2019–0093, *Workshop on Non-Compete Clauses Used in Employment Contracts*, <https://www.regulations.gov/document/FTC-2019-0093-0001/comment>.

²⁰⁶ Fed. Trade Comm'n, *Solicitation for Public Comments on Contract Terms that May Harm Competition* (Aug 5, 2021), <https://www.regulations.gov/document/FTC-2021-0036-0022>.

¹⁹⁴ See Public Comments of 19 State Attorneys General in Response to the Federal Trade Commission's January 9, 2020 Workshop on Non-Compete Clauses in the Workplace at 6 n.23 (listing the settlements).

¹⁹⁵ Statement of Interest of the United States, *Beck v. Pickert Med. Grp.*, No. CV21–02092 (Nev. Dist. Ct. Feb. 25, 2022).

¹⁹⁶ See Antitrust Guidance for Human Resource Professionals, *supra* note 37 at 3–4 (citing cases).

¹⁹⁷ *U.S. v. Neeraj Jindal and John Rodgers*, No. 4:20-cr-358-ALM-KPJ (E.D. Tex. Dec. 9, 2020); *U.S. v. Surgical Care Affiliates, LLC and SCAI Holdings, LLC*, No. 3:21-cr-011-L (N.D. Tex. Jan. 5, 2021); *U.S. v. Ryan Hee and VDA OC, LLC*, formerly ADVANTAGE ON CALL, LLC, No. 2:21-cr-00098-RFB-BNW (D. Nev. Mar. 26, 2021); *U.S. v. DaVita, Inc. and Kent Thiry*, No. 21-cr-00229-RBJ (D. Colo. Nov. 3, 2021); *U.S. v. Patel, et al.*, 3:21-cr-220-VHB-RAR (D. Conn. Dec. 15, 2021); *U.S. v. Manaha, et al.*, 2:22-cr-00013-JAW (D. Me. Jan. 27, 2022). The defendants in the *Jindal* case were found not guilty of the wage-fixing charge, and the defendants in the *DaVita* cases were found not guilty of all charges. *Jindal*, Jury Verdict (E.D. Tex. Apr. 14, 2022); *DaVita*, Verdict (D. Colo. Apr. 15, 2022). However, both courts found that the conduct alleged in the indictment properly fell within the confines of the *per se* rule. *Jindal*, Memorandum Opinion and Order, 2021 WL 5578687 (E.D. Tex. Nov. 29, 2021) at *4–*8; *DaVita*, Order Denying Defendants' Motion to Dismiss, 2022 WL 266759 (D. Colo. Jan. 28, 2022) at *4–*8. The court in *Manaha* likewise recently denied a motion to dismiss, holding the indictment charged a recognized form of *per se* illegal conduct. 2022 WL 3161781, at **7, 9 (D. Me. Aug. 8, 2022).

comment from the public in connection with this event and received 27 comments.²⁰⁷

As it has developed this proposed rule, the Commission has closely considered the views expressed at these forums and the public comments it has received through these engagement efforts. The comments have informed the Commission's understanding of the evidence regarding the effects of non-compete clauses; the law currently governing non-compete clauses; and the options for how the Commission may seek to restrict the unfair use of non-compete clauses through rulemaking, among other topics.

The Commission has also focused on non-compete clauses in connection with its enforcement, merger review, and research work. With respect to enforcement, in 2021, the Commission initiated investigations into the use of non-compete clauses by manufacturers of glass containers used for food and beverage packaging. On December 28, 2022, the Commission accepted, subject to final approval, consent agreements with two manufacturers in the industry.²⁰⁸ The glass container industry is highly concentrated and is characterized by substantial barriers to entry and expansion. Among these barriers, it is difficult to identify and employ personnel with skills and experience in glass container manufacturing.²⁰⁹

The complaints allege the manufacturers required employees across a variety of positions—including employees who work with the glass plants' furnaces and forming equipment and in other glass production, engineering, and quality assurance roles—to enter into non-compete clauses. The complaints allege this conduct has a tendency or likelihood to impede rivals' access to the restricted employees' labor, to limit workers' mobility, and thus to harm workers, consumers, competition, and the competitive process. As such, the complaints allege each company has engaged in an unfair method of competition in violation of Section 5 of

the FTC Act.²¹⁰ The proposed consent orders would prohibit each manufacturer from “entering or attempting to enter, maintaining or attempting to maintain, or enforcing or attempting to enforce a Non-Compete Restriction with an Employee, or communicating to an Employee or a prospective or current employer of that Employee that the Employee is subject to a Non-Compete Restriction.”²¹¹

In 2021, the Commission also initiated investigations into the use of non-compete clauses in the security guard services industry. On December 28, 2022, the Commission accepted, subject to final approval, a consent agreement with Prudential Security, Inc., Prudential Command Inc., and the firms' co-owners (collectively “Prudential Respondents”). Prudential Security, Inc. and Prudential Command Inc. provided security guard services to clients in several states.

The Commission's complaint alleges the Prudential Respondents' use of non-compete clauses is an unfair method of competition under Section 5 because it is restrictive, coercive, and exploitative and negatively affects competitive conditions.²¹² The complaint further alleges the Prudential Respondents' imposition of non-compete clauses took advantage of the unequal bargaining power between Prudential Respondents and their employees, particularly low-wage security guard employees, and thus reduced workers' job mobility, limited competition for workers' services, and ultimately deprived workers of higher wages and more favorable working conditions.²¹³ Under the terms of the proposed order, Prudential Respondents—including any companies the co-owners may control in the future—must cease and desist from entering, maintaining, enforcing, or attempting to enforce any non-compete clause.²¹⁴

These consent orders have been placed on the public record for 30 days in order to receive comments from interested persons. After 30 days, the Commission will again review the consent agreements and the comments received and will decide whether it should make the proposed orders final or take other appropriate action.²¹⁵

In addition, as part of a 2020 settlement with the Commission, three national rent-to-own companies agreed to refrain from enforcing non-compete clauses that were entered into in connection with reciprocal purchase agreements.²¹⁶

With respect to merger review, on August 11, 2015, the Commission approved a final order settling charges that Zimmer Holdings, Inc.'s acquisition of Biomet, Inc. would have eliminated competition between the companies in the markets for certain orthopedic medical products. Among other things, the order requires Zimmer to “remove any impediments or incentives” that may deter workers from accepting employment with the divested businesses, including non-compete clauses.²¹⁷

On November 10, 2021, the Commission approved a final order settling charges that 7-Eleven's acquisition of Marathon Petroleum Corporation's Speedway subsidiary violated federal antitrust laws. Among other things, the order prohibits 7-Eleven from enforcing any non-compete clauses against any franchisees or employees working at or doing business with the divested assets.²¹⁸

On January 10, 2022, the Commission approved a final order settling charges that dialysis service provider DaVita, Inc.'s acquisition of University of Utah Health's dialysis clinics would reduce competition in vital outpatient dialysis services in the Provo, Utah market. As part of the order, DaVita was required to remove certain non-compete clauses and prohibited from enforcing or entering into non-compete clauses with certain parties.²¹⁹ And on August 9, 2022, the Commission issued a final consent order in which ARKO Corp. and its subsidiary GPM agreed to roll back a sweeping non-compete clause they

²¹⁶ Fed. Trade Comm'n, Press Release, *Rent-to-Own Operators Settle Charges that They Restrained Competition through Reciprocal Purchase Agreements* (Feb. 21, 2020), <https://www.ftc.gov/news-events/news/press-releases/2020/02/rent-own-operators-settle-charges-they-restrained-competition-through-reciprocal-purchase-agreements>.

²¹⁷ Fed. Trade Comm'n, *In the Matter of Zimmer Holdings, Inc. et al.*, No. C-4534, Decision and Order (Aug. 11, 2015), <https://www.ftc.gov/system/files/documents/cases/150820zimmerdo.pdf>.

²¹⁸ Fed. Trade Comm'n, Press Release, *FTC Approves Final Order Requiring Divestitures of Hundreds of Retail Gas and Diesel Fuel Stations Owned by 7-Eleven, Inc.* (Nov. 10, 2021), <https://www.ftc.gov/news-events/news/press-releases/2021/11/ftc-approves-final-order-requiring-divestitures-hundreds-retail-gas-diesel-fuel-stations-owned-7>.

²¹⁹ Fed. Trade Comm'n, *In the Matter of Davita Inc. and Total Renal Care, Inc.*, No. C-4752, Decision and Order (Jan. 10, 2022) at 12–14, https://www.ftc.gov/system/files/documents/cases/211_0056_c4752_davita_utah_health_order.pdf.

²⁰⁷ Fed. Trade Comm'n, Docket FTC-2021-0057, *Making Competition Work: Promoting Competition in Labor Markets*, <https://www.regulations.gov/docket/FTC-2021-0057/comments>.

²⁰⁸ Fed. Trade Comm'n, Decision and Order, *In re O-I Glass, Inc. et al.*, Matter No. 211 0182 (December 28, 2022); Fed. Trade Comm'n, Decision and Order, *In re Ardaugh Group S.A. et al.*, Matter No. 211 0182 (December 28, 2022).

²⁰⁹ Fed. Trade Comm'n, Analysis of Agreements Containing Consent Order to Aid Public Comment, *In re O-I Glass Inc. et al.*, *In re Ardaugh Group S.A. et al.*, Matter No. 211 0182 (December 28, 2022) at 2.

²¹⁰ *Id.* at 1–2.

²¹¹ *Id.* at 7.

²¹² Fed. Trade Comm'n, Analysis of Agreement Containing Consent Order to Aid Public Comment, *In re Prudential Sec., Inc. et al.*, Matter No. 211 0026 at 1, 5–7 (December 28, 2022).

²¹³ *Id.* at 1.

²¹⁴ *Id.*

²¹⁵ *Id.* at 1–2; Glass Container Analysis to Aid Public Comment, *supra* note 209 at 1.

imposed on a company to which they sold 60 gas stations.²²⁰

With respect to research, in September 2021, the Commission issued a study analyzing acquisitions by five large technology companies that were not reported to the Commission and the U.S. Department of Justice under the Hart-Scott-Rodino Act.²²¹ The study found 76.7% of transactions included non-compete clauses for founders and key employees of the acquired entities. The study also found that higher-value transactions were more likely to use non-compete clauses.²²² The study does not explain why the companies used non-compete clauses or analyze the effects of these particular non-compete clauses on competition.

The Commission seeks comment on its description, in this Part II.D, of the Commission's work on non-compete clauses prior to this NPRM.

III. Legal Authority

Section 5 of the FTC Act declares “unfair methods of competition” to be unlawful.²²³ Section 5 further directs the Commission “to prevent persons, partnerships, or corporations . . . from using unfair methods of competition in or affecting commerce.”²²⁴ Section 6(g) of the FTC Act authorizes the Commission to “make rules and regulations for the purpose of carrying out the provisions of” the FTC Act, including the Act's prohibition of unfair methods of competition.²²⁵ Taken together, Sections 5 and 6(g) provide the Commission with the authority to issue regulations declaring practices to be unfair methods of competition.²²⁶

Courts have made clear Section 5's prohibition of unfair methods of competition encompasses all practices that violate either the Sherman or Clayton Acts.²²⁷ However, courts have long held the scope of Section 5 is not

confined to the conduct that is prohibited under the Sherman Act, Clayton Act, or common law.²²⁸ Section 5 reaches incipient violations of the antitrust laws—conduct that, if left unrestrained, would grow into an antitrust violation in the foreseeable future.²²⁹ Additionally, Section 5 reaches conduct that, while not prohibited by the Sherman or Clayton Acts, violates the spirit or policies underlying those statutes.²³⁰

IV. The Commission's Preliminary Determination That Non-Compete Clauses Are an Unfair Method of Competition

The Commission preliminarily determines it is an unfair method of competition for an employer to enter into or attempt to enter into a non-compete clause with a worker; maintain with a worker a non-compete clause; or represent to a worker that the worker is subject to a non-compete clause where the employer has no good faith basis to believe the worker is subject to an enforceable non-compete clause.²³¹ This preliminary determination is the basis for this proposed rule, which would provide that each of these practices is an unfair method of competition under Section 5.²³² This Part IV sets forth a

²²⁸ See, e.g., *Fed. Trade Comm'n v. Motion Picture Advert. Serv. Co.*, 344 U.S. 392, 394–95 (1953) (“The ‘Unfair methods of competition’, which are condemned by [Section] 5(a) of the [FTC] Act, are not confined to those that were illegal at common law or that were condemned by the Sherman Act. Congress advisedly left the concept flexible to be defined with particularity by the myriad of cases from the field of business.”) (internal citations omitted).

²²⁹ See, e.g., *Cement Inst.*, 333 U.S. at 708 (“A major purpose of [the FTC] Act was to enable the Commission to restrain practices as ‘unfair’ which, although not yet having grown into Sherman Act dimensions would most likely do so if left unrestrained.”); *Fashion Originators' Guild*, 312 U.S. at 466; *Triangle Conduit & Cable Co. v. Fed. Trade Comm'n*, 168 F.2d 175, 176 (7th Cir. 1948).

²³⁰ See, e.g., *Fashion Originators' Guild*, 312 U.S. at 463 (stating that “[i]f the purpose and practice of the combination of garment manufacturers and their affiliates runs counter to the public policy declared in the Sherman and Clayton Acts, the Federal Trade Commission has the power to suppress it as an unfair method of competition”); *E.I. du Pont de Nemours & Co. v. Fed. Trade Comm'n (Ethyl)*, 729 F.2d 128, 136–37 (2d Cir. 1984) (finding that the Commission may bar “conduct which, although not a violation of the letter of the antitrust laws, is close to a violation or is contrary to their spirit”). On November 10, 2022, the Commission issued a policy statement describing the key principles of general applicability concerning whether conduct is an unfair method of competition under Section 5. *Fed. Trade Comm'n, Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act* (Nov. 10, 2022).

²³¹ For ease of reference, this Part IV employs the term “use of non-compete clauses” as a shorthand to refer to this conduct.

²³² See proposed § 910.2(a).

series of preliminary findings that provide the basis for this preliminary determination. The Commission's preliminary determination and each of these preliminary findings are subject to further consideration in light of the comments received and the Commission's additional analysis. The Commission seeks comment on all aspects of this Part IV.²³³

A. Non-Compete Clauses Are an Unfair Method of Competition Under Section 5

1. Non-Compete Clauses Are Unfair

Courts have held conduct is an “unfair method of competition” under Section 5 where the conduct is facially unfair. In *Atlantic Refining Co. v. FTC* and *FTC v. Texaco, Inc.*, the Court held the Commission established an unfair method of competition where an oil company used its economic power over its gas stations to coerce them into buying certain tires, batteries, or accessories only from firms that paid the oil company a commission.²³⁴ In *Texaco*, the Court held the conduct was an unfair method of competition even though Texaco's conduct was not overtly coercive, reasoning that Texaco's conduct was “inherently coercive” because its “dominant economic power was used in a manner which tended to foreclose competition.”²³⁵ In *FTC v. R.F. Keppel & Bro.*, the Court held the Commission established an unfair method of competition where a manufacturer exploited the inability of children to protect themselves in the marketplace by marketing inferior goods to them through use of a gambling scheme.²³⁶ In *E.I. du Pont de Nemours & Co. v. FTC (Ethyl)*, the U.S. Court of Appeals for the Second Circuit reaffirmed that coercive conduct is quintessentially covered by Section 5's prohibition of unfair methods of competition.²³⁷

The Court has also held that, for coercive conduct to constitute unfair

²³³ The Commission intends for this Part IV to satisfy the requirements in Section 22 of the FTC Act that, in an NPRM, the Commission issue a preliminary regulatory analysis that contains “a concise statement of the need for, and the objectives of, the proposed rule.” 15 U.S.C. 57b–3.

²³⁴ *Atl. Refin. Co.*, 381 U.S. at 369–70; *Texaco, Inc.*, 393 U.S. at 228–29.

²³⁵ 393 U.S. 223 at 228–29 (1968). See also *Shell Oil Co. v. Fed. Trade Comm'n*, 360 F.2d 470, 487 (5th Cir. 1966) (“A man operating a gas station is bound to be overawed by the great corporation that is his supplier, his banker, and his landlord.”).

²³⁶ 291 U.S. 304, 313 (1934).

²³⁷ 729 F.2d 128, 140 (2d Cir. 1984) (“In short, in the absence of proof of a violation of the antitrust laws or evidence of collusive, coercive, predatory, or exclusionary conduct, business practices are not “unfair” in violation of § 5 unless those practices either have an anticompetitive purpose or cannot be supported by an independent legitimate reason.”).

²²⁰ Fed. Trade Comm'n, Press Release, *FTC Approves Final Order Restoring Competitive Markets for Gasoline and Diesel in Michigan and Ohio* (Aug. 9, 2022), <https://www.ftc.gov/news-events/news/press-releases/2022/08/ftc-approves-final-order-restoring-competitive-markets-gasoline-diesel-michigan-ohio>.

²²¹ Fed. Trade Comm'n, *Non-HSR Reported Acquisitions by Select Technology Platforms, 2010–2019: An FTC Study* (September 2021) at 1.

²²² *Id.* at 21–22. The table states that the figure is 77.3%. The reason for this discrepancy is not clear.

²²³ 15 U.S.C. 45(a)(1).

²²⁴ 15 U.S.C. 45(a)(2).

²²⁵ 15 U.S.C. 46(g).

²²⁶ *Nat'l Petroleum Refiners Ass'n v. Fed. Trade Comm'n*, 482 F.2d 672, 697–98 (D.C. Cir. 1973).

²²⁷ See, e.g., *Fed. Trade Comm'n v. Cement Inst.*, 333 U.S. 683, 693 (1948) (holding practices that violate the Sherman Act are unfair methods of competition); *Fashion Originators' Guild of Am. v. Fed. Trade Comm'n*, 312 U.S. 457, 464 (1941) (holding practices that violate the Clayton Act are unfair methods of competition).

method of competition, it must burden commerce. In *Atlantic Refining*, the Court determined “a full-scale economic analysis of competitive effect” was not required; due to the nature of the conduct at issue, the Commission merely needed to show the conduct burdened “a not insubstantial portion of commerce.”²³⁸

In the cases described above, courts condemned conduct under Section 5 based on the facial unfairness of the conduct. In other cases, however, courts have condemned restrictive or exclusionary conduct under Section 5 based not on the facial unfairness of the conduct, but on the impact of the conduct on competition. For example, in *FTC v. Motion Picture Advertising Service Co.*, the Court held an exclusive dealing arrangement violated Section 5 where there was “substantial evidence” the contracts “unreasonably restrain competition.”²³⁹ Similarly, in *L.G. Balfour Co. v. FTC*, the U.S. Court of Appeals for the Seventh Circuit held a firm’s exclusive dealing contracts violated Section 5 where such contracts were “anti-competitive.”²⁴⁰ As the U.S. Court of Appeals for the Sixth Circuit stated in *Hastings Manufacturing Co. v. FTC*, the Section 5 jurisprudence has established that “acts [that are] not in themselves illegal or criminal, or even immoral, may, when repeated and continued and their impact upon commerce is fully revealed, constitute an unfair method of competition within the scope of the Commission’s authority to regulate and forbid.”²⁴¹

For the reasons described below, the Commission preliminarily finds the use by employers of non-compete clauses is an “unfair” method of competition under Section 5. The Commission’s preliminary findings differ based on whether the worker is a senior executive. For workers who are not senior executives, the Commission preliminarily finds the use by employers of non-compete clauses is “unfair” under Section 5 in three independent ways. First, non-compete clauses are restrictive conduct that negatively affects competitive conditions. Second, non-compete clauses are exploitative and coercive at the time of contracting while burdening

a not insignificant volume of commerce. Third, non-compete clauses are exploitative and coercive at the time of the worker’s potential departure from the employer while burdening a not insignificant volume of commerce.

For workers who are senior executives, the Commission preliminarily finds the use by employers of non-compete clauses is “unfair” under Section 5 because such non-compete clauses are restrictive conduct that negatively affects competitive conditions. As described below in Part IV.A.1.a.ii, the Commission preliminarily concludes non-compete clauses for senior executives may harm competition in product markets in unique ways. The second and third preliminary findings described above—that non-compete clauses are exploitative and coercive at the time of contracting and at the time of a worker’s potential departure—do not apply to workers who are senior executives.²⁴²

The Commission seeks comment on whether this different unfairness analysis should apply to other highly paid or highly skilled workers who are not senior executives. Furthermore, in Part VI.C below, the Commission seeks comment on how this category of workers—whether “senior executives” or a broader category of highly paid or highly skilled workers—should be defined, and whether different regulatory standards should apply to this category of workers.

The Commission seeks comment on its preliminary finding that non-compete clauses are an “unfair” method of competition under Section 5.

a. Non-Compete Clauses Are Restrictive Conduct That Negatively Affects Competitive Conditions

First, the Commission preliminarily finds non-compete clauses are an “unfair” method of competition under Section 5 because they are restrictive conduct that negatively affects competitive conditions.

As noted above, courts have condemned restrictive or exclusionary conduct under Section 5 based not on the facial unfairness of the conduct, but on the impact of the conduct on competition.²⁴³ Non-compete clauses are restrictive conduct. By their express

terms, non-compete clauses restrict a worker’s ability to work for a competitor of the employer—for example, by accepting a job with a competitor or starting a business that would compete against the employer. Non-compete clauses also restrict rivals from competing against the employer to attract their workers. Because non-compete clauses facially restrain competition in the labor market, courts have long held they are restraints of trade and proper subjects for scrutiny under the antitrust laws.²⁴⁴ Furthermore, as described in detail in this NPRM, there is considerable empirical evidence showing non-compete clauses negatively affect competition in labor markets and product and service markets.²⁴⁵ This evidence is summarized below.

i. Non-Compete Clauses Negatively Affect Competitive Conditions in Labor Markets

As described in greater detail above in Part II.B.1, non-compete clauses negatively affect competitive conditions in labor markets by obstructing the sorting of workers and employers into the strongest possible matches. Labor markets function by matching workers and employers. In a well-functioning labor market, a worker who is seeking a better job—more pay, better working conditions, more enjoyable work, or whatever the worker may be seeking—can enter the labor market by looking for work. Employers who have positions available compete for the worker’s services. The worker’s current employer may also compete with these prospective employers by seeking to retain the worker—for example, by offering to raise the worker’s pay or promote the worker. Ultimately, the worker chooses the job that best meets their objectives. In general, the more jobs available—*i.e.*, the more options the worker has—the greater the possibility the worker will find a strong match.

Just as employers compete for workers in a well-functioning labor market,

²⁴⁴ See, e.g., *Am. Tobacco Co.*, 221 U.S. at 181–83 (holding several tobacco companies violated Sections 1 and 2 of the Sherman Act due to the collective effect of six of the companies’ practices, one of which was the “constantly recurring” use of non-compete clauses); *Newburger, Loeb & Co., Inc.*, 563 F.2d at 1082 (“Although such issues have not often been raised in the federal courts, employee agreements not to compete are proper subjects for scrutiny under section 1 of the Sherman Act. When a company interferes with free competition for one of its former employee’s services, the market’s ability to achieve the most economically efficient allocation of labor is impaired. Moreover, employee-noncompetition clauses can tie up industry expertise and experience and thereby forestall new entry.”)

²⁴⁵ See *supra* Part II.B.

²³⁸ 381 U.S. at 370–71. See also *Texaco, Inc.*, 393 U.S. at 230 (finding that the practice unfairly burdened competition for a not insignificant volume of commerce); *R.F. Keppel & Bro.*, 291 U.S. at 309 (“A practice so widespread and so far reaching in its consequences is of public concern if in other respects within the purview of the statute.”).

²³⁹ 344 U.S. 392, 395–96 (1953).

²⁴⁰ 442 F.2d 1, 14 (7th Cir. 1971).

²⁴¹ 153 F.2d 253, 257 (6th Cir. 1946).

²⁴² As described below in Part VII.B.1.a.iv, the Commission estimates that, when non-compete clauses are more enforceable, CEO earnings are reduced. This may result from the negative effects on competitive conditions that non-compete clauses have on labor markets (discussed in greater detail below in Part IV.A.1.a.i) rather than from exploitation or coercion.

²⁴³ See *supra* Part IV.A.1.

workers compete for jobs. In general, the more workers who are available—*i.e.*, the more options the employer has—the stronger the match the employer will find. Through these processes—employers competing for workers, workers competing for jobs, and employers and workers matching with one another—competition in the labor market leads to higher earnings for workers, greater productivity for employers, and better economic conditions.

In a perfectly competitive labor market, if a job that a worker would prefer more—for example, because it has higher pay or is in a better location—were to become available, the worker could switch to it quickly and easily. However, this perfectly competitive labor market exists only in theory. In practice, labor markets substantially deviate from perfect competition. Non-compete clauses, in particular, impair competition in labor markets by restricting a worker's ability to change jobs. If a worker is bound by a non-compete clause, and the worker wants a better job, the non-compete clause will prevent the worker from accepting a new job within the scope of the non-compete clause. These will often be the most natural alternative employment options for a worker: jobs in the same geographic area and in the worker's field of expertise. The result is less competition among employers for the worker's services. Since the worker is prevented from taking these jobs, the worker may decide not to enter the labor market at all, or the worker may enter the labor market but take a job outside of their field of expertise in which they are less productive.

Non-compete clauses affect competition in labor markets through their use in the aggregate. The effect of an individual worker's non-compete clause on competition in a particular labor market may be marginal or may be impossible to discern statistically. However, the use of a large number of non-compete clauses across a labor market demonstrably affects the opportunities of all workers in that market. By making it more difficult for many workers in a labor market to switch to new jobs, non-compete clauses inhibit optimal matches from being made between employers and workers across the labor force. As a result, where non-compete clauses are prevalent in a market, workers are more likely to remain in jobs that are less optimal with respect to the worker's ability to maximize their productive capacity. This materially reduces wages for workers—not only for workers who are subject to non-compete clauses, but

other workers in a labor market as well, since jobs that would otherwise be better matches for an unconstrained worker are filled by workers subject to non-compete clauses.

The Section 5 analysis as to whether conduct negatively affects competitive conditions does not require a showing that the conduct caused actual harm.²⁴⁶ However, whether conduct causes actual harm can be relevant to whether it is an unfair method of competition.²⁴⁷ There is significant empirical evidence that non-compete clauses cause actual harm to competition in labor markets, and that these harms are substantial.

As described above in Part II.B.1.a, the Commission estimates at least one in five American workers—or approximately 30 million workers—is bound by a non-compete clause. The proliferation of non-compete clauses is restraining competition in labor markets to such a degree that it is materially impacting workers' earnings—both across the labor force in general, and also specifically for workers who are not subject to non-compete clauses. The available evidence indicates increased enforceability of non-compete clauses substantially reduces workers' earnings, on average, across the labor market generally or for specific types of workers.²⁴⁸ The Commission estimates the proposed rule, which would prohibit employers from using non-compete clauses, would increase workers' total earnings by \$250 to \$296 billion per year.²⁴⁹

In addition to the evidence showing non-compete clauses reduce earnings for workers across the labor force, there is also evidence non-compete clauses reduce earnings specifically for workers who are *not* subject to non-compete clauses.²⁵⁰ One study finds when the use of non-compete clauses by employers increases, that drives down

wages for workers who do not have non-compete clauses but who work in the same state and industry. This study also finds this effect is stronger where non-compete clauses are more enforceable. This study shows the reduction in earnings (and also reduced labor mobility) is due to a reduction in the rate of the arrival of job offers.²⁵¹ Another study finds similarly that changes in non-compete clause enforceability in one state have negative impacts on workers' earnings in bordering states and that the effects are nearly as large as the effects in the state in which enforceability changed (though the effect tapers off as the distance to the bordering state increases).²⁵² The authors conclude that, since the workers across the border are not directly affected by the law change—because contracts that they have signed do not become more or less enforceable—this effect must be due to changes in the local labor market.²⁵³

The Commission preliminarily concludes non-compete clauses negatively affect competitive conditions in labor markets regardless of the worker's income or job function. Whether a worker is a senior executive or a security guard, non-compete clauses block the worker from switching to a job in which they would be better paid and more productive—restricting that worker's opportunities as well as the opportunities of other workers in the relevant labor market. The available data do not allow the Commission to estimate earnings effects for every occupation. However, the evidentiary record indicates non-compete clauses depress wages for a wide range of subgroups of workers across the spectrum of income and job function. The Commission therefore estimates the proposed rule would increase earnings for workers in all of the subgroups of the labor force for which sufficient data is available.²⁵⁴

The Commission seeks comment on its preliminary finding that non-compete clauses negatively affect competitive conditions in labor markets.

ii. Non-Compete Clauses Negatively Affect Competitive Conditions in Markets for Products and Services

The adverse effects of non-compete clauses on product and service markets largely result from reduced labor mobility. Several studies show the use of non-compete clauses by employers

²⁴⁶ See *Fed. Trade Comm'n v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 (1972) (explaining that “unfair competitive practices [are] not limited to those likely to have anticompetitive consequences after the manner of the antitrust laws”); *In re Coca-Cola Co.*, 117 F.T.C. 795, 915 (FTC 1994) (rejecting argument that Section 5 violation requires showing “anticompetitive effects”).

²⁴⁷ See *Ethyl*, 729 F.2d at 138 (evidence of actual harm can be “a relevant factor in determining whether the challenged conduct is unfair”).

²⁴⁸ See *supra* Part II.B.1. While there is evidence that increased enforceability of non-compete clauses increases the rate of earnings growth for physicians, Lavetti, Simon, & White, *supra* note 53 at 1051, the Commission estimates that the proposed rule may increase physicians' earnings, although the study does not allow for a precise calculation. See *infra* Part VII.B.1.a.ii.

²⁴⁹ See *infra* Part VII.B.1 (describing the Commission's assessment of the benefits of the proposed rule).

²⁵⁰ See *supra* Part II.B.1.c.

²⁵¹ Starr, Frake, & Agarwal, *supra* note 76 at 4.

²⁵² Johnson, Lavetti, & Lipsitz, *supra* note 63 at 51.

²⁵³ *Id.* at 30.

²⁵⁴ See *infra* Part VII.B.1.a.

reduces labor mobility. All of these studies have found decreased rates of labor mobility, as measured by job separations, hiring rates, job-to-job mobility, implicit mobility defined by job tenure, and within- and between-industry mobility.²⁵⁵ The Commission does not view reduced labor mobility from non-compete clauses—in and of itself—as evidence that non-compete clauses negatively affect competition in product and service markets. Instead, reduced labor mobility is best understood as the primary driver of the effects in product and service markets the Commission is concerned about.

Reduced labor mobility from non-compete clauses negatively affects competitive conditions in product and service markets in several respects. First, there is evidence non-compete clauses increase consumer prices and concentration in the health care sector. There is also evidence non-compete clauses increase industrial concentration more broadly. Non-compete clauses may have these effects by inhibiting entrepreneurial ventures (which could otherwise enhance competition in goods and service markets) or by foreclosing competitors' access to talented workers.²⁵⁶

Second, non-compete clauses foreclose the ability of competitors to access talent by effectively forcing future employers to buy out workers from their non-compete clauses if they want to hire them. Firms must either make inefficiently high payments to buy workers out of non-compete clauses with a former employer, which leads to deadweight economic loss, or forego the payment—and, consequently, the access to the talent the firm seeks. Whatever choice a firm makes, its economic outcomes in the market are harmed, relative to a scenario in which no workers are bound by non-compete clauses. There is evidence of this mechanism in the market for CEOs.²⁵⁷

Third, the weight of the evidence indicates non-compete clauses have a negative impact on new business formation. New business formation increases competition first by bringing new ideas to market, and second, by forcing incumbent firms to respond to new firms' ideas instead of stagnating. Non-compete clauses restrain new business formation by preventing workers subject to non-compete clauses from starting their own businesses. In addition, firms are more willing to enter markets in which they know there are potential sources of skilled and

experienced labor, unhampered by non-compete clauses.²⁵⁸

Fourth, the weight of the evidence indicates non-compete clauses decrease innovation. Innovation may directly improve economic outcomes by increasing product quality or decreasing prices, or may promote competition because successful new products and services force competing firms to improve their own products and services. Non-compete clauses affect innovation by reducing the movement of workers between firms, which decreases knowledge flow between firms. Non-compete clauses also prevent workers from starting businesses in which they can pursue innovative new ideas.²⁵⁹

As noted above in Part II.B.2.e, there is also evidence non-compete clauses increase employee training and other forms of investment. The Commission considers this evidence below in Part IV.B as part of its analysis of the justifications for non-compete clauses.

The Commission believes non-compete clauses for senior executives may harm competition in product markets in unique ways, to the extent that senior executives may be likely to start competing businesses, be hired by potential entrants or competitors, or lead the development of innovative products and services. Non-compete clauses for senior executives may also block potential entrants, or raise their costs, to a high degree, because such workers are likely to be in high demand by potential entrants. As a result, prohibiting non-compete clauses for senior executives may have relatively greater benefits for consumers than prohibiting non-compete clauses for other workers. The Commission seeks comment on this analysis as well as whether this reasoning may apply to highly paid and highly skilled workers who are not senior executives.

The Commission seeks comment on its preliminary finding that non-compete clauses negatively affect competitive conditions in markets for products and services.

b. Non-Compete Clauses Are Exploitative and Coercive at the Time of Contracting

The Commission preliminarily finds non-compete clauses for workers other than senior executives are exploitative and coercive because they take advantage of unequal bargaining power between employers and workers at the time the employer and worker enter into the non-compete clause.

As noted above, courts have held conduct that is exploitative and coercive can violate Section 5 where it burdens a not insignificant volume of commerce.²⁶⁰ Courts have long recognized bargaining power between employers and workers is unequal and, as a result, workers are vulnerable to exploitation and coercion through the use of non-compete clauses at the time of contracting. Courts have expressed this concern since at least the early eighteenth century. In the foundational English case *Mitchel v. Reynolds*, the court cited “the great abuses these voluntary restraints are liable to . . . from masters, who are apt to give their apprentices much vexation” by using “many indirect practices to procure such bonds from them, lest they should prejudice them in their custom, when they come to set up for themselves.”²⁶¹ As another court stated, more recently:

The average, individual employee has little but his labor to sell or to use to make a living. He is often in urgent need of selling it and in no position to object to boiler plate restrictive covenants placed before him to sign. To him, the right to work and support his family is the most important right he possesses. His individual bargaining power is seldom equal to that of his employer. . . . Under pressure of need and with little opportunity for choice, he is more likely than the seller to make a rash, improvident promise that, for the sake of present gain, may tend to impair his power to earn a living, impoverish him, render him a public charge or deprive the community of his skill and training.²⁶²

Indeed, courts have cited the imbalance of bargaining power between workers and employers as a central reason for imposing stricter scrutiny on non-compete clauses between employers and workers than on non-compete clauses between businesses or between the seller and buyer of a business.²⁶³

The imbalance of bargaining power between employers and workers results from several factors. Many of these

²⁶⁰ See *supra* Part IV.A.1.

²⁶¹ 1 P. Wms. at 190.

²⁶² *Arthur Murray Dance Studios of Cleveland v. Witter*, 105 NE2d 685, 703–04 (Ohio Ct. Com. Pl. 1952). See also Restatement (Second) of Contracts (1981) sec. 188 cmt. g (“Postemployment restraints are scrutinized with particular care because they are often the product of unequal bargaining power and because the employee is likely to give scant attention to the hardship he may later suffer through loss of his livelihood.”).

²⁶³ See, e.g., *Alexander & Alexander, Inc. v. Danahy*, 488 NE2d 22, 29 (Mass. App. Ct. 1986); *Diepholz v. Rutledge*, 659 NE 989, 991 (Ill. Ct. App. 1995); *Palmetto Mortuary Transp., Inc. v. Knight Sys., Inc.*, 818 SE2d 724, 731 (S.C. 2018).

²⁵⁵ See *supra* Part II.B.2.

²⁵⁶ See *supra* Part II.B.2.a.

²⁵⁷ See *supra* Part II.B.2.b.

²⁵⁸ See *supra* Part II.B.2.c.

²⁵⁹ See *supra* Part II.B.2.d.

factors relate to the nature of the employer-worker relationship in the United States generally. Most workers depend on income from their jobs to get by—to pay their rent or mortgage, pay their bills, and keep food on the table. For these workers, particularly the many workers who live paycheck to paycheck, loss of a job or a job opportunity can severely damage their finances.²⁶⁴ For these reasons, the loss of a job or an employment opportunity is far more likely to have serious financial consequences for a worker than the loss of a worker or a job candidate would have for most employers. In addition, employers generally have considerable labor market power, due to factors such as concentration and the difficulty of searching for a job.²⁶⁵ The considerable labor market power of employers has significantly diminished the bargaining power of U.S. workers.²⁶⁶

Several additional factors contribute to the imbalance of bargaining power between employers and workers generally. These include the decline in union membership, which forces more workers to negotiate with their employers individually;²⁶⁷ increased reliance by employers on various forms of outsourcing, which allows employers to fill persistent vacancies without having to raise wages or improve conditions for incumbent workers;²⁶⁸ and the proliferation of no-poaching agreements, which limit the mobility of workers and, as a result, their bargaining power.²⁶⁹

While the employer-worker relationship is defined by an imbalance of bargaining power generally, the imbalance of bargaining power is particularly acute in the context of negotiating employment terms such as

non-compete clauses, for several reasons. First, as courts have long recognized, employers are repeat players who are likely to have greater experience and skill at bargaining, in the context of negotiating employment terms, than individual workers.²⁷⁰ Second, and relatedly, workers are not likely to seek the assistance of counsel in reviewing employment terms,²⁷¹ while employers are more likely to seek the assistance of counsel in drafting them.

Third, research indicates consumers exhibit cognitive biases in the way they consider contractual terms,²⁷² and the same may be true of workers. Consumers rarely read standard-form contracts.²⁷³ Consumers also tend to focus their attention on a few salient terms of the transaction, such as price and quantity, and tend to disregard other terms, particularly terms that are relatively obscure.²⁷⁴ Consumers are particularly likely to disregard contingent terms—terms concerning scenarios that may or may not come to pass—or to be unable to assess what the impact of those terms may be.²⁷⁵ Consumers also tend to disregard onerous terms or terms that involve difficult trade-offs, such as giving up legal rights or future opportunities.²⁷⁶ Workers likely display similar cognitive biases in the way they consider employment terms. These reasons explain why the imbalance of bargaining power between workers and employers is particularly high in the context of negotiating employment terms such as non-compete clauses.

There is considerable evidence employers are exploiting this imbalance of bargaining power through the use of non-compete clauses. Non-compete clauses are typically standard-form

contracts,²⁷⁷ which, as noted above, workers are not likely to read. The evidence shows workers rarely bargain over non-compete clauses²⁷⁸ and rarely seek the assistance of counsel in reviewing non-compete clauses.²⁷⁹ Furthermore, research indicates that, in states where non-compete clauses are unenforceable, workers are covered by non-compete clauses at roughly the same rate as workers in other states,²⁸⁰ suggesting that employers may believe workers are unaware of their legal rights, or that employers may be seeking to take advantage of workers' lack of knowledge of their legal rights. In addition, there is evidence employers often provide workers with non-compete clauses after they have accepted the job offer—in some cases, on or after their first day of work—when the worker's negotiating power is at its weakest, since the worker may have turned down other job offers or left their previous job.²⁸¹

Because there is a considerable imbalance of bargaining power between workers and employers in the context of negotiating employment terms, and because employers take advantage of this imbalance of bargaining power through the use of non-compete clauses, the Commission preliminarily finds non-compete clauses are exploitative and coercive at the time of contracting.

As noted above, for coercive conduct to constitute unfair method of competition, it must also burden a not insignificant volume of commerce. The Commission preliminarily finds non-compete clauses burden a not insignificant volume of commerce due to their negative effects on competitive conditions in labor markets and product and service markets, which are described above.²⁸²

This preliminary finding does not apply to workers who are senior executives. Non-compete clauses for senior executives are unlikely to be exploitative or coercive at the time of contracting, because senior executives are likely to negotiate the terms of their employment and may often do so with the assistance of counsel. The Commission seeks comment on whether there are other categories of highly paid or highly skilled workers (*i.e.*, other

²⁶⁴ See, e.g., Jennie E. Brand, *The Far-Reaching Impact of Job Loss and Unemployment*, 41 Ann. Rev. of Socio. 359 (2015); CareerBuilder, *Living Paycheck to Paycheck is a Way of Life for Majority of U.S. Workers. According to New CareerBuilder Survey* (Aug. 24, 2017), <https://press.careerbuilder.com/2017-08-24-Living-Paycheck-to-Paycheck-is-a-Way-of-Life-for-Majority-of-U-S-Workers-According-to-New-CareerBuilder-Survey> (reporting that 78% of American workers live paycheck to paycheck); Jeff Ostrowski, Bankrate, *Survey: Fewer than 4 in 10 Americans could pay a surprise \$1,000 bill from savings* (Jan. 11, 2021), <https://www.bankrate.com/banking/savings/financial-security-january-2021/>.

²⁶⁵ Treasury Labor Market Competition Report, *supra* note 41 at i-ii.

²⁶⁶ *Id.* at ii (“As this report highlights, a careful review of the credible academic studies places the decrease in wages at roughly 20 percent relative to the level in a fully competitive market”).

²⁶⁷ See, e.g., Alan Krueger, *Luncheon Address: Reflections on Dwindling Worker Bargaining Power and Monetary Policy* at 272 (Aug. 24, 2018), https://www.kansascityfed.org/Jackson%20Hole/documents/6984/Lunch_JH2018.pdf.

²⁶⁸ *Id.*

²⁶⁹ *Id.* at 273.

²⁷⁰ See, e.g., *Samuel Stores, Inc. v. Abrams*, 108 A. 541, 543 (Conn. 1919).

²⁷¹ In one survey, only 7.9% of workers with non-compete clauses reported consulting a lawyer in connection with the non-compete clause. Starr, Prescott, & Bishara, *supra* note 42, at 72.

²⁷² See, e.g., Arnov-Richman (2006), *supra* note 56 at 981; Russell Korobkin, *Bounded Rationality, Standard Form Contracts, and Unconscionability*, 70 U. Chi. L. Rev. 1203, 1206 (2003); Robert Hillman & Jeffrey Rachlinski, *Standard-Form Contracting in the Electronic Age*, 77 N.Y.U. L. Rev. 429, 450–54 (2002).

²⁷³ Korobkin, *supra* note 272 at 1206.

²⁷⁴ Arnov-Richman (2006), *supra* note 56 at 981; Hillman & Rachlinski, *supra* note 272 at 452.

²⁷⁵ See, e.g., Estlund, *supra* note 144 at 413 (2006). See also Fed. Trade Comm'n, *Credit Practices Rule*, 49 FR 7740, 7744 (Mar. 1, 1984) (noting that consumers tend to disregard contingent provisions and concentrate their search on factors such as interest rates and payment terms).

²⁷⁶ Arnov-Richman (2006), *supra* note 56 at 981; Korobkin, *supra* note 272 at 1203–31.

²⁷⁷ Starr, Prescott, & Bishara, *supra* note 42 at 72 (“Taken together, the evidence in this section indicates that employers present (or employees receive) noncompete proposals as take-it-or-leave-it propositions.”).

²⁷⁸ *Id.*

²⁷⁹ *Id.*

²⁸⁰ *Id.* at 81.

²⁸¹ Marx (2011), *supra* note 55 at 706.

²⁸² See *supra* Part IV.A.1.a.i-ii.

than senior executives) to whom this preliminary finding should not apply.

The Commission seeks comment on all aspects of its preliminary finding that non-compete clauses are exploitative and coercive at the time of contracting.

c. Non-Compete Clauses Are Exploitative and Coercive at the Time of the Worker's Potential Departure From the Employer

The Commission preliminarily finds non-compete clauses for workers other than senior executives are exploitative and coercive at the time of the worker's potential departure from the employer, because they force a worker to either stay in a job they want to leave or choose an alternative that likely impacts their livelihood.

For most workers who want to leave their jobs, the most natural employment options will be work in the same field and in the same geographic area. However, where a worker is bound by a non-compete clause, the worker's employment options are significantly limited. A worker who is subject to a non-compete clause, and who wants to leave their job, faces an undesirable choice that will likely affect their livelihood: either move out of the area; leave the workforce for a period of time; leave their field for period of time; pay the employer a sum of money to waive the non-compete clause; or violate the non-compete clause and risk a lawsuit from the employer. By forcing a worker who wants to leave their job to either stay in their job or take an action that will likely negatively affect their livelihood, non-compete clauses coerce workers into remaining in their current jobs. Courts have long expressed concern about this coercive effect of non-compete clauses—that non-compete clauses may threaten a worker's livelihood if they leave their job.²⁸³

Workers have an inalienable right to quit their jobs.²⁸⁴ The Supreme Court has described this “right to change employers” as a critical “defense against oppressive hours, pay, working conditions, or treatment.”²⁸⁵ Strictly speaking, non-compete clauses do not prevent workers from quitting their jobs. However, non-compete clauses “burden the ability to quit, and with it the ability to demand better wages and working conditions and to resist oppressive conditions in the current job.”²⁸⁶ Non-

compete clauses burden the ability to quit by forcing workers to either remain in their current job or, as described above, take an action—such as leaving the labor force for a period of time or taking a job in a different field—that would likely affect their livelihood. For this reason, the Commission finds non-compete clauses are exploitative and coercive at the time of the worker's potential departure.

As noted above, for coercive conduct to constitute unfair method of competition, it must also burden a not insignificant volume of commerce. The Commission preliminarily finds non-compete clauses burden a not insignificant volume of commerce due to their negative effects on competitive conditions in labor markets and product and service markets, which are described above.²⁸⁷

This preliminary finding does not apply to workers who are senior executives. Non-compete clauses for senior executives are unlikely to be exploitative or coercive at the time of the executive's departure. Because many senior executives negotiate their non-compete clauses with the assistance of expert counsel, they are likely to have bargained for a higher wage or more generous severance package in exchange for agreeing to the non-compete clause.²⁸⁸ The Commission seeks comment on whether there are other categories of highly paid or highly skilled workers (*i.e.*, other than senior executives) to whom this preliminary finding should not apply.

The Commission seeks comment on all aspects of its preliminary finding that non-compete clauses are exploitative and coercive at the time of the worker's potential departure from the employer.

2. Non-Compete Clauses Are a Method of Competition

For conduct to be an “unfair method of competition” under Section 5, it must be both “unfair” and a “method of competition.” In *Ethyl*, the court distinguished between a “condition” of a marketplace, such as an oligopolistic market structure, and a “method” of competition, which it described as “specific conduct which promotes” an anticompetitive result.²⁸⁹ When an

employer uses a non-compete clause, it undertakes conduct in a marketplace. This conduct implicates competition; indeed, it has demonstrable effects on competition in both labor markets and markets for products and services.²⁹⁰ For these reasons, the Commission preliminarily finds non-compete clauses are a method of competition under Section 5. The Commission seeks comment on this preliminary finding.

B. The Justifications for Non-Compete Clauses Do Not Alter the Commission's Preliminary Determination

For the reasons described above in Part IV.A, the Commission preliminarily determines non-compete clauses are an unfair method of competition under Section 5. In this Part IV.B, the Commission preliminarily finds the justifications for non-compete clauses do not alter the Commission's preliminary determination that non-compete clauses are an unfair method of competition.

The circumstances under which a business justification can overcome a finding that conduct is an unfair method of competition are narrow. In *Fashion Originators' Guild of America v. FTC*, the Court held that, in light of “the purpose and object of this combination, its potential power, its tendency to monopoly, [and] the coercion it could and did practice upon a rival method of competition,” the Commission did not err by refusing to hear evidence related to justifications, “for the reasonableness of the methods pursued by the combination to accomplish its unlawful object is no more material than would be the reasonableness of the prices fixed by unlawful combination.”²⁹¹ In *Atlantic Refining*, the Court similarly held the Commission did not err by refusing to consider “evidence of economic justification for the program,” because, while the arrangements at issue “may well provide Atlantic with an economical method of assuring efficient product distribution among its dealers . . . the Commission was clearly justified in refusing the participants an opportunity to offset these evils by a showing of economic benefit to themselves.”²⁹²

Similarly, in *L.G. Balfour Co.*, the Commission challenged as an unfair method of competition the use of exclusive dealing contracts by a firm that manufactured and sold jewelry and other items bearing the insignia of fraternities and high schools. The firm argued the contracts were justified, in

²⁸³ See, e.g., *Mitchel*, 1 P. Wms. at 190 (citing “the mischief which may arise from [non-compete clauses] . . . to the party, by the loss of his livelihood”).

²⁸⁴ *Bailey v. Alabama*, 219 U.S. 219, 242 (1911).

²⁸⁵ *Pollock v. Williams*, 322 U.S. 4, 17–18 (1944).

²⁸⁶ See *Estlund*, *supra* note 144 at 407.

²⁸⁷ See *supra* Part IV.A.1.a.i–ii.

²⁸⁸ See, e.g., Stewart J. Schwab & Randall S. Thomas, *An Empirical Analysis of CEO Employment Contracts: What Do Top Executives Bargain For?*, 63 Wash. & Lee L. Rev. 231, 256–57 (2006) (noting that 84% of CEO employment contracts that included both a non-compete clause and a severance payment have a severance payment that is equal to or greater than the length of the non-compete period).

²⁸⁹ 729 F.2d at 139.

²⁹⁰ See *supra* Part II.B.

²⁹¹ 312 U.S. at 467–68.

²⁹² 381 U.S. at 371.

part because the fraternities and schools benefitted from uniformity in the design and workmanship of the items. The court reasoned “[w]hile it is relevant to consider the advantages of a trade practice on individual companies in the market, this cannot excuse an otherwise illegal business practice.”²⁹³ The court found the exclusive contracts were not justified, because the fraternities and schools had other means for accomplishing the goal of maintaining high quality for their jewelry and because the firm did not establish that its competitors could not satisfy its customers’ needs.²⁹⁴

In this Part IV.B, the Commission considers the commonly cited business justifications for non-compete clauses but preliminarily finds they do not alter the Commission’s preliminary determination that non-compete clauses are an unfair method of competition, for two reasons. First, employers have alternatives to non-compete clauses that reasonably achieve the same purposes while burdening competition to a less significant degree. Second, the asserted benefits from these commonly cited justifications do not outweigh the considerable harm from non-compete clauses.

1. Commonly Cited Justifications for Non-Compete Clauses

The most cited justifications for non-compete clauses are that they increase employers’ incentive to make productive investments, including in worker training, client attraction, or in creating or sharing trade secrets with workers. According to these justifications, without non-compete clauses, employment relationships are subject to an investment hold-up problem. Investment hold-up occurs where an employer—faced with the possibility a worker may depart after receiving some sort of valuable investment—opts not to make that investment in the first place, thereby decreasing the firm’s productivity and overall social welfare. For example, according to these justifications, an employer may be more reticent to invest in trade secrets or other confidential information; to share this information with its workers; or to train its workers if it knows the worker may depart for or may establish a competing firm. Courts have cited these justifications when upholding non-compete clauses under state common law or antitrust law.²⁹⁵

²⁹³ 442 F.2d at 15, citing *Motion Picture Advert. Serv. Co.*, 344 U.S. 392.

²⁹⁴ *Id.* at 14–15.

²⁹⁵ See, e.g., *U.S. v. Addyston Pipe & Steel Co.*, 85 F. 271, 281 (6th Cir. 1898); *Polk Bros., Inc. v.*

As described above in Part II.B.2.e, there is evidence non-compete clauses increase worker training and capital investment (e.g., investment in physical assets, such as machines). Non-compete clauses may increase an employer’s incentive to train their workers or invest in capital equipment because workers bound by non-compete clauses are less likely to leave their jobs for competitors. The author of the study assessing effects on capital investment finds there are likely two mechanisms driving these effects. First, firms may be more likely to invest in capital when they train their workers because worker training and capital expenditure are complementary (i.e., the return on investment in capital equipment is greater when workers are more highly trained). Second, non-compete clauses reduce competition, and firms’ returns to capital expenditure are greater when competition is lower, incentivizing firms to invest more in capital.²⁹⁶

The Commission is not aware of any evidence of a relationship between the enforceability of non-compete clauses and the rate at which companies make other types of productive investments, such as investments in creating or sharing trade secrets. Similarly, the Commission is not aware of any evidence non-compete clauses reduce trade secret misappropriation or the loss of other types of confidential information. The Commission’s understanding is there is little reliable empirical data on trade secret theft and firm investment in trade secrets in general, and no reliable data on how non-compete clauses affect these practices. The Commission understands these are difficult areas for researchers to study, due to, for example, the lack of a governmental registration requirement for trade secrets and the unwillingness of firms to disclose information about their practices related to trade secrets.²⁹⁷

The Commission is also not aware of any evidence that increased investment due to non-compete clauses leads to reduced prices for consumers. Indeed, the only empirical study of the effects of non-compete clauses on consumer prices—in the health care sector—finds increased final goods prices as the enforceability of non-compete clauses increases.²⁹⁸

Forest City Enters., 776 F.2d 185, 189 (7th Cir. 1985).

²⁹⁶ Jeffers, *supra* note 92 at 29.

²⁹⁷ See, e.g., David S. Levine & Christopher B. Seaman, *The DTSA at One: An Empirical Study of the First Year of Litigation Under the Defend Trade Secrets Act*, 53 Wake Forest L. Rev. 105, 120–22 (2018).

²⁹⁸ See *supra* Part II.B.2.a.

2. Employers Have Alternatives to Non-Compete Clauses for Protecting Valuable Investments

There are two reasons why the business justifications for non-compete clauses do not alter the Commission’s preliminary determination non-compete clauses are an unfair method of competition. The first is employers have alternatives to non-compete clauses for protecting valuable investments. These alternatives may not be as protective as employers would like, but they reasonably accomplish the same purposes as non-compete clauses while burdening competition to a less significant degree.

As noted above, the most commonly cited justifications for non-compete clauses are that they increase an employer’s incentive to make productive investments—such as investing in trade secrets or other confidential information, sharing this information with its workers, or training its workers—because employers may be more likely to make such investments if they know workers are not going to depart for or establish a competing firm. However, non-compete clauses restrict considerably more activity than necessary to achieve these benefits. Rather than restraining a broad scope of beneficial competitive activity—by barring workers altogether from leaving work with the employer for a competitor and starting a business that would compete with the employer—employers have alternatives for protecting valuable investments that are much more narrowly tailored to limit impacts on competitive conditions. These alternatives restrict a considerably smaller scope of beneficial competitive activity than non-compete clauses because—while they may restrict an employee’s ability to use or disclose certain information—they generally do not prevent workers from working for a competitor or starting their own business altogether.²⁹⁹

a. Trade Secret Law

Trade secret law provides employers with an alternative means of protecting their investments in trade secrets. Trade secret law is a form of intellectual property law that protects confidential

²⁹⁹ See, e.g., *MAI Basic Four, Inc. v. Basis, Inc.*, 880 F.2d 286, 287–88 (10th Cir. 1989) (stating that workers subject to NDAs—unlike workers subject to non-compete clauses—“remain free to work for whomever they wish, wherever they wish, and at whatever they wish,” subject only to the terms that prohibit them from disclosing or using certain information.”).

business information.³⁰⁰ It also serves as an alternative to the patent system, “granting proprietary rights to particular technologies, processes, designs, or formulae that may not be able to satisfy the rigorous standards for patentability.”³⁰¹ Even where information meets standards for patentability, companies may choose to rely on trade secret law and not obtain a patent, because they wish to keep information out of the public domain.³⁰²

Trade secret law has developed significantly in recent decades. Prior to the late 1970s, trade secret law across the states was inconsistent, leading to significant uncertainty regarding the scope of trade secret protections and the appropriate remedies for misappropriation.³⁰³ Recognizing the need for more uniform laws, the American Bar Association approved the Uniform Trade Secrets Act (“UTSA”) in 1979.³⁰⁴ Forty-seven states and the District of Columbia have adopted the UTSA.³⁰⁵ The three states that have not adopted the UTSA offer protection to trade secrets under a different statute or under common law.³⁰⁶

The UTSA provides a civil cause of action for trade secret misappropriation, which refers to disclosure or use of a trade secret by a former employee without express or implied consent.³⁰⁷ The UTSA also provides for injunctive and monetary relief, including compensatory damages, punitive damages, and attorney’s fees.³⁰⁸ In some states, under the “inevitable disclosure doctrine,” courts may enjoin a worker from working for a competitor of the worker’s employer where it is inevitable the worker will disclose trade secrets in the performance of the worker’s job duties.³⁰⁹ The inevitable disclosure doctrine is highly controversial. Several states have declined to adopt it altogether, citing the doctrine’s harsh effects on worker mobility.³¹⁰ Other states have required employers to meet

high evidentiary burdens related to inevitability, irreparable harm, and bad faith before issuing an injunction pursuant to the doctrine.³¹¹

In addition, in 2016, Congress enacted the Defend Trade Secrets Act of 2016 (“DTSA”), which established a civil cause of action under federal law for trade secret misappropriation.³¹² The DTSA brought the rights of trade secret owners “into alignment with those long enjoyed by owners of other forms of intellectual property, including copyrights, patents, and trademarks.”³¹³ Similar to state laws modeled on the UTSA, the DTSA authorizes civil remedies for trade secret misappropriation, including injunctive relief, damages (including punitive damages), and attorney’s fees.³¹⁴ The DTSA also authorizes a court, in “extraordinary circumstances,” to issue civil *ex parte* orders for the “seizure of property necessary to prevent the propagation or dissemination of the trade secret that is the subject of the action.”³¹⁵

Furthermore, trade secret theft is a federal crime. The Economic Espionage Act of 1996 (“EEA”) makes it a federal crime to steal a trade secret for either (1) the benefit of a foreign entity (“economic espionage”) or (2) the economic benefit of anyone other than the owner (“theft of trade secrets”).³¹⁶ The EEA authorizes substantial criminal fines and penalties for these crimes.³¹⁷ The EEA further authorizes criminal or civil forfeiture, including of “any property constituting, or derived from, any proceeds obtained directly or indirectly as a result of” an EEA offense.³¹⁸ The EEA also requires offenders to pay restitution to victims of trade secret theft.³¹⁹

Under these laws, the term “trade secret” is defined expansively and includes a wide range of confidential information. The UTSA generally defines a “trade secret” as information that (1) derives independent economic value from not being generally known to other persons who can obtain economic value from its disclosure or use and (2) is the subject of reasonable efforts to

maintain its secrecy.³²⁰ The DTSA and EEA use a similar definition.³²¹ The Supreme Court has held “some novelty” is required for information to be a trade secret, because “that which does not possess novelty is usually known.”³²² Overall, the definition of “trade secret” covers a wide range of information employers seek to protect from disclosure. As the high court of one state noted, “[t]here is virtually no category of information that cannot, as long as the information is protected from disclosure to the public, constitute a trade secret.”³²³

The viability of trade secret law as a means for redressing trade secret theft is illustrated by the fact that firms regularly bring claims under trade secret law. A recent analysis by the legal analytics firm Lex Machina finds 1,382 trade secret lawsuits were filed in federal court in 2021.³²⁴ Perhaps due to the enactment of the DTSA, the number of cases filed increased 30% from 2015 to 2017—from 1,075 to 1,396 cases—and has remained steady ever since.³²⁵ In addition, an analysis by the law firm Morrison Foerster finds 1,103 trade secret cases were filed in state courts in 2019.³²⁶ The number of cases filed in state court has held steady since 2015, when 1,161 cases were filed.³²⁷ The fact that a considerable number of trade secret lawsuits are filed in federal and state court—approximately 2,500 cases per year—and the fact that this number has held steady for several years suggests employers view trade secret law as a viable means of obtaining redress for trade secret theft.

In sum, intellectual property law already provides significant legal protections for an employer’s trade secrets. Trade secret law may not be as protective as some firms might like, but overall, it provides employers with a viable means of protecting their investments in trade secrets.

b. Non-Disclosure Agreements

Employers that seek to protect valuable investments also have the

³⁰⁰ Brian T. Yeh, Protection of Trade Secrets: Overview of Current Law and Legislation, Cong. Rsch. Serv. Report R43714 (April 22, 2016) at 4.

³⁰¹ *Id.*

³⁰² *Id.* at 4–5.

³⁰³ Uniform Trade Secrets Act With 1985 Amendments (Feb. 11, 1986), Prefatory Note at 1.

³⁰⁴ *Id.* Prefatory Note at 3.

³⁰⁵ See Levine & Seaman, *supra* note 297 at 113.

³⁰⁶ Yeh, *supra* note 300 at 6 n.37.

³⁰⁷ UTSA, *supra* note 303 at sec. 1(2).

³⁰⁸ *Id.* at secs. 2–4.

³⁰⁹ See, e.g., *PepsiCo, Inc. v. Redmond*, 54 F.3d 1262 (7th Cir. 1995) (affirming the district court’s order enjoining an employee from assuming his responsibilities at a competing employer for six months).

³¹⁰ See *Bayer Corp. v. Roche Molecular Sys., Inc.*, 72 F. Supp. 2d 1111, 1120 (N.D. Cal. 1999); *LeJeune v. Coin Acceptors, Inc.*, 849 A.2d 451, 471 (Md. 2004).

³¹¹ See, e.g., Eleanore R. Godfrey, *Inevitable Disclosure of Trade Secrets: Employee Mobility v. Employer Rights*, 3. J. High Tech. L. 161 (2004).

³¹² Defend Trade Secrets Act of 2016, Public Law 114–153, 130 Stat. 376 (May 11, 2016).

³¹³ U.S. Senate, Report to Accompany S. 1890, the Defend Trade Secrets Act of 2016, S. Rept. 114–220 at 3.

³¹⁴ 18 U.S.C. 1836(b)(3).

³¹⁵ 18 U.S.C. 1836(b)(2).

³¹⁶ 18 U.S.C. 1831 (economic espionage); 18 U.S.C. 1832 (theft of trade secrets).

³¹⁷ 18 U.S.C. 1831–1832.

³¹⁸ 18 U.S.C. 1834, 2323.

³¹⁹ 18 U.S.C. 1834, 2323.

³²⁰ UTSA, *supra* note 303 at sec. 1(4).

³²¹ 18 U.S.C. 1839(3).

³²² *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 476 (1974).

³²³ *U.S. West Commc’ns, Inc. v. Off. of Consumer Advoc.*, 498 NW2d 711, 714 (Iowa 1993). See also *Confold Pac., Inc. v. Polaris Indus., Inc.*, 433 F.3d 952 (7th Cir. 2006) (Posner, J.).

³²⁴ Lex Machina, Infographic, *Trade Secret Litigation Report 2021*, <https://lexmachina.com/resources/infographic-trade-secret-report/>.

³²⁵ Kenneth A. Kuwayti, John R. Lanham, & Candice F. Heinze, Morrison Foerster, Client Alert, *Happy Anniversary, DTSA: The Defend Trade Secrets Act at Five* (May 25, 2021).

³²⁶ *Id.*

³²⁷ *Id.*

ability to enter into NDAs with their workers.³²⁸ NDAs, which are also commonly known as confidentiality agreements, are contracts in which a party agrees not to disclose information the contract designates as confidential. NDAs may also prohibit workers from using information that is designated as confidential. If a worker violates an NDA, the worker may be liable for breach of contract.

Employers regularly use NDAs to protect trade secrets and other confidential business information. Researchers estimate between 33% and 57% of U.S. workers are subject to at least one NDA.³²⁹ In most states, NDAs are more enforceable than non-compete clauses.³³⁰

The widespread use of NDAs by firms has raised concerns that NDAs may inhibit innovation and worker mobility.³³¹ Scholars have also raised concerns that overbroad NDAs can function as *de facto* non-compete clauses.³³² However, the protection of trade secrets and other limited confidential business information is widely recognized as a legitimate use of NDAs.³³³

NDAs that are unusually broad in scope may function as *de facto* non-compete clauses, hence falling within the scope of the proposed rule.³³⁴ However, appropriately tailored NDAs, which would fall outside the scope of the proposed rule,³³⁵ burden competition to a lesser degree than non-compete clauses. Such NDAs may prevent workers from disclosing or

using certain information, but they generally do not prevent workers from working for a competitor or starting their own business altogether. As the U.S. Court of Appeals for the Tenth Circuit has stated, workers subject to NDAs—unlike workers subject to non-compete clauses—“remain free to work for whomever they wish, wherever they wish, and at whatever they wish,” subject only to the terms that prohibit them from disclosing or using certain information.³³⁶

c. Other Means of Protecting Valuable Investments

In addition to trade secret law and NDAs, employers have additional means of protecting valuable investments. For example, if an employer wants to prevent a worker from leaving right after receiving valuable training, the employer can sign the worker to an employment contract with a fixed duration. An employer can establish a term of employment long enough for the employer to recoup its training investment without restricting a worker's ability to compete with the employer after the worker's employment ends. Employers that wish to retain their workers can also pay the worker more, offer them better hours or better working conditions, or otherwise improve the conditions of their employment. These are all viable alternatives for protecting training investments, and other investments an employer may make, that do not restrict a worker's ability to work for a competitor of the employer or a rival's ability to compete against the worker's employer to attract the worker.

Proponents of non-compete clauses sometimes assert that, without non-compete clauses, firms will be unable to protect their trade secrets or other valuable investments. However, there are three states in which non-compete clauses are generally unavailable to employers today: California, North Dakota, and Oklahoma. In these three states, employers generally cannot enforce non-compete clauses, so they must protect their investments using one or more of the alternatives described above. The experiences of these states suggest the alternatives described above are fundamentally viable for protecting valuable firm investments.

Non-compete clauses have been void in California since 1872, in North Dakota since 1877, and in Oklahoma since 1890.³³⁷ California is a state where

large companies have succeeded—it is home to four of the world's ten largest companies by market capitalization—and it also maintains a vibrant startup culture.³³⁸ Since the 1980s, California has become the global center of the technology sector, and technology firms are highly dependent on protecting trade secrets and other confidential information.³³⁹ (Indeed, researchers have posited that high-tech clusters in California may have been aided by increased labor mobility due to the unenforceability of non-compete clauses.³⁴⁰) In North Dakota and Oklahoma, the energy industry has thrived, and firms in the energy industry depend on the ability to protect trade secrets and other confidential information.

The economic success in these three states of industries highly dependent on trade secrets and other confidential information illustrates that companies have viable alternatives to non-compete clauses for protecting valuable investments. Relative to non-compete clauses, these alternatives are more narrowly tailored to limit impacts on competitive conditions.

The Commission seeks comment on its preliminary finding that employers have reasonable alternatives to non-compete clauses for protecting their investments.

3. The Asserted Benefits From These Justifications Do Not Outweigh the Harms From Non-Compete Clauses

The second reason why the commonly cited business justifications for non-compete clauses do not alter the Commission's preliminary determination that non-compete clauses are an unfair method of competition is that, overall, the asserted benefits from these justifications do not outweigh the harms from non-compete clauses.

As described above, the Commission preliminarily finds that, for some workers, non-compete clauses are exploitative and coercive because they take advantage of unequal bargaining power between employers and workers at the time of contracting.³⁴¹ The

N.W.2d 26, 30 (N.D. 1993) (North Dakota); Brandon Kemp, *Noncompetes in Oklahoma Mergers and Acquisitions*, 88 Okla. Bar J. 128 (Jan. 21, 2017) (Oklahoma).

³³⁸ Josh Dylan, *What Is Market Cap In Stocks?*, *Nasdaq.com* (Aug. 12, 2022); Ewing Marion Kauffman Found., *State Entrepreneurship Rankings*, https://www.realclearpublicaffairs.com/public_affairs/2019/02/25/kauffman_foundation_state_entrepreneurship_rankings.html.

³³⁹ See, e.g., Gilson, *supra* note 88 at 594–95.
³⁴⁰ *Id.*; Fallick, Fleischman, & Rebitzer, *supra* note 89.

³⁴¹ See *supra* Part IV.A.1.b.

³²⁸ In this NPRM, we use the term “NDA” to refer to contractual provisions that are designed to protect trade secrets or other business information that has economic value. Employers may also seek to use NDAs to protect other kinds of information, such as information about discrimination, harassment, sexual assault, corporate wrongdoing, or information that may disparage the company or its executives or employees. These types of NDAs have been widely criticized for, among other things, their pernicious effects on workers. See, e.g., Rachel Arnov-Richman et al., *Supporting Market Accountability, Workplace Equity, and Fair Competition by Reining In Non-Disclosure Agreements*, UC-Hastings Research Paper Forthcoming at 2–6 (January 2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4022812.

³²⁹ *Id.*

³³⁰ See Chris Montville, *Reforming the Law of Proprietary Information*, 56 Duke L.J. 1159, 1179–83 (2007).

³³¹ See Rex N. Alley, *Business Information and Non-Disclosure Agreements: A Public Policy Framework*, 116 Nw. L. Rev. 817, 832 (2022).

³³² See, e.g., Arnov-Richman et al., *supra* note 328 at 5. See also Brown, 57 Cal. App. 5th at 319.

³³³ See Montville, *supra* note 330 at 1179–83.

³³⁴ See proposed § 910.1(b)(2) (describing the functional test for whether a contractual term is a non-compete clause) and *infra* Part V (in the section-by-section analysis for proposed § 910.1(b)).

³³⁵ *Id.*

³³⁶ *MAI Basic Four, Inc.*, 880 F.2d at 287–88.

³³⁷ Gilson, *supra* note 88 at 616 (California); *Werlinger v. Mutual Service Casualty Ins. Co.*, 496

Commission also preliminarily finds that, for some workers, non-compete clauses are exploitative and coercive at the time of the worker's potential departure from the employer because they force a worker to either stay in a job they want to leave or choose an alternative that likely impacts their livelihood.³⁴² For these workers, for whom non-competes are facially unfair, the justifications for non-compete clauses must overcome a high bar to alter the Commission's preliminary determination that non-compete clauses are an unfair method of competition.³⁴³

In addition, non-compete clauses cause considerable harm to competition in labor markets and product and service markets. There is evidence non-compete clauses harm both workers and consumers. Non-compete clauses obstruct competition in labor markets because they inhibit optimal matches from being made between employers and workers across the labor force. The available evidence indicates increased enforceability of non-compete clauses substantially reduces workers' earnings, on average, across the labor force generally and for specific types of workers.³⁴⁴

In addition to the evidence showing non-compete clauses reduce earnings for workers across the labor force, there is also evidence non-compete clauses reduce earnings specifically for workers who are not subject to non-compete clauses.³⁴⁵ These workers are harmed by non-compete clauses, because their wages are depressed, but they do not necessarily benefit from any incentives for increased training that non-compete clauses may provide.

Overall, these harms to workers are significant. The Commission estimates that the proposed rule, which would prohibit employers from using non-compete clauses, would increase workers' total earnings by \$250 to \$296 billion per year.³⁴⁶

The available evidence also indicates non-compete clauses negatively affect competition in product and service markets. There is evidence non-compete clauses increase consumer prices and concentration in the health care sector.³⁴⁷ There is also evidence non-compete clauses foreclose the ability of competitors to access talent by effectively forcing future employers to buy out workers from their non-compete

clauses if they want to hire them.³⁴⁸ The weight of the evidence also indicates non-compete clauses have a negative impact on new business formation and innovation.³⁴⁹ These harms are significant. For example, with respect to consumer prices in the health care sector alone, the Commission estimates health spending would decrease by \$148 billion annually due to the proposed rule.³⁵⁰

In the Commission's preliminary view, the asserted benefits from non-compete clauses do not outweigh these harms. In short, while there is considerable evidence non-compete clauses harm both workers and consumers, the evidence that non-compete clauses benefit workers or consumers is scant.

As described above, the most common justification for non-compete clauses is they increase employers' incentive to make productive investments in, for example, trade secrets, customer lists, worker training, and capital investment. There is evidence non-compete clauses increase employee training and capital investment, as noted above.³⁵¹ However, the considerable harms to workers and consumers are not outweighed because an employer has some marginally greater ability to protect trade secrets, customer lists, and other firm investments, or because the worker is receiving increased training, or because the firm has increased capital investments. If they were, workers would have higher earnings when non-compete clauses are more readily available to firms (*i.e.*, when legal enforceability of non-compete clauses increases) or prices for consumers would be lower. However, the empirical economic literature shows workers generally have lower, not higher, earnings when non-compete clause enforceability increases.

Moreover, the Commission is also not aware of any evidence these potential benefits of non-compete clauses lead to reduced prices for consumers. Indeed, the only empirical study of the effects of non-compete clauses on consumer prices—in the health care sector—finds increased final goods prices as the enforceability of non-compete clauses increases.³⁵² Furthermore, the Commission is not aware of any evidence non-compete clauses reduce trade secret misappropriation or the loss of other types of confidential information. The Commission's

understanding is there is little reliable empirical data on trade secret theft and firm investment in trade secrets in general, and no reliable data on how non-compete clauses affect these practices. The Commission is also not aware of evidence that, in the three states in which non-compete clauses are generally void, the inability to enforce non-compete clauses has materially harmed workers or consumers in those states.

As a result, the Commission preliminarily finds the asserted benefits from non-compete clauses do not outweigh the harms. The Commission seeks comment on this preliminary finding.

V. Section-by-Section Analysis

The Commission is proposing to create a new Subchapter J in Chapter 16 of the Code of Federal Regulations. Subchapter J would be titled "Rules Concerning Unfair Methods of Competition." Within Subchapter J, the Commission is proposing to create 16 CFR part 910—the Non-Compete Clause Rule.³⁵³ The Commission describes each section of the proposed rule below.

Section 910.1 Definitions

Proposed § 910.1 would contain definitions of terms that would be used in the Rule.

1(a) Business Entity

Proposed § 910.1(a) would define the term business entity. This term would be used in proposed § 910.3, which would contain an exception for certain non-compete clauses. Under the exception, the Rule would not apply to a non-compete clause entered into by a person who is selling a business entity or otherwise disposing of all of the person's ownership interest in the business entity, or by a person who is selling all or substantially all of a business entity's operating assets, when the person restricted by the non-compete clause is a substantial owner of, or substantial member or substantial partner in, the business entity at the time the person enters into the non-compete clause. The proposed rule would also use the term business entity in proposed § 910.1(e), which would define substantial owner, substantial member, or substantial partner as an owner, member, or partner holding at least a 25% ownership interest in a business entity.

Proposed § 910.1(a) would define the term business entity as a partnership, corporation, association, limited

³⁵³ For ease of reference, this Part V refers to proposed 16 CFR part 910 as "the Rule."

³⁴² See *supra* Part IV.A.1.c.

³⁴³ See, e.g., *Fashion Originators' Guild*, 312 U.S. at 467–68; *Atl. Refining Co.*, 381 U.S. at 371.

³⁴⁴ See *supra* Part II.B.1.b.

³⁴⁵ See *supra* Part II.B.1.c.

³⁴⁶ See *infra* Part VII.B.1.a.

³⁴⁷ See *supra* Part II.B.2.a.

³⁴⁸ See *supra* Part II.B.2.b.

³⁴⁹ See *supra* Part II.B.2.c–d.

³⁵⁰ See *infra* Part VII.B.2.c.

³⁵¹ See *supra* Part II.B.2.e.

³⁵² See *supra* Part II.B.2.a.

liability company, or other legal entity, or a division or subsidiary thereof. The Commission is proposing to include divisions and subsidiaries in the definition because it believes the exception in proposed § 910.3 should apply where a person is selling a division or subsidiary of a business entity. The primary rationale for the sale-of-a-business exception in proposed § 910.3—that the exception may help to protect the value of a business acquired by a buyer—would also apply where a person is selling a division or subsidiary of a business entity. Applying the sale-of-a-business exception where a person is selling a division or subsidiary of a business entity would also be consistent with many state laws that exempt non-compete clauses from certain requirements when they are between the seller and buyer of a business, including a division or subsidiary of the business.³⁵⁴

The Commission seeks comment on proposed § 910.1(a).

1(b) Non-Compete Clause

Proposed § 910.1(b)(1) would define non-compete clause as a contractual term between an employer and a worker that prevents the worker from seeking or accepting employment with a person or operating a business after the conclusion of the worker's employment with the employer. The Commission believes this is a generally accepted definition of the term non-compete clause.

Proposed § 910.1(b)(1) would limit the coverage of the Rule to non-compete clauses between employers and workers. The Rule would not apply to other types of non-compete clauses—for example, non-compete clauses between two businesses, where neither is a worker pursuant to the Rule's definition of "worker."³⁵⁵ While such non-compete clauses would not be covered by the Rule, they would still be subject to federal antitrust law and all other applicable law.

Furthermore, pursuant to proposed § 910.1(b)(1), the Rule would apply only to post-employment restraints—*i.e.*, restrictions on what the worker may do after the conclusion of the worker's employment with the employer. The Rule would not apply to concurrent-employment restraints—*i.e.*, restrictions on what the worker may do during the worker's employment.

Some non-compete clauses do not use language that expressly prohibits a

worker from competing against their employer, but instead effect the same restriction by requiring workers to pay damages if they compete against their employer. State courts generally view these contractual terms as non-compete clauses.³⁵⁶ These contractual terms would also be non-compete clauses under proposed § 910.1(b)(1), because they prevent a worker from seeking or accepting work with a person or operating a business after the conclusion of the worker's employment with the employer (unless the damages specified in the contract are paid).

Proposed § 910.1(b)(2) would clarify the definition of non-compete clause in proposed § 910.1(b)(1) by explaining that whether a contractual term is a non-compete clause for purposes of the Rule would depend on a functional test. In other words, whether a contractual term is a non-compete clause would depend not on what the term is called, but how the term functions.

In addition to non-compete clauses, employers and workers enter into many other types of covenants that restrict what a worker may do after the worker leaves their job, including, among others, NDAs; non-solicitation agreements; and TRAs.³⁵⁷ The definition of non-compete clause would generally not include these types of covenants, because these covenants generally do not prevent a worker from seeking or accepting work with a person or operating a business after the conclusion of the worker's employment with the employer. These other types of covenants may affect the way a worker competes with their former employer after the worker leaves their job. However, they do not generally prevent a worker from competing with their former employer altogether; and they do not generally prevent other employers from competing for that worker's labor. For example, if a worker leaves their job with their employer and goes to work for a competitor, an NDA the worker signed with their employer may prevent the worker from disclosing certain information to the competitor. However, a standard NDA would not prevent the worker from seeking or accepting work with the competitor.

The Commission is concerned, however, that some employers may seek to evade the requirements of the Rule by implementing restrictive employment covenants other than non-compete clauses that restrain such an unusually

large scope of activity that they are *de facto* non-compete clauses. Under proposed § 910.1(b)(2), such functional equivalents would be non-compete clauses for purposes of the Rule, whether drafted for purposes of evasion or not.

Courts have taken this approach when analyzing whether a contractual term is a non-compete clause under state law. For example, in *Brown v. TGS Mgmt. Co., LLC*, a California state court held an NDA that defined confidential information "so broadly as to prevent [the plaintiff] from ever working again in securities trading" operated as a *de facto* non-compete clause and therefore could not be enforced under California law, which generally prohibits enforcement of non-compete clauses. The NDA in this case restrained a far broader scope of activity than a typical NDA. For example, it defined "confidential information" as any information that is "usable in" or "relates to" the securities industry. As a result, the court concluded it effectively prevented the worker from working in the securities industry after his employment ended and was therefore a *de facto* non-compete clause.³⁵⁸ Similarly, in *Wegmann v. London*, the U.S. Court of Appeals for the Fifth Circuit concluded liquidated damages provisions in a partnership agreement were *de facto* non-compete clauses "given the prohibitive magnitudes of liquidated damages they specify."³⁵⁹

The purpose of § 910.1(b)(2) is to clarify that, if an employer implements a restrictive covenant not called a "non-compete clause" but so unusually broad in scope it functions as such, the covenant would be within the definition of non-compete clause in proposed § 910.1(b)(1). Proposed § 910.1(b)(2) would state that the term non-compete clause includes a contractual term that is a *de facto* non-compete clause because it has the effect of prohibiting the worker from seeking or accepting work with a person or operating a business after the conclusion of the worker's employment with the employer.

Proposed § 910.1(b)(2) would also provide two examples of contractual terms that may be *de facto* non-compete clauses. The first example, based on *Brown v. TGS Mgmt. Co., LLC*, would be a non-disclosure agreement between an employer and a worker written so broadly it effectively precludes the worker from working in the same field

³⁵⁴ See, e.g., Cal. Bus. & Prof. Code sec. 16601; Mass. Gen. Laws Ann. ch. 149, sec. 24L (definition of "noncompetition agreement"); R.I. Gen. Laws sec. 28-59-2(8)(iii).

³⁵⁵ See proposed § 910.1(f).

³⁵⁶ See, e.g., *Wichita Clinic, P.A. v. Louis*, 185 P.3d 946, 951 (Kan. Ct. App. 2008); *Intermountain Eye & Laser Ctrs.*, 127 P.3d 121, 127 (Idaho 2005); *BDO Seidman v. Hirshberg*, 712 NE2d 1220, 1222-23 (N.Y. 1999).

³⁵⁷ See *supra* Part II.A.

³⁵⁸ 57 Cal. App. 5th 303, 306, 316-319 (Cal. Ct. App. 2020).

³⁵⁹ 648 F.2d 1072, 1073 (5th Cir. 1981).

after the conclusion of the worker's employment with the employer. The second example, based on *Wegmann v. London*, would be a covenant between an employer and a worker that requires the worker to pay the employer or a third-party entity for training costs if the worker's employment terminates within a specified time period, where the required payment is not reasonably related to the costs the employer incurred for training the worker.

The Commission stresses this list of examples would be a non-exclusive list. Restrictive employment covenants other than NDAs and TRAs may also constitute *de facto* non-compete clauses, depending on the facts. In addition, NDAs and TRAs may constitute *de facto* non-compete clauses under factual scenarios other than the scenarios outlined in these examples.

The Commission seeks comment on proposed § 910.1(b)(1) and (2). In addition, the Commission is concerned that workplace policies similar to non-compete clauses—such as a term in an employee handbook stating workers are prohibited from working for competitors after their employment ends—could potentially have negative effects similar to non-compete clauses if workers believe they are binding, even if they do not impose a contractual obligation. Therefore, the Commission also seeks comment on whether non-compete clause should be defined not only as a “contractual term” between an employer and a worker, but also as a provision in a workplace policy.³⁶⁰

1(c) Employer

The Rule would apply only to non-compete clauses between employers and workers.³⁶¹ Proposed § 910.1(c) would define employer as a person, as defined in 15 U.S.C. 57b–1(a)(6), that hires or contracts with a worker to work for the person. 15 U.S.C. 57b–1(a)(6) defines person as any natural person, partnership, corporation, association, or other legal entity, including any person acting under color or authority of state law. Thus, proposed § 910.1(c) would effectively define employer as any natural person, partnership, corporation, association, or other legal entity, including any person acting under color or authority of state law, that hires or contracts with a worker to work for the person.

A person, as defined in 15 U.S.C. 57b–1(a)(6), that hires or contracts with a worker to work for the person would be an employer under proposed § 910.1(c) regardless of whether the

person meets another legal definition of employer, such as a definition in federal or state labor law.

Some entities that would otherwise be employers may not be subject to the Rule to the extent they are exempted from coverage under the FTC Act. These entities include certain banks, savings and loan institutions, federal credit unions, common carriers, air carriers and foreign air carriers, and persons subject to the Packers and Stockyards Act of 1921,³⁶² as well as an entity that is not “organized to carry on business for its own profit or that of its members.”³⁶³ Where an employer is exempt from coverage under the FTC Act, the employer would not be subject to the Rule.

Furthermore, state and local government entities—as well as some private entities—may not be subject to the Rule when engaging in action protected by the state action doctrine. States are subject to the antitrust laws.³⁶⁴ However, under the state action doctrine, federal statutes do not limit the sovereign states' autonomous authority over their own officers, agents, and policies in the absence of clear congressional intent to do so.³⁶⁵ The key question is whether the conduct at issue is “compelled by direction of the state acting as a sovereign.”³⁶⁶ The state action doctrine may also be invoked by private entities in certain limited scenarios—specifically, where (1) the challenged restraint is clearly articulated as and affirmatively expressed as state policy, and (2) the policy is actively supervised by the state itself.³⁶⁷ Thus, some entities that would otherwise be employers under proposed § 910.1(c) may not be subject to the Rule when engaging in action protected by the state action doctrine. Where private entities are involved, this would likely require a highly fact-specific inquiry.

The Commission seeks comment on proposed § 910.1(c).

1(d) Employment

The proposed rule would define the term non-compete clause as a contractual term between an employer and a worker that prevents the worker from seeking or accepting employment with a person, or operating a business, after the conclusion of the worker's employment with the employer.

Proposed § 910.1(d) would define employment as work for an employer, as the term employer is defined in § 910.1(c). This proposed definition would clarify that an employment relationship exists, for purposes of the Rule, regardless of whether an employment relationship exists under another law, such as a federal or state labor law. The Commission seeks comment on proposed § 910.1(d).

1(e) Substantial Owner, Substantial Member, and Substantial Partner

The proposed rule would use the terms substantial owner, substantial member, and substantial partner in proposed § 910.3, which would exempt certain non-compete clauses from coverage under the Rule. This exception would only be available where the party restricted by the non-compete clause is a substantial owner of, or substantial member or substantial partner in, the business entity. Limiting the exception to substantial owners, substantial members, and substantial partners would ensure the exception is only available where the seller's stake in the business is large enough that a non-compete clause may be necessary to protect the value of the business acquired by the buyer.

Proposed § 910.1(e) would define substantial owner, substantial member, and substantial partner as an owner, member, or partner holding at least a 25% ownership interest in a business entity. The Commission is proposing a threshold of 25% ownership interest because the Commission believes the exception should be available where, for example, a few entrepreneurs sharing ownership interest in a startup sell their firm. In such a scenario, a non-compete clause may be necessary to protect the value of the business acquired by the buyer. For this reason, a threshold of, for example, 51% may be too high.

However, the Commission believes the exception should not be available where the ownership interest in question is so small the transfer of ownership interest would not be necessary to protect the value of the business acquired by the buyer. For example, the exception should not be available where a worker with a small amount of company stock sells stock back to the company as part of a stock redemption agreement when the worker's employment ends. The Commission believes a 25% threshold strikes the appropriate balance between a threshold that may be too high (and would exclude many scenarios in which a non-compete clause may be necessary to protect the value of the business acquired by the buyer) and a threshold

³⁶² 15 U.S.C. 45(a)(2).

³⁶³ 15 U.S.C. 44.

³⁶⁴ *Goldfarb v. Va. State Bar*, 421 U.S. 773, 791–92 (1975).

³⁶⁵ *Parker v. Brown*, 317 U.S. 341, 350–51 (1943) (construing the Sherman Act).

³⁶⁶ *Goldfarb*, 421 U.S. at 791.

³⁶⁷ *Cal. Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980).

³⁶⁰ See, e.g., D.C. Code sec. 32–581.01(15).

³⁶¹ See proposed § 910.1(b)(1).

that may be too low (and would allow the exception to apply more broadly than is needed to protect such an interest).

Instead of establishing a threshold, the Rule could simply use the terms substantial owner, substantial member, and substantial partner in proposed § 910.3 and leave the interpretation of those terms to case-by-case adjudication. However, if the Rule does not define a threshold, sellers of businesses may be unsure whether or not they are substantial owners, substantial members, and substantial partners under proposed § 910.3. Defining a threshold would provide greater clarity to the public and facilitate compliance with the Rule.

The Commission seeks comment on proposed § 910.1(e).

1(f) Worker

The Rule would apply only to non-compete clauses between employers and workers.³⁶⁸ Proposed § 910.1(f) would define worker as a natural person who works, whether paid or unpaid, for an employer. Proposed § 910.1(f) would further state the term worker includes, without limitation, an employee, individual classified as an independent contractor, extern, intern, volunteer, apprentice, or sole proprietor who provides a service to a client or customer.

As this definition states, the term worker would include not only employees, but also individuals classified as independent contractors, as well as other kinds of workers. Under proposed § 910.1(f), the term worker would include any natural person who works, whether paid or unpaid, for an employer, without regard to whether the worker is classified as an “employee” under the Fair Labor Standards Act (FLSA) or any other statute that draws a distinction between “employees” and other types of workers. Thus, gig economy workers such as rideshare drivers would be considered workers for purposes of proposed § 910.1(f).

The Commission is concerned that, if the Rule were to define workers as “employees” according to, for example, the FLSA definition, employers may misclassify employees as independent contractors to evade the Rule’s requirements. Furthermore, the Commission has no reason to believe non-compete clauses that apply to workers such as independent contractors or interns negatively affect competitive conditions to a lesser degree than non-compete clauses that apply to employees. Such non-compete

clauses may, in fact, be more harmful to competition, given that these other types of workers tend to have shorter employment relationships. In addition, the Commission does not believe employers have stronger business justifications for applying non-compete clauses to independent contractors than they would to employees.

Proposed § 910.1(f) would also state the term worker does not include a franchisee in the context of a franchisee-franchisor relationship. The Commission believes that, in some cases, the relationship between a franchisor and franchisee may be more analogous to the relationship between two businesses than the relationship between an employer and a worker. In addition, the evidentiary record before the Commission relates primarily to non-compete clauses that arise solely out of employment. The Commission has surveyed the available evidence relating to non-compete clauses and is not aware of research on the effects of applying additional legal restrictions to non-compete clauses between franchisors and franchisees. Therefore, the Commission believes it would be appropriate to clarify that a franchisee—in the context of a franchisor-franchisee relationship—is not a worker for purposes of proposed § 910.1(f).

Proposed § 910.1(f) would further clarify, however, the term worker includes a natural person who works for the franchisee or franchisor. In addition, proposed § 910.1(f) would clarify non-compete clauses between franchisors and franchisees would remain subject to federal antitrust law as well as all other applicable law. These laws include state laws that apply to non-compete clauses in the franchise context. The Commission is not proposing to find that non-compete clauses between franchisors and franchisees are beneficial to competition.

The Commission seeks comment on proposed § 910.1(f).

Section 910.2 Unfair Methods of Competition

2(a) Unfair Methods of Competition

Proposed § 910.2(a) would state it is an unfair method of competition for an employer to enter into or attempt to enter into a non-compete clause with a worker; maintain with a worker a non-compete clause; or represent to a worker that the worker is subject to a non-compete clause where the employer has no good faith basis to believe the worker is subject to an enforceable non-compete clause. In effect, proposed § 910.2(a) would categorically ban employers from using non-compete clauses, because—as

of the compliance date—employers would be prohibited from maintaining pre-existing non-compete clauses and entering into new non-compete clauses.³⁶⁹

Part IV above explains the legal basis for the Commission’s preliminary determination that the practices listed in proposed § 910.2(a) are unfair methods of competition. This section-by-section analysis for proposed § 910.2(a) describes how each of the three prongs of proposed § 910.2(a) would function and explains why the Commission is proposing a categorical ban on non-compete clauses.

How Proposed § 910.2(a) Would Function

Proposed § 910.2(a) would prohibit an employer from entering into or attempting to enter into a non-compete clause with a worker and maintaining with a worker a non-compete clause. Proposed § 910.2(a) would use both the term “enter into” and the term “maintain” to make clear it is an unfair method of competition for an employer to either (1) enter into or attempt to enter into new non-compete clauses as of the Rule’s compliance date or (2) maintain pre-existing non-compete clauses as of the compliance date. The Commission believes non-compete clauses entered into before the compliance date implicate the concerns described above in Part IV to the same degree as non-compete clauses entered into as of the compliance date.³⁷⁰ As a result, the Commission believes it would be appropriate to require employers to rescind non-compete clauses entered into before the compliance date, as well as to refrain from entering into or attempting to enter into new non-compete clauses starting on the compliance date.

Furthermore, requiring employers to rescind existing non-compete clauses would not impose significant compliance costs, due to the safe harbor in proposed § 910.2(b)(3). Under this safe harbor, an employer could comply with the requirement to rescind existing non-compete clauses by providing notice to the affected workers. In addition, proposed § 910.2(b)(2)(C) would further reduce compliance costs by providing language that would presumptively meet this notice requirement.

³⁶⁹ However, employers could still use non-compete clauses where they qualify for the exception in proposed § 910.3 for non-compete clauses between the seller and buyer of a business.

³⁷⁰ See *supra* Part IV (describing the reasons for the Commission’s preliminary determination that non-compete clauses between employers and workers are an unfair method of competition).

³⁶⁸ See proposed § 910.1(b)(1).

Proposed § 910.2(a) would prohibit an employer from attempting to enter into a non-compete clause with a worker. An employer attempts to enter a non-compete clause with a worker where, for example, the employer provides the worker with the non-compete clause, but the worker does not sign it. The Commission is concerned that attempting to enter into a non-compete clause with a worker would have *in terrorem* effects because, in this situation, the worker may still believe they are subject to a non-compete clause even if they did not sign it. For example, the worker may not recall whether they signed the non-compete clause or may not realize they are not bound by the non-compete clause unless they signed it.

Proposed § 910.2(a) would also prohibit an employer from representing to a worker that the worker is covered by a non-compete clause where the employer has no good faith basis to believe the worker is subject to an enforceable non-compete clause. Workers often lack knowledge of whether employers may enforce non-compete clauses.³⁷¹ In addition, the available evidence indicates that, in states where non-compete clause are void, workers are subject to non-compete clauses at approximately the same rate as workers in other states, suggesting that employers may believe workers are unaware of their legal rights.³⁷² Because many workers lack knowledge of whether their employer may enforce a non-compete clause under state law, they may also be unaware of any final rule issued by the Commission prohibiting employers from entering into or maintaining non-compete clauses. Employers may seek to exploit this lack of awareness by representing to workers that they are subject to a non-compete clause when they are not. This would likely have an *in terrorem* effect on workers, causing them to refrain from looking for work or taking another job, thereby furthering the adverse effects on competition motivating this proposed rule. As a result, the Commission believes it is appropriate for the Rule to prohibit employers from representing to workers that they are covered by a non-compete clause.

In addition, workers—particularly low-income workers—may lack resources to litigate against their employers. As a result, mere threats to enforce a non-compete clause may deter workers from looking for work with a

competitor or starting their own business, which would result in the anticompetitive effects described above in Part IV.A.

Under this “representation” prong of proposed § 910.2(a), an employer would be prohibited from, among other things, threatening to enforce a non-compete clause against a worker; advising a worker that, due to a non-compete clause, they should not pursue a particular job opportunity; or simply telling the worker that the worker is covered by a non-compete clause. However, under proposed § 910.2(a), this prohibition on representation would only apply where the employer has no good faith basis to believe the worker is subject to an enforceable non-compete clause. Proposed § 910.2(a) includes this “no good faith basis” exception to ensure the representation prong is consistent with the First Amendment. The Supreme Court has held “there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity.”³⁷³ Accordingly, “[t]he government may ban forms of communication more likely to deceive the public than to inform it, or commercial speech related to illegal activity.”³⁷⁴ A rule that prohibits an employer from representing to a worker that the worker is subject to a non-compete clause—where the employer has no good faith basis to believe that the worker is subject to an enforceable non-compete clause—would meet this test because, under such circumstances, an employer would be making a false claim and asserting an illegal restraint on worker activity. An employer would have no good faith basis to believe that a worker is subject to an enforceable non-compete clause where non-compete clauses are not enforceable in the relevant state or where the validity of the Rule—which would prohibit employers from maintaining or entering into non-compete clauses—has been adjudicated and upheld.

Proposed § 910.2(a) would not apply retroactively. An employer would not violate proposed § 910.2(a) where—prior to the compliance date—it entered into or attempted to enter into a non-compete clause with a worker; maintained with a worker a non-compete clause; or represented to a worker that the worker is subject to a non-compete clause. Instead, proposed § 910.2(a) would require employers to

refrain from these practices starting on the compliance date.

Why the Commission Is Proposing a Categorical Ban on Non-Compete Clauses

Except for certain non-compete clauses between the seller and buyer of a business,³⁷⁵ the proposed rule would categorically ban employers from using non-compete clauses with workers. The proposed rule would prohibit an employer from using a non-compete clause with any of its workers, without regard to the worker’s earnings or job function.

The Commission is proposing a categorical ban on non-compete clauses because, fundamentally, non-compete clauses obstruct labor market competition through a similar mechanism for all workers. Non-compete clauses block workers in a labor market from switching to jobs in which they would be better paid and more productive. This harms workers who are subject to non-compete clauses. This also harms other workers in the labor market, since jobs that may be better matches for those workers are filled by workers who are unable to leave their jobs due to non-compete clauses.³⁷⁶ And this harms other firms and potential entrants into the market, who have a more limited pool of workers from which to hire. Regardless of a worker’s income or job status, non-compete clauses block workers from switching to jobs in which they would be better paid and more productive—restricting the opportunities of all workers in that labor market.

The available data do not allow the Commission to estimate earnings effects for every occupation. However, the evidentiary record indicates non-compete clauses depress wages for a wide range of subgroups of workers across the spectrum of income and job function—from hourly workers to highly paid, highly skilled workers such as executives. The Commission therefore estimates the proposed rule would increase earnings for workers in all of the subgroups of the labor force for which sufficient data is available.³⁷⁷ Excluding these workers from the proposed rule would deny these workers the benefits of higher earnings through increased competition in the market for their labor.

The Commission recognizes there are compelling reasons for banning non-compete clauses that apply more strongly to lower-wage workers. Non-

³⁷¹ See Prescott & Starr, *supra* note 57 at 10–11.

³⁷² See Starr, Prescott, & Bishara, *supra* note 42 at 81.

³⁷³ *Cent. Hudson Gas & Elec. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 563 (1980).

³⁷⁴ *Id.* at 563–64.

³⁷⁵ See proposed § 910.3.

³⁷⁶ See *supra* Part II.B.1.

³⁷⁷ See *infra* Part VII.B.1.a.

compete clauses for lower-wage workers—such as sandwich shop workers, warehouse workers, or security guards³⁷⁸—may be more likely than non-compete clauses for higher-wage workers to be exploitative and coercive at the time of contracting and at the time of the worker's potential departure from the employer.³⁷⁹ In addition, the most commonly cited justifications for non-compete clauses appear particularly weak when applied to relatively lower-wage workers, to the extent such workers are less likely to have access to trade secrets or confidential information.³⁸⁰

The Commission believes there are also compelling reasons for banning non-compete clauses that apply more strongly to highly paid or highly skilled workers such as senior executives. As described above, the weight of the available evidence indicates non-compete clauses negatively affect new business formation, innovation, and the ability of competitors to hire skilled workers.³⁸¹ Non-compete clauses for highly paid or highly skilled workers such as senior executives may be contributing more to these harms than non-compete clauses for some other workers, to the extent such workers may be likely to start competing businesses, be hired by potential entrants or competitors, or develop innovative products and services. Non-compete clauses for highly paid or highly skilled workers such as senior executives may also block potential entrants, or raise their costs, to a high degree, because such workers are likely to be in high demand by potential entrants. As a result, prohibiting non-compete clauses for highly paid or highly skilled workers such as senior executives may have relatively greater benefits for consumers than prohibiting non-compete clauses for other workers.

For these reasons, the Commission preliminarily believes a categorical ban on non-compete clauses would best achieve the objective of the proposed rule, which is to remedy the adverse effects of non-compete clauses on competition in labor markets and product and service markets. However, the Commission also believes several alternatives to a categorical ban may also accomplish the objectives of the proposed rule to some degree, including different standards for senior

executives. These alternatives are described in detail in Part VI.

The Commission seeks comment on proposed § 910.2(a).

2(b) Existing Non-Compete Clauses

Proposed § 910.2(b) would clarify employers' obligations, and impose additional requirements, related to non-compete clauses entered into by the employer prior to the compliance date ("existing non-compete clauses").

2(b)(1) Rescission Requirement

Proposed § 910.2(b)(1) would state that, to comply with proposed § 910.2(a)—which states it is an unfair method of competition for an employer to maintain with a worker a non-compete clause—an employer that entered into a non-compete clause with a worker prior to the compliance date must rescind the non-compete clause no later than the compliance date. The reasons why the Commission is proposing this rescission requirement are described above in the section-by-section analysis for proposed § 910.2(a).

The requirements in § 910.2(b)(1)–(3) do not apply where a worker's obligation not to compete elapsed prior to the compliance date. This is because the requirements in § 910.2(b)(1)–(3) derive from § 910.2(a), which establishes it is an unfair method of competition to maintain with a worker a non-compete clause. An employer does not maintain with a worker a non-compete clause, in violation of the Rule, where the obligation not to compete elapsed prior to the compliance date. For example, if a worker left their job in 2019 and was subject to a two-year obligation not to compete, that obligation would have elapsed in 2021, and the employer would not violate the Rule by failing to rescind the non-compete clause.

The Commission seeks comment on proposed § 910.2(b)(1).

2(b)(2) Notice Requirement

Proposed § 910.2(b)(2) would require that the employer provide notice to a worker that the worker's non-compete clause has been rescinded. Proposed § 910.2(b)(2) would have three subparagraphs that would impose various requirements related to the notice.

First, proposed § 910.2(b)(2)(A) would state that an employer that rescinds a non-compete clause pursuant to § 910.2(b)(1) must provide notice to the worker that the worker's non-compete clause is no longer in effect and may not be enforced against the worker. Proposed § 910.2(b)(2)(A) would contain a notice requirement because the

Commission believes the available evidence indicates that many workers are not aware of the applicable law governing non-compete clauses or their rights under those laws.³⁸² As a result, if the Commission were to issue a final Non-Compete Clause Rule, many workers who had entered into non-compete clauses may be unaware that, due to the Rule, their employer is no longer permitted to maintain the non-compete clause. As a result, these workers may continue to refrain from leaving their job to work for a competitor or start their own business. This would negatively affect competitive conditions in the same manner the Commission is concerned about.³⁸³ A notice requirement would help address this concern by ensuring workers are informed that their non-compete clause is no longer in effect and may not be enforced against them.

Proposed § 910.2(b)(2)(A) would state further that the employer must provide the notice to the worker in an individualized communication. As such, an employer could not satisfy the notice requirement by, for example, posting a notice at the employer's workplace that workers' non-compete clauses are no longer in effect. Proposed § 910.2(b)(2)(A) would also state that the employer must provide the notice on paper or in a digital format such as, for example, an email or text message. As such, a notice communicated orally would not meet the notice requirement. Allowing employers to provide the notice in a digital format would also reduce compliance costs for employers. Proposed § 910.2(b)(2)(A) would also require the employer to provide the notice to the worker within 45 days of rescinding the non-compete clause.

Second, proposed § 910.2(b)(2)(B) would state that the employer must provide the notice to a worker who currently works for the employer. The Commission believes that most employers have contact information available for their current workers and can use this contact information to provide the notice.

Proposed § 910.2(b)(2)(B) would also state that the employer must provide the notice to a worker who formerly worked for the employer, provided that the employer has the worker's contact information readily available. Providing the notice to former workers may be even more vital than providing the notice to current workers because former workers may be refraining actively from competitive activity because they believe they are subject to

³⁷⁸ See *supra* Part II.A (listing illustrative examples of non-compete clauses).

³⁷⁹ See *infra* Part IV.A.1.b–c.

³⁸⁰ See *supra* Part IV.B (describing the most commonly cited justifications for non-compete clauses).

³⁸¹ See *supra* Part II.B.2.b–d.

³⁸² See Prescott & Starr, *supra* note 57 at 10–11.

³⁸³ See *supra* Part IV.A.1.a.

a non-compete clause. However, employers may not have contact information readily available for all former workers. Proposed § 910.2(b)(2)(B) would therefore require employers to provide the notice to former workers only where the employer has the worker's contact information readily available. The Commission believes that this requirement would strike the appropriate balance between providing notice to affected workers and minimizing compliance costs for employers.

Third, proposed § 910.2(b)(2)(C) would provide model language that would satisfy the requirement in proposed § 910.2(b)(2)(A) that the employer "provide notice to the worker that the worker's non-compete clause is no longer in effect and may not be enforced against the worker." The model language is designed to communicate the relevant information in a simple and straightforward manner. Proposed § 910.2(b)(2)(C) would also clarify that an employer may also use language that is different from the model language, provided that the language communicates to the worker that the worker's non-compete clause is no longer in effect and may not be enforced against the worker. Proposed § 910.2(b)(2)(C) would reduce compliance costs and increase compliance certainty for employers by providing employers with model language they could use, while simultaneously providing employers with the flexibility to use other language that would communicate the required information.

The Commission seeks comment on proposed § 910.2(b)(2)(A)–(C).

2(b)(3) Safe Harbor

Proposed § 910.2(b)(3) would contain a safe harbor for compliance with the rescission requirement in proposed § 910.2(b)(1). Proposed § 910.2(b)(3) would state that an employer complies with the rescission requirement described in § 910.2(b)(1) where it provides notice to a worker pursuant to § 910.2(b)(2). Consequently, to comply with the rescission requirement for purposes of the Rule, an employer could simply send a notice to a worker that is compliant with proposed § 910.2(b)(2). An employer that does so would not need to take any other steps to comply with the rescission requirement in proposed § 910.2(b)(1). The Commission believes that this safe harbor would strike an appropriate balance between ensuring that workers receive adequate notice of their rights under the Non-

Compete Clause Rule and minimizing compliance costs for employers.

The Commission seeks comment on proposed § 910.2(b)(3).

Section 910.3 Exception

Proposed § 910.3 would exempt certain non-compete clauses between the seller and buyer of a business from coverage under the Rule. Proposed § 910.3 would state that the requirements of the Rule shall not apply to a non-compete clause that is entered into by a person who is selling a business entity or otherwise disposing of all of the person's ownership interest in the business entity, or by a person who is selling all or substantially all of a business entity's operating assets, when the person restricted by the non-compete clause is a substantial owner of, or substantial member or substantial partner in, the business entity at the time the person enters into the non-compete clause. Proposed § 910.3 would also clarify that non-compete clauses covered by this exception would remain subject to federal antitrust law as well as all other applicable law.

The exception in proposed § 910.3 would apply only in a narrow set of circumstances. The Rule, as a whole, would only apply to non-compete clauses between employers and workers.³⁸⁴ As a result, the exception in proposed § 910.3 would apply only where the party restricted by the non-compete clause is a worker (for example, where the seller of a business is going to work for the acquiring business). Where the person restricted by the non-compete clause is not a worker, the Rule would not apply as an initial matter.

The Commission is proposing the exception in § 910.3 because non-compete clauses between the seller and buyer of a business may be unique in certain respects from non-compete clauses arising solely out of employment. Specifically, non-compete clauses between the seller and buyer of a business may be distinct from non-compete clauses that arise solely out of employment because they may help protect the value of the business acquired by the buyer.

This view is consistent with the law of the majority of the states, under which non-compete clauses between the seller and buyer of a business are treated differently from non-compete clauses arising solely out of employment. For example, while non-compete clauses are generally void in California, North Dakota, and Oklahoma, each of these three states exempts non-compete

³⁸⁴ See proposed § 910.1(b).

clauses between the seller and buyer of a business from this general rule.³⁸⁵ In the majority of the 47 states that enforce non-compete clauses under some circumstances, non-compete clauses between sellers and buyers of businesses are reviewed under a more lenient standard than non-compete clauses that arise solely out of employment.³⁸⁶ A frequently cited reason for this difference in treatment is that such non-compete clauses implicate an additional interest relative to non-compete clauses that arise solely out of employment: they protect the value of the business acquired by the buyer.³⁸⁷ If non-compete clauses between the seller and buyer of a business help protect the value of the business acquired by the buyer, restricting these types of non-compete clauses could potentially affect business acquisitions, including the incentives of various market actors to start, sell, or buy businesses.

The Commission further notes that the evidentiary record described above in Part II.B relates primarily to non-compete clauses that arise solely out of employment. Unlike non-compete clauses that arise solely out of employment, there has been little empirical research on the prevalence of non-compete clauses between the seller and buyer of a business. The Commission is also not aware of empirical research on the economic effects of applying additional legal restrictions to these types of non-compete clauses. In part, this is because all states permit non-compete clauses between buyers and sellers of businesses to some degree, and because the laws that apply to these types of non-compete clauses have seen fewer changes recently than the laws that apply to non-compete clauses that arise solely out of employment. As a result, there have been few natural experiments that allow researchers to assess how restricting these types of non-compete clauses may affect competition, including any effects on business acquisitions.

For these reasons, the Commission believes it may be appropriate to exempt non-compete clauses between the seller

³⁸⁵ Cal. Bus. & Prof. Code sec. 16601; N.D. Cent. Code sec. 9–08–06(1); Okla. Stat. Ann. tit. 15, secs. 218 (sale of a business) and 219 (dissolution of a partnership).

³⁸⁶ See, e.g., Fla. Stat. Ann. sec. 542.335(1)(d); *Hess Newmark Owens Wolf, Inc. v. Owens*, 415 F.3d 630, 634 (7th Cir. 2005); *Jiffy Lube Int'l, Inc. v. Weiss Bros., Inc.*, 834 F. Supp. 683, 691 (D.N.J. 1993).

³⁸⁷ See, e.g., *Strategix, Ltd. v. Infocrossing West, Inc.*, 142 Cal. App. 4th 1068, 1072–73 (Cal. Ct. App. 4th 2006); *Reed Mill & Lumber Co.*, 165 P.3d at 736; *Bybee*, 178 P.3d at 622.

and buyer of a business from coverage under the Rule. Proposed § 910.3 would clarify, however, that these non-compete clauses would remain subject to federal antitrust law and all other applicable law, including state law requiring non-compete clauses to be tailored to protect a legitimate business interest and to be limited in duration, geographic area, and the scope of activity prohibited.

Exempting non-compete clauses between the seller and buyer of a business from coverage under the Rule would not represent a finding that such non-compete clauses are beneficial to competition. It would simply reflect the Commission's view that it would be appropriate to tailor the Rule to non-compete clauses that arise solely out of employment—given that non-compete clauses between the seller and buyer of a business may implicate unique interests and have unique effects, and that the evidentiary record does not permit the Commission to assess these potential effects as thoroughly as the potential effects of restricting non-compete clauses that arise solely out of employment.

The exception in proposed § 910.3 would only apply where the seller of the business is a substantial owner of, or substantial member or substantial partner in, the business at the time the person enters into the non-compete clause. Proposed § 910.1(e) would define substantial owner, substantial member, or substantial partner as an owner, member, or partner holding at least a 25% ownership interest in a business entity. The exception would therefore not allow non-compete clauses to be applied to a business's workers in connection with the sale of a business, where those workers are not substantial owners, members, or partners. The reasons for this proposed 25% threshold are described above in the section-by-section analysis for proposed § 910.1(e).

The Commission seeks comment on proposed § 910.3.

Section 910.4 Relation to State Laws

The Supremacy Clause of the U.S. Constitution provides that the Constitution, and the laws of the United States made pursuant to the Constitution, “shall be the supreme Law of the Land.”³⁸⁸ Hence, federal law preempts any state law that conflicts with the exercise of federal power.³⁸⁹

³⁸⁸ U.S. Const. art. VI, cl. 2.

³⁸⁹ *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (citing roots in the Supremacy Clause); *McCulloch v. Md.*, U.S. Supreme Court, 4 Wheat 159 (1819) (citing the Supremacy Clause and the Necessary and Proper Clause (Article I, Section 8, clause 18)).

Such conflict preemption occurs either “where it is impossible for a private party to comply with both state and federal law” or where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”³⁹⁰

Congressional intent to preempt state law can be expressed in the statutory language itself (express preemption) or implied in the structure and purpose of federal law (implied preemption).³⁹¹ Federal regulations “have no less preemptive effect than federal statutes,”³⁹² and agencies themselves, implementing federal statutes, can expressly preempt conflicting state laws and regulations.³⁹³

In some instances, a federal law may fully preempt contrary state laws. In others, federal law may impliedly or expressly respect the continuing and concurrent exercise of state power, thus setting a regulatory “floor” but not a “ceiling.”³⁹⁴ The Commission notes that “Congress intended the federal antitrust laws to supplement, not displace, state antitrust remedies.”³⁹⁵

The proposed rule would contain an express preemption provision. Proposed § 910.4 would provide that the Rule shall supersede any state statute, regulation, order, or interpretation to the extent that such statute, regulation, order, or interpretation is inconsistent with the Rule.³⁹⁶ Proposed § 910.4 would further provide that a state statute, regulation, order, or interpretation is not inconsistent with the provisions of the Rule if the protection such statute, regulation, order, or interpretation affords any worker is greater than the protection provided under the Rule.

This preemption provision would reflect the Commission's intent that the Non-Compete Clause Rule establish a regulatory floor, not a ceiling. Under the proposed preemption provision, state laws that are inconsistent with the Rule would be preempted. One example would be a state law providing that an employer may enforce a non-compete clause against a worker where the non-compete clause is tailored to a legitimate business interest and

³⁹⁰ *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000).

³⁹¹ *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992); *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

³⁹² *Fid. Fed. Sav. & Loan Ass'n*, 458 U.S. at 153.

³⁹³ *Id.*; see also *U.S. v. Shimer*, 367 U.S. 374, 383 (1961).

³⁹⁴ See, e.g., *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 384–85 (2015).

³⁹⁵ *Cal. v. ARC Am. Corp.*, 490 U.S. 93, 102 (1989).

³⁹⁶ In this Part V, we refer to state statutes, regulations, orders, or interpretations as “state laws” for ease of reference.

reasonably limited in duration, geographic area, and scope of activity prohibited. Such a law would be inconsistent with proposed § 910.2(a), which would state that it is an unfair method of competition—and therefore a violation of Section 5 of the FTC Act—for an employer to enter into, attempt to enter into, or maintain a non-compete clause with a worker. Under proposed § 910.4, proposed § 910.2(a) would preempt the contrary state law to the extent that it conflicts with proposed § 910.2(a).

However, under the second sentence of proposed § 910.4, a state law would not conflict with the provisions of the Rule if the state law afforded greater protection to the worker than the protection provided under the Rule. For example, as noted above, proposed § 910.3 would exempt certain non-compete clauses between the seller and buyer of a business from coverage under the Rule. If a state were to prohibit employers from entering into, attempting to enter into, or maintaining all non-compete clauses—including non-compete clauses between the seller and buyer of a business—an employer could comply with both the state law and the Rule by not entering into, attempting to enter into, or maintaining non-compete clauses between the seller and buyer of a business.

The Commission seeks comment on proposed § 910.4.

Section 910.5 Compliance Date

The proposed rule would establish a separate effective date and compliance date. Under proposed § 910.5, the proposed rule's effective date would be the date that is 60 days after the final rule is published in the **Federal Register**. The proposed rule's compliance date would be the date that is 180 days after the final rule is published in the **Federal Register**. In this NPRM, the Commission refers to the 180-day period between the publication of the final rule and the compliance date as the “compliance period.”

Compliance With § 910.2(a). The Commission expects that employers would need to undertake the following two types of tasks during the compliance period to be prepared to comply with § 910.2(a) starting on the compliance date. First, starting on the compliance date, employers would be prohibited from maintaining existing non-compete clauses (*i.e.*, non-compete clauses that the employer entered into with a worker prior to the compliance

date).³⁹⁷ As a result, during the compliance period, an employer would need to assess whether to implement replacements for existing non-compete clauses, such as NDAs; draft those covenants; and then negotiate and enter into those covenants with the relevant workers. Second, an employer would be prohibited from entering into new non-compete clauses starting on the compliance date.³⁹⁸ As a result, during the compliance period, employers would need to, for example, remove any non-compete clauses from employment contracts that they provide to new workers. The Commission believes that 180 days—or approximately six months—would be enough time for employers to accomplish each of these two tasks.

Compliance With § 910.2(b)(1)–(3). To comply with § 910.2(b)(1)–(3) starting on the compliance date, an employer would be required to rescind, no later than the compliance date, any non-compete clauses that it entered into prior to the compliance date.³⁹⁹ Where an employer rescinds a non-compete clause, the employer would be required to provide notice to the worker that the worker’s non-compete clause is no longer in effect and may not be enforced against the worker.⁴⁰⁰ This notice may be provided in a digital format, such as an email or text message.⁴⁰¹ The Rule would require the employer to provide the notice to the worker within 45 days of rescinding the non-compete clause.⁴⁰² Employers would be required to provide the notice to current workers, as well as former workers where the employer has the former worker’s contact information readily available.⁴⁰³ To reduce compliance costs, the Rule would provide model language that employers may use for the notice.⁴⁰⁴ However, employers would have the flexibility to use language other than the model language, provided that it communicates to the worker that the worker’s non-compete clause is no longer in effect and may not be enforced against the worker.⁴⁰⁵ The Rule would also provide a safe harbor that would allow an employer to comply with the Rule’s rescission requirement by providing a compliant notice.⁴⁰⁶ The Commission believes that this would significantly reduce compliance costs.

The Commission believes that the 180-day compliance period would provide employers with sufficient time to prepare to rescind existing non-compete clauses no later than the compliance date.

The Commission is proposing an effective date of 60 days after publication of the final rule in the **Federal Register** because it expects that the final rule would likely be a major rule under the Congressional Review Act (CRA). Under the CRA, a “major rule” may not take effect fewer than 60 days after the rule is published in the **Federal Register**.⁴⁰⁷ The CRA further states that a rule is a “major rule” if it has an annual effect on the economy of \$100 million or more.⁴⁰⁸ The Commission believes that the impacts of the proposed rule, if finalized, would be large enough that the final rule would be a major rule under the CRA.⁴⁰⁹

The Commission seeks comment on proposed § 910.5.

VI. Alternatives to the Proposed Rule

In this Part VI, the Commission describes alternatives to the proposed rule.⁴¹⁰ This Part VI addresses the alternatives related to the rule’s fundamental design. These alternatives flow from two key questions: (1) whether the rule should impose a categorical ban on non-compete clauses or a rebuttable presumption of unlawfulness, and (2) whether the rule should apply uniformly to all workers or whether there should be exemptions or different standards for different categories of workers. The different permutations of the answers to each of these questions yield the different alternatives for the rule’s fundamental design.

This Part VI does not generally address alternatives related to the design of specific regulatory provisions. For example, proposed § 910.1(e) defines a substantial owner, substantial member, or substantial partner as an owner, member, or partner holding at least a 25% ownership interest in a business entity. In a final rule, the Commission could set this standard at a

different percentage level—for example, 50% or 10%. The Commission seeks comment on these types of granular questions not in this Part VI, but in the section-by-section analysis for the relevant provision in Part V above.

A. Two Key Dimensions of Alternatives

In Part IV above, the Commission preliminarily finds that the use of non-compete clauses by employers is an “unfair” method of competition under Section 5. For workers who are not senior executives, the Commission preliminarily finds that non-compete clauses are “unfair” under Section 5 in three independent ways. First, the use by employers of non-compete clauses is restrictive conduct that negatively affects competitive conditions. Second, non-compete clauses are exploitative and coercive at the time of contracting while burdening a not insignificant volume of commerce. Third, non-compete clauses are exploitative and coercive at the time of the worker’s potential departure from the employer while burdening a not insignificant volume of commerce.⁴¹¹

For workers who are senior executives, the Commission preliminarily finds that the use by employers of non-compete clauses is “unfair” under Section 5 because such non-compete clauses are restrictive conduct that negatively affects competitive conditions. Indeed, as described above in Part IV.A.1.a.ii, the Commission preliminarily believes that non-compete clauses for senior executives may harm competition in product markets in unique ways. (The second and third preliminary findings described above—that non-compete clauses are exploitative and coercive at the time of contracting and at the time of a worker’s potential departure—do not apply to senior executives.) In Part IV, the Commission seeks comment on whether this different unfairness analysis should also apply to highly paid or highly skilled workers who are not senior executives.

The objective of the proposed rule is to remedy these adverse effects from the use of non-compete clauses. The proposed rule would seek to accomplish this objective by prohibiting an employer from entering into or attempting to enter into a non-compete clause with a worker; maintaining with a worker a non-compete clause; and, under certain circumstances,

⁴¹¹ See *supra* Part IV.A.1. The Commission also preliminarily finds that non-compete clauses are a “method of competition.” See *supra* Part IV.A.2.

³⁹⁷ See proposed § 910.2(a).

³⁹⁸ *Id.*

³⁹⁹ See proposed § 910.2(b)(1).

⁴⁰⁰ See proposed § 910.2(b)(2)(A)–(C).

⁴⁰¹ See proposed § 910.2(b)(2)(A).

⁴⁰² *Id.*

⁴⁰³ *Id.*

⁴⁰⁴ See proposed § 910.2(b)(2)(C).

⁴⁰⁵ *Id.*

⁴⁰⁶ See proposed § 910.2(b)(3).

⁴⁰⁷ 5 U.S.C. 801(a)(3)(A).

⁴⁰⁸ 5 U.S.C. 804(2).

⁴⁰⁹ See *infra* Part VII (analyzing the costs and benefits of the proposed rule).

⁴¹⁰ The Commission intends for this Part VI to satisfy the requirements in Section 22 of the FTC Act that, in an NPRM, the Commission issue a preliminary regulatory analysis that shall contain “a description of any reasonable alternatives to the proposed rule which may accomplish the stated objective of the rule in a manner consistent with applicable law” and “a preliminary analysis of the effectiveness of the proposed rule and each alternative in meeting the stated objectives of the proposed rule.” 15 U.S.C. 57b–3(b)(1)(B)–(C).

representing to a worker that the worker is subject to a non-compete clause.⁴¹²

The proposed rule would ban non-compete clauses categorically, with a limited exception for certain non-compete clauses between the seller and buyer of a business.⁴¹³ In Part V, the Commission explains why it is proposing a categorical ban on non-compete clauses.⁴¹⁴

There are two key dimensions of alternatives related to the rule's fundamental design. First, instead of a categorical ban, the Commission could adopt a rebuttable presumption of unlawfulness. Under this approach, it would be presumptively unlawful for an employer to use a non-compete clause, but the use of a non-compete clause would be permitted if the employer could meet a certain evidentiary burden, based on a standard that would be articulated in the rule. Second, instead of applying to all workers uniformly, the Rule could include exemptions or different standards for different categories of workers. These exemptions or different standards could be based on a worker's job functions, earnings, another factor, or some combination of factors.

1. Categorical Ban vs. Rebuttable Presumption

The Commission could adopt a rebuttable presumption of unlawfulness instead of a categorical ban. Under this approach, it would be presumptively unlawful for an employer to use a non-compete clause. However, the use of a non-compete clause would be permitted if the employer could meet a certain evidentiary burden, based on a standard that would be articulated in the rule. The rationale behind this approach would be that prohibiting employers from using non-compete clauses is an appropriate default rule in light of the adverse effects on competition from their use in the aggregate; however, there may be specific sets of facts under which their use may be justified, so it would be appropriate to permit employers to use them in those cases.

Conceptually, the rebuttable presumption approach would be similar to "quick look" analysis under antitrust

law. In antitrust cases, most restraints are analyzed under the rule of reason, which entails an intensive, fact-specific assessment of market power and market structure to determine a restraint's actual effect on competition.⁴¹⁵ However, where "the great likelihood of anticompetitive effects can be easily ascertained," a court may also adopt a truncated, or "quick look," rule of reason analysis.⁴¹⁶ Courts apply quick look analysis where, "based upon economic learning and the experience of the market, it is obvious that a restraint of trade likely impairs competition."⁴¹⁷ In such cases, "the restraint is presumed unlawful and, in order to avoid liability, the defendant must either identify some reason the restraint is unlikely to harm consumers or identify some competitive benefit that plausibly offsets the apparent or anticipated harm."⁴¹⁸ A rebuttable presumption in the Rule would mirror this approach. Non-compete clauses would be presumed unlawful, based on the "economic learning and experience of the market" summarized in Part IV above, but the use of a non-compete clause would be permitted if the employer could make a showing that satisfies a certain standard.

The rebuttable presumption approach would also be similar in many respects to the current common law governing non-compete clauses. In most states, non-compete clauses are disfavored, but are permitted if an employer can identify a legitimate business interest and if the non-compete clause is reasonable with respect to geographic area, duration, and the scope of activity prohibited.⁴¹⁹ Similarly, under the rebuttable presumption approach, non-compete clauses would be presumptively unlawful but would be permitted under certain circumstances.

One important question related to the rebuttable presumption approach is what the test for rebutting the presumption should be. The Commission preliminarily believes that, if it were to adopt a rebuttable presumption in a final rule, it would adopt a test that is more restrictive than the current common-law standard. Otherwise, the Rule would be no more restrictive than current law, and the objective of the Rule—to remedy the adverse effects to competition from employers' use of non-compete clause—would not be achieved.

One option would be a test derived from the quick look test. For example, the rule could allow an employer to rebut the presumption where the employer "shows by clear and convincing evidence that the non-compete clause is unlikely to harm competition in labor markets or product or service markets, or identifies some competitive benefit that plausibly outweighs the apparent or anticipated harm." Alternatively, the test could focus exclusively on either of these two prongs: unlikelihood of harm to competition, or presence of a competitive benefit that plausibly outweighs the apparent or anticipated harm to competition. A term other than "clear and convincing evidence," such as "preponderance of the evidence," could also be used.

Another option would be a test that piggybacks on state law. For example, the rule could allow an employer to rebut the presumption where the employer "shows by clear and convincing evidence that a non-compete clause is necessary to protect a legitimate business interest." This would be a higher standard than the current common law test because it would require an employer to show not only that it has a "legitimate business interest" under state law, but that it cannot protect this interest in another way—for example, through the use of an NDA. The test could also use the term "reasonably necessary" instead of "necessary," or a term other than "clear and convincing evidence, such as "preponderance of the evidence." The Commission could also establish what "legitimate business interests" could justify a non-compete clause and which could not.

The Commission preliminarily believes the categorical ban in the proposed rule would advance the proposed rule's objectives to a greater degree than the rebuttable presumption approach. The Commission is concerned that the rebuttable presumption approach could foster confusion among employers and workers because the question of whether an employer may use a non-compete clause would depend on an abstract legal test rather than a bright-line rule. Under a categorical ban, it would be clear non-compete clauses are prohibited. In contrast, under the rebuttable presumption approach, it may be difficult for both employers and workers to know whether a particular non-compete clause meets the abstract legal test articulated in the rule. For example, it may be difficult for an employer or worker to know whether a particular non-compete clause is

⁴¹² See proposed § 910.2(a). For ease of reference, this Part VI employs the term "use of non-compete clauses" to refer to the specific conduct that the proposed rule would prohibit.

⁴¹³ See proposed § 910.3. As described in Part V (in the section-by-section analysis for proposed § 910.1(c)), the proposed rule would also not apply to employers to the extent they are exempt under Section 5(a)(2) of the FTC Act, and the proposed rule may not apply under certain circumstances due to the state action doctrine.

⁴¹⁴ See *supra* Part V, in the section-by-section analysis for proposed § 910.2(a).

⁴¹⁵ See, e.g., *Am. Express Co.*, 138 S. Ct. at 2284.

⁴¹⁶ See, e.g., *Calif. Dental Ass'n v. Fed. Trade Comm'n*, 526 U.S. 756, 770 (1999).

⁴¹⁷ *Polygram Holding, Inc. v. Fed. Trade Comm'n*, 416 F.3d 29, 36 (D.C. Cir. 2005).

⁴¹⁸ *Id.*

⁴¹⁹ See *supra* Part II.C.1.

“unlikely to harm competition in labor markets or product or service markets,” whether “there is some competitive benefit that plausibly outweighs the apparent or anticipated harm,” or whether a non-compete clause is “necessary” to protect a legitimate business interest. Furthermore, because only the Commission can enforce a rule issued under Section 6(g), the development of the law—and therefore clarity for employers—would be slow in coming.

However, the rebuttable presumption could also have some advantages over a categorical ban. If there were to be specific factual scenarios, unanticipated by the Commission, in which a particular non-compete clause did not implicate the anticompetitive concerns the Commission is concerned about, the rebuttable presumption would allow the clause to be used.

The Commission seeks comment on whether it should adopt a rebuttable presumption instead of a categorical ban and what the test for rebutting the presumption should be.

2. Uniform Rule vs. Differentiation

In addition to establishing a categorical ban on non-compete clauses, the proposed rule would apply uniformly to all workers. Employers covered by the rule—*i.e.*, employers other than those exempt from coverage under the FTC Act⁴²⁰—would be prohibited from using a non-compete clause with a worker, except in limited scenarios where the non-compete clause is between the seller and buyer of a business.⁴²¹

Rather than applying a rule uniformly to all workers, the Commission could apply different rules to different categories of workers based on a worker’s job function, occupation, earnings, another factor, or some combination of factors. For example, the rule could ban non-compete clauses for workers generally, but could apply a rebuttable presumption to non-compete clauses for workers whose earnings are above a certain threshold (or could exempt such workers altogether).

This Part VI uses the term “more-lenient standards” to refer to the more relaxed regulatory standards that would apply to certain categories of workers—such as the workers above the earnings threshold in the example above—under this approach. This Part VI also uses the term “more-stringent standards” to refer to the stricter standards that would

apply to certain categories of workers, such as the workers below the earnings threshold in the second example above.

As described above in Part II.C.1, the recent non-compete clause statutes many states have enacted have generally differentiated among categories of workers. Most of these states have restricted non-compete clauses only for workers below a threshold based on the worker’s earnings or a similar factor, such as whether the worker is non-exempt under the FLSA or whether the worker is an hourly worker.⁴²²

There are three main ways a rule could differentiate among workers. First, a rule could apply different standards to workers based on the workers’ job functions or occupations. For example, a rule could apply more-lenient standards to non-compete clauses for senior executives or could exempt them from coverage altogether.

Second, a rule could apply different standards to workers based on some combination of job functions/occupations and a worker’s earnings. For example, the rule could apply more-lenient standards to workers who qualify for the FLSA exemptions for “executives” and “learned professionals.”⁴²³ Workers qualify for these FLSA exemptions (which exempt the worker from minimum-wage and overtime-pay rules) if they earn above a certain amount and perform certain types of job duties.⁴²⁴ Another potential alternative could be to apply more-lenient standards to a worker who qualifies for any FLSA exemption.⁴²⁵

Third, like the recent state statutes described above, a rule could apply different standards based on the worker’s earnings. An earnings threshold could be relatively high (as in, *e.g.*, the State of Washington, where a non-compete clause is void unless the worker’s annual earnings exceed \$100,000 for employees and \$250,000 for independent contractors); in the middle (as in, *e.g.*, Virginia, where employers may not enter into, enforce, or threaten to enforce a non-compete clause with a worker whose average weekly earnings are less than the Commonwealth’s average weekly wage); or relatively low (as in, *e.g.*, Maryland, where non-compete clauses are void

where a worker earns equal to or less than \$15 per hour or \$31,200 per year).⁴²⁶ The Commission also believes if it were to adopt a threshold based on earnings, it would be appropriate to index the earnings level to inflation, to ensure as well as possible that the threshold continues to correspond to the Commission’s justification for it.

A rule could also differentiate among workers based on a different factor, or based on some combination of factors.

The Commission preliminarily concludes applying the rule uniformly to all workers would advance the proposed rule’s objectives to a greater degree than differentiating among workers. As described in Part V above, non-compete clauses obstruct labor market competition in a similar way for all workers, regardless of a worker’s income or job status.⁴²⁷ Whether a labor market includes high earners or low-wage workers, non-compete clauses block workers in that market from switching to jobs in which they would be better paid and more productive—restricting the opportunities of all workers in that labor market. The Commission estimates the proposed rule would increase earnings for workers across the labor force, as well as for workers in all of the subgroups of the labor force for which sufficient data are available—from hourly workers to highly paid, highly skilled workers such as executives.⁴²⁸ Excluding these workers from the proposed rule would deny these workers the benefits of higher earnings through increased competition in the market for their labor.

The Commission also preliminarily concludes a rule that applies uniformly to all workers would better ensure workers are aware of their rights under the rule. For example, the Commission believes employers generally know whether a particular worker is exempt under the FLSA, but many workers may not know this themselves. Therefore, if the Rule were to prohibit non-compete clauses with FLSA non-exempt workers, and an employer were to enter into a non-compete clause with an FLSA non-exempt worker in violation of the Rule, the worker may not know whether the non-compete clause is valid.

If the Commission were to adopt a final rule differentiating among categories of workers, it may also adopt a severability clause indicating the Commission intends for the standards to

⁴²² See *supra* Part II.C.1.

⁴²³ See 29 CFR 541.100; 29 CFR 541.200.

⁴²⁴ See Dep’t of Labor, *Fact Sheet #17A: Exemption for Executive, Administrative, Professional, Computer & Outside Sales Employees Under the Fair Labor Standards Act (FLSA)* (Sept. 2019).

⁴²⁵ See Dep’t of Labor, *Handy Reference Guide to the Fair Labor Standards Act*, entry under Exemptions, <https://www.dol.gov/agencies/whd/compliance-assistance/handy-reference-guide-flsa#8>.

⁴²⁶ See *supra* note 149 and accompanying text.

⁴²⁷ See *supra* Part V (in the section-by-section analysis for proposed § 910.2(a)).

⁴²⁸ See *infra* Part VII.B.1.a.

⁴²⁰ See *supra* Part V, in the section-by-section analysis for proposed § 910.1(c), for additional discussion of this issue.

⁴²¹ See proposed § 910.3.

be severable.⁴²⁹ If a regulatory provision is severable, and one part of the provision is invalidated by a court, the court may allow the other parts of the provision to remain in effect.⁴³⁰ When analyzing whether a provision is severable, courts consider both (a) the agency's intent and (b) whether severing the invalid parts of the provision would impair the function of the remaining parts.⁴³¹ Including a severability clause would clarify the Commission's intent that, if a court were to invalidate the standards for one category of workers, the other standards would remain in effect. The Commission also believes if it were to adopt a final rule differentiating between categories of workers, and a court were to strike down the rules for one category, that would not impair the function of the remaining provisions. If every worker falls into only one category, and one or more (but not all) of the standards were to be invalidated, an employer could simply comply with the standards that remain in effect.

The Commission seeks comment on whether it should differentiate between workers rather than adopting a rule that applies uniformly to all workers. In addition, the Commission seeks comment on what the specific threshold(s) should be.

B. Discrete Alternatives

As described above, there are two key dimensions of alternatives related to the fundamental design of the rule. The first is whether the rule should impose a categorical ban on non-compete clauses or a rebuttable presumption of unlawfulness. The second is whether the rule should apply uniformly to all workers or whether there should be exemptions or different standards for different categories of workers, using one or more thresholds based on a worker's job functions, earnings, some other factor, or some combination of factors. The different permutations of the answers to each of these questions yield the different alternatives for the rule's fundamental design. As a result, the number of potential alternatives to the proposed rule is nearly limitless. However, for the purpose of focusing public comment, this Part VI.B describes four discrete alternatives to the proposed rule. The Commission preliminarily believes each of these alternatives may further the objectives of the proposed rule, to some degree.

⁴²⁹ The Commission may adopt a severability clause even if it did not apply different standards to the different categories of workers.

⁴³⁰ See, e.g., *Davis Cnty. Solid Waste Mgmt. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir. 1997).

⁴³¹ *Id.* at 1460.

For each of the alternatives described below, the Commission could adopt a variety of different thresholds. As described above in Part VI.A.2, a threshold could be based on job functions, the worker's occupation, earnings, some other factor, or some combination of factors. A threshold could be set relatively high, relatively low, or in the middle.

1. Alternative #1: Categorical Ban Below Threshold, Rebuttable Presumption Above

Under Alternative #1, the rule would categorically ban the use of non-compete clauses for some workers and apply a rebuttable presumption of unlawfulness to non-compete clauses for the other workers. For example, the rule could ban non-compete clauses generally, but apply a rebuttable presumption to workers who qualify for the FLSA exemptions for executives or learned professionals.⁴³² Or the rule could ban non-compete clauses but apply a rebuttable presumption to workers who earn more than \$100,000 per year.

The Commission is not proposing this approach due to the preliminary concerns, described above in Parts VI.A.1 and VI.A.2, about the rebuttable presumption approach and about differentiating among categories of workers. However, the Commission seeks comment on this alternative.

2. Alternative #2: Categorical Ban Below Threshold, No Requirements Above

Under Alternative #2, the rule would categorically ban the use of non-compete clauses for some workers and not apply any requirements to the other workers. In effect, the other workers would simply be exempt from coverage under the rule. This approach would be similar to the recent non-compete clause statutes many states have enacted.⁴³³ For example, like the recent State of Washington statute, the rule could prohibit the use of non-compete clauses for employees earning \$100,000 or less per year and independent contractors earning less than \$250,000 or less per year. Or, like the recent Massachusetts and Rhode Island statutes, the rule could prohibit the use of non-compete clauses for workers who are non-exempt under the FLSA.

The Commission is not proposing this approach due to its preliminary concerns, described above in Part VI.A.2, about differentiating among categories of workers. However, the

⁴³² See *supra* note 423–424 and accompanying text.

⁴³³ See *supra* note 149.

Commission seeks comment on this alternative.

3. Alternative #3: Rebuttable Presumption for All Workers

Under Alternative #3, the rule would apply a rebuttable presumption of unlawfulness to non-compete clauses for all workers. This approach would be similar to the proposed rule in that it would apply uniformly to all U.S. workers. However, instead of a categorical ban, the rule would apply a rebuttable presumption. The Commission is not proposing this approach due to its preliminary concerns with the rebuttable presumption approach, which are described above in Part VI.A.1. However, the Commission seeks comment on this alternative.

4. Alternative #4: Rebuttable Presumption Below Threshold, No Requirements Above

Under Alternative #4, the rule would apply a rebuttable presumption of unlawfulness to non-compete clauses for some workers and not apply any requirements to the other workers. This approach would be similar to Alternative #2, except that, instead of categorically banning non-compete clauses for workers below the threshold, the rule would apply a rebuttable presumption. The Commission is not proposing this approach due to the preliminary concerns, described above in Parts VI.A.1 and VI.A.2, about the rebuttable presumption approach and about differentiating among categories of workers. However, the Commission seeks comment on this alternative.

The Commission seeks comment on each of these alternatives described in this Part VI.B, including whether the alternative would advance the objectives of the proposed rule to a greater or lesser degree than the proposed rule, and how the Commission should design the rule if it were to adopt the alternative.

C. Different Standards for Senior Executives

In addition to seeking comment generally on whether the rule should apply uniformly to all workers or differentiate between categories of workers,⁴³⁴ the Commission seeks comment specifically on whether it should adopt different standards for non-compete clauses with senior executives.⁴³⁵

⁴³⁴ See *supra* Part VI.A.2.

⁴³⁵ The Commission could also define senior executives as a separate category, but apply the

The proposed rule would categorically ban non-compete clauses for all workers, including senior executives. However, the Commission recognizes non-compete clauses for senior executives may present distinct concerns. As described in Part IV, the Commission preliminarily finds that, like non-compete clauses for other workers, non-compete clauses for senior executives negatively affect competitive conditions in labor markets.⁴³⁶ The Commission also preliminarily finds non-compete clauses for senior executives negatively affect competitive conditions in product and service markets, and they may do so in unique ways.⁴³⁷ However, unlike non-compete clauses for other workers, the Commission does not preliminarily find non-compete clauses for senior executives are exploitative and coercive at the time of contracting or at the time of the worker's potential departure.⁴³⁸

Given that non-compete clauses for senior executives may present distinct concerns, the Commission is interested in the public's views about whether different standards for senior executives would be appropriate. For example, the Commission could adopt a categorical ban on non-compete clauses for workers in general, but apply a rebuttable presumption of unlawfulness for senior executives or exempt senior executives altogether.

The Commission seeks comment on how, if the Commission were to adopt different standards for senior executives, this category of workers should be defined. The Commission is not aware of a generally accepted legal definition of "senior executive." This term may be challenging to define, given the variety of organizational structures used by employers. The Commission could cross-reference a definition in an existing federal regulation, such as the definition of "named executive officer" in Securities and Exchange Commission (SEC) Regulation S-K⁴³⁹ or the definition of "executive officers" in SEC Rule 3b-7;⁴⁴⁰ adopt a definition closely based on a definition in an existing federal regulation; adopt a new definition; define the category according to a worker's earnings; use some combination of these approaches; or use a different approach. The Commission seeks comment on what definition would draw the appropriate line—with

same standards to senior executives as to other workers.

⁴³⁶ See *supra* Part IV.A.1.a.i.

⁴³⁷ See *supra* Part IV.A.1.a.ii.

⁴³⁸ See *supra* Part IV.A.1.b-c.

⁴³⁹ 17 CFR 229.402(a)(3).

⁴⁴⁰ 17 CFR 203.501(f).

respect to which workers should be covered by the different standards—while providing sufficient clarity to employers and workers.

In addition, the Commission seeks comment on whether these different standards should also be applied to other highly paid or highly skilled workers who are not senior executives, including specifically how such a category should be defined.

D. Coverage of Non-Compete Clauses Between Franchisors and Franchisees

The proposed rule would state the term "worker" does not include a franchisee in the context of a franchisee-franchisor relationship.⁴⁴¹ As a result, the proposed rule would not cover non-compete clauses between franchisors and franchisees.⁴⁴² As described above in Part V, the Commission believes that, in some cases, the relationship between a franchisor and franchisee may be more analogous to the relationship between two businesses than the relationship between an employer and a worker. In addition, the evidentiary record before the Commission relates primarily to non-compete clauses that arise solely out of employment; the Commission has surveyed the available evidence relating to non-compete clauses and is not aware of research on the effects of applying additional legal restrictions to non-compete clauses between franchisors and franchisees. Therefore, the Commission believes it is appropriate to clarify that a franchisee—in the context of a franchisor-franchisee relationship—is not a "worker" for purposes of proposed § 910.1(f).⁴⁴³ (Proposed § 910.1(f) would explain, however, the term "worker" includes a natural person who works for the franchisee or franchisor, and non-compete clauses between franchisors and franchisees would remain subject to federal antitrust law as well as all other applicable law.)

While the Commission is not currently proposing to cover franchisor/franchisee non-compete clauses for these reasons, the Commission recognizes that, in some cases, these non-compete clauses may present concerns under Section 5 similar to the concerns presented by non-compete clauses between employers and workers. Many franchise agreements may contain non-compete clauses.⁴⁴⁴ By

⁴⁴¹ See proposed § 910.1(f).

⁴⁴² For ease of reference, this Part VI refers to these types of non-compete clauses as "franchisor/franchisee non-compete clauses."

⁴⁴³ See *supra* Part V (in the section-by-section analysis for proposed § 910.1(f)).

⁴⁴⁴ See, e.g., Brian Callaci, Sergio Pinto, Marshall Steinbaum, & Matthew Walsh, *Vertical Restraints*

restricting a franchisee's ability to start a new business, franchisor/franchisee non-compete clauses could potentially stifle new business formation and innovation, reduce the earnings of franchisees, and have other negative effects on competitive conditions similar to non-compete clauses between employers and workers. Franchisor/franchisee non-compete clauses could also potentially be exploitative and coercive in some cases, such as where there is an imbalance of bargaining power between the parties. While the relationship between franchisors and franchisees may, in some cases, be more analogous to a business-to-business relationship, many franchisees lack bargaining power in the context of their relationship with franchisors and may be susceptible to exploitation and coercion through the use of non-compete clauses.⁴⁴⁵

For these reasons, the Commission seeks comment on whether the Rule should cover franchisor/franchisee non-compete clauses and why. The Commission also seeks comment on whether, if the Rule were to cover franchisor/franchisee non-compete clauses, they should be categorically banned or subject to a rebuttable presumption of unlawfulness (and if the latter, what the standard for rebutting the presumption should be). The Commission further seeks comment on whether, if the rule were to cover franchisor/franchisee non-compete clauses, the rule should apply uniformly to all such non-compete clauses or whether certain categories of franchisor/franchisee non-compete clauses should be exempted or subject to different standards. The Commission encourages commenters to submit data or other evidence that could inform the Commission's consideration of this issue.

E. Other Alternatives

This Part VI.E describes two alternatives the Commission believes would likely not further the objectives of the proposed rule. However, this assessment is preliminary. Based on the public comments and the Commission's

and Labor Markets in Franchised Industries (July 6, 2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4155571 (finding that, in a sample of 530 franchising contracts, various types of vertical restraints were prevalent, while not specifically addressing non-compete clauses). The Commission has also frequently encountered non-compete clauses in franchise agreements. See *supra* Part II.D (describing consent orders that restricted a franchisor's ability to enforce non-compete clauses).

⁴⁴⁵ See, e.g., Brian Callaci & Sandeep Vaheesan, *Antitrust Remedies for Fissured Work*, Cornell L. Rev. (forthcoming), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4076274 at 21–22.

additional analysis, the Commission could potentially decide to adopt one or both of the alternatives described below in a final rule instead of, or in addition to, the proposed rule or one of the alternatives described above. The Commission seeks comment on each of the two alternatives described in this Part VI.E, as well as whether there are other alternatives not described in Part VI that the Commission should consider.

1. Disclosure Rule

The Commission could potentially adopt disclosure requirements related to non-compete clauses.⁴⁴⁶ For example, research suggests many workers often do not find out about non-compete clauses until after they have accepted an employment offer.⁴⁴⁷ This concern could be addressed by requiring an employer to disclose to a worker, before making the employment offer, that the worker will be subject to a non-compete clause. The employer could also potentially be required to explain the terms of the non-compete clause and how the worker would be affected by signing the non-compete clause.

While there is evidence disclosure of non-compete clauses to workers prior to acceptance of a job offer may increase earnings, increase rates of training, and increase job satisfaction for that worker,⁴⁴⁸ the Commission does not believe this alternative would achieve the objectives of the proposed rule. Merely ensuring workers are informed about non-compete clauses would not address one of the Commission's central concerns: that, in the aggregate, they are negatively affecting competitive conditions in labor markets—including impacts on workers who are not bound by non-compete clauses—and in markets for products and services. Moreover, the benefits of a disclosure rule may be limited due to the differential in bargaining power between many workers and their employers, which would hamper those workers' ability to negotiate for better employment terms.⁴⁴⁹

2. Reporting Rule

The Commission could also potentially require employers to report certain information to the Commission relating to their use of non-compete clauses. For example, employers that use non-compete clauses could be

required to submit a copy of the non-compete clause to the Commission. This would enable the Commission to monitor the use of non-compete clauses. It would also potentially discourage employers from using non-compete clauses where they are clearly not justified under existing law.

However, the Commission does not believe a reporting rule would achieve the objectives of the proposed rule. Merely requiring employers to submit their non-compete clauses to the Commission may not meaningfully reduce the prevalence of non-compete clauses. As a result, it may not remedy the extent to which non-compete clauses adversely affect competitive conditions in labor markets and product and service markets. A reporting rule would also impose significant and recurring compliance costs on employers.

The Commission seeks comment on all aspects of this Part VI, including whether the Commission should adopt one of the alternatives described above, or a different alternative, instead of the proposed rule.

VII. Analysis of Benefits and Costs of the Proposed Rule and Alternatives

The proposed rule would provide it is an unfair method of competition—and thus a violation of Section 5 of the FTC Act—for an employer to enter into or attempt to enter into a non-compete clause with a worker; maintain with a worker a non-compete clause; or represent to a worker that the worker is subject to a non-compete clause where the employer has no good faith basis to believe the worker is subject to an enforceable non-compete clause.⁴⁵⁰ The proposed rule is targeted at increasing competition in labor markets by allowing workers to move more freely between jobs and increasing competition in product markets by ensuring firms are able to hire talented workers and workers are able to found entrepreneurial ventures.

The proposed rule is intended to alleviate two primary competitive problems. First, non-compete clauses anticompetitively interfere in the functioning of labor markets without generating compensating benefits. Non-compete clauses prevent firms from competing for workers' services and increase barriers to voluntary labor mobility, obstructing the smooth functioning of labor markets, resulting in lower wages and diminished worker and firm productivity.

The second competitive problem is non-compete clauses create negative

spillovers in labor markets and in product and service markets. In labor markets, non-compete clauses negatively impact workers who are not themselves bound by non-compete clauses by preventing the opening of vacancies and thereby creating mismatches between labor and firms. In product and service markets, non-compete clauses prevent entrepreneurial growth, which negatively impacts consumers by reducing competition in those markets. Non-compete clauses also foreclose competitors' ability to access labor market talent, negatively affecting those competitors' ability to effectively compete in the marketplace. Additionally, non-compete clauses impede innovation, which may negatively impact technological growth rates.

Section 22 of the FTC Act requires the Commission to issue a preliminary regulatory analysis when publishing a proposed rule that would declare a practice to be an unfair method of competition under Section 5 of the FTC Act.⁴⁵¹ The preliminary regulatory analysis must contain (1) a concise description of the need for, and objectives of, the proposed rule; (2) a description of any reasonable alternatives to the proposed rule which may accomplish the stated objective of the rule in a manner consistent with applicable law; and (3) for the proposed rule, and for each of the alternatives described in the analysis, a preliminary analysis of the projected benefits and any adverse economic effects and any other effects.⁴⁵²

In the preliminary analysis below, we describe the anticipated impacts of the rule as proposed. Where possible, we quantify the benefits and costs. If a benefit or cost is quantified, we indicate the sources of the data relied upon. If an assumption is needed, the text makes clear which quantities are being assumed. We measure the benefits and costs of the rule against a baseline in which no rule regarding non-compete clauses has been promulgated by the Commission. The Commission solicits comments from the public to improve the assumptions used in this preliminary analysis before promulgation of any final rule.

This preliminary analysis attempts to include in its scope the broadest set of economic actors possible. The Commission invites submission of information pertaining to additional economic actors who would be affected by the proposed rule. Several of the benefits and costs described in this

⁴⁴⁶ The Commission's Franchise Rule requires non-compete clauses to be disclosed to a franchisee. 16 CFR 436(i); 436(q).

⁴⁴⁷ Marx (2011), *supra* note 55 at 706.

⁴⁴⁸ Starr, Prescott, and Bishara, *supra* note 42 at 75.

⁴⁴⁹ See *supra* Part IV.A.1.b.

⁴⁵⁰ See proposed § 910.2(a).

⁴⁵¹ 15 U.S.C. 57b-3.

⁴⁵² 15 U.S.C. 57b-3(b)(1)(A)-(C).

analysis are either quantifiable, but not monetizable (especially with respect to separation between transfers, benefits, and costs), or not quantifiable at all. The Commission therefore also invites submission of information which could be applied to quantify or monetize estimates contained in the analysis.

For some of the economic effects of non-compete clauses, conflicting evidence exists in the academic literature. We classify these effects under both benefits and costs, and discuss divergences in the evidence, as well as relative strengths and weaknesses of the evidence.

The Commission seeks comment on all aspects of the preliminary analysis presented in this Part VII as well as submissions of additional data that could inform the Commission's analysis of the benefits, any adverse economic effects, and any other effects of the proposed rule.

A. Overview of the Effects of the Proposed Rule

In this preliminary regulatory analysis, we have quantified and monetized those costs and benefits for which we are able and described all other costs and benefits. The Commission finds substantial benefits of the proposed rule: workers' earnings would likely increase by \$250–\$296 billion annually (though some portion of this represents an economic transfer from firms to workers), new firm formation and competition would increase, health care prices would fall (and prices in other markets may fall), and innovation would increase, though several of these benefits overlap (*e.g.*, increases in competition may fully or in part drive decreases in prices and increases in innovation). The Commission also finds some costs of the proposed rule: direct compliance and contract updating would result in \$1.02 to \$1.77 billion in one-time costs, and firm investment in worker training and capital assets would fall.

The nature of the estimates, however, creates substantial difficulty in calculating a bottom-line present value of the net benefit to the economy of the proposed rule. The Commission believes the substantial labor and product market benefits of the proposed rule would exceed the costs, and additionally would persist over a substantially longer time horizon than some of the one-time costs of compliance and contract updating. However, we do not present here an estimate of the net benefit, as it would necessarily omit major components of both costs and benefits. In particular, the numbers reported above are not

comparable in order to estimate the net benefit of the rule: as noted, some portion of the earnings increase estimate represents transfers rather than benefits; several benefits and costs are unmonetized in this analysis; and several of the annualized benefits and costs (including the portion of the earnings increase attributable to benefit) may persist indefinitely, as compared with the one-time compliance and contract updating costs.

B. Estimated Benefits of the Proposed Rule

In this Part VII.B, we describe the beneficial impacts of the proposed rule; provide preliminary quantitative, monetized estimates where possible; and describe benefits we can only assess qualitatively. We enumerate benefits in two broad categories (further divided into subcategories): benefits related to labor markets and benefits related to goods and service markets.

Overall, the Commission estimates worker earnings would increase by \$250–\$296 billion annually as a result of the proposed rule. While the Commission believes some of this increase represents an economic benefit, some portion of this increase likely represents a transfer of income from firms to workers, or from consumers to workers if firms pass labor costs on to consumers. The Commission also finds, however, the proposed rule would increase the rate of new firm formation, the rate of innovation, and the extent of competition in product and service markets, which may lead to lower prices for consumers, though the sizes of these effects are not quantifiable based on the estimates in the economic literature (except in the case of healthcare).

1. Benefits Related to Labor Markets

By preventing workers from changing employers or embarking upon entrepreneurial ventures, non-compete clauses prevent beneficial labor market competition in two primary ways. First, non-compete clauses prevent workers from leaving their job for higher-paying jobs, or from leveraging such an offer to increase their earnings at their current employer. Second, non-compete clauses reduce voluntary churn in labor markets. While churn is not necessarily beneficial in and of itself, voluntary churn allows workers (who would otherwise be bound by non-compete clauses) and firms to sort into the best possible matches and opens vacancies, which allow workers who are not necessarily bound by non-compete clauses to find better matches. Both mechanisms exhibit, at least in part, as earnings losses for workers when non-

compete clauses enforceability increases; however, the extent to which earnings gains associated with the proposed rule represent benefits versus transfers may depend on the mechanism. We describe in which cases we are and are not able to categorize, quantify, and monetize these estimates below.

a. Earnings

The primary impact of the proposed rule is an increase in earnings or earnings growth for workers, and more efficient functioning of labor markets. A full analysis of this benefit would seek to quantify the entire range of heterogeneity in the effect of the proposed rule on earnings. In other words, for any given worker, the likely impact on that worker's earnings is based on whether that worker has a non-compete clause, whether non-compete clauses are broadly used in their occupation/industry/local area, how much that worker earns, that worker's demographics, and much more. While some studies have sought to quantify heterogeneous impacts of non-compete clauses and their enforceability on subgroups of workers, this accounting is limited to fairly small sectors of the population. For this reason, we focus primarily on estimates of average effects across the American labor force, though we provide details on what heterogeneity has been analyzed below.

The study containing the most direct estimate of the increase in workers' earnings given a prohibition on non-compete clauses finds that earnings would increase across the labor force by an average of 3.3–13.9%.⁴⁵³ For several reasons, we primarily focus on the low end of this range: in addition to generating the most conservative estimate, this range represents an out-of-sample approximation and is furthermore based on enforceability in 2014. Since then, some states have passed legislation causing non-compete clauses to be more difficult to enforce for subsets of their workforces, therefore causing a prohibition on non-compete clauses today to have a slightly lesser effect than a prohibition would have had in 2014.⁴⁵⁴ Using total annual wage earnings in the United States for private employers in 2020 (the most recent year with finalized numbers) as a baseline,⁴⁵⁵ we estimate a total annual earnings

⁴⁵³ Johnson, Lavetti, & Lipsitz, *supra* note 63 at 2.

⁴⁵⁴ See *supra* Part II.C.1.

⁴⁵⁵ National annual earnings are taken from Bureau of Labor Statistics, *Employment and Wages Data Viewer* (last visited Dec. 9, 2022), https://data.bls.gov/cew/apps/data_views/data_views.htm#tab=Tables.

increase of \$250.05 billion. We also report the total annual earnings increase that is associated with other levels of

the percentage increase in earnings that fall within the range reported in the study in Table 1, in addition to 10-year

discounted earnings increases using both 3% and 7% discount rates.

TABLE 1

Percentage increase in earnings (%)	Total annual earnings increase (\$ billion)	Total 10-year earnings increase, 3% discount rate (\$ billion)	Total 10-year earnings increase, 7% discount rate (\$ billion)
3.3	250.05	2,132.97	1,756.24
5.0	378.86	3,231.78	2,660.98
7.0	530.41	4,524.49	3,725.37
9.0	681.95	5,817.20	4,789.76
11.0	833.50	7,109.91	5,854.15
13.0	985.04	8,402.63	6,918.54
13.9	1,053.24	8,984.35	7,397.51

Another study estimates decreased non-compete clause enforceability would increase earnings by approximately 1%. This study uses, as a control group, occupations which use non-compete clauses at a low rate: the estimate therefore represents the differential effect on occupations which use non-compete clauses at a *high* rate, relative to the control group. While the study does estimate the separate impact of non-compete clause enforceability for each group, there is no way to disentangle this effect from state-specific effects (e.g., that California does not typically enforce non-compete clauses, and also differs from other states in many ways).⁴⁵⁶ Since workers in occupations which use non-compete clauses at a low rate may also be affected by changes in non-compete clause enforceability, the reported increase in earnings likely underestimates the impact on the entire labor force. The change in enforceability which generates this estimate is a one standard deviation change, as measured using non-compete clause enforceability scores⁴⁵⁷ for all 50 states and the District of Columbia in 1991. Applying the 1% earnings effect estimate to each state (based on the scores in 2009), we calculate that each state moving to non-enforceability (as would be the case under the proposed rule) would result in an overall annual earnings increase of \$295.9 billion.⁴⁵⁸

The Commission’s preliminary finding is therefore the proposed rule would increase workers’ earnings workforce-wide by \$250–\$296 billion annually. We discuss in Part VII.B.1.b the extent to which the Commission believes this increase represents a benefit of the proposed rule versus a transfer.

Four broad classes of workers merit specific attention, as researchers have generated empirical estimates of the effects of non-compete clause enforceability based specifically on those sectors. These classes are (a) high-tech workers; (b) physicians; (c) workers paid on an hourly basis; and (d) CEOs. We clarify that the effects we present on each of these specific classes of workers are contained within the broader estimates presented above: that is, the estimates above contain each of these classes of workers, plus the rest of the labor force. The specific estimates for each class of workers are therefore presented to indicate the range of effects observed in the labor market and to illustrate the scope of empirical work that has been performed on the topic.

i. High-Tech Workers

One study examines the impact of non-compete clause enforceability on high-tech workers in Hawaii.⁴⁵⁹ That study includes estimates for the entirety of the high-tech work force, as well as for newly hired workers. Since the ban in Hawaii did not void previously signed non-compete clauses, while the proposed rule would, we use the

calculating the benefits to those in high-use occupations versus those in low-use occupations. The benefit of this approach is that it yields a total predicted earnings increase for the economy as a whole, rather than a comparison between different types of workers. However, it is likely an overestimate for workers in low-use occupations, and an underestimate for those in high-use occupations.

⁴⁵⁹ Balasubramanian et al., *supra* note 68 at S349.

estimate for newly hired workers. This is because that estimate reflects the effects on those workers who were subject to a regime with no non-compete clause enforceability. Extrapolating from the estimates for Hawaii to the average impact on high-tech workers in each state, a prohibition such as the one in this proposed rule would increase earnings of high-tech workers in the average state by 4.8%.⁴⁶⁰ Caution is recommended in interpreting this extrapolation, however, since results from one sector within one state may not necessarily inform outcomes that would occur in the rest of the country.

ii. Physicians

One study reports the effects of non-compete clause use and enforceability on the earnings growth of physicians.⁴⁶¹

Due to the limitations of the study design, the main estimate concerns the impact of non-compete clause use on earnings growth, rather than the level of earnings.⁴⁶² However, assuming physicians begin at an identical level of earnings, a physician with a non-compete clause would have an estimated 89% earnings growth over a ten-year period, versus an estimated 36% for a physician without a non-compete clause. In other words, the physician with a non-compete clause would have earnings approximately

⁴⁶⁰ The increase in earnings in each state is calculated as
$$e^{(0.0441 * (\text{State's Enforceability Score} - \text{Lowest State Enforceability Score}) / (\text{Hawaii's Enforceability Score} - \text{Lowest State's Enforceability Score})) - 1}$$
, where 0.0441 represents the impact of Hawaii’s prohibition on log earnings for newly hired high-tech workers (Table 2, Panel A, Column 5).

⁴⁶¹ Lavetti, Simon, & White, *supra* note 53 at 1025.

⁴⁶² In Table 4 of the study, the table which reports earnings effects, the authors include a “job-match” fixed effect, which rules out several alternate explanations for the authors’ findings but leaves the authors unable to estimate the base effect of having a non-compete clause on earnings.

⁴⁵⁶ Starr, *supra* note 66 at 792–93.

⁴⁵⁷ Non-compete clause enforceability scores, used for this estimate as well as several others, are calculated using various methods based on legal descriptions provided in various editions of “Non-Compete Clauses: A State-by-State Survey” by Brian M. Malsberger.

⁴⁵⁸ The total earnings increase is calculated as the sum over all states of:

$$[e^{(0.0099 * (\text{State's Enforceability Score} - \text{Lowest State Enforceability Score})) - 1}] * (\text{Total Annual Wages of the State})$$

This calculation assumes that all workers benefit from the increase in earnings, as opposed to

39% greater than the physician without.⁴⁶³

This estimate, however, is based solely on non-compete clause use, and does not consider the impact of enforceability changing. Use of non-compete clauses is likely determined by several characteristics of an employer (e.g., the value of trade secrets or client attraction, productivity gains associated with training, nearness of potential competitors), some of which may also cause changes in earnings levels or earnings growth. Taking the separate effect of non-compete clause enforceability into account, it is possible that the estimated effect on earnings growth would differ from the estimates reported above.

The combined effect of enforceability and use on earnings growth may separately be estimated using another model in the same study.⁴⁶⁴ We note that the authors state this model presents only “suggestive evidence.” Furthermore, while this model does estimate the effect of non-compete clause use on physicians’ earnings (in contrast to that reported above, which only examines earnings growth), as well as the interaction between use and enforceability, it does not report the baseline effect of non-compete clause enforceability, independent of use.⁴⁶⁵ Using those estimates, nonetheless, allows for estimation of the impact of simultaneously removing non-compete clause enforceability and non-compete clause use on earnings at various levels of experience (omitting the baseline effect of enforceability, which is not reported). For a physician with 10 years of experience in the state which enforces non-compete clauses most readily, the estimates suggest a prohibition on non-compete clauses and removing that physician’s non-compete clause would lead to a 12.7% increase in earnings, in contrast with the results of the model reported above.⁴⁶⁶ For the identical situation for a physician with just 1 year of experience, the increase in earnings would be 37.4%. We emphasize, however, that if the baseline effect of enforceability (which the authors are unable to estimate) is large,

⁴⁶³ Calculated as $1.89/1.36 - 1 = 39\%$.

⁴⁶⁴ The estimates are presented in Table 6, Column 2.

⁴⁶⁵ In Table 6 of the study, the authors use local market fixed effects: again, these fixed effects are necessary to rule out alternate explanations for their findings, but prevent estimation of the baseline impact of non-compete clause enforceability on earnings.

⁴⁶⁶ The increase in earnings are calculated as $e^B - 1$, where B is the sum of each of the coefficients on NCA, $NCA * \text{Log Exp}$, $\text{Bishara Score} * \text{NCA}$, and $\text{Bishara Score} * \text{NCA} * \text{Log Exp}$, each multiplied by the relevant variable.

it could qualitatively change the effect on earnings of a simultaneous change in enforceability and use that we report.

iii. Workers Paid on an Hourly Basis

One study analyzed how Oregon’s 2008 prohibition on non-compete clauses for hourly workers impacted their wages.⁴⁶⁷ The study estimates Oregon’s prohibition increased hourly workers’ earnings by 2.3%, with twice the effect (4.6%) on workers in occupations which use non-compete clauses at a relatively high rate.⁴⁶⁸ Extrapolating from the estimates for Oregon to the average impact on hourly workers in each state, a prohibition such as the one in this proposed rule would increase earnings of hourly workers in the average state by 2.3%.⁴⁶⁹ Caution is recommended in interpreting this extrapolation, however, since results from one segment of the workforce within one state may not necessarily inform outcomes that would occur in the rest of the country.

iv. CEOs

One estimate of the impact of non-compete clause enforceability finds that moving from full enforceability of non-compete clauses to a prohibition would increase earnings growth by 8.2% and the level of earnings by 12.7% for CEOs.⁴⁷⁰ Again ignoring heterogeneity and implementing a linear extrapolation using 2009 enforceability scores, the average CEO would experience a 9.4% increase in earnings due to the prohibition in the proposed rule.⁴⁷¹

Another study simultaneously examines the effect of use of a non-compete clause and the enforceability thereof.⁴⁷² This study finds that decreased enforceability of non-compete clauses led to lower earnings for CEOs when use of non-compete clauses is held constant. However, this study also finds that, when non-compete clause enforceability decreases (as it would

⁴⁶⁷ Lipsitz & Starr, *supra* note 46 at 143.

⁴⁶⁸ *Id.* at Table 3, columns 3 and 4, respectively; percent changes are calculated as $e^b - 1$, where b is the relevant reported coefficient.

⁴⁶⁹ The increase in earnings in each state is calculated as $e^{(0.023 * (\text{State's Enforceability Score} - \text{Lowest State Enforceability Score}) / (\text{Oregon's Enforceability Score} - \text{Lowest State's Enforceability Score}))} - 1$, where 0.023 represents the impact of Oregon’s prohibition on log earnings for hourly workers (Table 3, Column 3).

⁴⁷⁰ Garmaise, *supra* note 69 at 376–425. We assume the average level of in-state competition for the estimate of the effect on the level of earnings, as reported in Table 1.

⁴⁷¹ We first calculate the difference between each state’s score and the lowest score (which represents a full prohibition) after normalizing scores to a 0 to 1 scale. Then, we find the average of that difference (0.742) and multiply by the estimated change of 12.7% to arrive at 9.4%.

⁴⁷² Kini, Williams, & Yin, *supra* note 52 at 4701.

under the proposed rule), non-compete clause use does not stay constant; it decreases.⁴⁷³ As a result, the Commission believes the appropriate way to extrapolate based on the findings of this study is to take into account both the impact of non-compete clause enforceability decreasing and the effect of non-compete clause use decreasing.

When this relationship is taken into account, decreases in non-compete clause enforceability (as would occur under the proposed rule) result in greater earnings for CEOs. The study estimates an increase in enforceability of 1 on a 0 to 12 scale increases CEO noncompete use by 10.2 percentage points in their sample: therefore, a prohibition on non-compete clauses would affect CEOs’ earnings via the effect the study attributes to enforceability alone, as well as by changing the use of non-compete clauses by CEOs, which has its own effect on earnings, according to the study.⁴⁷⁴

Assuming a baseline level of enforceability, it is possible to use the estimates from this study to calculate the impact on CEOs’ earnings of simultaneously decreasing enforceability and non-compete clause use to zero (which would mirror the effect of the proposed rule). At the highest level of enforceability (9; Florida from 1997–2014), setting enforceability to zero and eliminating non-compete clauses from contracts would increase CEOs’ earnings by 11.4%, based on this study. From a lower baseline level of enforceability (for example, 3, as in New York from 1992 to 2014), setting enforceability to zero and eliminating non-compete clauses from contracts would increase earnings by 14.1%.⁴⁷⁵

Based on the results of these two studies, the Commission therefore believes total compensation for CEOs would increase by 9.4% as a result of the proposed rule. This estimate is based on the first study discussed: while the results from the second study are qualitatively similar, the extent to which its results can be extrapolated are murkier due to the reliance on the secondary estimate of how non-compete clause use changes with non-compete clause enforceability. Ultimately, this finding is in accordance with findings

⁴⁷³ The study estimates that an increase in enforceability of 1 on a 0 to 12 scale increases CEO noncompete use by 10.2 percentage points in their sample. *Id.* at 4718.

⁴⁷⁴ *Id.*

⁴⁷⁵ The estimated impact of an increase in enforceability on CEOs with non-compete clauses is calculated as the effect of the sum of the coefficients on CEO noncompete \times HQ Enforce and HQ enforce (i.e., $0.4\% = e^{(0.047 - 0.043)} - 1$).

in other segments of the labor force. Similar to typical workers, non-compete clauses prevent employers from competing for the labor of CEOs, including by offering better remuneration. Therefore, CEOs, like other workers, are locked into jobs in ways that prevent them from taking advantage of positive changes in labor market conditions.

b. Discussion of Transfers Versus Benefits

It is difficult to determine the extent to which the earnings effects discussed above represent transfers versus benefits. In the context of this analysis, transfers refer to “monetary payments from one group to another that do not affect total resources available to society.”⁴⁷⁶ In other words, transfers do not represent a net benefit or cost to the economy as a whole.

Broad increases in earnings when non-compete clauses are prohibited may simply represent a transfer of income from firms to workers (or, if firms pass labor costs on to consumers, from consumers to workers). There may, however, be a related benefit if the earnings increase of workers is related to market power or efficiency in the labor market. In other words, if a prohibition on non-compete clauses leads to a more efficient allocation of labor in the market, perhaps due to a rebalancing of power between workers and employers which decreases monopsony power, then the resulting earnings increases may represent a net benefit to the economy.

Additionally, if earnings increases are due to higher quality matching which results from increased labor market churn, then increased pay reflects a benefit to the economy, since workers’ higher pay reflects higher productivity.

Several pieces of evidence support the idea that at least part of the increase in earnings represents a social benefit, rather than just a transfer. As described above in Part II.B.1.c, two studies have sought to estimate the external impact of non-compete clause use or enforceability: that is, the effect of use or enforceability on individuals other than those directly affected by use or enforceability.

First, one study demonstrates when the use of non-compete clauses by employers increases, that decreases wages for workers who do not have non-compete clauses but who work in the same state and industry. This study also finds this effect is stronger where non-compete clauses are more

enforceable.⁴⁷⁷ Since the affected workers are not bound by non-compete clauses themselves, the differential in earnings does not completely represent a transfer due to a change in bargaining power between a worker bound by a non-compete clause and their employer, though available data does not allow for an estimate of the magnitude of transfers versus the total increase in economic benefit.

A second study directly estimates the external impact of a change in non-compete clause enforceability.⁴⁷⁸ While use of non-compete clauses is not observed in the study, the impacts of changes in a state’s laws are assessed on outcomes in a neighboring state. Since the enforceability of the contracts of workers in neighboring states are not affected by these law changes, the effect must represent a change related to the labor market, which workers in both states share. The estimate suggests workers in the neighboring state experience impacts on their earnings that are 87% as large as workers in the state in which enforceability changed.⁴⁷⁹ In other words, two workers who share a labor market would experience nearly the same increase in their earnings due to a prohibition on non-compete clauses, even if the prohibition only impacts one worker. While the study does not directly estimate the differential effects by use, the effects on workers unaffected by a change in enforceability may be similar to the effects on workers not bound by non-compete clauses.

Overall, these two studies suggest there are market-level dynamics governing the relationship between earnings and the enforceability of non-compete clauses: that restrictions on the enforceability of non-compete clauses impact competition in labor markets by alleviating frictions and allowing for more productive matching. Changes in enforceability or use of non-compete clauses affect earnings of workers who do not have non-compete clauses or who work in local labor markets near, but not in, locations which experience changes in enforceability. If non-compete clauses simply changed the relative bargaining power of workers and firms, without affecting market frictions or competition, then these patterns would not be observed.

With a full accounting of all other costs and benefits, one could perform a “sensitivity analysis” to estimate how

much the percentage of earnings increases that represent benefits, rather than transfers, would affect the net impact of the proposed rule. However, as discussed, we are unable to fully monetize, or even quantify, several costs and benefits associated with the proposed rule. We present, instead, a partial sensitivity analysis which answers the question: for a given level of costs, what percentage of the earnings increases would offset those costs? The costs may be interpreted as the overall *net* cost of the rule, excluding benefits associated with earnings increases: that is, the costs listed in the table are the direct compliance and contract updating costs, plus the nonquantifiable and nonmonetizable costs, minus all benefits, excluding benefits associated with earnings increases.

The estimates are presented in Table 2. In order to present the most conservative estimates possible, we assume the earnings increase represents the lowest end of the range we estimate from the empirical literature (\$250.05 billion). We discount annually at the rate of 7% (which is more conservative than a 3% discount rate, given that the costs are more front-loaded than the benefits due to the upfront compliance costs and costs of contract updating), and assume that annualized benefits and costs persist for 10 years. The first estimate, for zero or negative net cost, demonstrates that, if the non-earnings-related benefits of the proposed rule outweigh the total costs of the proposed rule, then the costs are already offset, and no portion of the earnings increase must be a benefit. The next estimate for costs is the midpoint of the estimates presented for direct compliance and contract updating costs, as estimated in Part VII.C: if the costs of the proposed rule (excluding direct compliance and contract updating costs) exactly offset the benefits (excluding earnings-related benefits), then if 0.08% of the earnings increases are benefits, they would exactly offset the estimated \$1.394 billion costs of direct compliance and contract updating (where that estimate is the midpoint of the estimated range). While the Commission does not have detailed or complete enough quantifiable and monetizable estimates to determine whether net costs are positive or negative, the rest of Table 2 presents estimates for the portion of the earnings increase which would offset net costs greater than \$1.394 billion, should they exist.

⁴⁷⁷ Starr, Frake, & Agarwal, *supra* note 76 at 961–80.

⁴⁷⁸ Johnson, Lavetti, & Lipsitz, *supra* note 63 at 26.

⁴⁷⁹ Calculated as $-0.181 / -0.207 = 87\%$. Coefficients taken from *id.* at Table 6, Column 2.

⁴⁷⁶ Off. of Mgmt. & Budget, *Circular A-4* (Sept. 17, 2003) at 38.

TABLE 2

Net cost estimate (\$ million)	Portion of earnings increase that offsets the cost estimate (%)
0 or Negative	0.00
1,394	0.08
5,000	0.28
10,000	0.57
15,000	0.85
20,000	1.14
25,000	1.42
30,000	1.71
35,000	1.99
40,000	2.28
45,000	2.56
50,000	2.85

2. Benefits Related to Product and Service Markets

There is evidence the proposed rule would positively impact the markets for products and services in multiple ways. Studies show that new firm formation would rise under a prohibition on non-compete clauses, for two primary reasons: first, workers would be free to form spin-offs which compete with their employers, contributing to increased competition and growth. Second, firms are more willing to enter markets in which they know there are potential sources of skilled and experienced labor, unhampered by non-compete clauses.

Another possible benefit of the proposed rule related to markets for products and services is that worker flows across employers contribute to knowledge sharing, resulting in increased levels of innovation.

We note that, to the extent productivity increases of firms may be shared with workers, some of the benefits outlined in this Part VII.B.2 may overlap with the earnings estimates outlined above in Part VII.B.1.a. Similarly, to the extent harms to incumbent firms (due to, e.g., increased competition) may negatively impact workers, those would also be reflected in the earnings estimates.

a. Increased Firm Formation and Competition

Intra-industry employee spinoffs (*i.e.*, firms formed by entrepreneurs who previously worked for a firm against which they now compete—also known as within-industry spinouts or WSOs) have been shown to be highly successful, on average, when compared with typical entrepreneurial ventures.⁴⁸⁰ Non-compete clauses

typically reduce the prevalence of intra-industry spinoffs, and therefore prevent entrepreneurial activity that is likely to be highly successful. One estimate implies that a one-standard-deviation increase in non-compete clause enforceability decreases the rate of WSOs by 0.13 percentage points (against a mean of 0.4%).⁴⁸¹ The proposed prohibition, by extrapolation, would result in an overall increase in the rate of WSOs by 0.56 percentage points, which would more than double the rate of WSOs. We note this is a linear approximation and cannot account for heterogeneous effects of enforceability across states, nor can it account for nonlinearities in the impact of enforceability (as neither analysis is reported in the study).

The study also estimates the impact on the entry rate of non-WSOs (*i.e.*, spinoffs into other industries), and calculates a coefficient statistically indistinguishable from zero (0.07 percentage point increase associated with a one standard deviation increase in enforceability).⁴⁸²

Another study similarly estimates the impacts of non-compete clause enforceability on departures of employees to found new firms, as well as on all new firm entry.⁴⁸³ These outcomes differ slightly from the ones previously reported: for employee departures to found new firms, the target industry of the employee spinoff is not reported (so the effect encompasses both within-industry and out-of-industry spinoffs). The latter outcome encompasses all new firm entry, not just spinoffs. There are pros and cons of this approach, relative to studying only spinoffs. On the one hand, it examines an outcome less likely to be directly impacted by non-compete clauses. On the other hand, if firms are encouraged to enter when non-compete clauses are more easily enforceable (due to, e.g., greater projected protection of knowledge assets), then this approach will likely identify effects that may appear only weakly when looking just at spinoffs.

For each outcome, the estimated effect of an increase in non-compete clause enforceability (which is, in this study, measured by a collection of discrete legal changes) is negative: an increase in non-compete clause enforceability decreases the rate at which employees

leave to become founders of firms by 0.78 percentage points, against a mean in the sample of 5% (though the result is statistically indistinguishable from zero),⁴⁸⁴ and decreases the rate of new firm entry by 0.06 firms per million people (against a mean of 0.38) for firms in the knowledge sector, compared with firms in other sectors (for which there is no statistically significant effect). Due to the design of the study, the change in legal enforceability is not quantified, and therefore no extrapolation is possible to the country as a whole.

Three more estimates related to firm entry exist in the literature. One examines the differential impacts of venture capital (“VC”) funding on firm entry: it finds a 1% increase in VC funding increases business formation by 2.3% when non-compete clauses are not enforceable, and by 0.8% when non-compete clauses are enforceable.⁴⁸⁵ Another study examined the extent to which a legal enforceability increase in Michigan affected firm entry, and found that, among all sectors, there was no change in the entry rate of new firms (none of the estimated coefficients were statistically significant).⁴⁸⁶ Among high-tech firms, the increase in enforceability was associated with a 40.3% increase in entry when compared with states that did not enforce non-compete clauses. However, the study also notes that, compared with its neighbors, or using a statistical technique to match Michigan’s trend in firm entry (synthetic control method), the estimated effect was statistically indistinguishable from zero. Finally, a study examining the effect of an increase in enforceability in Florida found small firm (fewer than 50 employees) entry fell by 5.6%, while large firm (greater than 1,000 employees) entry increased by 8.5%. Similarly, employment at large businesses rose by 15.8% following the change, while employment at smaller businesses effectively did not change.⁴⁸⁷ The net effect was a 4.4% increase in concentration, as measured by a Herfindahl-Hirschman Index, due to the overall increase in the size of

⁴⁸⁴ The estimated effect is statistically significant at the 10% level, and nearly doubles to 0.014, when attention is focused on firms which employ at least 40% of workers in the state in which their headquarters resides. This is important because it ensures that a greater portion of the workforce is subject to the local non-compete clause policy regime: a broadly dispersed company has workers subject to many different legal policies surrounding non-compete clauses, and it is therefore not surprising that the estimate is unable to distinguish a large impact of the policy changes.

⁴⁸⁵ Samila & Sorenson, *supra* note 112 at 425–38.

⁴⁸⁶ Carlino, *supra* note 86.

⁴⁸⁷ Kang & Fleming, *supra* note 120 at 674.

⁴⁸⁰ For reviews of the literature, see, e.g., Steven Klepper, *Spinoffs: A Review and Synthesis*, 6

European Mgmt. Rev. 159–71 (2009) and April Franco, *Employee Entrepreneurship: Recent Research and Future Directions*, in *Handbook of Entrepreneurship Research* (2005) 81–96.

⁴⁸¹ Starr, Balasubramanian, & Sakakibara, *supra* note 87 at 561.

⁴⁸² *Id.* at 561.

⁴⁸³ Jeffers (2019), *supra* note 92 at 1.

firms. It is important to note that firm entry, in this study, is not necessarily new business formation. Indeed, the authors describe many business entries into Florida are existing businesses which are seeking to move or establish new franchises. The observed effects may therefore be due to relocations across state lines, which would likely not occur under the proposed rule.

For the previously mentioned three sets of estimates, it is again difficult to extrapolate to a population-wide measure of impact, since the “size” of the enforceability change is not quantified.

In Part II.B.2.c above, the Commission states the weight of the evidence demonstrates new firm formation would increase under the proposed rule; however, the Commission is unable to extrapolate from the studies which examine this outcome in order to quantify or monetize the effect.

b. Innovation

Scholars have posited that a lack of non-compete clause enforceability led Silicon Valley to become a hub of technological innovation. One paper theorizes that, as workers freely flowed between knowledge firms, those workers shared ideas and generated innovations greater than what a fixed set of workers, not interacting with outside workers, could have generated.⁴⁸⁸ Studies have shown labor mobility is greater when non-compete clauses are more difficult to enforce.⁴⁸⁹ However, those same studies did not directly show innovation is aided by the free flow of knowledge workers.

If non-compete clauses inhibit innovation by creating barriers to knowledge-sharing, then a prohibition on non-compete clauses, by alleviating those barriers, would increase innovation. Studies have sought to directly quantify this effect, primarily focused on patenting activity.

One study examined the impact of non-compete clause enforceability on venture capital’s relationship with innovation. The study found that, when non-compete clauses are enforceable, venture capital induced less patenting, by 6.6 percentage points.⁴⁹⁰ Two other studies directly focused on the relationship between non-compete clause enforceability and patenting. One, examining seven changes in non-compete clause enforceability, finds a 26.6% decline in the value of patents (as

measured by changes in stock prices surrounding the date a patent is granted) associated with increases in non-compete clause enforceability.⁴⁹¹ The other, examining the impact of a legal change in enforceability in Michigan, finds an increase in non-compete clause enforceability leads to an increase in the number of patents per 10,000 residents of 0.054 (against a mean of 2.20 in Michigan prior to the legal change).⁴⁹² There is no clear reason for this discrepancy in findings. It may be due to the setting being studied: the study finding a 26.6% decline in patent value considers several legal changes in non-compete clause enforceability, rather than just using one (as in the Michigan study) or relying on cross-sectional differences (as in the study of venture capital).

While the Commission believes the strongest evidence (due to the robustness of the findings across several legal changes) indicates innovation would likely increase under the proposed rule, as described above in Part II.B.2.d, the Commission is unable to extrapolate from the relevant studies to quantify or monetize this benefit.

c. Prices

Several of the effects discussed above, as well as costs of the proposed rule on products and service markets, may possibly filter through to consumer prices. Prices, therefore, may act as a summary metric for the impacts on consumers. We note this metric is highly imperfect: for example, increased innovation due to the proposed rule could cause quality increases in products, which drives prices up. Consumers may be better off, even though prices increased. For this reason, as well as to avoid double-counting (since prices may take into account changes in innovation, investment, market structure, wages, and other outcomes), we consider evidence on prices to be corroborating evidence, rather than a unique cost or benefit on its own.

One study estimates the impact of non-compete clause enforceability on consumer prices in the market for physician services.⁴⁹³ The study estimates moving from the lowest observed non-compete clause enforceability score to the highest would increase prices by 53.3%. Extrapolating to the effect of the proposed prohibition nationwide (using 2009 enforceability scores), and applying percentage price decreases to

state-level physician spending,⁴⁹⁴ we estimate health spending would decrease by \$148.0 billion annually. We note, again, this is a large (linear) extrapolation from the estimate provided in the study. Furthermore, this amount is partially a transfer from physician practices to consumers, and additionally, we reiterate this estimate likely encompasses some of the prior estimates (*i.e.*, those regarding new firm formation or innovation), and we therefore do not count it as a standalone benefit of the proposed rule.

With respect to other industries, if the relationship between non-compete clause enforceability and prices observed in healthcare markets holds, the Commission believes prices would decrease, product and service quality would increase, or both under the proposed rule. Insofar as such effects may be driven by increases in competition (see Part VII.B.2.a), it is likely output would also increase. However, the evidence in the economic literature is solely based on healthcare markets (which do comprise a large portion of spending in the United States, but are far from all consumer spending), and while there is evidence that there are relationships between non-compete clause enforceability and concentration, innovation, new firm formation, and other product market outcomes, the Commission cannot say with certainty similar effects would be present for other products and services.

In many settings, it is theoretically plausible increases in worker earnings from restricting non-compete clauses may increase consumer prices by raising firms’ costs (though there is countervailing evidence, especially in goods manufacturing).⁴⁹⁵ We note an absence of empirical evidence that this mechanism persists in practice, as well as countervailing forces, such as the impacts on concentration described above and positive impacts on innovation (see Part II.B.2.d). Additionally, greater wages for workers freed from non-compete clauses may be due to better worker-firm matching, which could simultaneously increase wages and increase productivity, which

⁴⁹⁴ The latest available numbers are from 2014. See Ctrs. for Medicare & Medicaid Servs., *National Health Expenditure Data, Health Expenditures by State of Provider, 1980–2014* (last visited Dec. 9, 2022), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsStateHealthAccountsProvider>. We use physician and clinical spending in 2014 by state of provider.

⁴⁹⁵ Sebastian Heise, Fatih Karahan, & Ayşegül Şahin *The Missing Inflation Puzzle: The Role of the Wage-Price Pass-Through*, 54 J. Money, Credit & Banking 7 (2022).

⁴⁸⁸ Gilson, *supra* note 88.

⁴⁸⁹ See, e.g., Fallick, Fleischman, & Rebitzer, *supra* note 89 at 472–81; Johnson, Lavetti, & Lipsitz, *supra* note 42.

⁴⁹⁰ Samila & Sorenson, *supra* note 112 at 432.

⁴⁹¹ He, *supra* note 124 at 22.

⁴⁹² Carlino, *supra* note 86 at 40.

⁴⁹³ Hausman & Lavetti, *supra* note 101 at 258.

could lead to lower prices. Finally, as described in Part II.B.2.a, increases in healthcare prices are not due to pass-through of greater labor costs.

C. Estimated Costs of the Proposed Rule

In this Part VII.C, we describe the costs associated with the proposed rule; provide preliminary quantitative, monetized estimates where possible; and describe costs we can only assess qualitatively. We welcome public comment regarding the scope of the costs outlined in this Part VII.C, especially with respect to direct compliance costs and the costs of updating contractual practices.

The Commission estimates firms' direct compliance costs and the costs of firms updating their contractual practices would total \$1.02 to \$1.77 billion. The Commission also finds worker training and firm investment in capital assets would likely decrease under the proposed rule. Finally, the Commission finds inconclusive evidence that the job creation rate would diminish under the proposed rule. Given the evidence available, the Commission is unable to monetize the estimates of worker training, firm investment in capital assets, and job creation, however.

1. Direct Compliance Costs

In order to comply with the proposed rule, firms must remove non-compete clauses from workers' contracts in two ways. First, to comply with proposed § 910.2(a), which states it is an unfair method of competition to maintain with a worker a non-compete clause, firms would need to no longer include non-compete clauses in the contracts of incoming workers, which may include revising existing employment contracts. Second, to comply with proposed § 910.2(b)(1) and (2), firms would need to rescind existing non-compete clauses no later than the compliance date and provide notice to workers that the worker's non-compete clause is no longer in effect and may not be enforced against the worker.

In order to reduce compliance costs and increase compliance certainty, proposed § 910.2(b)(3) would provide that an employer complies with the rescission requirement in proposed § 910.2(b)(1) where it provides notice to a worker pursuant to § 910.2(b)(2). Furthermore, proposed § 910.2(b)(2)(C) includes model language which may be provided to the worker in order to inform the worker that their non-compete clause is no longer in effect. We estimate composing and sending this message in a digital format to all of a firm's workers and applicable former

workers would take 20 minutes of a human resources specialist's time. According to the Bureau of Labor Statistics, the median wage for a human resources specialist was \$29.95 per hour in 2021.⁴⁹⁶ The cost of compliance for currently employed workers is therefore $\$29.95/3=\9.98 per firm. According to the U.S. Census Bureau's Statistics of U.S. Businesses database, in 2019 (the most recent year with data available), there were 6.10 million firms and 7.96 million establishments in the United States.⁴⁹⁷ We estimate the percentage of firms using non-compete clauses in the U.S. at 49.4%. This estimate is based on Colvin and Shierholz's 2017 survey of business establishments. Colvin and Shierholz estimate 49% of establishments of more than 50 employees use non-compete clauses for at least some of their employees, and 32% of establishments use non-compete clauses for all of their employees.⁴⁹⁸

Conservatively assuming each establishment must engage in its own communication (*i.e.*, that a firm's headquarters does not have the ability to send a company-wide email, for example), this means the total direct compliance cost for rescinding existing non-compete clauses and providing notice is $\$9.98*7.96$ million*0.494=\$39.25 million.

To ensure incoming workers' contracts do not include non-compete clauses and they fully comply with the proposed rule, firms may employ in-house counsel, outside counsel, or human resource specialists (depending on the complexity of the relevant non-compete clause). For many firms, this process would likely be straightforward (*i.e.*, simply not using non-compete clauses or removing one section from a boilerplate contract). For other firms, it may be more difficult and require more time. We assume that, on average, ensuring contracts for incoming workers do not have non-compete clauses would take the equivalent of one hour of a lawyer's time (valued at \$61.54),⁴⁹⁹ resulting in a total cost of $\$61.54*7.96$ million*0.494=\$241.96 million. We acknowledge there may be substantial heterogeneity in the costs for individual

⁴⁹⁶ See Bureau of Lab. Stats., *Occupational Outlook Handbook, Human Resources Specialists*, <https://www.bls.gov/ooh/business-and-financial/human-resources-specialists.htm>.

⁴⁹⁷ The dataset is available at U.S. Census Bureau, *2019 SUSB Annual Data Tables by Establishment Industry*, <https://www.census.gov/data/tables/2019/econ/sub/2019-susb-annual.html> (last visited Dec. 9, 2022).

⁴⁹⁸ Alexander J.S. Colvin & Heidi Shierholz, Econ. Pol'y Inst., *Noncompete Agreements* (2019) at 1.

⁴⁹⁹ Bureau of Lab. Stats., *Occupational Outlook Handbook: Lawyers*, <https://www.bls.gov/ooh/legal/lawyers.htm>.

firms; however, we believe this number is conservative. For firms whose costs of removing non-compete clauses for incoming workers is greater, the work of ensuring contracts comply with the law would overlap substantially with the costs of updating contractual practices, described in the next section.

2. Costs of Updating Contractual Practices

Firms may seek to update their contractual practices by expanding the scope of non-disclosure agreements (NDAs) or other contractual provisions to ensure they are expansive enough to protect trade secrets and other valuable investments. To do so, firms may use in-house counsel or outside counsel to examine and amend current contracts or enter into new contracts with workers.

The Commission is not aware of empirical evidence on how much it costs firms to update their contractual practices when they can no longer use non-compete clauses. However, there is evidence indicating firms that use non-compete clauses are already using other types of restrictive employment provisions. Firms may be doing so because, among other things, they are uncertain whether a non-compete clause will be enforceable, or because they desire the additional protections NDAs and other types of restrictive employment provisions can offer. Balasubramanian et al. find that 97.5% of workers with non-compete clauses are also subject to a non-solicitation agreement, non-disclosure agreement, or a non-recruitment agreement, and 74.7% of workers with non-compete clauses are also subject to all three other types of provisions.⁵⁰⁰ Firms that are already using multiple layers of protection may not need to expand the scope of existing restrictive employment provisions or enter into new ones.

Among the approximately one half of firms that use non-compete clauses,⁵⁰¹ we assume the average firm employs the equivalent of four to eight hours of a lawyer's time to update their contractual practices. We emphasize this is an average to underline the fact that there would likely be large differences in the extent to which firms update their contractual practices. Many firms, including those which use non-compete clauses only with workers who do not

⁵⁰⁰ Balasubramanian, Starr, & Yamaguchi, *supra* note 40 at 35. We calculate 97.5% as $(1-0.6\%/24.2\%)$, where 0.6% represents the proportion of workers with only a non-compete clause, and no other post-employment restriction, and 24.2% represents the proportion of workers with a non-compete clause, regardless of what other post-employment restrictions they have.

⁵⁰¹ Colvin & Shierholz, *supra* note 498 at 1.

have access to sensitive information, or those which are already using other types of restrictive employment provisions to protect sensitive information, may opt to do nothing. Other firms may employ several hours or multiple days of lawyers' time to arrive at a new contract.⁵⁰² Our estimated range of four to eight hours represents an average taken across these different possibilities. For example, if two-thirds of firms that currently use non-compete clauses opt to make no changes to their contractual practices (for example, because they are one of the 97.5% of firms which already implement other post-employment restrictions, or because they will rely on trade secret law in the future, or because they are using non-compete clauses with workers who do not have access to sensitive information), and one-third of such firms spend (on average) the equivalent of 1.5 to 3 days of an attorney's time, this would result in the estimate of 4–8 hours on average reported above.

We further emphasize this estimate is an average across all employers that would be covered by the rule. There is likely substantial heterogeneity in the amount of time firms would use to update contractual practices; very large firms that use non-compete clauses extensively would likely incur greater costs.

Under the assumption the average firm that uses a non-compete clause employs the equivalent of four to eight hours of a lawyer's time, we calculate the total expenditure on updating contractual practices to range from $\$61.54 * 4 * 49.4\% * 6,102,412 = \742.07 million to $\$61.54 * 8 * 49.4\% * 6,102,412 = \1.48 billion. Note that we assume decisions regarding protection of sensitive information and contract updating are made at the firm, rather than establishment, level, since sensitive information is likely shared across business establishments of a firm. The Commission seeks comment on this estimate.

3. Firm Investment

Non-compete clauses may impact investments made by firms in multiple ways.⁵⁰³ First, a firm may anticipate a greater return on investment in a worker with a non-compete clause—since the worker is unable to take the skills they attain to a competitor—and may therefore provide greater levels of

⁵⁰² These estimates are derived from outreach to employment attorneys active in assisting firms in writing their non-compete clauses.

⁵⁰³ For more discussion, see Jeffers (2019), *supra* note 92; Starr (2019), *supra* note 66 at 783–817.

training. Second, since non-compete clauses increase worker training, firms may increase investment that complements human capital when they are able to use non-compete clauses. Third, non-compete clauses decrease competition, which increases returns on investment at the firm level, inducing additional investment at the firm level. This increased investment at the firm level does not necessarily mean, however, investment would increase at the market level, since decreased competition may also decrease output, decreasing employed capital stock and investment in that capital stock.

Once again, the costs described in this section may overlap with estimates reported in preceding sections. For example, if increased enforceability of non-compete clauses increases training of workers, and increased training results in higher wages for workers, then the estimate of the wage decrease when enforceability increases already takes into account the extent to which increased training increases wages. That is, if training were held constant, the earnings increase associated with the proposed rule would likely be even larger.

With respect to worker training, one study finds that an increase in the non-compete clause enforceability index of one standard deviation (across states) results in an increase in the number of workers who reported receiving training of 14.7% for workers in occupations which use non-compete clauses at a high rate, relative to those in which non-compete clauses are used at a low rate.⁵⁰⁴ Extending this estimate to the U.S. workforce implies that, on average, 3.1% fewer workers would receive training in a given year, as a result of the proposed rule.⁵⁰⁵

An estimate of the impact of non-compete clause enforceability on firm investment in capital assets implies that an increase in enforceability leads to an

⁵⁰⁴ Starr (2019), *supra* note 66 at 796. Estimates are taken from Table 4, Column 4.

⁵⁰⁵ The total training decrease is calculated as the weighted average (where weights are equal to employment in 2020, the latest year available, taken from https://data.bls.gov/cew/apps/table_maker/v4/table_maker.htm) over all states of:

$$(e^{-0.0077 * (\text{State's Enforceability Score} - \text{Lowest State Enforceability Score})} - 1)$$

This calculation assumes that all workers are subject to the decrease in training, as opposed to calculating the decrease to those in high-use occupations versus those in low-use occupations. The benefit of this approach is that it yields a total predicted training decrease for the economy as a whole, rather than a comparison between different types of workers. However, it is likely an overestimate for workers in low-use occupations, and an underestimate for those in high-use occupations. It is the same methodology used to calculate earnings increases in Part VII.B.1.a for the estimate drawn from the same study.

increase in firms' net investment to asset ratio of 1.3 percentage points (against a mean of 3.5%). The magnitude of the enforceability increase which is associated with this change is not quantified according to the scale above, however, so it is not possible to extend this estimate to the population. Additionally, the estimate is constructed at the firm level, and it is not possible to extrapolate the estimate to the market level, given potential changes in the composition of the market associated with changes in non-compete clause enforceability.

The proposed rule may also impact the extent to which trade secrets are shared with workers. Non-compete clauses are commonly justified as a means by which firms are able to protect trade secrets, which may allow those trade secrets to be shared more freely with workers, positively impacting productivity. However, to the best of our knowledge, there is no available evidence on this topic which would allow us to quantify or monetize the cost, or identify whether it exists in practice.

4. Job Creation Rates

While non-compete clauses may, in theory, incentivize firms to create jobs by increasing the value associated with any given worker covered by a non-compete clause, the evidence is inconclusive. One estimate indicates the job creation rate at startups increased by 7.8% when Michigan increased non-compete clause enforceability.⁵⁰⁶ However, the job creation rate calculated in this study is the ratio of jobs created by startups to overall employment in the state: therefore, the job creation rate at startups may rise either because the number of jobs created by startups rose, or because employment overall fell. The study does not investigate which of these two factors drives the increase in the job creation rate at startups.

Another study finds that several increases in non-compete clause enforceability were associated with a 1.4% increase in average employment at new firms.⁵⁰⁷ However, the authors attribute the increase in average employment to a change in the composition of newly founded firms. The increases in enforceability prevented the entry of relatively small startups which would otherwise have existed. The remaining firms which entered were therefore larger on average: this increases the average job creation

⁵⁰⁶ Carlino, *supra* note 86 at 16.

⁵⁰⁷ Starr, Balasubramanian, & Sakakibara, *supra* note 87 at 561.

rate at new firms, because the average entering firm is relatively larger. However, in terms of total jobs created, it means that increases in enforceability generate fewer total jobs, if the mechanism identified by the authors is correct. A similar mechanism may explain the results in both studies above. If that is indeed the case, then an increased job creation rate among startups is not a cost of the proposed rule. Instead, it could actually be a benefit (albeit unquantifiable), since non-compete clauses prevent small firms from existing in the first place. The Commission therefore believes that, with respect to job creation rates, the evidence is inconclusive: it is unclear whether the negative results have causes which are actually benign, or even positive.

5. Litigation Costs

The proposed rule would likely reduce litigation costs associated with non-compete clauses, since there would be little to no uncertainty that the vast majority of those clauses are prohibited. However, it is also possible that costs associated with trade secret claims or other post-employment restrictions, such as non-disclosure agreements or non-solicitation agreements, would increase. The Commission is not aware of any evidence indicating the magnitude of the change in litigation costs associated with any of these claims, and it is therefore not clear whether the net impact on litigation costs would be a benefit or a cost of the proposed rule. The Commission seeks comment on the impact the rule would have on litigation costs.

D. Discussion of Alternatives

In Part VI of this NPRM, the Commission describes several alternatives to the proposed rule. Here, we discuss the extent to which implementation of each of these alternatives would change the analysis of benefits and costs presented above.

We treat Alternatives 1 and 3 first. Under Alternative 1, the rule would categorically ban the use of non-compete clauses for some workers and apply a rebuttable presumption of unlawfulness to non-compete clauses for other workers. For example, the rule could ban non-compete clauses generally, but apply the rebuttable presumption to workers who qualify for the FLSA exemptions for executives or learned professionals.⁵⁰⁸ Or the rule could ban non-compete clauses but apply the rebuttable presumption to

workers who earn more than \$100,000 per year. Under Alternative 3, non-compete clauses for all workers would be subject to a rebuttable presumption of illegality.

There are two primary ways in which a rebuttable presumption of illegality, rather than a prohibition, could affect the benefits and costs associated with the proposed rule. First, a rebuttable presumption may decrease costs associated with the proposed rule by allowing employers to use non-compete clauses in situations in which the true benefits of non-compete clauses exceed the costs. In other words, the non-compete clauses which survive a rebuttable presumption may contribute to economic efficiency to the extent a court is able to identify efficiency-enhancing non-compete clauses.

Second, a rebuttable presumption could increase costs by forcing cases involving non-compete clauses to be litigated more frequently, since the line defining a permissible non-compete clause would be less bright. Additionally, there may be situations in which the presumption would likely hold (*i.e.*, a given non-compete clause is likely prohibited under the presumption), but which are not fought by workers, fearing they might lose the case. In such cases, any costs and benefits associated with non-compete clauses (such as those outlined in the preceding sections) would accrue to the economy.

The two impacts of a change from a prohibition to a rebuttable presumption would likely be more drastic for workers above the threshold (for whom the presumption would be rebuttable under Alternative 1), as compared with those additional workers for whom the presumption would be rebuttable under Alternative 3. For the latter set of workers, there are fewer plausible cases in which the presumption would be rebutted, since higher-paid workers typically have access to greater levels of sensitive information. This means there is a smaller efficiency gain to be had from allowing non-compete clauses which could plausibly rebut the presumption; however, it also means there would likely be fewer litigated cases since there would be fewer marginal non-compete clauses. Therefore, the effect of moving from the proposed rule to Alternative 1 is likely more substantial than the effect of moving from Alternative 1 to Alternative 3.

The effects of Alternatives 2 and 4 may be analyzed similarly. Under Alternative 2, the rule would categorically ban the use of non-compete clauses for some workers and

not apply any requirements to other workers. For example, like the recent State of Washington statute, the rule could prohibit the use of non-compete clauses for employees earning \$100,000 or less per year and independent contractors earning less than \$250,000 or less per year. Or, like the recent Massachusetts and Rhode Island statutes, the rule could prohibit the use of non-compete clauses for workers who are non-exempt under the FLSA.⁵⁰⁹ Under Alternative 4, the rule would apply a rebuttable presumption of unlawfulness to non-compete clauses for some workers and not apply any requirements to other workers. Workers above the threshold are most likely to be those workers for whom firm investment and training are valuable, but they are also often uniquely positioned to found new firms, since they hold knowledge gained by working in their industry. Therefore, a large portion of the benefits associated with the proposed rule would be lost if workers above the threshold were not covered; however, a large portion of the costs would also be lost, since the need to restructure contracts to protect sensitive information would no longer be present for those workers, and firms would continue to train and invest in those workers in the same way they currently do. Additionally, the earnings effects for relatively lower-wage workers appear to be less, based on empirical work, though the legal changes analyzed were not perfectly comparable. This could indicate, again, there are more substantial benefits to be had from prohibiting non-compete clauses for workers above the threshold based on harms to labor markets, compared with workers below the threshold.

The alternative under which the rule would use a different standard for senior executives, discussed in Part VI.C, would yield similar effects to the analyses discussed above. If a rebuttable presumption were applied to senior executives, if there are some non-compete clauses that are efficient, and if courts are able to appropriately identify efficient non-compete clauses, then some non-compete clauses would likely be used (and may survive challenges) which are indeed efficient. On the other hand, costs associated with legal challenges would likely increase due to an increased frequency of legal challenges associated with a less bright line. If no requirement is applied to senior executives, then a large portion of the benefit of the proposed rule, as it applies to senior executives, would be lost: benefits associated with increased

⁵⁰⁸ See *supra* notes 423–424 and accompanying text.

⁵⁰⁹ See *supra* Part VI.B.2.

product market competition and benefits associated with increased labor market competition. The costs of restructuring contracts, however, would be lost, as well.

Another alternative, discussed in Part VI.D, concerns whether non-compete clauses between a franchisor and a franchisee would be covered by the proposed rule. As noted in Part VI.D, evidence concerning the impact of prohibiting non-compete clauses between franchisors and franchisees does not exist. The Commission is therefore unable to estimate the extent to which the costs and benefits which would result from the proposed rule covering those parties would be similar to those resulting from prohibiting worker non-compete clauses.

E. Other Major Effects

There are two substantial equity concerns associated with the proposed rule which are not captured above. The first relates to the economic outcomes of women and racial and ethnic minorities. Non-compete clauses may affect women and racial and ethnic minorities more negatively than other workers. For example, firms may use the monopsony power which results from use of non-compete clauses as a means by which to wage discriminate, or women (who may exhibit greater risk aversion, in practice⁵¹⁰) may be more reluctant to start businesses when non-compete clauses are enforceable. One estimate indicates that gender and racial wage gaps would close by 3.6–9.1% under a nationwide prohibition on non-compete clauses.⁵¹¹ Another estimate indicates the negative impact of non-compete clause enforceability on within-industry entrepreneurship is 15% greater for women than for men.⁵¹²

The second equity concern related to non-compete clauses is that workers may not be willing to file lawsuits against deep-pocketed employers to challenge their non-compete clauses, even if they predict a high probability of success. The proposed rule would substantially mitigate this concern by enacting a bright-line prohibition, which the Commission could enforce. This would mitigate uncertainty for workers and would be especially helpful for relatively low-paid workers,

⁵¹⁰ See, e.g., Catherine C. Eckel & Philip J. Grossman, *Men, Women and Risk Aversion: Experimental Evidence*, *Handbook of Experimental Economics Results* 1 (2008) 1061–073 and Gary Charness & Uri Gneezy, *Strong Evidence For Gender Differences in Risk Taking*, 83 J. Econ. Behavior & Org. 50–58 (2012).

⁵¹¹ Johnson, Lavetti, & Lipsitz, *supra* note 63 at 38.

⁵¹² Marx (2021), *supra* note 118 at 8.

for whom access to legal services may be prohibitively expensive.

VIII. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires an agency to either provide an Initial Regulatory Flexibility Analysis (IRFA) with a proposed rule or certify that the proposed rule would not have a significant impact on a substantial number of small entities.⁵¹³ The Commission does not expect the proposed rule, if adopted, would have a significant impact on a substantial number of small entities.

Although small entities across all industrial classes—*i.e.*, all North American Industry Classification System (NAICS) codes—would be affected, the estimated impact on each entity would be relatively small. The Small Business Administration (SBA) states that, as a rule of thumb, the impact of a proposed rule could be significant if the cost of the proposed rule (a) eliminates more than 10% of the businesses' profits; (b) exceeds 1% of the gross revenues of the entities in a particular sector, or (c) exceeds 5% of the labor costs of the entities in the sector.⁵¹⁴ As calculated in Part VIII.D, the Commission estimates direct compliance costs and the costs of updating contractual practices would result in costs of \$317.68 to \$563.84 for single-establishment firms. These costs would only exceed these sample limits if the average profit of regulated entities is \$3,177 to \$5,638, average revenue is \$31,768 to \$56,384, or average labor costs are \$6,353 to \$11,276, respectively. Furthermore, while there are additional nonmonetizable costs associated with the proposed rule, there are also nonmonetizable benefits which would at least partially offset those costs, as explained above in Part VII.

Although the Commission certifies under the RFA that the proposed rule would not have a significant impact on a substantial number of small entities, and hereby provides notice of that certification to the SBA, the Commission has determined it is appropriate to publish an IRFA in order to describe the impact of the proposed rule on small entities. The Commission seeks comment on all aspects of the IRFA in this Part VIII.

⁵¹³ 5 U.S.C. 603–605.

⁵¹⁴ Small Bus. Admin., *A Guide for Government Agencies: How to Comply With the Regulatory Flexibility Act* (August 2017) (hereinafter RFA Compliance Guide) at 19.

A. Reasons for the Proposed Rule

The Commission describes the reasons for the proposed rule above in Part IV.

B. Statement of Objectives and Legal Basis

The Commission describes the objectives and legal basis for the proposed rule above in Part IV and the legal authority for the rule above in Part III.

C. Description and Estimated Number of Small Entities to Which the Rule Would Apply

The proposed rule would impact all small businesses, across all industry classes, that use non-compete clauses. The Commission does not expect there are classes of businesses that would face disproportionate impacts from the proposed rule.

For the vast majority of industries, there is no granular data regarding the percentage of firms that use non-compete clauses (which could then be used to calculate the number of small entities in that industry using non-compete clauses). Due to this data limitation and given the relatively stable percentage of firms using non-compete clauses across the size distribution,⁵¹⁵ we estimate the total number of small firms across all industries in the U.S. economy. We then calculate the number of firms estimated to use non-compete clauses by applying an estimate of the percentage of firms using non-compete clauses to that total. Using the size standards set by the SBA,⁵¹⁶ we calculate that there are 5.95 million small firms and 6.24 million small establishments in the U.S.⁵¹⁷ Assuming

⁵¹⁵ See Colvin & Shierholz, *supra* note 498 at 5. We emphasize that, since smaller firms generally use non-compete clauses at a lower rate, based on the numbers reported in Table 1, our estimate of the number of affected small entities is likely larger than is true in practice.

⁵¹⁶ See Small Bus. Admin., *Table of Size Standards*, <https://www.sba.gov/document/support-table-size-standards>.

⁵¹⁷ We use the latest data available from the U.S. Census Bureau's Statistics of U.S. Businesses database, available based on firm revenue and firm size. U.S. Census Bureau, *Statistics of U.S. Businesses (SUSB)*, <https://www.census.gov/programs-surveys/susb.html> (last visited Dec. 9, 2022). We deflate to current dollars using Historical Table 10.1. Off. of Mgmt. & Budget, *Historical Tables*, <https://www.whitehouse.gov/omb/budget/historical-tables/> (last visited Dec. 9, 2022). As used in this analysis, per the U.S. Census Bureau, "a firm is a business organization consisting of one or more domestic establishments in the same geographic area and industry that were specified under common ownership or control." On the other hand, "an establishment is a single physical location at which business is conducted or services or industrial operations are performed." See U.S. Census Bureau, *Glossary*, <https://www.census.gov/programs-surveys/susb/about/glossary.html>.

49.4% of firms or establishments use non-compete clauses,⁵¹⁸ we estimate 2.94 million small firms, comprising 3.08 million small establishments, would be affected by the proposed rule. Since our estimate ignores differential use of non-compete clauses across industries (in the absence of more detailed data), these firms span all industries and various sizes below the standards set in the SBA's size standards.

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements

As calculated in Parts VIII.D.1 and VIII.D.2, the Commission estimates the direct compliance costs and the costs of updating contractual practices would total \$246.16 to \$492.32 for each small firm, plus an additional \$71.52 for each establishment owned by that firm. A single-establishment firm, for example, would bear estimated costs of \$317.68 to \$563.84, for example.

As described in greater detail in Part VII.C.3, the Commission also finds worker training and firm investment in capital assets would likely decrease under the proposed rule. Finally, as described in greater detail in Part VII.C.4, the Commission finds mixed evidence that the job creation rate would diminish under the proposed rule. Given the evidence available, the Commission is unable to monetize the estimates of worker training, firm investment in capital assets, and job creation, however.

1. Direct Compliance Costs

In order to comply with the proposed rule, small entities must remove non-compete clauses from workers' contracts in two ways. First, to comply with proposed § 910.2(a), which states it is an unfair method of competition to maintain with a worker a non-compete clause, small entities would need to no longer include non-compete clauses in the contracts of incoming workers, which may include revising existing employment contracts. Second, to comply with proposed § 910.2(b)(1) and (2), small entities would need to rescind existing non-compete clauses no later than the compliance date and provide notice to workers that the worker's non-compete clause is no longer in effect and may not be enforced against the worker.

In order to reduce compliance costs and increase compliance certainty, proposed § 910.2(b)(3) would provide that an employer complies with the rescission requirement in proposed § 910.2(b)(1) where it provides notice to

a worker pursuant to § 910.2(b)(2). Furthermore, proposed § 910.2(b)(2)(C) includes model language which may be provided to the worker in order to inform the worker that their non-compete clause is no longer in effect. We estimate composing and sending this message in a digital format to all of a firm's workers and applicable former workers would take 20 minutes of a human resources specialist's time. According to the Bureau of Labor Statistics, the median wage for a human resources specialist was \$29.95 per hour in 2021.⁵¹⁹ The cost of compliance for currently employed workers is therefore $\$29.95/3 = \9.98 per firm. As calculated in Part VIII.C, we estimate there are 2.94 million small firms, comprising 3.08 million small establishments, in the United States which use non-compete clauses.⁵²⁰ Conservatively assuming that each establishment must engage in its own communication (*i.e.*, a firm's headquarters does not have the ability to send a company-wide email, for example), this means the total direct compliance cost for workers who are already employed is $\$9.98 * 3.08 \text{ million} = \30.74 million .

To ensure incoming workers' contracts do not include non-compete clauses and they fully comply with the proposed rule, firms may employ in-house counsel, outside counsel, or human resource specialists (depending on the complexity of the relevant non-compete clause). For many firms, this process would likely be straightforward (*i.e.*, simply not using non-compete clauses or removing one section from a boilerplate contract). For other firms, it may be more difficult and require more time. We assume that, on average, ensuring contracts for incoming workers do not have non-compete clauses would take the equivalent of one hour of a lawyer's time (valued at \$61.54),⁵²¹ resulting in a total cost of $\$61.54 * 3.08 \text{ million} = \189.54 million . We acknowledge there may be substantial heterogeneity in the costs for individual firms; however, we believe this number is conservative. For firms whose costs of removing non-compete clauses for incoming workers is greater, the work of ensuring that contracts comply with the law would overlap substantially with

⁵¹⁹ See U.S. Bureau of Lab. Stats., *Occupational Outlook Handbook, Human Resources Specialists*, <https://www.bls.gov/ooh/business-and-financial/human-resources-specialists.htm>.

⁵²⁰ The dataset is available at U.S. Census Bureau, *2019 SUSB Annual Data Tables by Establishment Industry*, <https://www.census.gov/data/tables/2019/econ/susb/2019-susb-annual.html>, (last visited Dec. 9, 2022).

⁵²¹ U.S. Bureau of Lab. Stats., *Occupational Outlook Handbook, Lawyers*, <https://www.bls.gov/ooh/legal/lawyers.htm>.

the costs of updating contractual practices, described in the next section.

For each establishment of each firm, we estimate direct compliance costs would total $\$9.98 + \$61.54 = \$71.52$.

2. Costs of Updating Contractual Practices

Firms may seek to update their contractual practices by expanding the scope of non-disclosure agreements (NDAs) or other contractual provisions to ensure they are expansive enough to protect trade secrets and other valuable investments. To do so, firms may use in-house counsel or outside counsel to examine and amend current contracts or enter into new contracts with workers.

The Commission is not aware of empirical evidence on how much it costs firms to update their contractual practices when they can no longer use non-compete clauses. However, there is evidence indicating firms that use non-compete clauses are already using other types of restrictive employment provisions. Firms may be doing so because, among other things, they are uncertain whether a non-compete clause will be enforceable, or because they desire the additional protections NDAs and other types of restrictive employment provisions can offer. Balasubramanian et al. find that 97.5% of workers with non-compete clauses are also subject to a non-solicitation agreement, non-disclosure agreement, or a non-recruitment agreement, and 74.7% of workers with non-compete clauses are also subject to all three other types of provisions.⁵²² Firms already using multiple layers of protection may not need to expand the scope of existing restrictive employment provisions or enter into new ones.

Among the approximately one half of firms that use non-compete clauses,⁵²³ we assume the average firm employs the equivalent of four to eight hours of a lawyer's time to update their contractual practices. We emphasize this is an average to underline the likelihood of large differences in the extent to which firms update their contractual practices. Many firms, including those which use non-compete clauses only with workers who do not have access to sensitive information, or those which are already using other types of restrictive employment provisions to protect

⁵²² Balasubramanian, Starr, & Yamaguchi, *supra* note 40 at 35. We calculate 97.5% as $(1 - 0.6\% / 24.2\%)$, where 0.6% represents the proportion of workers with only a non-compete clause, and no other post-employment restriction, and 24.2% represents the proportion of workers with a non-compete clause, regardless of what other post-employment restrictions they have.

⁵²³ Colvin & Shierholz, *supra* note 498 at 1.

⁵¹⁸ See Colvin & Shierholz, *supra* note 498 at 1.

sensitive information, may opt to do nothing. Other firms may employ several hours or multiple days of lawyers' time to arrive at a new contract.⁵²⁴ Our estimated range of four to eight hours represents an average taken across these different possibilities. For example, if two-thirds of firms that currently use non-compete clauses opt to make no changes to their contractual practices (for example, because they are one of the 97.5% of firms which already implement other post-employment restrictions, or because they will rely on trade secret law in the future, or because they are using non-compete clauses with workers who do not have access to sensitive information), and one-third of such firms spend (on average) the equivalent of 1.5 to 3 days of an attorney's time, this would result in the estimate of 4–8 hours on average reported above.

We further emphasize this estimate is an average across all employers that would be covered by the rule. There is likely substantial heterogeneity in the amount of time firms would use to update contractual practices; very large firms that use non-compete clauses extensively would likely incur greater costs.

Under the assumption the average firm that uses a non-compete clause employs the equivalent of four to eight hours of a lawyer's time, we calculate the total expenditure on updating contractual practices to range from $\$61.54 \times 4 \times 2.94$ million = \$723.7 million to $\$61.54 \times 8 \times 2.94$ million = \$1.45 billion. Note that we assume decisions regarding protection of sensitive information and contract updating are made at the firm, rather than establishment, level, since sensitive information is likely shared across business establishments of a firm. The Commission seeks comment on this estimate.

For each firm, we estimate the cost of updating contractual practices would be $\$61.54 \times 4 = \246.16 to $\$61.54 \times 8 = \492.32 .

E. Identification of Duplicative, Overlapping, or Conflicting Federal Rules

The Commission is not aware of any duplicative, overlapping, or conflicting federal rules. As described above in Part II.C.1, the enforceability of a non-compete clause currently depends on state law. Non-compete clauses are also subject to federal antitrust law. However, the Commission is not aware of any federal regulations that would

duplicate, overlap, or conflict with the proposed rule.

F. Discussion of Significant Alternatives

In Part VI above, the Commission discusses significant alternatives to the proposed rule. Part VI also includes a preliminary assessment of whether each of the significant alternatives would accomplish the objectives of the proposed rule. In addition, the Commission's analysis of benefits and costs in Part VII includes an assessment of the benefits and costs of various alternatives.⁵²⁵

The Commission is not proposing an exemption for small entities or different regulatory requirements for small entities. The proposed rule would provide it is an unfair method of competition for an employer to enter into or attempt to enter into a non-compete clause with a worker; maintain with a worker a non-compete clause; or, under certain circumstances, to represent to a worker that the worker is subject to a non-compete clause.⁵²⁶ For the reasons described above in Part IV, the Commission is proposing to provide these practices are an unfair method of competition under Section 5. Based on the available evidence, the Commission does not believe the analysis in Part IV above is fundamentally different for non-compete clauses imposed by small entities. For this reason, the Commission is not proposing an exemption for small entities or different regulatory requirements for small entities. The Commission seeks comment on whether it should propose a small entity exemption or different requirements for small entities, including whether non-compete clauses used by small entities are less likely to have the anticompetitive effects described in Part IV.A above, and whether employers that are small entities are less likely than other employers to have alternatives available for protecting their investments, as described in Part IV.B above.

The Commission is also not proposing a delayed compliance date for small entities. Under proposed § 910.5, compliance with the proposed rule would be required as of the proposed compliance date, which would be 180 days after publication of the final rule in the **Federal Register**.⁵²⁷ In the Commission's preliminary view, this proposed compliance period would afford small entities a sufficient period of time to comply with the proposed

rule.⁵²⁸ The Commission seeks comment on whether this is the case.

IX. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA),⁵²⁹ federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" includes any requirement or request for persons to obtain, maintain, retain, report, or publicly disclose information.⁵³⁰ Under the PRA, the Commission may not conduct or sponsor, and, notwithstanding any other provision of law, a person is not required to respond to, an information collection unless the information collection displays a valid control number assigned by OMB.⁵³¹

The Commission believes the proposed rule would contain a disclosure requirement that would constitute a collection of information requiring OMB approval under the PRA. Proposed § 910.2(a) would state it is an unfair method of competition for an employer to enter into or attempt to enter into a non-compete clause with a worker; maintain with a worker a non-compete clause; or, under certain circumstances, represent to a worker that the worker is subject to a non-compete clause. Proposed § 910.2(b)(1) would state that, to comply with § 910.2(a), an employer that entered into a non-compete clause with a worker prior to the compliance date must rescind the non-compete clause no later than the compliance date.

Proposed § 910.2(b)(2)—the provision that would contain the disclosure requirement that would require OMB approval—would require employers to provide a notice to workers in certain circumstances. Specifically, proposed § 910.2(b)(2)(A) would require an employer that rescinds a non-compete clause pursuant to § 910.2(b)(1) to provide notice to the worker that the worker's non-compete clause is no longer in effect and may not be enforced against the worker. Proposed § 910.2(b)(2)(A) would also state the employer must provide the notice to the worker in an individualized communication and the employer must provide the notice on paper or in a digital format such as, for example, an email or text message. Proposed § 910.2(b)(2)(B) would state the employer must provide the notice to a

⁵²⁸ See *supra* Part V, in the section-by-section analysis for proposed § 910.5.

⁵²⁹ 44 U.S.C. 3501 *et seq.*

⁵³⁰ 44 U.S.C. 3502(3); 5 CFR 1320.3(c).

⁵³¹ 44 U.S.C. 3506(c)(1)(B); 5 CFR 1320.5(a)(3).

⁵²⁴ These estimates are derived from outreach to employment attorneys active in assisting firms in writing their non-compete clauses.

⁵²⁵ See *supra* Part VII.D.

⁵²⁶ See proposed § 910.2(a).

⁵²⁷ See proposed § 910.5.

worker who currently works for the employer. Proposed § 910.2(b)(2)(B) would also state that the employer must also provide the notice to a worker who formerly worked for the employer, provided the employer has the worker's contact information readily available. Finally, proposed § 910.2(b)(2)(C) would provide model language that would satisfy the notice requirement. Proposed § 910.2(b)(2)(C) would also state that an employer may also use different language, provided the notice communicates to the worker that the worker's non-compete clause is no longer in effect and may not be enforced against the worker.

The Commission estimates composing and sending this message in a digital format to all workers would take 20 minutes of a human resources specialist's time. According to the Bureau of Labor Statistics, the median wage for a human resources specialist in 2021 was \$29.95 per hour.⁵³² The cost of compliance for currently employed workers is therefore $\$29.95/3 = \9.98 per firm. According to the U.S. Census Bureau's Statistics of U.S. Businesses database, in 2019 (the most recent year for which data are available), there were 6.10 million firms and 7.96 million establishments in the United States.⁵³³ The Commission estimates the percentage of firms using non-compete clauses in the United States at 49.4%.⁵³⁴ This yields an estimated 3,932,240 covered establishments. Conservatively assuming that each establishment must engage in its own communication—*i.e.*, a firm's headquarters does not have the ability to send a company-wide email, for example—this means covered employers would incur an estimated labor cost burden of 1,310,747 hours to comply with this requirement (3,932,240 establishments \times 20 minutes). The Commission estimates the associated labor cost for notifying affected workers who are already employed is $\$9.98 \times 7.96 \text{ million} \times 0.494 = \$39,243,755$.

The proposed rule would impose only *de minimis* capital and non-labor costs. The Commission anticipates covered employers already have in place existing systems to communicate with and provide employment-related disclosures to workers. While the

proposed rule would require a one-time disclosure to some workers subject to a rescinded non-compete clause, the Commission anticipates this one-time disclosure would not require substantial investments in new systems or other non-labor costs. Moreover, many establishments are likely to provide the disclosure electronically, further reducing total costs.

The Commission invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information would 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) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of these information collections on respondents. The Commission seeks comment on all aspects of this Part IX.

Comments on the proposed reporting requirements subject to Paperwork Reduction Act review by OMB should additionally 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. The [reginfo.gov](http://www.reginfo.gov) web link is a United States Government website operated by OMB and the General Services Administration (GSA). Under PRA requirements, OMB's Office of Information and Regulatory Affairs (OIRA) reviews federal information collections.

X. Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before March 20, 2023. Write "Non-Compete Clause Rulemaking, Matter No. P201200" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including the <https://www.regulations.gov> website.

Because of the public health emergency in response to the COVID-19 outbreak and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the <https://www.regulations.gov> website. To ensure the Commission considers your online comment, please follow the instructions on the web-based form.

If you file your comment on paper, write "Non-Compete Clause Rulemaking, Matter No. P201200" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex C), Washington, DC 20580.

Because your comment will be placed on the publicly accessible website at <https://www.regulations.gov>, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by 15 U.S.C. 46(f) and 16 CFR 4.10(a)(2)—including, in particular, competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with 16 CFR 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at <https://www.regulations.gov>—as legally required by 16 CFR 4.9(b)—we cannot redact or remove your comment, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c) and the General Counsel grants that request.

Visit the Commission's website, www.ftc.gov, to read this NPRM and the fact sheet describing it. The FTC Act and other laws the Commission administers permit the collection of

⁵³² U.S. Bureau of Lab. Stats., *Occupational Outlook Handbook: Human Resources Specialists*, <https://www.bls.gov/ooh/business-and-financial/human-resources-specialists.htm>.

⁵³³ U.S. Census Bureau, 2019 SUBS Annual Data Tables by Establishment Industry (February 2022), <https://www.census.gov/data/tables/2019/econ/subs/2019-susb-annual.html> (last visited Dec. 9, 2022).

⁵³⁴ See Colvin & Shierholz, *supra* note 498 at 4.

public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 20, 2023. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

XI. Communications by Outside Parties to Commissioners or Their Advisors

Written communications and summaries or transcripts of oral communications respecting the merits of this proceeding, from any outside party to any Commissioner or Commissioner's advisor, will be placed on the public record, per 16 CFR 1.26(b)(5).

List of Subjects in 16 CFR Part 910 Antitrust

■ For the reasons set forth above, the Federal Trade Commission proposes to add a new subchapter J, consisting of part 910, to chapter I in title 16 of the Code of Federal Regulations to read as follows:

Subchapter J—Rules Concerning Unfair Methods of Competition

PART 910—NON-COMPETE CLAUSES

Sec.

- 910.1. Definitions.
- 910.2. Unfair methods of competition.
- 910.3. Exception.
- 910.4. Relation to State laws.
- 910.5. Compliance date.

Authority: 15 U.S.C. 45 and 46(g).

§ 910.1 Definitions.

(a) *Business entity* means a partnership, corporation, association, limited liability company, or other legal entity, or a division or subsidiary thereof.

(b) *Non-compete clause*, as used in this part:

(1) Means a contractual term between an employer and a worker that prevents the worker from seeking or accepting employment with a person, or operating a business, after the conclusion of the worker's employment with the employer.

(2) The term non-compete clause includes a contractual term that is a *de*

facto non-compete clause because it has the effect of prohibiting the worker from seeking or accepting employment with a person or operating a business after the conclusion of the worker's employment with the employer. For example, the following types of contractual terms, among others, may be *de facto* non-compete clauses:

(i) A non-disclosure agreement between an employer and a worker that is written so broadly that it effectively precludes the worker from working in the same field after the conclusion of the worker's employment with the employer.

(ii) A contractual term between an employer and a worker that requires the worker to pay the employer or a third-party entity for training costs if the worker's employment terminates within a specified time period, where the required payment is not reasonably related to the costs the employer incurred for training the worker.

(c) *Employer* means a person, as defined in 15 U.S.C. 57b-1(a)(6), that hires or contracts with a worker to work for the person.

(d) *Employment* means work for an employer, as the term employer is defined in paragraph (c) of this section.

(e) *Substantial owner*, *substantial member*, and *substantial partner* mean an owner, member, or partner holding at least a 25 percent ownership interest in a business entity.

(f) *Worker* means a natural person who works, whether paid or unpaid, for an employer. The term includes, without limitation, an employee, individual classified as an independent contractor, extern, intern, volunteer, apprentice, or sole proprietor who provides a service to a client or customer. The term worker does not include a franchisee in the context of a franchisee-franchisor relationship; however, the term worker includes a natural person who works for the franchisee or franchisor. Non-compete clauses between franchisors and franchisees would remain subject to Federal antitrust law as well as all other applicable law.

§ 910.2 Unfair methods of competition.

(a) *Unfair methods of competition*. It is an unfair method of competition for an employer to enter into or attempt to

enter into a non-compete clause with a worker; maintain with a worker a non-compete clause; or represent to a worker that the worker is subject to a non-compete clause where the employer has no good faith basis to believe that the worker is subject to an enforceable non-compete clause.

(b) *Existing non-compete clauses*.

(1) *Rescission requirement*. To comply with paragraph (a) of this section, which states that it is an unfair method of competition for an employer to maintain with a worker a non-compete clause, an employer that entered into a non-compete clause with a worker prior to the compliance date must rescind the non-compete clause no later than the compliance date.

(2) *Notice requirement*.

(i) An employer that rescinds a non-compete clause pursuant to paragraph (b)(1) of this section must provide notice to the worker that the worker's non-compete clause is no longer in effect and may not be enforced against the worker. The employer must provide the notice to the worker in an individualized communication. The employer must provide the notice on paper or in a digital format such as, for example, an email or text message. The employer must provide the notice to the worker within 45 days of rescinding the non-compete clause.

(ii) The employer must provide the notice to a worker who currently works for the employer. The employer must also provide the notice to a worker who formerly worked for the employer, provided that the employer has the worker's contact information readily available.

(iii) The following model language constitutes notice to the worker that the worker's non-compete clause is no longer in effect and may not be enforced against the worker, for purposes of paragraph (b)(2)(i) of this section. An employer may also use different language, provided that the notice communicates to the worker that the worker's non-compete clause is no longer in effect and may not be enforced against the worker.

Figure 1 to Paragraph (b)(2)(iii)—Model Language

BILLING CODE 6750-01-P

A new rule enforced by the Federal Trade Commission makes it unlawful for us to maintain a non-compete clause in your employment contract. As of [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE], the non-compete clause in your contract is no longer in effect. This means that once you stop working for [EMPLOYER NAME]:

- You may seek or accept a job with any company or any person—even if they compete with [EMPLOYER NAME].
- You may run your own business—even if it competes with [EMPLOYER NAME].
- You may compete with [EMPLOYER NAME] at any time following your employment with [EMPLOYER NAME].

The FTC's new rule does not affect any other terms of your employment contract.

For more information about the rule, visit [[link to final rule landing page](#)].

BILLING CODE 6750-01-C

(3) *Safe harbor.* An employer complies with the rescission requirement in paragraph (b)(1) of this section where it provides notice to a worker pursuant to paragraph (b)(2) of this section.

§ 910.3 Exception.

The requirements of this part 910 shall not apply to a non-compete clause that is entered into by a person who is selling a business entity or otherwise disposing of all of the person's ownership interest in the business entity, or by a person who is selling all or substantially all of a business entity's operating assets, when the person restricted by the non-compete clause is a substantial owner of, or substantial member or substantial partner in, the business entity at the time the person enters into the non-compete clause. Non-compete clauses covered by this exception would remain subject to Federal antitrust law as well as all other applicable law.

§ 910.4 Relation to State laws.

This part 910 shall supersede any State statute, regulation, order, or interpretation to the extent that such statute, regulation, order, or interpretation is inconsistent with this part 910. A State statute, regulation, order, or interpretation is not inconsistent with the provisions of this part 910 if the protection such statute, regulation, order, or interpretation affords any worker is greater than the protection provided under this part 910.

§ 910.5 Compliance date.

Compliance with this part 910 is required as of [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE].

By direction of the Commission, Commissioner Wilson dissenting.

April J. Tabor,
Secretary.

Note: the following statements will not appear in the Code of Federal Regulations.

Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro M. Bedoya

Today the Federal Trade Commission is proposing a rule that would prohibit businesses from using noncompete clauses in contracts with workers. Noncompete clauses generally restrict a company's workers from working for—or launching—a competitor for a period of time even after they have stopped working for that company. Researchers estimate that about one in five American workers is bound by a noncompete clause.

By design, noncompetes often close off a worker's most natural alternative employment options: jobs in the same geographic area and professional field. These restrictions can undermine core economic liberties, burdening Americans' ability to freely switch jobs.¹

¹ *Pollock v. Williams*, 322 U.S. 4, 17–18 (1944) (describing the “right to change employers” as a critical “defense against oppressive hours, pay, working conditions, or treatment”).

A recent Commission action illustrates the real-life stakes: Prudential, a security company in Michigan, enforced noncompetes against its workers, including security guards earning near-minimum wage.² These noncompetes included a \$100,000 liquidated damages clause. On multiple occasions, Prudential sued former employees who left for competitors offering higher wages. In one case, Prudential successfully pressured a competitor to fire one of those new hires. Media reports document countless other instances in which Americans who wish to change jobs—be it to pursue a better opportunity, to escape harassment, or to express disagreement with new workplace policies—are trapped in place by noncompete clauses.

Notably, the aggregate economic impact of noncompete clauses goes beyond any individual worker. Initiatives by several states to limit the use of noncompetes has given researchers the opportunity to closely study their effects. The Notice of Proposed Rulemaking (NPRM) published today carefully reviews the empirical evidence available to date and highlights several key findings.³

First, noncompete clauses reduce competition in labor markets, suppressing earnings and opportunity even for workers who are not directly subject to a noncompete. When workers subject to noncompete clauses are blocked from switching to jobs in which they would be better paid and more productive, unconstrained workers in that market are simultaneously denied the opportunity to replace them. This collective decline in job mobility means fewer job offers and an overall drop in wages, as firms have less incentive to compete for workers by offering higher pay, better benefits, greater say over scheduling, or more favorable conditions. The FTC estimates that the proposed ban on noncompetes would increase workers' total earnings by close to \$300 billion per year.⁴

² Complaint, *In re Prudential Security, Inc.*, File No. 221–0026 (Jan. 4, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/2210026prudentialsecuritycomplaint.pdf; see Press Release, Fed. Trade Comm'n, FTC Cracks Down on Companies That Impose Harmful Noncompete Restrictions on Thousands of Workers (Jan. 4, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/01/ftc-cracks-down-companies-impose-harmful-noncompete-restrictions-thousands-workers>.

³ Notice of Proposed Rulemaking for Non-Compete Clause Rule (“NPRM”), Part II.B (Jan. 5, 2023).

⁴ See NPRM Part VII.B.1 (describing the Commission's assessment of the benefits of the proposed rule).

Second, the existing evidence indicates that noncompete clauses reduce innovation and competition in product and service markets. Studies show that locking workers in place reduces innovation, likely by decreasing the flow of information and knowledge among firms. By preventing workers from starting their own businesses and limiting the pool of talent available for startups to hire, noncompetes also limit entrepreneurship and new business formation. This in turn reduces product quality while raising prices. Indeed, existing evidence from the health care sector suggests that the proposed ban would decrease consumer prices, potentially to the tune of \$150 billion a year.⁵

A recent Commission action shows how depriving new businesses of access to skilled workers can thwart competition. In the highly concentrated glass manufacturing sector, incumbent firms imposed noncompetes on thousands of employees. These noncompetes locked up highly specialized workers, tending to impede the entry and expansion of rivals by depriving them of access to qualified employees.⁶

The empirical evidence available to date, coupled with the Commission's years of work on noncompetes, forms the basis for the proposed rule.⁷ The

⁵ Drawing from a study on the financial industry, Commissioner Wilson suggests that suspending noncompetes here caused higher prices and more employee misconduct. See UmIt G. Gurun, Noah Stoffman & Scott E. Yonker, *Unlocking Clients: The Importance of Relationships in the Financial Advisory Industry*, 141 J. Fin. Econ. 1218 (2021). Notably, under the proposed rule, firms will still have contractual methods to protect their client lists, unlike the firms observed in this study, which were prohibited from using non-solicitation agreements in addition to noncompete clauses. Furthermore, the change in the financial industry may have curtailed beneficial entrepreneurship, since it only covered mobility of workers between member firms, and therefore continued to permit some noncompete clauses which could prevent workers from starting their own businesses.

⁶ Complaint, *In re O-I Glass, Inc.*, File No. 211–0182 (Jan. 4, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/2110182o-iglasscomplaint.pdf; Complaint, *In re Ardagh Group S.A.*, File No. 211–0182 (Jan. 4, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/2110182ardaghcomplaint.pdf; see Press Release, Fed. Trade Comm'n, FTC Cracks Down on Companies That Impose Harmful Noncompete Restrictions on Thousands of Workers (Jan. 4, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/01/ftc-cracks-down-companies-impose-harmful-noncompete-restrictions-thousands-workers>.

⁷ The Commission has conducted extensive public outreach relating to noncompete clauses. See, e.g., Fed. Trade Comm'n, *Hearings on Competition and Consumer Protection in the 21st Century*, <https://www.ftc.gov/enforcement-policy/hearings-competition-consumer-protection> (including discussion of noncompete agreements during the Oct. 15–17, 2018 and June 12, 2019 hearings, and inviting public comment on topics

proposal determines that employers' use of noncompetes is an unfair method of competition under Section 5 of the FTC Act. It recognizes that noncompetes may be unlawful in different contexts for different reasons; for example, employers' use of noncompetes to bind low-wage workers may be coercive and unfair in ways that the use of noncompetes to bind senior executives is not. Still, the proposal concludes that, in the aggregate, employers' use of noncompetes undermines competition across markets in ways that are harmful to workers and consumers and warrant a prohibition.

The proposed rule also draws on key lessons learned from state efforts to limit or ban the use of noncompetes. For example, research shows that some employers continue to use noncompetes even in states that have declared them null and void. As a result, workers in states where noncompetes are unenforceable are about as likely to have one in their contract as workers in other states.⁸ In practice this causes confusion and uncertainty for workers about whether they are bound by an enforceable noncompete, which can dissuade them from seeking or accepting another job. To address this, the proposed rule would both prohibit employers from representing to workers

including “the use of non-competition agreements and the conditions under which their use may be inconsistent with the antitrust laws”); Fed. Trade Comm'n, *Non-Competes in the Workplace: Examining Antitrust and Consumer Protection Issues* (Jan. 9, 2020), <https://www.ftc.gov/news-events/events/2020/01/non-competes-workplace-examining-antitrust-consumer-protection-issues>; Fed. Trade Comm'n, *Making Competition Work: Promoting Competition in Labor Markets* (Dec. 6–7, 2021), <https://www.ftc.gov/news-events/events/2021/12/making-competition-work-promoting-competition-labor-markets>; Fed. Trade Comm'n, *Solicitation for Public Comments on Contract Terms that May Harm Competition* (Aug 5, 2021), <https://www.regulations.gov/document/FTC-2021-0036-0022>. The FTC has also focused on noncompete clauses in connection with its merger review work. See Press Release, Fed. Trade Comm'n, FTC Approves Final Order Restoring Competitive Markets for Gasoline and Diesel in Michigan and Ohio (Aug. 9, 2022), <https://www.ftc.gov/news-events/news/press-releases/2022/08/ftc-approves-final-order-restoring-competitive-markets-gasoline-diesel-michigan-ohio>; Press Release, Fed. Trade Comm'n, FTC Approves Final Order Imposing Strict Limits on Future Mergers by Dialysis Service Provider DaVita, Inc. (Jan. 12, 2022), <https://www.ftc.gov/news-events/news/press-releases/2022/01/ftc-approves-final-order-imposing-strict-limits-future-mergers-dialysis-service-provider-davita-inc>; Press Release, Fed. Trade Comm'n, FTC Approves Final Order Requiring Divestitures of Hundreds of Retail Gas and Diesel Fuel Stations Owned by 7-Eleven, Inc. (Nov. 10, 2021), <https://www.ftc.gov/news-events/news/press-releases/2021/11/ftc-approves-final-order-requiring-divestitures-hundreds-retail-gas-diesel-fuel-stations-owned-7>.

⁸ Evan P. Starr, James J. Prescott, & Norman D. Bishara, *Noncompete Agreements in the U.S. Labor Force*, 64 J.L. & Econ. 53, 81 (2021).

that they are covered by a noncompete clause and require them to actively notify workers presently covered that these clauses are now void and cannot be enforced.

Action by federal enforcers is particularly appropriate here given that the harms from noncompetes flow across state lines. Many labor markets are spread across more than one state, and product markets are typically multistate as well, so the use of noncompetes in one state can harm workers and consumers in others. Moreover, employers may seek to circumvent state laws restricting noncompetes through the use of choice-of-law provisions and forum selection clauses, so that one state's lenient approach to noncompetes may have spillover effects into other states.⁹

The Federal Trade Commission is particularly well suited to this task. Congress designed the FTC to be an expert administrative agency that could enforce the prohibition against unfair methods of competition through rulemaking as well as through case-by-case adjudication. Although the Commission has primarily pursued antitrust enforcement through adjudication, rulemaking can deliver several benefits—including greater legal clarity and predictability, greater administrability and efficiency of enforcement, and greater public participation and airing of a maximally broad range of viewpoints and criticisms.¹⁰

Several factors seem to make noncompetes especially ripe for enforcement through rulemaking rather than adjudication, including the magnitude and scope of the apparent harms. Private litigation in this area may also be limited, given that there is no

⁹ Non-compete clauses often contain choice-of-law provisions designating a particular state's law for resolution of any future disputes. See Gillian Lester & Elizabeth Ryan, *Choice of Law and Employee Restrictive Covenants: An American Perspective*, 31 Comp. Lab. & Pol'y J. 389, 396–402 (2010). Some non-compete clauses include forum selection clauses, which specify the court and location where any dispute will be heard. *Id.* at 402–04. When contracting with workers in states with relatively stringent non-compete laws, companies may include choice-of-law and forum-selection provisions that designate jurisdictions with less stringent non-compete laws. The default rule under conflict-of-laws principles is that the court honors the parties' choice of law, meaning that the burden is on the worker to argue that the law of a different forum should apply. *Id.* at 394.

¹⁰ See, e.g., Rohit Chopra & Lina Khan, *The Case for "Unfair Methods of Competition" Rulemaking*, 87 U. Chi. L. Rev. 357 (2020); Nat'l Petroleum Refiners Ass'n v. FTC, 482 F.2d 672, 683 (D.C. Cir. 1973) (noting that "utilizing rule-making procedures opens up the process of agency policy innovation to a broad range of criticism, advice and data that is ordinarily less likely to be forthcoming in adjudication").

private right of action under Section 5 of the FTC Act—and that arbitration clauses and class action waivers in employment contracts often can functionally preclude lawsuits by workers.

Moreover, the FTC has notable expertise in this area. The Commission began deepening its work on noncompetes under Chairman Joseph Simons four years ago. Since then, the agency has held multiple workshops and sought and received public comments on three separate occasions. Our staff have closely studied the available economic research and reviewed hundreds of comments from employers, advocates, trade associations, members of Congress, state and local officials, unions, and workers.

In her dissent, Commissioner Wilson questions the Commission's authority to engage in "unfair methods of competition" rulemaking.¹¹ But the rulemaking authority we are exercising today is firmly rooted in the text and structure of the FTC Act and supported both by judicial precedent interpreting the scope of the law as well as further statutory language from the 1970s.¹²

¹¹ Commissioner Wilson argues that our enforcement actions are in direct tension with a Seventh Circuit decision, *Snap-On Tools Corp. v. FTC*, 321 F.2d 825 (7th Cir. 1963). *Snap-On Tools* is distinguishable on several fronts, including the fact that it concerned noncompetes used in the business-to-business context, not those used by an employer to restrict its workers. Additionally, while the majority stated that it is "not prepared to say that [the termination restriction] is a per se violation of the antitrust laws," *id.* at 837, the Commission did not argue for a per se rule and so the issue was not litigated. *Id.* at 830–31; *id.* at 839 (Hastings, C.J., dissenting). Notably, the question before the Seventh Circuit was *not* whether the noncompete clause itself constituted an unfair method of competition. The Commission had held that the termination restriction provision was unlawful because it was used as an enforcement mechanism to ensure compliance with the other provisions. *Id.* at 836–37. Thus, once the court found that the other restrictive provisions in the agreement were lawful, it also held that the clause restricting competition upon termination did not violate the FTC Act. *Id.* at 837.

¹² The plain text of the FTC Act clearly authorizes the Commission to issue rules. Specifically, Section 6(g) enables the agency to "make rules and regulations for the purpose of carrying out the provisions" of the law. Several other provisions support the conclusion that Section 6(g) confers substantive rulemaking authority. For instance, Section 18 explicitly preserves "any authority of the Commission to prescribe rules (including interpretive rules), and general statements of policy, with respect to unfair methods of competition in or affecting commerce." The D.C. Circuit endorsed this plain reading of 6(g) in *Petroleum Refiners*, 482 F.2d at 698, when it considered and rejected an argument that Section 6(g) only authorized the FTC to promulgate procedural or interpretive rules. *Petroleum Refiners* is the only case that directly addresses the FTC's Section 6(g) rulemaking authority. This holding—that the FTC may "promulgate rules defining the meaning of the statutory standards of the illegality [the agency was] empowered to prevent," *id.* at 698—represents the current state of the law.

Commissioner Wilson also suggests that the Commission's authority for the NPRM will be challenged under the major questions doctrine, which the Supreme Court recently applied in *West Virginia v. EPA*. Here, however, the FTC is operating under clear statutory authority. Identifying and addressing unfair methods of competition is central to the mandate that Congress gave the Commission in the text of our authorizing statute. Indeed, a greater threat to the "vesting of federal legislative power in Congress" would be for this Commission to repudiate or ignore Congress's clear direction to the Commission to consider rules to address unfair methods of competition.¹³

This proposal is the first step in the FTC's rulemaking process. It identifies several potential alternative rules, including those that would cover only a subset of workers or that would apply different legal standards to different categories of workers. Receiving input from a broad set of market participants, including those who have experienced firsthand the effects of noncompete clauses, will be critical to our efforts. I urge members of the public to review our proposal and submit comments.

A few topics are especially worthy of close consideration. First, should the rule apply different standards to noncompetes that cover senior executives or other highly paid workers? As the NPRM notes, these workers may be less vulnerable to coercion, but restraining them through noncompetes may still harm competition—for example, by making it harder and more expensive for potential entrants to recruit individuals for leadership positions. I am keen for input on this question, including on how any such category of workers should be defined and what standards should be applied. For example, if the Commission were to adopt a "rebuttable presumption" of illegality for noncompetes affecting these workers, what showing should be required to overcome the presumption?

Second, should the rule cover noncompetes between franchisors and franchisees? The current proposal does not cover noncompetes used by franchisors to restrict franchisees, but we recognize that in some cases they may raise concerns that are analogous to those raised by noncompetes between employers and workers. We welcome the public's views on this topic, as well as data or other evidence that could inform our consideration of this issue.

Third, what tools other than noncompetes might employers use to

¹³ *West Virginia v. EPA*, 142 S. Ct. 2587, 2617 (2022) (Gorsuch, J., concurring).

protect valuable investments, and how sufficient are these alternatives? The proposal identifies several potential mechanisms that employers may use—including trade secrets law and confidentiality agreements—and we preliminarily find that these alternatives reasonably achieve the goal of protecting investments without unduly burdening competition. We welcome feedback on the Commission's preliminary analysis of this issue.

I am deeply grateful to staff in the Office of Policy Planning, the Bureau of Competition, the Bureau of Economics, and the Office of General Counsel for their careful and thorough work on this proposal. I am also grateful to the many scholars, advocates, and journalists whose work in recent years has shed light on the proliferation of noncompetes and the resulting harms that can manifest.

While the NPRM is just the first step toward a final rule, it marks the Commission's commitment to exercising the full set of tools and authorities that Congress gave us and to ensuring that our work is protecting all Americans. I look forward to working closely with my colleagues to continue this critical effort.

Statement of Commissioner Slaughter Joined by Commissioner Alvaro M. Bedoya

One of the great privileges of working at the Federal Trade Commission is the opportunity—and responsibility—we have to help real people in their everyday lives. We offer that help not only when we challenge massive mergers but also when we tackle the myriad smaller ways in which people are denied agency and autonomy. When we fight fraud, manipulative business opportunities, anticompetitive schemes, and bogus fees, we help restore meaningful choice and dignity to consumers and workers. These principles are the bedrock of a democratic society, but too often they are denied to Americans who are not rich and powerful. Addressing the scourge of noncompete clauses that restrict the job mobility of workers advances our mission by ensuring that workers have the chance to compete to earn a fair wage and family-supporting benefits.

I am therefore pleased to support the Commission's Notice of Proposed Rulemaking ("NPRM") on the Noncompete Clause Rule under Sections 5 and 6(g) of the Federal Trade Commission Act. I am grateful to the cross-agency team who worked on this NPRM and thank them for their hard work and collaborative drafting process.

I also want to thank the civil-society organizations and academics who filed a petition with the FTC in 2019 calling for a rulemaking to address noncompetes in employment contracts.¹ This petition increased the awareness of and knowledge about the issue not only within the agency but also with the public more broadly. That heightened focus was on display in the FTC's noncompete workshop in January 2020.² As I did at that workshop, I again thank the labor community for engaging with the competition community to tackle the pocketbook issues that sit at the intersection of labor and antitrust law and that have profound effects on workers.³ Several years of activity by the Commission related to noncompete clauses in employment contracts have culminated in this NPRM, which is another milestone in our effort to more thoroughly incorporate labor competition and effects on workers into our antitrust law analyses.

I write separately to emphasize two points. First, noncompete clauses, and the restrictions they place on workers regarding their future employment or business creation, are deeply troubling. Based on the research discussed in the NPRM, they have serious ramifications for individual workers and labor competition broadly, as well as for consumers. Although sometimes referred to as noncompete "agreements," they rarely represent actual agreements. Instead, they are often imposed on workers with no ability to bargain as a condition of employment. Even when noncompetes have been ruled unenforceable by courts or outlawed by legislation, firms continue to use them, as was alleged in a recent case the FTC settled over noncompetes imposed on minimum wage-earning security guards.⁴

¹ Open Markets Inst. et al., Petition for Rulemaking to Prohibit Worker Non-Compete Clauses (March 20, 2019), <https://static1.squarespace.com/static/5e449c8c3ef68d752f3e70dc/t/5eaa04862ff52116d1dd04c1/1588200595775/Petition-for-Rulemaking-to-Prohibit-Worker-Non-Compete-Clauses.pdf>.

² Fed. Trade Comm'n, Non-Competes in the Workplace: Examining Antitrust and Consumer Protection Issues, <https://www.ftc.gov/news-events/events/2020/01/non-compete-clauses-workplace-examining-antitrust-consumer-protection-issues>.

³ Remarks of FTC Commissioner Rebecca Kelly Slaughter, New Decade, New Resolve to Protect and Promote Competitive Markets for Workers, FTC Workshop on Non-Compete Clauses in the Workplace (Jan. 9, 2020), https://www.ftc.gov/system/files/documents/public_statements/1561475/slaughter_-_noncompete_clauses_workshop_remarks_1-9-20.pdf.

⁴ In the Matter of Prudential Security, Inc., a corporation; Prudential Command Inc., a corporation; Greg Wier, a natural person; and Matthew Keywell, FTC Matter/File Number

Workers restrained by noncompetes are unable to pursue certain job opportunities and are therefore deprived of higher wages and more favorable working conditions and benefits. Similarly, businesses that need to hire workers are inhibited from attracting and hiring noncompete-restrained workers through better working conditions, pay, and benefits.⁵ Even more alarming is the evidence that shows noncompetes reduce earnings for workers not individually bound by them.⁶ Studies also show reduced entrepreneurship, new-business formation, or both when workers are inhibited by noncompetes.⁷ Finally, American consumers can suffer from noncompete clauses through paying higher prices for lower-quality goods and services.⁸ For all these reasons, it is clear that it is more than appropriate for the FTC to use our rulemaking authority under Sections 5 and 6(g) to address noncompete clauses in employment contracts.

Second, I strongly encourage the public to share their lived experiences and perspectives with the Commission. I have heard personally about how noncompete clauses can strike fear into workers and make them anxious about their livelihoods. These stories come from a variety of different industries and

2210026 (January 4, 2023), Complaint ¶ 22, <https://www.ftc.gov/legal-library/browse/cases-proceedings/2210026-prudential-security-et-al-matter>; Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro M. Bedoya in the Matters of Prudential Security, O-I Glass Inc., and Ardagh Group S.A., January 4, 2023, <https://www.ftc.gov/legal-library/browse/cases-proceedings/public-statements/statement-chair-lina-m-khan-joined-commissioners-slaughter-bedoya-matters-prudential-security-o-i>.

⁵ Notice of Proposed Rulemaking, Non-Compete Clause Rule, Part II.B.1.

⁶ See Matthew S. Johnson, Kurt Lavetti, & Michael Lipsitz, The Labor Market Effects of Legal Restrictions on Worker Mobility 2 (2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3455381; Evan Starr, Justin Frake, & Rajshree Agarwal, *Mobility Constraint Externalities*, 30 *Org. Sci.* 961, 6 (2019).

⁷ See Sampsa Samila & Olav Sorenson, Noncompete Covenants: Incentives to Innovate or Impediments to Growth, 57 *Mgmt. Sci.* 425, 432 (2011); Jessica Jeffers, The Impact of Restricting Labor Mobility on Corporate Investment and Entrepreneurship 22 (2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3040393; Evan Starr, Natarajan Balasubramanian, & Mariko Sakakibara, Screening Spinouts? How Noncompete Enforceability Affects the Creation, Growth, and Survival of New Firms, 64 *Mgmt. Sci.* 552, 561 (2018).

⁸ See Naomi Hausman & Kurt Lavetti, Physician Practice Organization and Negotiated Prices: Evidence from State Law Changes, 13 *a.m. Econ. J. Applied Econ.* 258, 284 (2021); Michael Lipsitz & Mark Tremblay, Noncompete Agreements and the Welfare of Consumers 6 (2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3975864.

professions, from fast-food workers to family physicians.⁹ Public input from individuals who are or who have been bound by noncompetes and from firms that use them is a critically important step in the rulemaking process, and it will help the Commission weigh the proposed broad ban on noncompete clauses as well as the alternative approaches discussed in the NPRM. I look forward to working with my fellow Commissioners to achieve a just outcome that promotes fair competition.

Dissenting Statement of Commissioner Christine S. Wilson

Today, the Commission announced a notice of proposed rulemaking (“NPRM”) for a Non-Compete Clause Rule. “The proposed rule would provide that it is an unfair method of competition—and therefore a violation of Section 5—for an employer to enter into or attempt to enter into a non-compete clause with a worker; [or to] maintain with a worker a non-compete clause”¹ For the many reasons described below, on the current record, I do not support initiating the proposed rulemaking and consequently dissent.

The proposed Non-Compete Clause Rule represents a radical departure from hundreds of years of legal precedent that employs a fact-specific inquiry into whether a non-compete clause is unreasonable in duration and scope, given the business justification for the restriction. The Commission undertakes this radical departure despite what appears at this time to be a lack of clear evidence to support the proposed rule. What little enforcement experience the agency has with employee non-compete provisions is very recent (within the last week) and fails to demonstrate harm to consumers and competition. Lacking enforcement experience, the Commission turns to academic literature—but the current record shows that studies in this area are scant, contain mixed results, and provide insufficient support for the scope of the proposed rule. And one study illustrates clearly, in the financial services sector, the negative unintended consequences of suspending non-compete provisions, including higher fees and broker misconduct. The suspension of non-competes across all industry sectors in the U.S. undoubtedly will impose a

⁹ See *People of the State of Ill. v. Jimmy John’s Enters., LLC*, No. 2016–CH–07746 (Cook County Cir. Ct. filed June 8, 2016); See also Kurt Lavetti, Carol Simon, & William D. White, *The Impacts of Restricting Mobility of Skilled Service Workers Evidence from Physicians*, 55 J. Hum. Res. 1025, 1042 (2020).

¹ Notice of Proposed Rulemaking for Non-Compete Clause Rule (“NPRM”) Part I (Jan. 5, 2023).

much larger raft of unintended consequences.

Setting aside the substance of the rule, the Commission’s competition rulemaking authority itself certainly will be challenged. The NPRM is vulnerable to meritorious challenges that (1) the Commission lacks authority to engage in “unfair methods of competition” rulemaking, (2) the major questions doctrine addressed in *West Virginia v. EPA* applies, and the Commission lacks clear Congressional authorization to undertake this initiative; and (3) assuming the agency does possess the authority to engage in this rulemaking, it is an impermissible delegation of legislative authority under the non-delegation doctrine, particularly because the Commission has replaced the consumer welfare standard with one of multiple goals. In short, today’s proposed rule will lead to protracted litigation in which the Commission is unlikely to prevail.

The NPRM invites public comment on both a sweeping ban on non-competes and various alternatives pursuant to the Administrative Procedure Act, not the Magnuson-Moss Act. Stakeholders should note that this solicitation for public comment is likely the only opportunity they will have to provide input not just on the proposed ban, but also on the proposed alternatives. For this reason, I encourage all interested parties to respond fully to all parts of the NPRM’s solicitation of public comments.

Non-Compete Clauses Merit Fact-Specific Inquiry

Based on the current record, non-compete clauses constitute an inappropriate subject for rulemaking. The competitive effects of a non-compete agreement depend heavily on the context of the agreement, including the business justification that prompted its adoption. But don’t take my word for it—the need for fact-specific inquiry aligns with hundreds of years of precedent. When assessing the legality of challenged non-compete agreements, state and federal courts (and English courts before them) have examined the duration and scope of non-compete clauses, as well as the asserted business justifications, to determine whether non-compete clauses are unreasonable and therefore unenforceable.²

The NPRM itself acknowledges, at least implicitly, the relevance of the circumstances surrounding adoption of

² See, e.g., *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 281 (6th Cir. 1898) (Taft, J.), aff’d in relevant part, 175 U.S. 211 (1899); *Mitchel v. Reynolds*, 1 P. Wms. 181 (1711).

non-compete clauses. For example, the NPRM proposes an exception to the ban on non-compete clauses for provisions associated with the sale of a business, acknowledging that these non-compete clauses help protect the value of the business acquired by the buyer.³ Recognizing that senior executives typically negotiate many facets of their employment agreements, the NPRM distinguishes situations in which senior executives are subject to non-compete provisions.⁴ And to stave off potential legal challenges, the NPRM proposes more carefully tailored alternatives to a sweeping ban on non-compete clauses that instead would vary by employee category.

Despite the importance of context and the need for fact-specific inquiries, the Commission instead applies the approach of the newly issued Section 5 Policy Statement⁵ to propose a near-complete ban on the use of non-compete clauses. Pursuant to this approach, the Commission invokes nefarious-sounding adjectives—here, “exploitive and coercive”—and replaces the evaluation of actual or likely competitive effects with an unsubstantiated conclusion about the “tendency” for the conduct to generate negative consequences for “affecting consumers, workers or other market participants.”⁶

Using the approach of the Section 5 Policy Statement that enables the majority summarily to condemn conduct it finds distasteful, the Commission today proposes a rule that prohibits conduct 47 states have chosen

³ NPRM Part V, Section 910.3.

⁴ Accordingly, the Commission seeks comments on whether senior executives should be treated differently from the proposed ban on non-compete clauses. See NPRM Parts IV.A.1.b, IV.A.1.c. In a similar vein, recent consent agreements issued for public comment that prohibit the use of non-compete agreements in the glass container industry do not prohibit non-compete clauses for senior executives and employees involved in research and development. See *O-I Glass, Inc.*, File No. 211–0182, https://www.ftc.gov/system/files/ftc_gov/pdf/2110182o-iglassdraftorderappxa.pdf (Jan. 4, 2023) (Decision and Order Appendix A); *Ardagh Glass Group S.A.*, File No. 211–0182, https://www.ftc.gov/system/files/ftc_gov/pdf/2110182ardaghdraftorderappxa.pdf (Jan. 4, 2023) (Decision and Order Appendix A); Christine S. Wilson, Comm’r, Fed. Trade Comm’n, *Dissenting Statement regarding In the Matter of O-I Glass, Inc. and In the Matter of Ardagh Group S.A.* (Jan. 4, 2023), <https://www.ftc.gov/legal-library/browse/cases-proceedings/public-statements/dissenting-statement-commissioner-christine-s-wilson-regarding-matters-o-i-glass-inc-ardagh-group-sa>.

⁵ Fed. Trade Comm’n, *Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act* (Nov. 10, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/p221202sec5enforcementpolicystatement_002.pdf.

⁶ *Id.* at 9.

to allow.⁷ Similarly, the Commission's proposed rule bans conduct that courts have found to be legal,⁸ a concern the Commission dismisses with a claim that the Section 5 prohibition on "unfair methods of competition" extends beyond the antitrust laws. But the majority's conclusions and today's proposed rule forbid conduct previously found lawful under Section 5 of the FTC Act. Specifically, applying FTC Act Section 5, the Seventh Circuit found that "[r]estrictive [non-compete] clauses . . . are legal unless they are unreasonable as to time or geographic scope[.]"⁹ In other words, the Seventh Circuit found that a fact-specific inquiry is required under Section 5.

The NPRM announced today conflicts not only with the Seventh Circuit's holding, but also with several hundred years of precedent. With all due respect to the majority, I am dubious that three unelected technocrats¹⁰ have somehow hit upon the right way to think about non-competes, and that all the preceding legal minds to examine this issue have gotten it wrong. The current rulemaking record does not convince me otherwise.

I. Non-Compete Agreements—the First Application of the Section 5 Policy Statement

The proposed Non-Compete Clause Rule "would provide that it is an unfair method of competition—and therefore a violation of Section 5—for an employer to enter into or attempt to enter into a

⁷ NPRM Part I.I.C.1. Further, the NPRM explains "[s]tates have been particularly active in restricting non-compete clauses in recent years." *Id.* The Commission's rulemaking will end states' varying approaches to address non-compete agreements. The Commission's preemption of states' approaches is premature to the extent that the Commission admits that it does not know where to draw lines regarding the treatment of non-compete provisions (*i.e.*, the Commission seeks comments on alternatives to the proposed ban based on earnings levels, job classifications, or presumptions). The Commission ignores the advice of Justice Brandeis and instead proposes to end states' experimentation to determine the optimal treatment of non-compete clauses. *See New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) ("To stay experimentation in things social and economic is a grave responsibility. Denial of the right to experiment may be fraught with serious consequences to the nation. It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.").

⁸ *See United States v. Empire Gas Corp.*, 537 F.2d 296, 307–08 (8th Cir. 1976); *Lektro-Vend Corp. v. Vendo Co.*, 660 F.2d 255, 267 (7th Cir. 1981); *Newburger, Loeb & Co., Inc. v. Gross*, 563 F.2d 1057, 1081–83 (2d Cir. 1977); *Bradford v. New York Times Co.*, 501 F.2d 51, 57–59 (2d Cir. 1974).

⁹ *Snap-On Tools Corp. v. Fed. Trade Comm'n*, 321 F.2d 825, 837 (7th Cir. 1963).

¹⁰ This characterization is not an insult, but a fact. I, too, am an unelected technocrat.

non-compete clause with a worker; [or] to maintain with a worker a non-compete clause . . ." ¹¹ The proposed ban on non-compete clauses is based only on alleged violations of Section 5 of the FTC Act; it is not premised on the illegality of non-compete clauses under the Sherman or Clayton Acts.

When the Commission issued the Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act ("Policy Statement") in November 2022, I warned that the approach described by the Policy Statement would enable the Commission majority to condemn conduct it disfavors, even when that conduct repeatedly has been found lawful.¹² I predicted that the approach to Section 5 enforcement contained in the Policy Statement would facilitate expansive enforcement, often without requiring evidence of anticompetitive effects. And I cautioned that subjects of investigations would not be able to defend their conduct because procompetitive justifications would not be credited. The Non-Compete Clause Rule NPRM provides a graphic illustration of these concerns.

A. The NPRM's Determination That Non-Compete Clauses Are Unfair

The NPRM states that there are 3 *independent* ways for classifying non-compete clauses as an "unfair" method of competition.¹³ In November, I objected to the enforcement approach described in the Section 5 Policy Statement—specifically, permitting the Commission majority to condemn conduct merely by selecting and assigning to disfavored conduct one or more adjectives from a nefarious-sounding list.¹⁴ Here, two of the three explanations the Commission provides for concluding that non-compete clauses are unfair rely on invocation of the adjectives "exploitive and coercive."¹⁵ The third explanation for the illegality of non-compete clauses demonstrates how little evidence the majority requires to conclude that conduct causes harm.

¹¹ NPRM Part I.

¹² *See* Christine S. Wilson, Comm'r, Fed. Trade Comm'n, Dissenting Statement Regarding the "Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act" (Nov. 10, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyWilsonDissentStmnt.pdf.

¹³ NPRM Part IV.A.1.

¹⁴ *See* Wilson, *supra* note 12.

¹⁵ The Policy Statement claimed that determinations of unfairness would be based on a sliding scale. Here, the NPRM identifies independent ways to determine that non-compete clauses are unfair; no sliding scale is applied.

According to the NPRM, "non-compete clauses are exploitive and coercive at the time of contracting."¹⁶ The NPRM explains that the "clauses for workers other than senior executives are exploitive and coercive because they take advantage of unequal bargaining power[.]"¹⁷ The business community will be surprised to learn that "unequal bargaining power" can lead to a conclusion that any negotiated outcome may be condemned as "exploitive and coercive," which then can be parlayed into a finding that the conduct violates Section 5. Indeed, this assertion is particularly troubling not merely because it presages an approach that is literally limitless, but also because the imbalance of bargaining power, as in this setting, arises wholly apart from any conduct by the business.¹⁸ The reader may note that the NPRM cites legal decisions to support the assignment of adjectives. Yet, a careful reading of the courts' discussions of the imbalance of bargaining power between employers and employees reveals that while the imbalance may provide a reason to scrutinize non-compete clauses, it is not used to condemn or invalidate them.¹⁹ Remarkably, in each case cited in footnote 253 of the NPRM, the court found the non-compete clauses to be enforceable.

Next, the NPRM finds that "non-compete clauses are exploitive and coercive at the time of the worker's potential departure from the employer[.]"²⁰ The NPRM reaches this conclusion regardless of whether the clauses are enforced. This conclusion is

¹⁶ NPRM Part IV.A.1.b The NPRM explains that this conclusion does not apply to senior executives and also seeks comment on whether there is a broader category of highly paid or highly skilled employees for whom the conclusion is inappropriate. *Id.*

¹⁷ *Id.*

¹⁸ According to the NPRM, unequal bargaining power arises because employees depend on job income to pay bills, job searches entail significant transaction costs, the prevalence of unions has declined, employers outsource firm functions, employers have more experience negotiating because they have multiple employees, employees typically do not hire lawyers to negotiate agreements, and employees may not focus on the terms of their contracts. *Id.*

¹⁹ *See Alexander & Alexander, Inc. v. Danahy*, 488 NE2d 22, 29 (Mass. App. Ct. 1986) (finding injunction to enforce non-compete agreement proper); *Diepholz v. Rutledge*, 659 NE 989, 991 (Ill. Ct. App. 1995) (finding non-compete agreement enforceable, but also finding no violation of terms of non-compete agreement); *Palmetto Mortuary Transp., Inc. v. Knight Sys., Inc.*, 818 SE2d 724, 731 (S.C. 2018) (finding non-compete agreement enforceable).

²⁰ NPRM Part IV.A.1.c. Again, the NPRM explains that this conclusion does not apply to senior executives and also invites comments on whether there is a broader category of highly paid or highly skilled employees for whom the conclusion is inappropriate. *Id.*

contrary to legal precedent, which requires enforcement of non-compete provisions before finding harm.²¹

Finally, the NPRM finds that “non-compete clauses are restrictive conduct that negatively affects competitive conditions.”²² Although this basis for concluding that non-compete provisions are unfair does not rely solely on the selection of an adjective, here, the NPRM demonstrates how little evidence the majority requires before finding that conduct is unfair pursuant to the Section 5 Policy Statement.

Until yesterday, the Commission had announced no cases (and therefore had no experience and no evidence) to conclude that non-compete clauses harm competition in labor markets. In fact, the only litigated FTC case challenging a non-compete clause found that a non-compete provision covering franchise dealers did *not* violate Section 5 of the FTC Act.²³ Notably, the NPRM omits any reference to this case. The Commission has accepted settlements regarding non-compete clauses in contracts between businesses,²⁴ but the majority itself has distinguished those cases from non-compete clauses in labor contracts.²⁵ And in those B2B cases, the non-compete clauses were associated with the sale of a business, a situation that falls within the narrow exception to the ban provided in the proposed Non-Compete Clause Rule.

Just yesterday, though, the Commission rushed out the announcement of three consent agreements that resolve allegations that non-compete provisions constitute an

unfair method of competition.²⁶ The first consent involves security guard services, and the other two involve the manufacturing of glass containers. These consents undoubtedly were designed to support assertions that the FTC now has experience with non-compete agreements in employee contracts. But even a cursory read of the complaints reveals the diaphanous nature of this “experience.”

Remarkably, none of these cases provides evidence showing the anticompetitive effects of non-compete clauses beyond the conclusory allegations in the complaints. The complaints in the glass container industry assert that non-compete provisions may prevent entry or expansion by competitors, but contain no allegations regarding firms that have tried unsuccessfully to obtain personnel with industry-specific skills and experience.²⁷ Regarding the effects on employees, the complaints make no allegations that the non-compete clauses were enforced by respondents²⁸ and the Analysis to Aid Public Comment accompanying the consent agreements points only to studies not tied to the glass container industry. These cases provide no evidence that the non-compete provisions limited competition for employees with industry-specific expertise, thereby lowering wages or impacting job quality. Similarly, in the case against Prudential Security, Inc.,²⁹ the complaint alleges that individual former employees were limited in their ability to work for other firms in the security guard industry,³⁰ but contain no allegations that the firm’s non-compete provisions had market effects on wages or effects in a properly defined market for security guard services.

The NPRM also asserts FTC experience with non-compete

provisions by pointing to Commission merger consent agreements that restrict the use of non-compete agreements. The complaints in those cases did not allege harm from non-compete clauses and the provisions in the consent agreements were included to ensure that the buyers of divestiture assets could obtain employees familiar with the assets and necessary for the success of the divestitures at issue.

Finally, the NPRM claims Commission experience with non-compete agreements to support the Non-Compete Clause Rule from a Commission workshop in January 2020.³¹ But the NPRM fails to reflect the variety of views expressed during that workshop, including testimony that the economic literature is “[s]till far from reaching a scientific standard for concluding [that non-compete agreements] are bad for overall welfare . . . Also [we] don’t yet fully understand the distribution of effects on workers . . . Welfare tradeoffs are likely context-specific, and may be heterogeneous.”³²

Indeed, the NPRM ignores that testimony and instead focuses on economic literature that purportedly demonstrates that non-compete clauses are unfair because they negatively affect competitive conditions. But an objective review of that literature reveals a mixed bag. For example, the first study described in the NPRM³³ finds that “decreasing non-compete clause enforceability from the approximate enforceability level of the fifth-strictest state to that of the fifth-most-lax state would increase workers’ earnings by 3–4%.” Yet, this study also finds that these effects vary strongly across different groups of individuals. For example, the authors find that “enforceability has little to no effect on earnings for non-college educated workers” and instead find that enforceability primarily impacts college-educated workers. Similarly, it finds that strict non-compete clause enforceability has very different effects for different demographic groups: it has little to no effect on men, and much

²¹ See, e.g., *O’Regan v. Arbitration Forums, Inc.*, 121 F.3d 1060, 1065–66 (7th Cir. 1997) (“to apply antitrust laws to restrictive employment covenants, there must be some attempted enforcement of an arguably overbroad portion of the covenant in order for there to be a federal antitrust violation.”); *Lektro-Vend Corp. v. Vendo Co.*, 660 F.2d 255, 267 (7th Cir. 1981) (“a section 1 violation requires proof that the defendant knowingly enforced the arguably overbroad section of the ancillary noncompetition covenant”).

²² NPRM Part IV.A.1.a.

²³ See *Snap-On Tools Corp. v. Fed. Trade Comm’n*, 321 F.2d at 837.

²⁴ See ARKO Corp., FTC File No. 211–0187, https://www.ftc.gov/system/files/ftc_gov/pdf/2110087C4773ArkoExpressComplaint.pdf (Aug. 5, 2022); DTE Energy Co., FTC File No. 191–0068, https://www.ftc.gov/system/files/documents/cases/191_0068_c-4691_dte-enbridge_complaint.pdf (Dec. 13, 2019).

²⁵ See Lina M. Khan, Chair, Fed. Trade Comm’n, Joined by Rebecca Kelly Slaughter and Alvaro M. Bedoya, Comm’rs, Fed. Trade Comm’n, Statement regarding In the Matter of ARKO Corp./Express Stop, https://www.ftc.gov/system/files/ftc_gov/pdf/2110187GPMExpressKhanStatement.pdf (June 10, 2022) (distinguishing non-compete clauses in labor contracts and effects on workers from non-compete clause in merger agreement where both parties remain in market).

²⁶ On December 28, 2022, the Commission voted to accept for public comment three consent agreements involving non-compete agreements. For two of those matters, the Commission vote occurred less than a week after the Commission received the papers. See Ardagh Glass Group S.A., File No. 211–0182, https://www.ftc.gov/system/files/ftc_gov/pdf/2110182ardaghacco.pdf (Jan. 4, 2023) (Agreement Containing Consent Order (signatures dated Dec. 21, 2022)).

²⁷ See O–I Glass, Inc., File No. 211–0182, https://www.ftc.gov/system/files/ftc_gov/pdf/2110182oiglasscomplaint.pdf (Jan. 4, 2023) (complaint ¶¶ 6, 8); Ardagh Glass Group S.A., File No. 211–0182, https://www.ftc.gov/system/files/ftc_gov/pdf/2110182ardaghcomplaint.pdf (Jan. 4, 2023) (complaint ¶¶ 6, 8).

²⁸ See Wilson, Dissenting Statement regarding In the Matter of O–I Glass, Inc. and In the Matter of Ardagh Glass Group S.A., *supra* note 4.

²⁹ Prudential Security, Inc., File No. 221–0026, https://www.ftc.gov/system/files/ftc_gov/pdf/2210026prudentialsecuritycomplaint.pdf (Dec. 28, 2022) (consent agreement accepted for public comment).

³⁰ *Id.* (complaint at ¶¶ 23, 25).

³¹ Fed. Trade Comm’n, *Non-Competes in the Workplace: Examining Antitrust and Consumer Protection Issues*, <https://www.ftc.gov/news-events/events/2020/01/non-compete-clauses-workplace-examining-antitrust-consumer-protection-issues>.

³² Kurt Lavetti, *Economic Welfare Aspects of Non-Compete Agreements*, Remarks at the Fed. Trade Comm’n Workshop on Non-Compete Clauses in the Workplace (Jan. 9, 2020), https://www.ftc.gov/system/files/documents/public_events/1556256/non-compete=workshop-slides.pdf.

³³ Matthew S. Johnson, Kurt Lavetti, & Michael Lipsitz, *The Labor Market Effects of Legal Restrictions on Worker Mobility 2*, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3455381 (2020).

larger effects on women and Black men and women. The NPRM interprets these differential effects as facts in favor of the Non-Compete Clause Rule, as it would diminish race and gender wage gaps, but there is no corresponding discussion of the Rule's effect on the wage gap based on education. An alternative interpretation of these findings is that the scientific literature is still muddled as to who is helped and who is harmed by non-compete clauses, and that it would be better for the Commission to tailor a rule to those settings where a scientific consensus exists.

Similarly, the NPRM often bases its conclusions about the effects of non-compete clauses on limited support. For example, the NPRM contends that increased enforceability of non-compete clauses increases consumer prices. Yet, under the current record, this conclusion is based on only one study in healthcare markets and another study that considers the relationship between non-compete clauses and concentration.³⁴ The NPRM does not provide a basis to conclude that findings with respect to the market for physicians and healthcare are generalizable, instead acknowledging that no comparable evidence exists for other markets.³⁵ Also, the study that considers the effects of non-compete clauses on concentration does not draw conclusions about prices; the NPRM's conclusion that non-compete provisions lead to higher prices requires assumptions about a relationship between concentration and prices. Moreover, the NPRM omits studies showing that reducing the enforceability of non-compete restrictions leads to higher prices for consumers. A study by Gurun, Stoffman, and Yonker finds that an agreement not to enforce post-employment restrictions among financial advisory firms that were members of the Broker Protocol led brokers to depart their firms, and consumers to follow their brokers, at high rates. The study found, however, that clients of firms in the Broker Protocol paid higher fees and experienced higher levels of broker misconduct.³⁶ In other words, suspending non-competes resulted in higher prices and a decrease in the quality of service provided. These unintended consequences illustrate the inevitably far-reaching and unintended consequences that today's NPRM will

visit upon employees, employers, competition, and the economy.

B. The NPRM's Treatment of Business Justifications

The NPRM explains that "the additional incentive to invest (in assets like physical capital, human capital, or customer attraction, or in the sharing of trade secrets and confidential commercial information) is the primary justification for use of non-compete clauses."³⁷

It acknowledges that "there is evidence that non-compete clauses increase employee training and other forms of investment,"³⁸ and describes two studies demonstrating that increased non-compete clause enforceability increased firm-provided training and investment.³⁹ It also describes studies that examine non-compete clause use and investment.⁴⁰ Despite the studies, the NPRM concludes, "the evidence that non-compete clauses benefit workers or consumers is scant."⁴¹ In other words, the NPRM treats asymmetrically the evidence of harms (mixed evidence given great credence) and benefits (robust evidence given no credence). These early examples of cherry-picking evidence that conforms to the narrative provide little confidence in the integrity of the rulemaking process or the ultimate outcome.

Implicitly, though, the NPRM credits some business justifications for non-compete provisions. It excludes from the ban those non-compete clauses associated with the sale of a business, implicitly acknowledging that these non-compete clauses are necessary to

protect the goodwill of the transferred business. Also, the NPRM likely credits business justifications when it seeks comment on whether senior executives should be covered by the rule. Nonetheless, on its face, the NPRM expressly discounts business justifications and makes no effort to distinguish and determine circumstances where investment incentives are important.

The NPRM also discounts procompetitive business justifications by asserting that trade secret law, non-disclosure agreements, and other mechanisms can be used to protect firm investments. While the NPRM explains that these mechanisms may protect investments, the existing record provides no evidence that these mechanisms are effective substitutes for non-compete agreements.⁴² The NPRM cites no instances where these mechanisms have been used effectively in lieu of non-compete clauses, even though natural experiments exist and could be studied (e.g., when states have changed the enforceability of non-compete clauses). "[M]erely identifying alternative mechanisms to solve a potential employee investment problem does not provide . . . guidance as to which mechanism achieves the objective at the lowest social cost."⁴³ Moreover, the NPRM's observation that firms successfully operate in states where non-compete clauses are not enforceable is unpersuasive; the NPRM offers no meaningful cross-state comparisons and the observation does not show that firms and competition are equally or even more successful in those states than in states where non-compete clauses are permissible.

II. The Proposed Non-Compete Clause Rule Will Trigger Numerous and Likely Successful Legal Challenges Regarding the Commission's Authority To Issue the Rule

This section describes the numerous, and meritorious, legal challenges that undoubtedly will be launched against the Non-Compete Clause Rule. Defending these challenges will entail lengthy litigation that will consume

³⁷ NPRM Part II.B.2.e.

³⁸ *Id.*

³⁹ Evan Starr, *Consider This: Training, Wages, and the Enforceability of Non-Compete Clauses*, 72 I.L.R. Rev. 783, 799 (2019) (moving from mean non-compete enforceability to no non-compete clause enforceability would decrease the number of workers receiving training by 14.7% in occupations that use non-compete clauses at a high rate); Jessica Jeffers, *The Impact of Restricting Labor Mobility on Corporate Investment and Entrepreneurship* 22 (2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3040393 (knowledge-intensive firms invest 32% less in capital equipment following decreases in the enforceability of non-compete clauses).

⁴⁰ Matthew S. Johnson & Michael Lipsitz, *Why Are Low-Wage Workers Signing Noncompete Agreements?*, 57 J. Hum. Res. 689, 700 (2022) (finding firms that use non-compete clauses in hair salon industry train employees at 11% higher rate and increase investment in particular customer-attraction device by 11%); Evan P. Starr, James J. Prescott, & Norman D. Bishara, *Noncompete Agreements in the U.S. Labor Force*, 64 J.L. & Econ. 53, 53 (2021) (finding no statistically significant impact on training and trade secrets from use of non-compete clauses, but unable to examine other types of investments).

⁴¹ NPRM Part IV.B.3.

⁴² There is a limited literature regarding the efficacy of trade secret protection and non-disclosure agreements. See Jie Gong & I.P.L. Png, *Trade Secrets Law and Inventory Efficiency: Empirical Evidence from U.S. Manufacturing*, <https://ssrn.com/abstract=2102304> (July 8, 2012) (investigating effects of operational know-how information spillovers under various levels of enforcement of trade secret law).

⁴³ Camila Ringeling, Joshua D. Wright, et al., *Noncompete Clauses Used in Employment Contracts*, Comment of the Global Antitrust Institute 6 (Feb. 7, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3534374.

³⁴ NPRM Part II.B.2.a.

³⁵ NPRM Part VII.B.2.c.

³⁶ Umit G. Gurun, Noah Stoffman, & Scott E. Yonker, *Unlocking Clients: The Importance of Relationships in the Financial Advisory Industry*, 141 J. Fin. Econ. 1218 (2021).

substantial staff resources. I anticipate that the Rule will not withstand these challenges, so the Commission majority essentially is directing staff to embark on a demanding and futile effort. In the face of finite and scarce resources, this NPRM is hardly the best use of FTC bandwidth.

There are numerous paths for opponents to challenge the Commission's authority to promulgate the Non-Compete Clause Rule. First, I question whether the FTC Act provides authority for competition rulemaking. The NPRM states that the Commission proposes the Non-Compete Clause Rule pursuant to Sections 5 and 6(g) of the FTC Act. Section 6(g) of the FTC Act authorizes the Commission to "make rules and regulations for the purpose of carrying out the provisions of the subchapter" where Section 6(g) otherwise provides that the Commission may "from time to time classify corporations."⁴⁴ Section 6(g) was believed to provide authority only for the Commission to adopt the Commission's procedural rules. For decades, consistent with the statements in the FTC Act's legislative history, Commission leadership testified before Congress that the Commission lacked substantive competition rulemaking authority.⁴⁵

⁴⁴ 15 U.S.C. 46(g). Section 6 of the FTC Act provides

§ 46. Additional powers of Commission
The Commission shall also have power . . .
(g) Classification of corporations; regulations
From time to time classify corporations and (except as provided in section 57a(a)(2) of this title) to make rules and regulations for the purpose of carrying out the provisions of this subchapter.

⁴⁵ See *Nat'l Petroleum Refrs Ass'n v. FTC*, 482 F.2d 672, 696 nn. 38, 39 (D.C. Cir. 1973). See also Noah Joshua Phillips, *Against Antitrust Regulation*, American Enterprise Institute Report 3, <https://www.aei.org/research-products/report/against-antitrust-regulation/> (Oct. 13, 2022) ("[T]he Conference Committee [considering legislation that created the Federal Trade Commission] was between two bills, neither of which contemplated substantive rulemaking. . . . The legislative history does not demonstrate congressional intent to give the FTC substantive rulemaking power: The House considered and rejected it, the Senate never proposed it, and neither the Conference Committee's report nor the final debates mentioned it."); 51 Cong. Rec. 12916 (1914), reprinted in *The Legislative History of the Federal Antitrust Laws and Related Statutes* 4368 (Earl W. Kintner ed., 1982) statement of Sen. Cummins ("[I]f we were to attempt to go further in this act and to give the commission the authority to prescribe a code of rules governing the conduct of the business men of this country for the future, we would clash with the principle that we can not confer upon the commission in that respect legislative authority; but we have not made any such attempt as that, and no one proposes any attempt of that sort."); *id.* at 14932, reprinted in *The Legislative History of the Federal Antitrust Laws and Related Statutes* 4732 (Earl W. Kintner ed., 1982) (statement of Rep. Covington) ("The Federal trade commission will have no power to prescribe the methods of

Ignoring this history, the Commission embarked on a substantive rulemaking binge in the 1960s and 1970s.⁴⁶ The vast majority of these substantive rules pertained to consumer protection issues. Only one substantive rule was grounded solely in competition;⁴⁷ that rule was not enforced and subsequently was withdrawn.⁴⁸ Another substantive rule was grounded in both competition and consumer protection principles, and prompted a federal court challenge. There, the D.C. Circuit in 1973 held in *National Petroleum Refiners*⁴⁹ that the FTC did have the power to promulgate substantive rules.

Two years later, however, Congress enacted the Magnuson-Moss Act,⁵⁰ which required substantive consumer protection rules to be promulgated with heightened procedural safeguards under a new Section 18 of the FTC Act. Notably, the Magnuson-Moss Act expressly excluded rulemaking for unfair methods of competition from Section 18. FTC Chairman Miles Kirkpatrick (1970–73) explained that it was not clear whether Congress in the Magnuson-Moss Act sought to clarify existing rulemaking authority or to grant substantive rulemaking authority to the FTC for the first time.⁵¹ If the latter, then the FTC only has substantive *consumer protection* rulemaking power, and lacks the authority to engage in substantive *competition* rulemaking. This uncertainty about the language of the statute will be a starting point for

competition to be used in the future. In issuing orders it will not be exercising power of a legislative nature . . . The function of the Federal trade commission will be to determine whether an existing method of competition is unfair, and, if it finds it to be unfair, to order the discontinuance of its use. In doing this it will exercise power of a judicial nature."); *id.* at 13317, reprinted in *The Legislative History of the Federal Antitrust Laws and Related Statutes* 4675 (Earl W. Kintner ed., 1982) (statement of Sen Walsh) ("We are not going to give to the trade commission the general power to regulate and prescribe rules under which the business of this country shall in the future be conducted; we propose simply to give it the power to denounce as unlawful a particular practice that is pursued by that business.").

⁴⁶ See Timothy J. Muris & Howard Beales, III, *The Limits of Unfairness Under the Federal Trade Commission Act* 13 (1991).

⁴⁷ FTC Men's and Boy's Tailored Clothing Rule, 16 CFR 412 (1968).

⁴⁸ Notice of Rule Repeal, 59 FR 8527 (1994).

⁴⁹ *Nat'l Petroleum Refrs Ass'n v. FTC*, 482 F.2d 672 (D.C. Cir. 1973).

⁵⁰ Magnuson-Moss Warranty—Federal Trade Commission Improvement Act, Public Law 93–637, 88 Stat. 2183 (1975).

⁵¹ See Miles W. Kirkpatrick, *FTC Rulemaking in Historical Perspective* 48 *Antitrust L.J.* 1561, 1561 (1979) ("One of the most important aspects of the Magnuson-Moss Act was its granting, or confirmation, depending upon your reading of the law at that time, of the FTC's rulemaking powers.").

challenges of the Non-Compete Clause Rule.

Second, the Commission's authority for the Rule likely will be challenged under the major questions doctrine, which the Supreme Court recently applied in *West Virginia v. EPA*.⁵² Under the major questions doctrine, "where a statute . . . confers authority upon an administrative agency," a court asks "whether Congress in fact meant to confer the power the agency has asserted."⁵³ The Supreme Court explained in *West Virginia v. EPA* that an agency's exercise of statutory authority involved a major question where the "history and the breadth of the authority that the agency has asserted, and the economic and political significance of that assertion, provide a reason to hesitate before concluding that Congress meant to confer such authority."⁵⁴

Challengers will ask a court to determine whether today's NPRM constitutes a major question. Using Justice Gorsuch's concurrence as a guide, agency action will trigger the application of the major questions doctrine if the agency claims, among other things, the power to (1) resolve a matter of great political significance, (2) regulate a significant portion of the American economy, or (3) intrude in an area that is the particular domain of state law.⁵⁵ First, the regulation of non-compete clauses is a question of political significance; Congress has considered and rejected bills significantly limiting or banning non-competes on numerous occasions,⁵⁶ a strong indication that the Commission is trying to "work around" the legislative process to resolve a question of political significance.⁵⁷ Second, the Rule proposes to regulate a significant portion of the American economy through a ban on non-competes. According to the NPRM, the "Commission estimates that approximately one in five American workers—or approximately 30 million workers—is bound by a non-compete clause."⁵⁸ Thus, the Non-Compete Clause Rule indisputably will negate millions of private contractual agreements and impact employer/employee relationships in a wide variety of

⁵² *West Virginia v. EPA*, 142 S. Ct. 2587 (2022).

⁵³ *Id.* at 2608.

⁵⁴ *Id.*

⁵⁵ *Id.* at 2600–01 (Gorsuch, J. concurring).

⁵⁶ Russell Beck, *A Brief History of Noncompete Regulation*, *Fair Competition Law* (Oct. 11, 2021), <https://faircompetitionlaw.com/2021/10/11/a-brief-history-of-noncompete-regulation/>.

⁵⁷ *West Virginia v. EPA*, 142 S.Ct. at 2600 (Gorsuch, J. concurring).

⁵⁸ NPRM Part II.B.1.a.

industries across the United States. Third, regulation of non-compete agreements has been the particular domain of state law. As the NPRM explains, 47 states permit non-competes in some capacity, while three states have chosen to prohibit them entirely, and state legislatures have been active in this area recently.⁵⁹

If a court were to conclude that the Non-Compete Clause Rule is a major question, the FTC would be required to identify clear Congressional authorization to impose a regulation banning non-compete clauses. Yet, as discussed above, that clear authorization is unavailable. The language in Section 6(b) is far from clear, and largely discusses the Commission's classification of corporations. I do not believe that Congress gave the FTC authority to enact substantive rules related to any provision of the FTC Act using this "oblique" and unclear language. In addition, the decision by Congress to omit unfair methods of competition rulemaking in the Magnuson-Moss Act, which immediately followed the decision in *National Petroleum Refiners*, is additional evidence that Congress has not clearly authorized the FTC to make competition rules that may have significant political or economic consequences. Moreover, Congress did not remove the known ambiguity when it enacted the FTC Improvements Act of 1980.⁶⁰

Third, the authority for the Non-Compete Clause Rule may be challenged under the non-delegation doctrine. The doctrine is based on the principle that Congress cannot delegate its legislative power to another branch of government, including independent agencies.⁶¹

⁵⁹ *Id.* Part II.C.1.

⁶⁰ See H.R. Rep. No. 96–917, 96th Cong., 2d sess. 29–30 (1980), reprinted in *The Legislative History of the Federal Antitrust Laws and Related Statutes 5862* (Earl W. Kintner ed., 1982) (conference report on FTC Improvements Act of 1980 explaining that when adopting a restriction on standards and certification rulemaking brought as an unfair or deceptive act or practice, conferees were not taking a position on the Commission's authority to issue a trade regulation rule defining 'unfair methods of competition' pursuant to section 6(g). "The substitute leaves unaffected whatever authority the Commission might have under any other provision of the FTC Act to issue rules with respect to 'unfair methods of competition.'").

⁶¹ Five Supreme Court justices have expressed interest in reconsidering the Court's prior thinking on the doctrine, which increases the risk that a challenge may be successful. See *Gundy v. United States*, 139 S. Ct. 2116, 2131 (2019) (Alito, J. concurring) (stating with respect to the nondelegation doctrine that "[i]f a majority of this Court were willing to reconsider the approach we have taken for the past 84 years, I would support that effort"); *id.* at 2131 (Gorsuch, J., dissenting, joined by Chief Justice Roberts and Justice Thomas) (expressing desire to "revisit" the Court's approach

Since the 1920s, the Supreme Court has found that Congress has not made an improper delegation of legislative power so long as Congress has set out "an intelligible principle to which the person or body authorized to fix [rules] is directed to conform."⁶² Applying this principle in *Schechter Poultry*,⁶³ the Supreme Court approved Congressional authorization for the FTC to prohibit unfair methods of competition, relying on the Commission's administrative enforcement proceedings where the Commission acts as "a quasi judicial body" and that "[p]rovision was made for formal complaint, for notice and hearing, for appropriate findings of fact supported by adequate evidence, and for judicial review . . ." ⁶⁴ The Court simultaneously found that provisions of the National Industrial Recovery Act to issue "codes of fair competition" were *improper* delegations of legislative power, distinguishing the impermissibly broad fair competition codes from the FTC Act's approach to address unfair methods of competition that are "determined in particular instances, upon evidence, in light of particular competitive conditions[.]" ⁶⁵

Notably, the Commission's proposed ban on non-compete clauses abandons the Commission's procedures that led the Supreme Court in *Schechter Poultry* to find that the Commission's enforcement of "unfair methods of competition" does not constitute an improper delegation of legislative power. In addition, to the extent that the Commission's Section 5 Policy Statement (which provides the basis for determining that non-compete clauses are an unfair method of competition) abandons the consumer welfare standard to pursue multiple goals, including protecting labor, the Commission's action more closely resembles the National Industrial Recovery Act codes that also sought to implement multiple goals under the guise of codes of fair competition.

III. Comments Are Encouraged

The NPRM invites public comment on many issues. I strongly encourage the submission of comments from all interested stakeholders. After all, unlike rulemaking for consumer protection

to the nondelegation doctrine); *Paul v. United States*, 140 S. Ct. 342, 342 (2019) (statement of Kavanaugh, J. respecting the denial of certiorari); Amy Coney Barrett, *Suspension and Delegation*, 99 Cornell L. Rev. 251, 318 (2014).

⁶² *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928).

⁶³ *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935).

⁶⁴ *Id.* at 533.

⁶⁵ *Id.*

rules under the Magnuson-Moss process, this is likely the only opportunity for public input before the Commission issues a final rule. For this reason, it is important for commenters to address the proposed alternatives to the near-complete ban on non-compete provisions. To the extent that the NPRM proposes alternatives to the current proposed rule, if the Commission were subsequently to adopt one of the alternatives, which would be a logical outgrowth of the current proposed rulemaking,⁶⁶ there would be no further opportunity for public comment. Moreover, the Commission believes that if it were to adopt alternatives that differentiate among categories of workers, the various rule provisions would be severable if a court were to invalidate one provision. Consequently, it is important for the public to address each of the alternatives proposed in the NPRM because the comment period on the proposed rule is the only opportunity for public input on those alternatives.

In addition to the issues for which the NPRM invites comments, I encourage stakeholders to address the following points:

- The NPRM references some academic studies regarding non-competes. What other academic literature addresses the issues in the NPRM, including the procompetitive justifications for non-compete provisions?
- The NPRM describes papers that exploit natural experiments to estimate the effects of enforcing non-compete clauses. While this approach ensures that the estimates are internally valid, it reflects the causal effects of non-compete agreements only in the contexts within which they are estimated. What should the Commission consider to understand whether and when these estimates are externally valid? How can the Commission know that the estimates calculated from the contexts of the literature are representative of the contexts outside of the literature?
- The NPRM draws conclusions based on "the weight of the literature," but the literature on the effects of non-compete agreements is limited, contains mixed results, and is sometimes industry-specific. Which conclusions in the NPRM are supported by the weight

⁶⁶ See *Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 210 (D.C. Cir. 2007); see also *Agape Church, Inc. v. FCC*, 738 F.3d 397, 412 (2013) (holding that FCC "sunset" rule was a logical outgrowth when proposed rule gave public notice that a viewability rule was in danger of being phased out, i.e., a sunset provision).

of the literature? Which conclusions in the NPRM contradict the weight of the literature? Which conclusions in the NPRM require additional evidence before they can be considered substantiated?

- Where the evidence provided in the NPRM is limited, is the evidence

sufficient to support either the proposed ban on non-compete clauses or the proffered alternative approaches to the proposed ban?

- What are the benefits and drawbacks of the currently proposed ban compared to the proposed alternative rule that would find a

presumption of unlawfulness, including the role of procompetitive justifications in rebutting a presumption?

[FR Doc. 2023-00414 Filed 1-18-23; 8:45 am]

BILLING CODE 6750-01-P



FEDERAL REGISTER

Vol. 88

Thursday,

No. 12

January 19, 2023

Part III

Department of Agriculture

7 CFR Part 205

National Organic Program (NOP); Strengthening Organic Enforcement;
Final Rule

DEPARTMENT OF AGRICULTURE**Agricultural Marketing Service****7 CFR Part 205**

[Doc. No. AMS–NOP–17–0065; NOP–17–02]

RIN 0581–AD09

**National Organic Program (NOP);
Strengthening Organic Enforcement****AGENCY:** Agricultural Marketing Service, USDA.**ACTION:** Final rule.

SUMMARY: This rulemaking amends the United States Department of Agriculture (USDA) organic regulations to strengthen oversight and enforcement of the production, handling, and sale of organic agricultural products. The amendments protect integrity in the organic supply chain and build consumer and industry trust in the USDA organic label by strengthening organic control systems, improving farm to market traceability, and providing robust enforcement of the USDA organic regulations. Topics addressed in this rulemaking include: applicability of the regulations and exemptions from organic certification; National Organic Program Import Certificates; recordkeeping and product traceability; certifying agent personnel qualifications and training; standardized certificates of organic operation; unannounced on-site inspections of certified operations; oversight of certification activities; foreign conformity assessment systems; certification of producer group operations; labeling of nonretail containers; annual update requirements for certified operations; compliance and appeals processes; and calculating organic content of multi-ingredient products.

DATES:*Effective date:* March 20, 2023*Implementation date:* March 19, 2024.**FOR FURTHER INFORMATION CONTACT:**

Jennifer Tucker, Ph.D., Deputy Administrator, National Organic Program. Telephone: 202–720–3252. Email: Jennifer.Tucker@usda.gov.

SUPPLEMENTARY INFORMATION:**I. Executive Summary**

This rulemaking amends several sections of the USDA organic regulations, 7CFR part 205, to strengthen oversight of the production, handling, certification, marketing, and sale of organic agricultural products as established by the Organic Foods Production Act of 1990 (OFPA, or “the

Act”).¹ When implemented, this rulemaking will improve organic integrity across the organic supply chain, and benefit stakeholders throughout the organic industry. These amendments close gaps in the current regulations to build consistent certification practices to deter and detect organic fraud, and improve transparency and product traceability. In addition, the amendments will assure consumers that organic products meet a robust, consistent standard and reinforce the value of the organic label.

The need for this rulemaking is driven by organic market growth and increasingly complex organic supply chains. Today’s organic market is characterized by long—and often global—supply chains where organic products are handled by many businesses before reaching the consumer. Often, these businesses are not certified organic—and therefore have no oversight from the USDA or USDA-accredited certifying agents. The absence of direct enforcement over some entities in the organic supply chain, in combination with price premiums for organic products, has created the opportunity for organic fraud. The amendments in this rulemaking are designed to mitigate the occurrence of organic fraud.

The Agricultural Marketing Service (AMS) is confident in the integrity and value of the USDA organic seal. Consumers can trust the organic label due to a rigorous oversight system that operates globally. However, the challenges of modern organic supply chains demand action to strengthen enforcement and uphold the integrity of the USDA organic label.

This rulemaking strengthens enforcement of the USDA organic regulations through several actions mandated by the Agriculture Improvement Act of 2018:

1. Reduce the types of uncertified entities in the organic supply chain that operate without USDA oversight—including importers, certain brokers, and traders of organic products. This will safeguard organic product integrity and improve traceability.

2. Require the use of NOP Import Certificates for all organic products entering the United States. This change expands the use of NOP Import Certificates to all organic products

imported into the United States, improving the oversight and traceability of imported organic products.

3. Clarify the NOP’s authority to oversee certification activities, including the authority to act against an agent or office of a certifying agent. Additionally, certifying agents must notify the NOP upon opening a new office, which will allow the NOP to provide more effective and consistent oversight of certifying agents and their activities.

Additionally, this rule includes several essential actions that work in alignment with the provisions above to further strengthen enforcement of the USDA organic regulations:

1. Require that nonretail containers used to ship or store organic products are labeled with organic identity and are traceable to audit trail documentation. This information will clearly identify organic products, reduce the mishandling of organic products, and support traceability.

2. Require certifying agents to conduct unannounced inspections of at least 5% of the operations they certify, complete mass-balance audits during annual on-site inspections, and verify traceability back to the previous certified operation in the supply chain during annual on-site inspections.

3. Require certifying agents to issue standardized certificates of organic operation generated from the USDA’s Organic Integrity Database (OID); this will simplify the verification of valid certificates of organic operation. Certifying agents must also keep accurate and current certified operation data in OID, which will further support verification of operations’ certified status.

4. Clarify how certified operations may submit changes to their organic system plan, with the goal of reducing paperwork burden for organic operations and certifying agents. This rule also builds consistency in certification practices by clarifying that certifying agents must conduct on-site inspections at least once per calendar year.

5. Establish specific qualification and training requirements for certifying agent personnel, including inspectors and certification reviewers. Requiring that personnel meet minimum education and experience qualifications and requiring continuing education will ensure high-quality and consistent certification activities across all certifying agents.

6. Clarify conditions for establishing, evaluating, and terminating equivalence determinations with foreign government organic programs, based on an

¹ The Organic Foods Production Act of 1990, 7 U.S.C. 6501–6524, is the statute from which the Agricultural Marketing Service derives authority to administer the NOP and authority to amend the regulations as described in this rulemaking. This document is available at: <https://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter94&edition=prelim>

evaluation of their organic foreign conformity systems. This will ensure the compliance of organic products imported from countries that have organic trade arrangements or agreements with the United States.

7. Clarify that the NOP may initiate enforcement action against any violator of the OFPA, including uncertified operations and responsibly connected parties; clarify what actions may be appealed and by whom; and clarify NOP's appeal procedures and options

for mediation (alternative dispute resolution).

8. Specify certification requirements for producer group operations, to provide consistent, enforceable standards and ensure compliance with the USDA organic regulations. Producer groups must meet certain criteria to qualify for certification, and must use an internal control system to monitor compliance.

9. Clarify the method of calculating the percentage of organic ingredients in a multi-ingredient product to promote

consistent interpretation and application of the regulation.

10. Require certified operations to develop and implement improved recordkeeping and organic fraud prevention processes and procedures; require certifying agents to conduct supply chain traceability audits and to develop and implement information-sharing processes.

Costs and Benefits

AMS estimates the following costs and benefits of this rule:

COSTS AND BENEFITS OF SOE RULEMAKING

	Average annual cost ^a		Total cost ^b	
	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate
Domestic Costs	\$10,548,510	\$7,884,601	\$158,227,651	\$118,269,011
Foreign Costs	8,769,681	6,550,892	131,545,210	98,263,398
Total Costs	19,318,191	14,435,494	289,772,861	216,532,409
Benefits	32,944,812	24,272,099	494,172,179	364,081,491

^a Estimated annual averages of the 15-year Net Present Value domestic costs discounted at 3 and 7 percent.

^b Estimated total domestic costs for affected industry in Net Present Value discounted at 3 and 7 percent.

Table of Contents

- I. Executive Summary
- II. Background
 - A. Authority
 - B. Purpose and Need for the Rule
 - C. History
 - D. Public Comment
 - E. Terminology
 - F. Does this action apply to me?
 - G. Compliance Date
- III. Overview of Amendments
 - A. Applicability and Exemptions From Certification
 - B. Imports to the United States
 - C. Labeling of Nonretail Containers
 - D. On-Site Inspections
 - E. Certificates of Organic Operation
 - F. Continuation of Certification
 - G. Paperwork Submissions to the Administrator
 - H. Personnel Training and Qualifications
 - I. Oversight of Certification Activities
 - J. Accepting Foreign Conformity Assessment Systems
 - K. Compliance and Noncompliance Procedures
 - L. Mediation
 - M. Adverse Action Appeal Process
 - N. Producer Group Operations
 - O. Calculating the Percentage of Organically Produced Ingredients
 - P. Supply Chain Traceability and Organic Fraud Prevention
 - Q. Technical Corrections
 - R. Additional Amendments Considered but Not Included in This Rule
- IV. Regulatory Analyses
 - A. Summary of Economic Analyses
 - B. Regulatory Impact Analysis
 - C. Executive Order 12988
 - D. Paperwork Reduction Act
 - E. Executive Order 13175

- F. Executive Order 13132
- G. Civil Rights Impact Analysis
- H. Related Documents

II. Background

A. Authority

The Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501–6524), authorizes the Agricultural Marketing Service (AMS) to establish and maintain national standards governing the marketing of organically produced agricultural products. AMS administers these standards through the National Organic Program (NOP). Final regulations implementing the NOP, also referred to as the USDA organic regulations, were published on December 21, 2000 (65 FR 80548) and became effective on October 21, 2002.² Through these regulations, AMS oversees national standards for the production, handling, labeling, and sale of organically produced agricultural products.

B. Purpose and Need for the Rule

Since full implementation of the USDA organic regulations, the organic industry has experienced significant change. Both demand for and sales of organic products have risen steadily; total U.S. sales of organic products

reached more than \$63 billion in 2021.³ The number of businesses producing, handling, marketing, and selling organic products has also grown to meet consumer demand. Rapid growth has attracted many businesses to the USDA organic label and increased the complexity of global organic supply chains.

Complexity makes oversight and enforcement of the organic supply chains difficult because organic products are credence goods, which means that their organic attributes, or “integrity,” cannot be easily verified by consumers or businesses who buy organic products for use or resale. The elements needed to guarantee organic integrity—transparent supply chains, trusted interactions between businesses, and mechanisms to verify product legitimacy—are more difficult to achieve in the increasingly complex modern organic industry. This is further compounded by inconsistent interpretation and implementation of the USDA organic regulations, caused by a lack of clarity in some portions of the regulation.

AMS is confident in the integrity and value of the USDA organic seal. Consumers can trust the organic label due to a rigorous oversight system that operates globally. However, the above challenges sometimes cause

² 7 CFR part 205 National Organic Program; Final Rule. December 21, 2000. Available on the AMS website: <https://www.federalregister.gov/documents/2000/12/21/00-32257/national-organic-program>

³ Organic Trade Association, Organic Industry Survey, 2022.

mishandling of organic products, where integrity is compromised due to improper handling. Additionally, high demand for organic products, the absence of direct enforcement over some entities in the organic supply chain, and organic price premiums increase the opportunity and incentive for organic fraud (when nonorganic products are deceptively represented as organic).

This rule addresses these risks and challenges by expanding oversight to higher-risk portions of organic supply chains, requiring organic operations to implement traceability and verification best practices, and clarifying oversight and enforcement practices to ensure more consistent implementation by certifying agents. This rule will help prevent loss of organic integrity—which can occur both through unintentional mishandling of organic products, and intentional fraud meant to deceive—and strengthen the trust consumers, farmers, and businesses have in the USDA organic label.

Mishandling of Organic Products and Complex Supply Chains

One of the most common risks to the integrity of an organic product is mishandling—when an entity unintentionally compromises the unique attributes that make a product organic. Once organic integrity is compromised, that product can no longer be sold as organic, and both its unique attributes and price premium are forfeit. Mishandling can occur at any point in a supply chain, including production, handling, transport, storage, sale, and processing. Examples of mishandling that can cause a loss of integrity include exposure to pesticides, fertilizers, fumigants, or cleaning agents that are not permitted in organic production; mixing (“commingling”) of organic and nonorganic products; relabeling or repackaging with incorrect identification; and inability to demonstrate organic status due to poor or incomplete information in records or transaction paperwork. The likelihood of such mishandling is greater in long, complex supply chains where many businesses, including businesses not certified organic, handle and sell organic products.

When the organic regulations were published in 2000, organic products were marketed mostly locally or regionally, and supply chains tended to be short and transparent; for example, farm to wholesale to retail to consumer. Demand and sales have grown considerably since then. This significant market growth has attracted more producers, handlers, product suppliers, importers, brokers, distributors, and

others to the organic market. Consider the example of an organic egg supply chain in the United States, beginning with the production of certified organic corn and ending with the sale of eggs to the consumer. This demonstrates the typical entities and transactions in an organic supply chain under the existing regulations:

- A certified organic farm produces organic corn.
- The corn is transported via an uncertified truck to a local grain elevator, where it is aggregated with other organic corn from nearby producers.
- An uncertified commodity trader buys the corn.
- The corn is transported via uncertified truck to an uncertified storage facility; both transport and storage are subcontracted and are not owned by the commodity trader.
- The commodity trader sells the corn to a certified organic grain supplier; the two parties remain anonymous because they use an uncertified broker to facilitate the transaction.
- The corn is transported via uncertified rail and river barge to the grain supplier; it is transloaded and stored temporarily several times before being delivered to the certified grain supplier.
- The certified organic grain supplier stores the corn and combines it with imported organic corn purchased from an importer via an uncertified broker.
- The certified grain supplier sells the corn to a certified organic feed processor; the corn is transported via an uncertified truck.
- The certified processor combines the corn with several other ingredients to create organic chicken feed.
- The certified processor sells the feed to a certified organic egg producer and transports it via an uncertified truck.
- The certified organic egg producer sells organic eggs to an uncertified distributor.
- The uncertified distributor sells the organic eggs to a retailer prior to final sale to the consumer.

This example illustrates the supply chain for a single ingredient—organic feed corn. The supply chain for the organic eggs at the end of this example is even more complex because it includes other ingredients that go into the chicken feed (e.g., soybean meal, oats, wheat, seed oils). Many of these ingredients are sourced both domestically and internationally. Each ingredient has its own unique supply chain; together they create a complex web converging on a single organic product. It is largely because of this

complexity that this rule introduces more specific traceability, verification, oversight, and enforcement practices for high-risk portions of organic supply chains.

Organic Fraud

In addition to mishandling, a growing risk to organic integrity is fraud—the deceptive representation, sale, or labeling of nonorganic agricultural products as organic. High demand for organic products, the absence of direct enforcement over some entities in the organic supply chain, and organic price premiums have increased the opportunity and incentive for organic fraud. Both NOP and organic stakeholders have uncovered organic fraud in organic supply chains, particularly in organic grain and oilseed supply chains. Because such supply chains are complex and involve multiple changes in ownership of high demand products, the incentive for fraud is high. Federal investigations show that organic grain and oilseed fraud can lead to tens of millions of dollars in fraudulent sales within just a few months. The following examples highlight some of the types of organic fraud that this rule seeks to prevent. The examples also demonstrate the magnitude of total organic fraud and how this rule’s additional oversight and enforcement mechanisms will reduce fraud.

- In 2019, four individuals were sentenced to prison terms for their roles in an organic grain fraud ring. The charges were brought by the U.S. Attorney’s Office for the Northern District of Iowa. All four were sentenced to prison terms. The lead defendant, who was sentenced to more than ten years, pled guilty to defrauding customers in a scheme involving at least \$142 million in nonorganic grains sold as organic. The lead defendant sold fraudulent grain to customers over a period of seven years, claiming the product was organically grown in Nebraska and Missouri.⁴ This rule includes more robust traceability and verification practices that would have helped identify and stop this type of fraud earlier, preventing further sale of the fraudulent products and reducing the impact of the fraud.

- In February 2020, a federal grand jury indicted an individual in South Dakota for allegedly selling \$71 million of nonorganic grains and oilseeds falsely labeled organic between 2012 and

⁴ <https://www.justice.gov/usao-ndia/pr/field-schemes-fraud-results-over-decade-federal-prison-leader-largest-organic-fraud>.

2018.⁵ The defendant pled guilty and was sentenced in 2021 to 51 months in federal prison. He was also ordered to pay more than \$15 million in restitution. The fraud ring spanned multiple states. After NOP revoked the business' organic certifications, the responsible parties established new brokerage firms to continue their fraud. Under the current organic regulations, these brokerages did not require organic certification and NOP had no oversight of their activities. This rule will require the certification and oversight of brokers like those involved in this case. This would allow the NOP to identify and prevent the fraud, minimizing damage to the U.S. market.

• In 2017, an investigation revealed three shipments of imported "organic" corn and soybeans—each weighing between 36 and 46 million pounds—were fraudulently labeled as organic. The associated transaction records indicated that all three shipments originated from producers in the Black Sea region that were not certified organic, and that the shipments were originally sold at lower conventional prices. In one case, a shipment of soybeans had been fumigated with aluminum phosphide, which is prohibited for use in organic production and handling. By the time this fraud was discovered, about 21 million pounds of this same shipment of soybeans had already been distributed—primary to organic producers as livestock feed.⁶ This rule will require the use of NOP Import Certificates to verify the source and integrity of organic imports, which will help detect and prevent fraudulently labeled imports, such as those in this example, from entering domestic supply chains.

• In July 2022, a Minnesota farmer was indicted for growing and selling fraudulent organic grains worth more than \$46 million. The farmer was certified organic but was growing grains with synthetic fertilizers and pesticides in violation of the USDA organic regulations. He sold this conventional grain (both what he produced conventionally as well as conventional grain he purchased) as organic, fraudulently presenting his certificate of organic operation to claim the grain was organic and withholding the grain's true

status from buyers.⁷ This rule includes more robust traceability and verification practices that would have helped identify and stop this type of fraud earlier, preventing further sale of the fraudulent products and reducing the impact of the fraud.

In several of the above examples, fraudulent livestock feed was sold to certified organic livestock producers, magnifying the effects of the fraud. NOP continues to investigate complaints and multiple cases of organic fraud at the production and handling levels. These examples demonstrate the magnitude of fraud that NOP intercepts with current oversight and enforcement techniques. SOE will significantly bolster the oversight and enforcement mechanisms that NOP, certifying agents, and operations have at their disposal. In the fraud cases discussed above, these mechanisms would have allowed earlier fraud detection and more effective enforcement action and would have greatly reduced or even prevented the fraud.

Patterns in USDA Organic Certification and Organic Imports

The scope and distribution of potential organic fraud can also be seen in changes in the number of operations certified to the USDA organic standards and changes in the amount of organic imports from certain regions. Two recent NOP efforts show both the potential type and magnitude of fraud in the marketplace; more importantly, they also demonstrate the potential of improved oversight and enforcement mechanisms.

In 2018 and 2019, NOP began making changes to improve oversight of organic imports, especially grain and oilseed imports from the Black Sea region. NOP conducted farm-level yield analysis to compare expected and actual yield, supply chain research to better understand the roles and relationships of high-risk entities, and targeted import surveillance to investigate credible reports of suspected fraud. As a result of this heightened oversight and enforcement action, at least 180 operations (60 percent) in the Black Sea region have lost their organic certification. In 2016, imports from the Black Sea region represented 49 percent of the total dollar value of imported organic grain and oilseeds (including corn, soybeans, wheat, barley, sunflowers, flaxseed, and peas). In 2018, imports of these grains and oilseeds from the region had dropped to 21

percent of the total dollar value. The steep drop in organic certification and downward supply trend in the Black Sea region give an indication of the magnitude and type of fraud, as well as the success of stronger oversight and enforcement strategy. Despite this enforcement success, key gaps in oversight remain, such as uncertified entities in import supply chains and non-mandatory use of NOP Import Certificates. This rule will help close these gaps and bolster NOP's ability to detect and prevent fraudulent organic imports.

In January 2021, AMS announced it would end its U.S.–India organic recognition, which had allowed India's Agricultural and Processed Food Products Export Development Authority (APEDA) to accredit certifying agents to provide USDA organic certification in India. AMS ended this recognition because NOP audits consistently found India's organic control system to be insufficient to protect the integrity of the USDA organic seal. In late 2020, prior to the end of U.S.–India recognition, there were 4,023 operations certified to the USDA organic standard in India. Operations formerly certified by AEDPA-accredited certifying agents were given an 18-month transition period to become certified by a USDA-accredited certifying agent. Since the end of the transition period in July 2022, only 1,471 operations in India remain certified to the USDA organic standard. Because failure to become recertified may indicate an inability to comply with the USDA organic regulations, this significant (63 percent) drop in the number of certified operations may indicate the general volume of noncompliant activity (including mishandling and fraud) that may have been taking place under the former recognition. Additionally, following the end of the U.S.–India recognition, imports of certified organic products from India has dropped from an average per quarter value of \$15.6 million to \$9.4 million, a 39 percent decrease. This drop in import value suggests that a significant number of organic imports from India may not have been fully compliant with the USDA organic standard. The end of the U.S.–India recognition demonstrates both the magnitude of potential fraud in the market, and how more effective oversight (in this case, certification only by USDA-accredited certifying agents) can successfully safeguard the integrity of the USDA organic label. Despite this success, there are still gaps in the oversight of foreign-accredited certifying agents and imports from these countries.

⁵ <https://www.wisfarmer.com/story/news/2020/02/18/south-dakota-man-indicted-71-million-organics-fraud/4801207002/>. <https://www.justice.gov/usao-sd/pr/florida-man-sentenced-conspiracy-commit-wire-fraud-and-money-laundering>.

⁶ https://www.washingtonpost.com/business/economy/the-labels-said-organic-but-these-massive-imports-of-corn-and-soybeans-were-not-2017/05/12/6d165984-2b76-11e7-a616-d7c8a68c1a66_story.html.

⁷ <https://www.justice.gov/usao-mn/pr/cottonwood-county-farmer-charged-46-million-organic-grain-fraud-scheme>.

This rule will allow NOP to more fully implement its oversight authority by codifying specific procedures for evaluating, accepting, and continuing equivalency or recognition with foreign organic programs.

These examples demonstrate how applying oversight and enforcement best practices can reduce organic fraud. SOE will reduce fraud by codifying best practices in critical areas—exemptions from certification, import oversight, traceability, recordkeeping, inspections and audits, oversight of certifying agents, and assessment of organic trade partners. Additionally, the examples above only show the positive results of improved oversight and enforcement at the federal level; SOE will build upon this success by requiring certifying agents and organic operations to use similar techniques. This means proven oversight and enforcement techniques will be deployed closer to where fraud occurs, which will facilitate earlier detection, stop more fraud before it cascades further into supply chains, and more directly deter fraudulent actors. Because this rule codifies best practices and requires key parties in organic supply chains use these practices, AMS expects that SOE's benefits will exceed those demonstrated in the examples above.

C. History

In response to their experiences in the organic system, stakeholders have called for the NOP to take steps to improve oversight of organic systems and enforcement of the USDA organic regulations. Commonly cited areas for improvement include certification of excluded handlers, organic import oversight, fraud prevention, organic trade arrangements, and organic inspector qualifications. Public discussions on many topics included in this rule occurred during multiple National Organic Standards Board (NOSB) meetings.⁸

This rule seeks to strengthen enforcement of the USDA organic regulations and protect the integrity of the organic label by (1) strengthening organic control systems; (2) improving organic import oversight; (3) clarifying organic certification standards; and (4) enhancing supply chain traceability. AMS identified the need for these changes through:

- Direct experience in administering the NOP, particularly complaint investigations and audits of accredited certifying agents;
- The Agriculture Improvement Act of 2018,⁹ which amended the OFPA.
- Recommendations of a 2017 Office of Inspector General report;¹⁰
- Recommendations of the NOP's federal advisory committee, the National Organic Standards Board (NOSB); and
- Industry stakeholder and consumer feedback.

AMS expects the amendments will bring more effective oversight and enforcement, improve organic integrity and product traceability, clarify existing standards to ensure fair competition, bolster consumer trust in the organic label, reduce organic fraud, and support continued industry growth. Information about each amendment is described in more detail below.

D. Public Comment

AMS published the Strengthening Organic Enforcement proposed rule on August 5, 2020, opening a 60-day public comment period. AMS received more than 1,500 public comments from a variety of stakeholders, including certifying agents, certified organic producers and handlers, uncertified handlers, retailers, organic inspectors, trade associations, organic advocates, scientific organizations, government organizations, and consumers. The majority of public comments supported the proposed amendments and agreed that the rule is needed to improve oversight and enforcement, drive consistent implementation of the organic regulations, and reduce organic fraud.

Many stakeholders provided meaningful feedback about the proposed policy revisions, including recommendations to improve the rule through greater specificity and clarity. Others discussed how the proposed amendments would affect them or suggested alternatives to the proposed policies. Popular topics of discussion included the need for certification; excluded handlers; exemptions from certification; implementation of the mandatory NOP Import Certificate requirements; supply chain traceability audits; recordkeeping and verification

requirements; fraud prevention plans for certified operations; oversight of producer groups; qualifications and training requirements for certifying agent personnel; labeling of nonretail containers; and unannounced inspections.

Some comments also discussed the proposed implementation timeframe of one year after publication of the final rule. Some comments asked AMS to implement the rule immediately, while others agreed that a one-year timeframe is reasonable and gives stakeholders time to comply with the new requirements. A few comments noted that some parts of the rule may require more than one year to implement and asked AMS to consider this in the final rule. Few comments addressed the costs and benefits of the rule in detail, but many comments noted in general that the costs of the rule are acceptable and outweighed by the benefits.

AMS took these public comments into consideration when revising the policy, implementation timeframe, and cost-benefit analysis of this rulemaking. For more information on the comments received and AMS's response to specific comments, refer to "III. Overview of Amendments."

E. Terminology

Throughout this rule, AMS refers to four concepts—organic integrity, organic fraud, audit trails, and supply chain traceability—which are integral to the purpose of this rule. AMS is explaining these concepts upfront to assist reader understanding:

- *Organic integrity*: The unique attributes that make a product organic and define its status as organic. A product that fully complies with the USDA organic regulations has integrity, and its organic qualities have not been compromised.
- *Organic fraud*: Deceptive representation, sale, or labeling of nonorganic agricultural products or ingredients as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" (7 CFR 205.2).
- *Audit trail*: Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as "100 percent organic," the organic ingredients of any agricultural product labeled as "organic" or "made with organic (specified ingredients)" or the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as organic in an ingredients statement (7 CFR 205.2).

⁸ The April 2021 NOSB meeting is the most recent example of a public discussion to address fraud concerns in the organic supply chain. A discussion document, meeting transcripts, and public comments are available at <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-crystal-city-va-0>.

⁹ The Agriculture Improvement Act of 2018, Public Law No: 115-334, is available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>.

¹⁰ USDA Office of Inspector General Audit Report 01601-0001-21: National Organic Program International Trade Arrangements and Agreements. September 2017: <https://www.usda.gov/sites/default/files/01601-0001-21.pdf>.

• *Supply chain traceability:* The ability to identify and track the movement, sale, custody, handling, and organic status of an agricultural product along a supply chain. Supply chain traceability audits are used to verify an agricultural product’s compliance with the USDA organic regulations.

F. Does this action apply to me?

You may be affected by this action if you are engaged in the organic industry. Potentially affected entities may include, but are not limited to, the following:

- Individuals or business entities that are considering organic certification;
- Existing production and handling operations that are currently certified organic under the USDA organic regulations;
- Brokers, traders, and importers of organic products that are not currently certified under the USDA organic regulations;

- Operations that use non-retail containers for shipping or storing organic products;
- Retailers that sell organic products;
- Operations that receive or review certificates of organic operation to verify compliance with USDA organic regulations;
- USDA-accredited certifying agents, inspectors, and certification review personnel;
- Operations that import organic products into the United States; and/or
- Operations that export organic products to the United States and the corresponding certifying agents.

This list is not exhaustive but identifies key entities likely to be affected by this action. Other types of entities may also be affected. To determine whether you or your business may be affected by this action, you should carefully examine the regulatory text and discussion below.

G. Compliance Date

AMS is establishing a compliance date for this final rule of March 19, 2024, or 12 months after the effective date of this final rule. This means that all entities affected by this rule, including certified operations and certifying agents, must comply with the provisions of this final rule by this date. This also means that operations requiring organic certification because of this final rule must be certified by the compliance date. AMS is setting this compliance date to allow affected entities time to read and understand this final rule, obtain organic certification if needed, and prepare for and implement other changes in this final rule.

III. Overview of Amendments

A. Applicability and Exemptions From Certification

The table below includes the regulatory provisions related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.2	Terms Defined.
205.100	Definitions for <i>Handle, Handler, Handling operation, and Retail establishment</i> . What has to be certified.
205.101	Paragraph (a). Exemptions from certification.
205.310	Entire section. Agricultural products produced or processed by an exempt operation. Paragraphs (a) and (b).

The USDA organic regulations require organic certification of businesses that sell, process, or package organic agricultural products as handling operations. This rulemaking clarifies that most operations that operate in the middle of organic supply chains must be certified organic. This may include entities that sell, trade, distribute, or import organic products. The activities of these operations may affect organic integrity; therefore, certification is necessary to assure consumers that organically produced products meet a consistent standard. In addition to clarifying who needs certification, this rulemaking also provides limited exemptions to organic certification for certain entities and activities that present a low risk to organic integrity.

This action may affect noncertified operations that handle organic products, sell organic products, or facilitate the sale or trade of organic products on behalf of a seller or oneself; certified organic operations; organic inspectors; and certifying agents. Readers should

carefully examine the regulatory text and policy discussion to determine if they are affected.

Background

The organic market has grown considerably since the USDA organic regulations took effect in 2002. The Organic Trade Association reports that total U.S. organic sales grew from \$3.4 billion in 1997 to \$61.9 billion in 2020.¹¹ This growth has created increasingly complex organic supply chains as additional domestic and international businesses choose to produce and sell organic products for the U.S. market. Some segments of organic supply chains remain uncertified under current regulation, creating gaps in oversight, increasing the opportunity for fraud, and complicating enforcement by the USDA and its enforcement partners.

Oversight and enforcement of organic supply chains are challenging because

organic products are credence goods, which means that their organic attributes, or “integrity,” cannot be easily verified by an individual. Guaranteeing organic integrity requires transparent supply chains, trusted interactions between businesses, and mechanisms to verify product legitimacy. This is best accomplished via certification, which requires operations to follow traceability and verification practices, and provides regular oversight in the form of audits and annual inspection. This rulemaking broadens the scope of who must be certified, opening more of the organic supply chain to oversight and mitigating the risks of noncertified businesses handling organic product.

OFPA authorizes the USDA to regulate and enforce the production, handling, and sale of organic products (7 U.S.C. 6503). This includes activity within organic supply chains, from production through final sale to the

¹¹ Organic Trade Association, Organic Industry Survey, 2018–2021

consumer.¹² AMS is exercising its authority to regulate entities in organic supply chains by requiring certification of some types of currently noncertified operations. This action is mandated by the 2018 Farm Bill, which states that the USDA must “issue regulations to limit the type of organic operations that are excluded from certification under section 205.101” of the organic regulations.¹³ This rulemaking supports the OFPA’s purpose “to assure consumers that organically produced products meet a consistent standard (7 U.S.C. 6506(a)(11)).”

Who needs to be certified?

Section 205.100(a) of the organic regulations states that any operation that produces or handles organic agricultural products must be certified organic. This means that operations conducting activities described in the definition of *handle* must be certified organic and must follow all applicable portions of the OFPA and the USDA organic regulations. In general, *handle* means to “sell, process, or package” organic agricultural products. Limited exemptions for operations that handle organic agricultural products are described in § 205.101(a)–(h).

The definition of *handle* includes the term *processing*, which is defined in § 205.2.¹⁴ Operations that process organic agricultural products must be certified. *Handle* further explains what to “sell” and “package” mean by including additional examples of handling activities. The examples represent typical supply chain activities that may affect organic integrity. This includes activities where there is physical contact with agricultural products, such as combining, aggregating, culling, conditioning, treating, packing, containerizing, repackaging, labeling, storing, receiving, or loading.¹⁵ Examples of operations

that often conduct these activities may include grain elevators; bulk grain handlers; warehouses that cull, label, or repack; central bakeries or kitchens that serve grocery chains; or ports of entry.

Handle also includes activities where there may not be physical contact with agricultural products, such as selling, trading, facilitating sale or trade on behalf of a seller or oneself, importing to the United States, or exporting from a foreign country for sale in the United States. These activities are included in the definition of *handle* because they have the potential to affect organic integrity. Operations that conduct these activities must be certified (unless exempt per § 205.101). Examples of operations that often conduct these activities may include sales brokers, commodity traders, ingredient sourcers, importers, or exporters.

The definition of *handle* is not an exhaustive list of activities that must be certified. There may be additional activities not listed in the definition that are similar to the listed activities and require certification, or different words or synonyms for the same or similar activities. The absence of a specific term in the definition of *handle* does not mean the activity is not handling or that an operation conducting this activity does not need certification.

What are the certification requirements for handlers?

All certified organic operations must follow the portions of the USDA organic regulations that apply to activities they conduct. Conversely, some portions of the regulation will not apply to every operation (e.g., a certified operation that only produces crops does not have to follow the livestock requirements of subpart C). Similarly, the scope of a handling operation’s certification only covers the activities it conducts. For example, the OSP of a certified importer would likely describe the operation’s system to maintain transaction records and audit trails, verify suppliers and NOP Import Certificates, and verify traceability. On-site inspection of such an operation would likely focus on a records review and evaluation, rather than evaluation of physical facilities.

Contractors are sometimes used in the organic industry to provide services to certified operations. Contractors that qualify for an exemption per § 205.101(a)–(f) do not need to be certified. Any contractor performing handling activities on behalf of an operation must be certified or described in the OSP of a certified operation.

It is common for some operations to handle both organic and nonorganic

agricultural products (i.e., a *split operation*). For a split operation, only the portion(s) of the operation that produces or handles organic agricultural products must be certified. If a portion of an operation qualifies for an exemption from certification described in § 205.101(a)–(h), only that portion may be exempt, and the remainder of the operation must be certified if it produces or handles organic agricultural products. For example, a grocery store chain’s retail locations may be exempt under § 205.101(b) or (c), but its importing and some distribution activities would likely need to be certified.

Organic Agricultural Products Received From an Exempt Operation

Agricultural products produced or processed on an exempt operation must follow all requirements of § 205.310. This means that an operation receiving products produced or processed by an exempt operation cannot represent the products as certified organic, cannot display the USDA organic seal on the products, and cannot use the products as organic ingredients in a product produced by the receiving operation. In effect, product received and then processed by an exempt operation loses its certified organic status and cannot be represented as organic.

However, exempt operations may perform limited handling of certified organic products, as described in each exemption at § 205.101; i.e., if an exempt operation handles certified organic products in a manner consistent with its applicable exemption, the products maintain their organic status. This means, for example, that an exempt warehouse may receive, store, and prepare for shipment packaged certified organic products. Conversely, if this warehouse opens or relabels such packaged products, then the certified organic status of the products is lost, and an operation receiving these products must not represent them as certified organic.

The USDA organic regulations require certified operations to implement recordkeeping and verification practices that ensure the integrity of organic agricultural products they receive, including products received from exempt or uncertified operations. Records must trace organic products back through any exempt operations to the last certified operation in the supply chain, and operations must verify their suppliers, including exempt operations. See §§ 205.103(b)(2) and 205.201(a)(3) in the section on Supply Chain Traceability and Fraud Prevention later in this rule.

¹² OFPA and the USDA organic regulations do not provide authority to regulate the transport of organic agricultural products.

¹³ See section 10104(a) of the Agriculture Improvement Act of 2018, Public Law No: 115–334, available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>.

¹⁴ 7 CFR 205.2 *Processing*. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

¹⁵ The regulations at § 205.2 define “label” and “labeling” to explain the type and location of information covered. Labeling as a handling activity refers to the act of applying a label to a product with an organic claim; applying other types of labels, such as for inventory or information accompanying a product, may not need certification.

Exemptions From Certification

The USDA organic regulations require certification of any operation that produces or handles organic agricultural products (§ 205.100(a)). However, the regulations provide limited exemptions to certain types of operations that conduct low-risk activities, and are therefore less likely to compromise organic integrity of the agricultural products they handle. These exemptions, and the conditions that must be met to qualify for each, are described in § 205.101.

The USDA organic regulations formerly used the terms “exemption” and “exclusion” to describe activities that do not require organic certification. This final rule removes use of the term “exclusion” from § 205.101 and throughout the organic regulation to reduce confusion and misinterpretation about who needs to be certified. The term “exemption” is now used exclusively to describe activities that do not require organic certification. Previous “exclusions” listed under former § 205.101(b) have been modified and are now listed under current § 205.101.

Responsibilities of Exempt Operations

Operations described in § 205.101 are exempt from the requirement to be certified organic under subpart E. However, these exempt operations must still follow all other applicable portions of the organic regulations, including the production and handling requirements of subpart C. For example, a very small vegetable farm may be exempt from certification per § 205.101(a); this means the farm does not have to be certified and inspected annually, and does not have to develop and submit an organic system plan. However, the farm *must* follow the other organic production and handling requirements of subpart C, including soil and fertility practices, crop rotation, weed management, and seed use practices. Exempt operations must also comply with § 205.272 and practices to prevent commingling and contact with prohibited substances.

Exempt operations must also follow the applicable labeling requirements of subpart D. Critically, this means exempt operations *must not* represent the agricultural products they produce or process as certified organic and must not use the USDA organic seal. Additionally, agricultural products produced or processed by an exempt operation must not be identified or represented as organic in a product processed by another operation (See § 205.310, Agricultural products produced or processed on an exempt

operation). Additionally, exempt operations are only permitted to perform the limited handling activities described in the applicable exemption; any handling outside of that described in the exemption may result in loss of organic status of products.

Operations that qualify for an exemption may voluntarily choose to become certified. By becoming certified, the operation may market the products it produces and processes as certified organic, display the USDA organic seal on its products, and represent these products as ingredients for use in other organic products.

Like certified operations, exempt operations are subject to penalties for violating the OFPA and the organic regulations. Section 205.100(c) of the organic regulations states that any person or responsibly connected person—including exempt operations—that knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty as specified in 7 CFR 3.91(b)(1)(xxxvi).¹⁶

Recordkeeping by Exempt Operations

Like certified operations, exempt operations play a critical role in maintaining the integrity of organic products as they travel from production to consumer. Therefore, exempt operations must maintain records of the organic products they produce and handle, including records that: demonstrate that agricultural products identified as organic were organically produced and handled; and verify quantities of organic agricultural products received and shipped or sold. Such records are necessary to maintain an audit trail for organic products; this will facilitate many other provisions of this rule, including supply chain traceability audits (§ 205.501(a)(21)), recordkeeping by certified operations (§ 205.103), on-site inspections (§ 205.403(d)), and fraud prevention plans (§ 205.201(a)(3)). Retail establishments that do not process agricultural products (see definition for *Handle* at § 205.2 and exemption from certification at § 205.101(b)) do not need to maintain such records. Exempt handlers must have required records available and must show those records to a representative of the Secretary upon request. Failure to produce compliant records may lead to enforcement action.

¹⁶ 7 CFR 3.91(b)(xxxvi): Civil penalty for knowingly labeling or selling a product as organic except in accordance with the Organic Foods Production Act of 1990, codified at 7 U.S.C. 6519(c). As of the publication of this rule the civil penalty amount is a maximum of \$20,130 per violation.

Small Producers and Handlers

Small organic producers and handlers are exempt from certification at § 205.101(a). This exemption is limited to producers and handlers with gross agricultural income from organic sales of no more than \$5,000 annually. These operations are exempt from certification under subpart E and from submitting an organic system plan, but must follow all applicable organic production and handling requirements of subpart C and labeling requirements of subpart D. This includes the requirements to prevent commingling and prevention of contact with prohibited substances (§ 205.272).

Such operations must not represent the agricultural products they produce or process as certified organic and must not use the USDA organic seal. Agricultural products produced or processed by these exempt operations must not be identified or represented as organic in a product processed by another operation (see § 205.310).

Retail Establishments

Retail businesses that handle organic agricultural products and sell directly to consumers may be exempt from certification. To qualify for an exemption, the operation must be a retail establishment and meet the conditions for the exemptions in § 205.101(b) and (c).

The regulations define *retail establishment* to include a range of transaction modes for selling to consumers that commonly occur in the modern marketplace. *Retail establishment* includes restaurants, delicatessens, bakeries, grocery stores, or any retail business with a restaurant, delicatessen, bakery, salad bar, bulk food self-service station, or other eat-in, carry-out, mail-order, or delivery service of raw or processed agricultural products. Retail is commonly described as selling directly to consumers, end-users, or the public. The definition for *retail establishment* aligns with that concept. Businesses which sell to other businesses (wholesale) do not qualify as retail establishments. Retail establishments may use virtual transactions for sales, but they must also have a physical location for consumers to purchase products.

Only operations that are retail establishments are eligible for the retailer exemptions. The definitions for *handler* and *handling operation* do not include final retailers of agricultural products that do not process agricultural products. This exemption from certification is also reinforced at section 205.101(b), which exempts retail establishments that sell, but do not

process, organic agricultural products to consumers.

Section 205.101(c) exempts retail establishments that process certified organic agricultural products at the point of sale to the consumer. Distributors or brand name owners that do not qualify as retail establishments should review the exemptions from certification at § 205.101(e) and (f), as those may apply to their activities.

Retail Operations That Don't Process

Retail establishments that do not process agricultural products are not handlers or handling operations and may be exempt from certification under § 205.101(b). The OFPA and § 205.2 define *processing* as cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, cutting, fermenting, eviscerating, pre-serving, dehydrating, freezing, or otherwise manufacturing, and includes the packaging, canning jarring, or otherwise enclosing food in a container. A retail establishment that is not processing may do other handling activities without certification. This could include, for example, removing produce from shipping boxes and washing and transferring product to display cases or opening bags of oats and transferring contents to bulk food dispensers. Although a retailer performing such handling activities may be exempt from certification, all retail establishments must comply with § 205.272, which requires measures to prevent commingling of organic products and contact with prohibited substances.

Retail establishments that do not process "100% organic" and "organic" unpackaged products may use the USDA organic seal and/or seal of the certifying agent in retail labeling and display of these unpackaged products (§ 205.308). Retail establishments that do not process "made with organic. . ." unpackaged products may use that claim in retail labeling and displays (§ 205.309).

Retail Establishments That Process

Retail establishments that process organic agricultural products may be exempt from certification under § 205.101(c). To qualify for this exemption, a retail establishment must process organic products at the point of final sale to the consumer. This means that the products must be processed and sold in the same physical location. This could include repackaging bulk containers of organic product into individual units for retail sale within an individual grocery store or a retail establishment that prepares ready-to-eat

meals and sells them online to consumers from the processing location.

Per § 205.310, organic agricultural products that are processed by exempt retail establishments (such as in the examples above) must not be sold, labeled or represented as "certified" organic, must not display the USDA seal or identify the certifying agent, and must not be used by another operation as ingredients in a certified organic product. Only retail establishments that are certified organic may use the USDA organic seal (or make certified organic claims) on products they process.

This exemption does not cover retail establishments that sell organic products to consumers which are processed at a location separate from the point of sale. This could include, for example, an online retailer that sells products processed at an uncertified facility or a central processing facility that prepares food sold in bakery and deli sections of grocery stores. In these scenarios, the processing facility is not co-located in the same physical location as the point of sale and the retail establishment exemption does not cover separate processing facilities. The processors would need to be separately certified in order for a retail establishment to sell their products as organic.

In addition, this exemption does not cover retailers that process and sell to consumers only via virtual transactions. "Virtual transaction" describes any form of transaction that does not occur in-person (e.g., telephone, mail-order, and/or online sales). Retailers that process and sell to consumers virtually without having a physical location for retail sales must be certified. These businesses do not meet the definition for retail establishment, and, by extension, the conditions for exemption from certification.

All exempt retail establishments must comply with the requirements of § 205.272, which describes handling requirements to prevent commingling and contact with prohibited substances. In addition, exempt retail establishments that process organic products must follow the labeling provisions specified in § 205.310 and maintain records to (1) demonstrate that agricultural products identified as organic were organically produced and handled; and (2) verify quantities received, sold, or produced from such agricultural products. Exempt handlers must have these records available and must show them to a representative of the Secretary upon request (7 U.S.C. 6519(a)(1)). Failure to produce compliant records may lead to enforcement action.

Operations That Handle Only Products With Less Than 70 Percent Organic Ingredients

Section 205.101(d) exempts from certification operations that only handle agricultural products with less than 70 percent organically produced ingredients, and operations that only identify organic ingredients on the product informational panel. This exemption is not new policy. It combines two existing exemptions: operations that handle products with less than 70 percent organic ingredients (former § 205.101(a)(3)) and operations that handle products that only identify organic ingredients on the information panel (former § 205.101(a)(4)). AMS combined these exemptions because they cover operations that handle products in the same labeling category (per § 205.305), and because these operations must follow identical use and labeling requirements. Operations that qualify for this exemption are exempt from certification under subpart E and from submitting an organic system plan, but must follow all applicable organic production and handling requirements of subpart C and labeling requirements of subpart D. This includes the labeling requirements for products with less than 70 percent organic content (§ 205.305) and the requirements to prevent commingling and prevention of contact with prohibited substances (§ 205.272).

Handlers covered under this exemption must have the records required by § 205.101(i) available and show them to a representative of the Secretary upon request (7 U.S.C. 6519(a)(1)). Failure to produce compliant records may lead to enforcement action. Such operations must not represent the agricultural products they produce or process as certified organic and must not use the USDA organic seal. Agricultural products produced or processed by these exempt operations must not be identified or represented as organic in a product processed by another operation (see § 205.310).

Storing or Selling Packaged Organic Products

The movement of packaged and sealed organic products through the supply chain is a lower-risk activity. Packaged products are less likely to be commingled, exposed to contaminants, or tampered with, and alterations are easier to detect. Handling operations that sell, distribute, or store packaged organic agricultural products may be exempt from organic certification. Two exemptions, at § 205.101(e) and (f),

apply to limited handling activities involving only organic agricultural products that are in sealed, tamper-evident packaging or containers. The key distinctions between these exemptions are that 205.101(f) covers operations that buy and sell, in addition to receiving, storing and/or preparing for shipment, and that 205.101(f) covers only retail-packaged products versus packaged products that are not in final retail packaging. Tamper-evident packaging or container means that the contents are sealed in a manner where an attempt to break the seal, access the contents, or relose the package would be obvious. These exemptions cover only the specified handling activities. These exemptions do not, for example, cover buying, selling, receiving, storing, or loading of unpackaged products; those activities require certification.

The exemption at § 205.101(e) is intended primarily for storage and warehouse facilities. Section 205.101(e) applies to handlers that are only receiving, storing and/or preparing for shipment products that are received in and remain in sealed, tamper-evident packaging until the products leave their custody. This allowance may cover, for example, warehouses and storage facilities, including some cold storage facilities that only receive and store packaged products and prepare them for shipment to another entity. Examples of tamper-evident packaging include produce boxes with “DO NOT TAMPER WITH” tape placed across the box flaps, sealed bulk bags of flour, or sealed drums and totes of olive oil. Storage facilities or warehouses that receive products that are not in sealed, tamper-evident packaging must be certified.

The exemption at § 205.101(f) is intended primarily for distributors. Section 205.101(f) applies to handlers that only buy, sell, receive, store and/or prepare for shipment retail-packaged organic agricultural products. This allowance may cover, for example, some distributors, brand name owners, and sales brokers that purchase and/or receive products in their finished retail packaging. Products must be received in and remain in the final retail packaging without alteration throughout their custody. This exemption does not apply to sales brokers, traders, or other handlers that buy and sell products that are not in their final retail packaging.

Preparing for shipment is an activity that is covered under both exemptions at § 205.101(e) and (f). This may include various tasks that must be performed with the sealed, tamper-evident packaging remaining intact and without altering product contents or any retail labeling. Examples of preparing for

shipment include putting packaged products into shipping containers, applying internal tracking numbers, shrink-wrapping shipping cartons to a pallet, breaking down pallets of fully packaged products, adding protective packaging to nonretail containers or retail displays of organic products, packing individual packaged products onto a shipping pallet, loading/unloading packaged products onto or from transport vehicles, and placing individual retail packages into a retail display which the certifying agent of the last certified handling operation has verified as compliant.

Handlers that qualify for an exemption at § 205.101(e) or (f) must use practices for preventing commingling and contamination of organic products, in compliance with § 205.272. In addition, exempt handlers must have records available and must show those records to a representative of the Secretary upon request, to show that organic products are organically produced and handled and to verify quantities of organic product received and shipped or sold. Failure to produce compliant records may lead to enforcement action.

Customs Brokers

Section 205.101(g) exempts Customs brokers from organic certification. Customs brokers facilitate the entry of products into the United States by helping meet import documentation and filing requirements and by acting as intermediaries between importers and the U.S. government. Customs brokers do not take ownership or physical possession of organic products and their actions present minimal risk to organic integrity. They are often distinct from sales or commodity brokers, who sell or facilitate the sale of organic products—those operations must be certified if they handle organic products. Customs brokers also play a critical role by filing NOP Import Certificate data in the U.S. Custom and Border Protection’s (CBP) Automated Commercial Environment (ACE) import entry system.

This exemption is limited to Customs brokers as defined by 19 CFR 111.1: “a person who is licensed under this part to transact customs business on behalf of others.” Customs business is further defined in 19 CFR 111.1 and includes “activities involving transactions with CBP [U.S. Customs and Border Protection] concerning the entry and admissibility of merchandise . . . payment of duties, taxes, or other charges . . . the preparation . . . of documents in any format and the electronic transmission of documents . . . intended to be filed with CBP in

furtherance of any other customs business activity . . .”¹⁷

To qualify for this exemption, Customs brokers must only conduct customs business. If a Customs broker conducts any additional activity within the definition of *handle*—such as selling, importing, or trading—the Customs broker must be certified.

Logistics Brokers

Section 205.101(h) exempts from certification operations that only arrange for the shipping, storing, transport, or movement of organic agricultural products. Sometimes known as “logistics brokers,” these operations facilitate the movement and storage of agricultural products by connecting a consigner (or consignee) with a carrier who can transport/store the products. Logistics brokers do not take ownership or physical possession of organic products. The activities they conduct present minimal risk to organic integrity because they only secure transport/storage to meet the needs of a third party who owns or is responsible for the agricultural product.

This exemption is limited to operations that only arrange for the shipping, storing, transport, or movement of agricultural products and do not conduct any other activity in the definition of *handle*. If such an operation conducts other handling activities—such as selling, importing, or trading—the operation must be certified.

Transport

Transport of agricultural products alone is not a handling activity and does not require certification (see definitions of *handle* in 7 CFR 205.2 and 7 U.S.C. 2502(8)). Transport generally refers to the movement of products in commerce. Examples of activities which are transportation and do not require certification include: moving organic hay or milk from a certified producer to a certified organic buyer or certified processing facility, moving organic grain or organic livestock from certified organic farms to a certified handling or slaughter facility, and food delivery services transporting prepared foods from a retail establishment to a consumer.

Any activities other than the movement of product on a transportation vehicle or moving products between transportation

¹⁷ See 19 CFR 111.1 for complete definitions of Customs broker and Customs business: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=ab6e30d35ef538ce07bc8021d6e1d4c3&mc=true&n=sp19.1.111.a&r=SUBPART&ty=HTML#se19.1.111_11.

vehicles (transloading) are handling and require certification. Handling activities which are adjacent to transport require certification unless they are covered by exemptions 205.101(e) or (f) for packaged products. Examples of adjacent activities which do not qualify as transport include combining, splitting, containerizing, packing/repacking, treating, sorting, opening, enclosing, or labeling/relabeling. In addition, loading or unloading of unpackaged products into or from a storage facility is not a form of transportation; this activity must be certified.

Certified operations are responsible for verifying that products handled by uncertified entities in their supply chain remain in compliance with the organic regulations. This includes verifying organic products transported by an uncertified transporter. A certified operation needs to describe procedures for verifying suppliers in the supply chain and the organic status of products received (§ 205.201(a)(3)). In addition, certified operations must maintain records back to last certified operation, which may encompass uncertified operations that fall between certified entities (§ 205.103(b)(2)). The certified organic operation responsible for the organic products that are transported must: maintain records, for the audit trail and traceability, in sufficient detail as to be readily understood and audited; demonstrate prevention of commingling and contamination during transportation (§ 205.272); fully describe the transportation practices in the organic system plan; and ensure that the transportation records for organic products are available for inspection. Certified operations that load or receive products from uncertified transporters can verify prevention of contamination/contact with prohibited substances through, for example, affidavits or other documentation of vehicle clean out.

Summary of Changes to the Final Rule

AMS made several revisions to the proposed regulatory text when writing this rulemaking. Changes to the rulemaking are discussed below. This is then followed by responses to specific themes from public comment.

- AMS revised the definition of *handle* to include additional examples of activities that require organic certification. AMS added these activities in response to public comments, which asked for additional clarity about who must be certified. The additional activities in the definition more clearly indicate activities that require certification and will help businesses

determine whether they need organic certification.

- AMS simplified the term *handler* and removed “except for operations that are exempt from certification” and “or a portion of [an operation]” from *handling operation*. These phrases are redundant because they are explained in § 205.100—What has to be certified. AMS also added “except final retailers of agricultural products that do not process agricultural products” to both definitions. This clarifies that certain final retailers are not handlers or handling operations and aligns the definitions with OFPA. The two definitions are now mostly synonymous, differing only in their reference to either a person or an operation.

- The proposed rule would have replaced the defined term *retail food establishment* with the updated term *retail operation*, which focused on the key activities of retailers, notably those selling “directly to final consumers.” Many public comments noted that the proposed phrase “direct to final consumers” was imprecise and would not be interpreted consistently by stakeholders. These comments also indicated that stakeholders are familiar with the meaning of the original defined term *retail food establishment* and how to apply it. Therefore, this final rule uses the defined term *retail establishment*, which has language very similar to the original *retail food establishment*, to ensure consistent stakeholder understanding. This final defined term removes the word “food” because retailers sometimes sell non-food items; it also avoids the potentially confusing phrase “directly to final consumers.” Finally, this definition for *retail establishment* adds more examples of types of retail establishments to help stakeholders determine whether they are a retail establishment.

- AMS removed “or a portion of an operation” from the descriptions of each exemption; this language was redundant because it is included in § 205.100—What has to be certified.

- AMS removed references to § 205.272 because they are redundant to the reference to subpart C in the introductory paragraph of § 205.101.

- In the introductory paragraph of § 205.101, AMS replaced references to § 205.310 with a reference to subpart D. This more broadly references the labeling requirements exempt operations must follow, including use of the USDA seal and labeling in retail environments.

- In § 205.101(b), AMS removed “sells” to clarify that retail

establishments may also perform some handling (not just selling) in the regular course of business.

- In § 205.101(c), AMS removed the reference to agricultural products “previously labeled for retail sale” and replaced it with the statement “certified under this part” to clarify that retailers may process certified organic products regardless of whether the products are labeled for retail sale or for other use (e.g., organic products labeled for food service).

- AMS revised § 205.101(e) to exempt only storage of products sealed in tamper-evident packaging. Storage of unpackaged organic products is a high-risk activity that requires certification to maintain integrity. Sealed, tamper-evident packaging makes organic products less susceptible to fraud and mishandling and helps maintain organic integrity during storage and handling by uncertified operations.

- AMS added new paragraph (f) in § 205.101 to exempt the sale of retail products sealed in tamper-evident packaging. Sale of this type of packaged retail products presents little risk to organic integrity, and operations storing and selling these products do not require organic certification.

- AMS added new paragraphs (g) and (h) to § 205.101 to exempt Customs brokers and logistics brokers because these operations only facilitate entry of imports into the United States, and their activities do not present a risk to organic integrity.

- AMS removed recordkeeping requirements from specific exemptions and replaced them with a general “Recordkeeping by exempt operations” paragraph at § 205.101(i).

- AMS revised § 205.310 to remove “or excluded” and replaced “handled” with “processed” to more clearly indicate that products processed by an exempt operation must not be used as an ingredient in an organic product processed by others.

Summary of Public Comment

AMS received many public comments from stakeholders across the organic industry discussing this section of the proposed rule. The majority of comments generally supported AMS’s proposed revisions and agreed that the organic regulations must clearly indicate who needs to be certified and reduce the types of uncertified operations in organic supply chain. Many commenters requested further clarification of the proposed changes, particularly about the need for organic certification and exemptions from certification.

Revised Definitions

The revised definition of *handle* was discussed in many comments. Some commenters requested expanding the definition to include terms such as “port,” “transload,” and “brand owner” to the regulatory text. Commenters also requested specific distinctions be made between “transport” and “transload,” noting current inconsistency in how these are interpreted by the industry.

Some comments discussed further clarification needed, including how “cold storage” fits into the rule. Other comments requested to further clarify *handle* by better defining “split.” Another commenter requested clarification for operations that repackage or repurpose certified organic products for on-site sale (e.g., delis). A few commenters also requested AMS discuss virtual transactions more clearly.

In response to AMS’s request for additional activities that may need to be certified, commenters suggested the following be added to the definition of *handle*: split, open, close, sort, combine, consolidate, aggregate, enclose, condition, treat, size, grade, transload, brand ownership, private label, import, export, commingle, transport, and deliver.

Exemptions

Certification of and exemption for brokers was frequently discussed in comments. Many commenters requested that brokering activities be exempt, with some requesting broad exemptions for all brokers and others favoring exemptions for certain brokering activities. These comments explained that exemptions are warranted because brokers typically do not take physical possession of the products. Many commenters also stated that all brokering activity should be certified, regardless of physical or financial possession.

Several comments requested changes or clarifications to the exemption for operations with organic sales of less than \$5,000, although the proposed rule did not revise existing policy. Most of these comments wrote in support of this exemption, though some proposed changes such as raising the maximum receipts to \$10,000 while still maintaining exempt status.

In general, some comments requested fewer exemptions, and asked AMS to implement a transition period for operations that would require certification under the rulemaking. Further comments wrote that operations that sell direct to consumers should be eligible for exemption. Several

comments requested that storage facilities which only receive product packaged by a certified operation be exempt. One comment requested that products, not operations, be eligible for exemption because operations can interact with organic and non-organic products.

Some comments also requested clarification about private label brands. There was no clear consensus among comments about the need to certify such operations. Many comments stated that these operations must be certified, and that doing so would improve traceability and integrity. Others requested that private labels be exempt to avoid additional costs and labeling inconsistencies. Further comments requested that “private label” be added to the definition of “retail establishment” because retail brands often sell private-labeled product.

Comments disagreed about the specific requirements exempt operations must follow. Some comments argued for more specific regulatory requirements for exempt operations (i.e., clarify what exempt operations can and cannot do). Many comments discussed the use of the USDA organic label by exempt operations, stating that exempt operations should not be permitted to use the certified organic label. They requested that whenever the organic label is used, the business must be certified.

Transport

Many comments requested specific exemptions for most transportation of organic products. Specifically, several comments requested that milk hauling and transportation between two certified operations should be exempt from certification. While the majority of comments requested these types of transportation be exempt, some comments disagreed, requesting limits on transportation exemptions. Other comments requested clarification for whether third-party delivery services that restaurants use are exempt. Finally, some comments also asked AMS to clarify whether transloading activities need to be certified.

Recordkeeping and Compliance

Some comments were concerned with verifying exempt operations compliance. Several commenters suggested requiring universal use of affidavits when doing business with exempt operations. Another suggested utilizing invoices to track compliance using mass-balance audits.

Many comments addressed recordkeeping. Several comments requested modifying recordkeeping

requirements to require exempt operations to maintain records for five years to align requirements for certified and exempt operations. Other comments wrote that the recordkeeping requirements are burdensome for exempt businesses and asked AMS to not require certain recordkeeping practices.

Responses to Public Comment

Definition of Handle

(*Comment*) AMS received many comments about the definition of *handle* and activities that should or should not require certification. Comments discussed a wide range of activities spanning all segments of the supply chain and suggested many additional activities to include in the definition of *handle*, including to split, open, close, sort, combine, consolidate, aggregate, enclose, condition, treat, size, grade, transload, brand ownership, private label, import, export, commingle, transport, and deliver. Conversely, comments also provided examples of activities that should not require certification, including storing packaged products, transporting, delivering, repackaging or splitting cases of retail-packaged products, loading, receiving, brokering, selling or trading packaged products, selling retail products, or labeling for inventory purposes.

(*Response*) AMS agrees that some of the activities presented by commenters require certification and has added more examples to the definition of *handle* to help clarify who and what activities must be certified. The definition of *handle* is not an exhaustive list of activities that must be certified. There may be additional activities not listed in the definition that require certification, or different words or synonyms for the same or similar activities. The absence of a specific term in the definition of *handle* does not mean the activity is not handling or that an operation conducting this activity does not need certification. More specific responses to certain activities are discussed below.

(*Comment*) Several comments noted the difference between the definitions of *handler* and *handling operation* and asked AMS to either clarify this difference, or harmonize the two definitions.

(*Response*) AMS simplified *handler* and removed “except for operations that are exempt from certification” and “or a portion of [an operation]” from *handling operation*. These phrases are redundant because they are explained in § 205.100—What has to be certified. AMS also added “except final retailers

of agricultural products that do not process agricultural products” to both definitions. This clarifies that certain final retailers are not handlers or handling operations, and aligns the definitions with OFPA. The two definitions are now mostly synonymous, differing only in their reference to either a person or an operation.

(*Comment*) Several comments asked AMS to include importing and exporting to the definition of *handle*, noting that the mandatory use of NOP Import Certificates requires certification of importers and exporters.

(*Response*) AMS agrees with these comments and has added importing to the United States and exporting for sale in the United States to the definition to help clarify that these activities require certification, and to support the mandatory use of NOP Import Certificates described in Section 2 of this rule, Imports to the United States.

(*Comment*) Commenters questioned the inclusion of “facilitating sale or trade” in the definition for *handle*. The comments explained that the meaning is vague and too broad and would result in customs brokers, freight forwarders, sales brokers, and administrative activities requiring certification.

(*Response*) The original definition for *handle* covered many activities in the supply chain, from post-production to retail sale. The updated definition is specific about which activities are included in “sell, process or package.” However, the list of activities is not exhaustive and does not capture all activities that may be considered as selling, processing, or packaging an agricultural product. AMS included “facilitating sale or trade on behalf of a seller or oneself” as a general category to capture activities which are integral to selling a product and may be known by various names. The definition for *handle* includes handling activities that fall under AMS’s authority, although sometimes certain activities listed in *handle* may not require certification. For example, entities that perform lower risk activities—such as Customs brokers, logistics providers (*e.g.*, freight forwarders), and limited handling of packaged products—may be exempt from certification (see § 205.101(e)—(h)).

Retail

(*Comment*) AMS received comments requesting clarification regarding whether distribution centers and transport vehicles associated with a retail establishment are exempt from certification. Some commenters requested that off-site warehouses and

distribution centers not be exempt unless they meet proposed § 205.101(e). According to commenters, this clarification is needed to ensure that distribution centers do not avoid certification by claiming to be an exempt retail establishment.

(*Response*) A warehouse or distribution center associated with a retail establishment is only exempt if it meets the criteria described in § 205.101(e) or (f). Transport vehicles associated with a retail establishment do not require certification if they only transport and do not handle organic agricultural products per § 205.2.

(*Comment*) AMS received comments asking whether virtual transactions with a final consumer are exempt from certification. Although a few comments asked NOP to either exempt or require certification of this activity, most comments did not give an opinion and only asked NOP for clarification.

(*Response*) AMS has provided additional clarification by noting that only businesses that meet the definition for *retail establishment* are exempt under § 205.101(b) and (c). Virtual businesses that only sell retail packaged products to consumers, but do not qualify as retail establishments, may be exempt from certification if they meet the criteria of § 205.101(f). AMS provides further detail in the “Retail establishments” section of the preamble.

(*Comment*) Comments noted that the proposed definition of *retail operation* did not include the list of examples that was provided in the preamble, and asked AMS to add them to the definition.

(*Response*) AMS agrees that the examples help clarify the definition and has added them to the final definition of *retail establishment*.

(*Comment*) Comments requested revising the exemption for retailers that process by not limiting this to processing only products that were previously labeled for retail sale. Comments indicated that retailers commonly source products labeled for food service.

(*Response*) AMS has removed that qualification from § 205.101(c) to clarify that exempt retail establishments may process certified organic products regardless of whether the products are labeled for retail sale.

(*Comment*) AMS received comments asking about the status of food delivery services, specifically those affiliated with or serving retail operations. Although a few comments asked NOP to either exempt or require certification of this activity, most comments did not give an opinion and only asked NOP for clarification.

(*Response*) Services which deliver products from a retail establishment to a consumer may not require certification. A service which delivers product from the retailer to the consumer after final sale and does not engage in handling is transport and does not require certification.

(*Comment*) Comments requested clearer guidance on what handling activities retail operations could engage in and remain exempt. Comments explained that the exemption for retailers that only sell and retailers that process creates uncertainty for the many retail operations that sell and handle. A few comments gave specific examples of activities that exempt retail establishments should be allowed to conduct, including removing/unpacking products, washing and transferring products to retail displays, and breaking down master cases of individual packaged products. However, most comments did not give an opinion and only asked NOP for clarification.

(*Response*) AMS has revised the definitions of *handler* and *handling operation* to exclude retailers that do not process organic agricultural products; these operations may not require certification. This is reinforced by the exemption for retailers that handle but do not process at § 205.101(b), which acknowledges that exempt retail establishments may perform some handling activities. AMS has also revised the definition for *handle* to be more specific about the types of activities included. The additional description will help to clarify the differences and overlap in handling and processing activities.

(*Comment*) Comments asked to clarify the meaning of “point of sale” in reference to virtual transactions for retailers. There was a suggestion to allow virtual transactions only when the sale occurs from a brick-and-mortar retail location, to prohibit retailers that sell only via an online platform.

(*Response*) The definition for retail establishment allows for virtual retail transactions. For a retail establishment to be exempt, the sales must occur at the same location as the processing, and there must also be a physical location for consumers to purchase products.

Storage

(*Comment*) AMS received comments stating that storage of unpackaged or bulk organic products is high-risk and should require certification. They also noted that the proposed rule eliminated the distinction between packaged and unpackaged product relating to receiving, storing, and loading activities; this could allow high-risk operations

such as grain elevators and ports of entry to be exempt from certification. Some comments requested AMS only exempt the storage of sealed, tamper-evident packaged products.

(Response) AMS has revised the exemption at § 205.101(e) to exempt only operations that store, receive, and prepare for shipment organic products in sealed, tamper-evident packages. Products must remain in their packages and the exempt operation must not handle the product beyond storing, loading, and preparing for shipment. Operations that store bulk products or products not packaged in sealed, tamper-evident packaging must be certified.

AMS made this change because the proposed rule would have exempted operations that store unpackaged or bulk organic products. Many public comments noted that storage of unpackaged organic products is a high-risk activity that requires certification to maintain integrity. AMS agrees that storage of unpackaged products is a high-risk activity. Lack of sealed or protective packaging increases the likelihood of contamination with prohibited materials (e.g., pesticides and fumigants), commingling with nonorganic products, and misidentification. These risks are especially great in high-activity areas, and storage of unpackaged products requires additional care and oversight to ensure organic integrity is maintained. Therefore, AMS is requiring certification of operations that store unpackaged products. Conversely, because packaging reduces the risk of contamination, commingling, and misidentification, AMS is granting an exemption from certification for operations that only store packaged products that are sealed upon arrival and remain in their packaging.

AMS has narrowed the exemption to include only operations that store, receive, and/or prepare for shipment organic products in sealed, tamper-evident packaging. Sealed, tamper-evident packaging makes organic products less susceptible to fraud and mishandling and helps maintain organic integrity during storage and handling by uncertified operations.

(Comment) Commenters requested AMS exempt from certification activities where packaged product remains in its container, such as breaking up pallets of packaged organic products that remain in its original inner packaging, or placing such products into a retail display.

(Response) Section 205.101(e) and (f) exempt operations that receive, store, and prepare for shipment organic

products enclosed in sealed, tamper-evident packages or containers. Preparing for shipment may include various tasks that must be performed with the sealed, tamper-evident packaging remaining intact and without altering product contents or any retail labeling. Examples of preparing for shipment include putting packaged products into shipping containers, applying internal tracking numbers, shrink-wrapping shipping cartons to a pallet, breaking down pallets of fully packaged products, adding protective packaging to nonretail containers or retail displays of organic products, packing individual packaged products onto a shipping pallet, placing individual retail packages into a retail display, and loading/unloading packaged products onto or from transport vehicles.

(Comment) Several comments asked if cold storage of organic agricultural products is exempt from certification, pointing to the inclusion of “chilling” in the definition of *processing*.

(Response) Cold storage of organic agricultural products may be exempt from organic certification if the activity meets the criteria of § 205.101(e), *i.e.*, only sealed, tamper-proof packaged organic products are stored. The act of cooling packaged organic products is a common low-risk storage activity that is different from “chilling” performed as part of organic product processing.

(Comment) Several commenters requested that AMS remove the verb “loads” from proposed § 205.101(e) for operations that store organic products, arguing that “load” could be conflated with handling activities such as placing or packaging bulk products into containers.

(Response) AMS uses “prepare for shipment” in exemptions at § 205.101(e)–(f) to clarify that these exempt operations may not perform activities such as packaging or loading bulk products into containers. Prepare for shipment means that these operations may move products into or onto a mode of transport, provided that the products are packaged per § 205.101(e)–(f).

(Comment) One commenter asked AMS to require certification of storage facilities that store both organic and nonorganic agricultural products. They argue that such “split” storage operations are a known source of contamination and commingling, and that certification is necessary to prevent this.

(Response) This rulemaking addresses the risks of contamination and commingling by split storage operations by (1) requiring the certification of

operations that handle unpackaged organic products and (2) limiting the exemption for storage operations to only those that handle sealed, tamper-proof packaged organic products. AMS believes these changes will mitigate the risks of split operations.

Additionally, § 205.100(a) states that “each operation or portion of an operation” that handles organic agricultural products must be certified. Similarly, the exemption at § 205.101(e), which allows storage of packaged organic products without certification, would be limited to only the portions of an operation that meet the narrow criteria of this exemption. This means that a portion of a split operation that stores unpackaged organic products needs to be certified.

Transport

(Comment) Commenters requested that AMS explicitly state what transportation activities are exempt from certification. They also noted that the regulatory text and preamble lack a specific exemption for transport of agricultural products.

(Response) The OFPA provides AMS authority to regulate the handling (*i.e.*, selling, processing, or packaging) of organic agricultural products; however, transportation activities are not included in this authority. Transport is generally described as the movement of products in commerce. Based on the OFPA, transport of organic agricultural products does not need to be certified; however, any handling activities that occur during transport must be. See the definition of *handle* for examples of activities that may require certification.

(Comment) AMS received several comments asking if milk haulers will require organic certification. Most comments requested only clarification on this topic, but several specifically requested that milk haulers be exempted from certification.

(Response) AMS is defining the need for certification based on activities performed, not type of business, because this will ensure that businesses conducting high-risk activities require certification (and conversely that businesses that conduct low-risk activities remain exempt). A milk hauler would be exempt from certification if they *only* transport organic milk (e.g., move milk from a dairy to a processor) but do not otherwise handle the milk (e.g., process or package loads of milk). Transport alone does not require certification.

(Comment) AMS received comments requesting that the transport exemption be limited to transport from one certified operator to another, or to a

final retailer, to ensure traceability of product throughout supply chains.

(*Response*) AMS is not restricting transport of organic agricultural products from one certified operation to another. This rule ensures traceability via other means: certified operations must maintain audit trail documentation for products they produce or handle (§ 205.103(b)(3)) and keep records to trace organic products received back to the last certified operation in the supply chain (§ 205.103(b)(2)). This means that certified operations must ensure traceability of products transported by uncertified operations, including if several uncertified transporters are used in sequence.

(*Comment*) Many comments discussed transloading organic agricultural products and asked AMS to clarify if this activity requires certification.

(*Response*) Transloading is commonly defined as the movement of agricultural products between modes of transport. AMS does not have the authority to regulate transport. Therefore, transloading strictly between modes of transportation does not need to be certified.

However, transloading is sometimes used to describe the movement of agricultural products from storage to transport or transport to storage. AMS considers these activities to be loading and receiving (see § 205.2 and the definition of *handle*). Moving unpackaged organic agricultural products from storage to transport, or from transport to storage, requires certification. If the organic agricultural products are enclosed in sealed, tamper-proof containers or packages, then loading and receiving is exempt from certification.

Small Operations

(*Comment*) Several comments discussed the exemption for small operations at § 205.101(a). A few commenters asked AMS to clarify if the exemption applies to both production and handling operations. Others requested that AMS allow ingredients produced or processed by such exempt operations to be used as certified organic ingredients produced by other operations. One commenter requested AMS increase the gross sales limit of \$5,000.

(*Response*) This rulemaking does not modify current policy regarding the exemption for small operations. Section 205.101(a) exempts operations that produce or *handle* agricultural products as “organic” but whose gross agricultural income from organic sales

totals \$5,000 or less annually. However, these operations must not sell, label, or represent agricultural products they produce or process as *certified* organic, and such products must not be used as certified organic ingredients in products processed by another operation (see § 205.310). Additionally, the \$5,000 gross sales threshold is set by the OFPA, and AMS does not have authority to increase this limit.

Selling and Representing

(*Comment*) Many comments requested that AMS provide exemptions for operations that do not physically handle or contact organic agricultural products, arguing that such operations do not threaten organic integrity.

(*Response*) AMS disagrees with commenters’ claim that lack of physical contact equals low risk. Organic integrity depends on oversight and transparency across the entire organic supply chain—including some operations that may never physically contact organic products. The need for certification is based on risk and this rule requires certification of high-risk operations such as importers, traders, and others that facilitate the sale of organic products. Although these operations may not physically contact organic products, they control critical events along organic supply chains where organic integrity can be compromised, including purchase, sale, transport, storage, and combining or splitting products. For example, an importer, broker, or trader could unintentionally compromise the integrity of organic products they buy or sell by not seeking or keeping records to demonstrate traceability and verify organic integrity. Without these records, there is no way to verify that a product was properly handled by the multiple physical handlers in a supply chain. A breach of integrity could go unreported, and the importer or trader would unintentionally sell a product that has lost its organic status and integrity. Similarly, brokers and traders could mistakenly direct contracted storage facilities and transporters to perform activities that compromise organic integrity, such as directing a storage facility to fumigate a container of organic wheat or directing a transporter to combine loads of organic and nonorganic corn.

Additionally, because importers, brokers, traders and others that facilitate sales have direct financial interest in the transaction of organic products, they have the incentive and opportunity to commit fraud. For example, an operation could falsify records to claim that a nonorganic product is certified

organic, or direct a contracted storage facility or transporter to mix organic and nonorganic products, and then claim the entire load is organic. NOP has investigated many notable cases of fraud committed by uncertified operations that did not physically contact the products in question (see the discussion on fraud under “Purpose and Need for the Rule”).

The risk of both unintentional breach of integrity and fraud has grown with the organic market as supply chains increase in complexity and more uncertified parties affect control of organic products and their transaction. Requiring certification based on risk ensures traceability, verification, accountability, and oversight at the most critical points of the supply chain, including the activities of brokers, traders, importers, and others who facilitate sale but may not physically contact organic products. The rule also provides reasonable exemptions for low-risk operations to reduce cost and administrative burden to the industry.

(*Comment*) Many comments discussed private labeling and brand ownership of organic products. Opinions differed about the need to certify these operations. Some commenters argued that requiring certification of these operations would improve transparency and traceability of products, while others claimed that doing so would be unnecessary and create potential problems with labeling and traceability.

(*Response*) “Brand owners” or operations that sell or distribute organic products produced by another operation on their behalf may be exempt from certification if they meet the criteria of § 205.101(f). This exemption allows the buying, selling, receiving, storing, and preparing for shipment of organic products that are packaged for retail sale. The products must be sealed in tamper-evident packaging ready for retail sale, and the operation must not open or otherwise handle the retail packages. Private labeling operations that process organic agricultural products must be certified.

(*Comment*) Commenters asked AMS to clarify if sales brokers need to be certified, including businesses that buy or sell only packaged organic products.

(*Response*) Operations that sell, trade, or facilitate sale or trade of organic agricultural products on behalf of a seller or oneself must be certified. However, AMS is providing an exemption for operations that only buy, sell, receive, store, or prepare for shipment organic products packaged for retail sale (§ 205.101(f)). The products must be sealed in tamper-evident

packaging labeled for retail sale, and the operation must not open or otherwise handle the retail packages. Sale of organic products not packaged for retail sale (e.g., bulk; unpackaged; packaged for nonretail sale; unsealed, non-tamper-evident packaging) must be certified.

Supply Chain Logistics

(Comment) Many comments asked AMS to provide a specific exemption for Customs brokers licensed by U.S. Customs and Border Protection, arguing that these operations only facilitate entry of imports into the United States, and that their activities do not present a risk to organic integrity.

(Response) AMS agrees that the activities of Customs brokers do not threaten organic integrity. Therefore, § 205.101(g) exempts from certification licensed Customs brokers that only conduct Customs business per 19 CFR 111.1. This exemption is limited to Customs business; other activities conducted by a Customs broker that fall within the definition of *handle*—including selling, importing, or trading organic agricultural products—may require certification.

(Comment) Several comments asked AMS to clarify if businesses that facilitate the storage and transport of organic agricultural products, such as logistics brokers and freight forwarders, require certification.

(Response) Logistics brokers, freight forwarders, and other businesses that facilitate storage and transport of agricultural products may be exempt if they meet the criteria of §§ 205.101(e) or (h). These exemptions only apply to operations that conduct or facilitate specific shipping, storing, or transport activities. This may include logistics brokers or freight forwarders who do not take ownership or physical possession of organic products and only provide a service by connecting a consigner (or consignee) with a carrier who transports/stores the products. Additionally, transport of organic

agricultural products does not require certification if the transport operation does not handle the products (see definition of *handle* in § 205.2). Other handling activities—such as selling, importing, or trading—must be certified.

(Comment) Many commenters responded to AMS’s request for comment about ports of entry. Most commenters agreed that the activities of ports—such as loading, storing, receiving, combining, and splitting—must be certified if unpackaged products are being handled. Comments stated that handling of unpackaged goods at ports should be certified because ports conduct physical activities that can compromise organic integrity. Ports unload, move, split, combine, and store both organic and nonorganic products, increasing the risk of commingling organic and nonorganic products, and the risk of contamination with substances not allowed in organic handling. In contrast, several comments from trade associations state that requiring certification of port activities may cause delays, increase costs, and may have limited positive impacts on organic integrity. Several comments asked AMS for more clarification about the need for ports of entry to be certified.

(Response) Ports of entry must be certified if the activities they conduct meet the definition of *handle* and do not clearly fit an exemption at § 205.101(a)–(h).

Recordkeeping and Verification

(Comment) Several comments noted that proposed § 205.101 did not clearly explain the requirements and recordkeeping practices each exempt operation must follow. A few comments also asked AMS to increase the recordkeeping requirement for exempt operations to five years to be consistent with requirements for certified operations.

(Response) AMS has revised § 205.101 to clarify the requirements and

recordkeeping practices that exempt operations must follow. Specific references to individual requirements are removed from each exemption, and the introductory paragraph explains universally that all exempt operations must follow the applicable production, handling, and labeling requirements of subparts C and D. The preamble further explains with specific examples of requirements exempt operations may have to follow.

AMS has also removed recordkeeping requirements from individual exemptions and replaced them with a single, consistent recordkeeping requirement that applies universally to most exempt operations. AMS retained the requirements for exempt operations to maintain records for at least three years because there was not a compelling reason for increasing that timeframe without prior notice.

(Comment) AMS received several comments asking who is responsible for verifying exempt operations’ compliance with the organic regulations.

(Response) Certified operations are responsible for verifying the compliance of the certified organic products they receive, including those received from exempt operations. Section 205.201(a)(3) requires a certified operation’s OSP to include monitoring practices and procedures to verify suppliers (including exempt suppliers) and the organic status of products they receive. AMS is not prescribing how certified operations should verify suppliers and products; this provides flexibility for operations to develop and implement practices that best suit their business and the products they handle.

B. Imports to the United States

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.2	Terms Defined.
205.273	Definitions for <i>Organic exporter</i> and <i>Organic importer</i> . Imports to the United States.
205.300	Entire section. Use of the term, “organic.” Paragraph (c).

Purpose, Scope, and Authority

AMS is amending the USDA organic regulations by adding a new section (205.273) requiring the use of the National Organic Program Import Certificate (“NOP Import Certificate”).

The NOP Import Certificate is a transaction certificate, or data set, that contains detailed information about the quantity and origin of organic product being imported into the United States. Any organic agricultural product

imported to the United States must be associated with a valid NOP Import Certificate, generated by the certifying agent of the final certified exporter sending the product to the United States.

The purpose of the NOP Import Certificate is to document the organic status and quantity of imported organic products as they travel from a certified organic exporter in a foreign country to a certified organic importer in the United States. The NOP Import Certificate ensures an auditable business transaction by documenting that the products in the shipment are organic and may be sold, represented, and distributed as organic within the United States.

The mandatory use of NOP Import Certificates is authorized by the Organic Foods Production Act (OFPA), as amended by the “2018 Farm Bill”.¹⁸ The OFPA specifies what information an NOP Import Certificate must include (7 U.S.C. 6502(13)) and also stipulates that the NOP Import Certificate must “be available as an electronic record” and captured in a tracking system maintained by the U.S. Government (7 U.S.C. 6514(d)). The OFPA also provides the Secretary with broad authority to establish appropriate and adequate enforcement procedures and any other requirements that the Secretary may determine to be necessary (7 U.S.C. 6506).

The NOP Import Certificate must be presented to U.S. Customs and Border Protection (CBP) through the CBP Automated Commercial Environment (ACE). The use of this standardized electronic format will ensure consistency in data for auditing, surveillance, and enforcement purposes. The OFPA, as amended by the 2018 Farm Bill, states that AMS must establish a system of tracking NOP Import Certificates, and that AMS “may integrate the system into any existing information tracking systems for imports of agricultural products” (7 U.S.C. 6514(d) and 6522(c)).¹⁹

Because the OFPA enables AMS to access information available in ACE (7 U.S.C. 6521(c)), AMS is using ACE to accept NOP Import Certificate data.²⁰ ACE is an automated and electronic system for processing commercial trade data. It is the primary system through which the global trade community files information about imports and exports so that admissibility into the United States may be determined by

¹⁸ See sections 10104(b)(3) and 10104(c) of the Agriculture Improvement Act of 2018, Public Law 115–334. Available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>.

¹⁹ See section 10104(c) of the Agriculture Improvement Act of 2018, Public Law 115–334. Available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>.

²⁰ See sections 10104(h) and (j) of the Agriculture Improvement Act of 2018, Public Law 115–334. Available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>.

government agencies (including AMS) to ensure compliance.

The data to be entered into ACE include fields for the information needed to meet the requirements of an NOP Import Certificate as defined in the OFPA: origin; destination; the certifying agent issuing the NOP Import Certificate; harmonized tariff code, when applicable; total weight; and the organic standard the product was certified to (7 U.S.C. 6502(13)). For the purposes of uploading and tracking NOP Import Certificates, the data must be available as an electronic format to meet the requirements of the OFPA (7 U.S.C. 6514(d)(1)).

Both the OFPA and the USDA organic regulations require certified operations to maintain and make available to the Secretary records that concern the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as organic. This includes sufficient records to provide an audit trail to determine the source, type and quantity, transfer of ownership, and transportation of any agricultural product labeled as organic. Likewise, both the OFPA and the USDA organic regulations require certifying agents to maintain and make available to the Secretary records concerning its activities.

This policy also aligns with international guidelines and norms related to organic oversight. NOP considered international standards established by the Codex Alimentarius Commission (Codex)²¹ and norms published by the International Federation of Organic Agriculture Movements (IFOAM).²² Both provide for and support the use of transaction shipment certificates such as the NOP Import Certificate.

Change From Current Policy

NOP Import Certificates are currently only used for organic products imported from countries with which AMS has an equivalence determination. The USDA has established equivalence determinations with Canada, the European Union, Switzerland, Japan,

²¹ Section 7 of the *Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* recommends imported organic products to be marketed only where the competent authority or designated body in the exporting country has issued a certificate of inspection stating that the lot designated in the certificate was obtained within an organic system of production, preparation, marketing, and inspection.

²² IFOAM Norms define a transaction certificate as a “document issued by a certification body or by the operator, declaring that a specified lot or consignment of goods is certified.”

South Korea, Taiwan, and the United Kingdom. Organic imports from Canada are accompanied by an organic certificate that includes an attestation statement that the products comply with the terms of the United States–Canada Organic Equivalency Arrangement. Organic imports from the European Union, Switzerland, Japan, South Korea, Taiwan, and the United Kingdom are accompanied by an NOP Import Certificate. The certifying agent of the exporter evaluates the request for an NOP Import Certificate, and upon verification of the organic shipment, completes and issues an NOP Import Certificate. Form NOP 2110–1 is currently used for this purpose.

In the past, AMS has not required NOP Import Certificates for organic exports from countries with which the United States does not have an organic equivalence determination. The rulemaking changes this to make the use of NOP Import Certificates mandatory, regardless of an imported product’s country of origin or if that country has an equivalency determination with USDA. Specifically, this rulemaking requires that all imported products intended to be sold, represented, labeled, or marketed as organic in the United States must be declared as organic to U.S. Customs and Border Protection (CBP), using an NOP Import Certificate.

Alignment of Policy With U.S. Customs and Border Protection Policies and Systems

The OFPA, as amended by the 2018 Farm Bill, requires the establishment of an Organic Agricultural Product Imports Interagency Working Group, consisting of members of both the USDA and CBP (see 7 U.S.C. 6521a).²³ The mandatory use of NOP Import Certificates supports the working group’s goal to ensure the compliance of organic agricultural products imported into the United States.

Under this policy, AMS and CBP will collaborate to verify that imported organic products are associated with NOP Import Certificates. In April 2020, the electronic version of the NOP Import Certificate was deployed in ACE as an optional filing step for organic imports. The use of the electronic NOP Import Certificate will be mandatory once this rule is fully implemented.

NOP Import Certificates will be required for any commodity imported into the United States that is being

²³ See section 10104(i) of the Agriculture Improvement Act of 2018, Public Law No: 115–334. Available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>.

manifested, sold, marketed, or labeled organic. NOP Import Certificates are required for organic commodities regardless of value or size and is not applicable for any de minimis exemptions under current CBP regulations.

Generating the NOP Import Certificate

This section describes how the NOP Import Certificate data are generated. NOP Import Certificates must be generated using the USDA's Organic Integrity Database. By the time the rule is fully implemented, both USDA-accredited certifying agents and organic certifying agents accredited by countries with which USDA holds an organic trade arrangement or agreement (equivalence determination or recognition arrangement) will have access to the Organic Integrity Database to generate NOP Import Certificates. Only the Organic Integrity Database can be used to generate valid NOP Import Certificates, and only accredited organic certifying agents (USDA or under an organic trade arrangement or agreement) are authorized to use the Organic Integrity Database.

Where does the data for the NOP Import Certificate come from?

The data for the NOP Import Certificate is generated in the Organic Integrity Database by the certifying agent of the exporter. The exporter is responsible for facilitating the trading, selling, consigning, shipping, or exporting of organic product from a foreign country to the United States. An organic exporter must be certified organic by certifying agents accredited by the USDA or certifying agents authorized by a trade arrangement or agreement. Organic exporters may be the final physical handler of organic products within a foreign country, or they may be the entities that facilitate, sell, or arrange the sale of organic products shipped to the United States.

This exporter is responsible for verifying that the organic product complies with organic standards. This includes, but is not limited to, verifying that the import has not been exposed to a prohibited substance, treated with a prohibited substance as a result of fumigation or treated with ionizing radiation at any point in the products' movements across country borders.

How does the certifying agent evaluate the request for an NOP Import Certificate?

The certifying agent determines the format of the NOP Import Certificate request from the certified operation, based on the data required for the

Organic Integrity Database to generate the NOP Import Certificate. The request for an NOP Import Certificate must include all information required by the organic exporter's certifying agent to complete the NOP Import Certificate. The certifying agent is required to confirm the authenticity of the organic products covered by the NOP Import Certificate using control systems it designs for this purpose. The certifying agent must have and implement a documented organic control system for intaking and approving or rejecting the validity of an NOP Import Certificate request.

The certifying agent is responsible for ensuring that the issued NOP Import Certificate is only associated with an amount of product that has been verified to be certified organic. The certifying agent has the authority to determine whether it will issue an NOP Import Certificate for a specific shipment, or for a specific timeframe (e.g., weekly, monthly, season) and amount or volume ceiling. This determination is to be based on the capacity and control systems of both the certifying agent and the certified operation. There is no limit on the length of timeframe a certifying agent chooses. However, the certifying agent must choose a timeframe that is appropriate to their administrative capacity and documented control system and allows them to verify the integrity of the specific type and volume of import.

Once the certifying agent verifies the authenticity of the organic export, the certifying agent enters or uploads the information needed into the Organic Integrity Database. Each NOP Import Certificate must be associated with a certified organic operation listed in the database, identified by a 10-digit code. The Organic Integrity Database will generate a unique NOP Import Certificate that includes both the 10-digit identifier for the operation and a unique numerical identifier for the NOP Import Certificate. The certifying agent will provide the NOP Import Certificate, or data set with the NOP Import Certificate number, back to the certified organic exporter requesting the NOP Import Certificate. The certifying agent can cancel or void a NOP Import Certificate in the Organic Integrity Database at any time.

Transmitting the NOP Import Certificate From Exporter to Importer

The certified organic exporter provides the NOP Import Certificate to the U.S. importer, who provides it to the specific entity responsible for entering import information into the ACE

system. This is typically an importer or designated Customs broker. The NOP Import Certificate data can be sent either electronically or via paper. The U.S. importer or Customs broker enters the NOP Import Certificate data into ACE as part of its standard import filing process; this process is governed by timelines determined by CBP. Organic certifying agents will not have access to ACE; this activity is done by the importer or its Customs broker, using the NOP Import Certificate data provided by the certifying agent to the exporter.

As the certified organic product itself moves from the exporting country into the United States, all entry documentation including, but not limited to bills of lading, bills of sale, commercial invoices, and packing lists must clearly state that the product is organic. Exporting and importing operations must maintain records required under § 205.103. CBP may hold shipments at the border to address health and safety issues or violations of U.S. trade laws with a specific commodity or shipment.

Importer Responsibilities

Upon receiving a shipment, an organic importer must verify that the organic product(s) comply with the USDA organic regulations. This includes ensuring that an NOP Import Certificate is associated with the product received. It also includes verifying that the import has not been treated with a prohibited substance as a result of fumigation or treated with ionizing radiation at any point in the products' movements across borders. Verification may take many forms, depending on the documentation provided, and country and commodity. The importer must have an organic control system that documents how this verification is conducted to protect the organic integrity of imported product. This control system is reviewed by the importer's certifying agent.

Both the organic exporter and U.S. organic importer must maintain records of NOP Import Certificates, and these records must be available for inspection by the NOP and certifying agents in accordance with § 205.103. Certifying agents that are overseeing imports of organic products into the United States must have a system for ensuring that operations receiving organic product are receiving and maintaining NOP Import Certificates, and that they are not accepting more product from any providers than is authorized by NOP Import Certificates.

Connecting NOP Import Certificate With ACE Import Data

Once NOP Import Certificate Data is entered into ACE, the data are transmitted to AMS for analysis, surveillance, and enforcement. AMS will align and validate the data generated in ACE with the original NOP Import Certificate entered into the Organic Integrity Database. This will connect the data about the actual imported product back to the data about the corresponding authorized export, aligning both sides of the transaction. This alignment will allow for the identification of any anomalies or indicators of fraud, such as: NOP Import Certificates in ACE that were not authorized (do not have a valid certificate number) by a certifying agent in the Organic Integrity Database (*e.g.*, fraudulent certificates); volumes of product entered in ACE that exceed those authorized in the Organic Integrity Database; and/or entries into ACE that are associated with an operation that is no longer certified. This type of automated data-driven surveillance is a common approach in trade oversight.

Timing of the NOP Import Certificate

The timing of the NOP Import Certificate data entry into ACE must comply with current CBP import filing requirements for Partner Government Agencies. The certified organic exporter must time the NOP Import Certificate request in such a way that the certifying agent has time to consider the request and generate the NOP Import Certificate, and the exporter has time to deliver it to the importer or Customs broker before the CBP filing requirements for the product.

Requiring an NOP Import Certificate provides trackable and auditable verification that organic products comply with the USDA organic regulations. This requirement will also support investigations if noncompliant products are exported and misrepresented as organic for sale in the United States. Given that the Organic Integrity Database will be the definitive tool for generating NOP Import Certificates, additional guidelines on data entry to generate NOP Import Certificates will be provided through that system.

Summary of Changes to the Final Rule

AMS made several changes to the regulatory text of the SOE proposed rule when writing this final rule. Changes to the final rule are discussed below and are followed by responses to specific themes from public comment.

- AMS removed “owner” from the definition of *organic exporter*, added

“certified” before “exporter,” and “to the United States” after “from a foreign country.” This clarifies that the organic exporter must be certified, and that the organic exporter may be the final physical handler of organic products within a foreign country, or they may be the entities that facilitate, sell, or arrange the sale of organic products shipped to the United States. This was done to clarify questions about “who needs to be certified” received during public comment.

- AMS removed “of record” from the definition of *organic importer* and added a statement that the organic importer is responsible for entering NOP Import Certificate data into ACE. This addresses public commenters’ request to clarify the role of the organic importer and the person responsible for entering data into ACE.

- AMS removed “through a U.S. Port of Entry,” as all imports must enter through such a Port, so the phrase is not needed.

- AMS removed references to “or equivalent data source” and “NOP Form 2110–1” throughout § 205.273 and clarified that the Organic Integrity Database must be used to issue NOP Import Certificates. AMS has determined that the Organic Integrity Database will be the only data source for NOP Import Certificates because it is a preexisting, proven tool that meets U.S. government security requirements, and already accepts data in multiple different forms to accommodate data inputs from other systems. The Organic Integrity Database is already used and understood by certifying agents, including many accredited by both the USDA and trade partner countries. It is a system that accepts data in multiple forms, that any government can engage with, and that minimizes onboarding time and learning curve. Using the Organic Integrity Database as a single source of certification and import data, while allowing multiple data upload methods, will provide secure access to import data that facilitates the use of NOP Import Certificates.

- AMS clarified that certifying agents may issue NOP Import Certificates for a specific timeframe, if appropriate, not limited to a single transaction. This addresses public commenters’ concerns about generating NOP Import Certificates for multiple shipments in short timeframes (*e.g.*, multiple shipments of fresh produce across the border). This change allows certifying agents to determine whether they will issue an NOP Import Certificate for a specific shipment or for a specific timeframe (*e.g.*, weekly, monthly, seasonally) and amount or volume

ceiling. Because certifiers conduct certification activities on a one-year cycle, it is expected that import certificates are unlikely to exceed one year in duration. The certifying agent must choose a timeframe that is appropriate to their administrative capacity and documented control system, and allows them to verify the integrity of the specific type and volume of import.

- AMS clarified the requirement that certifying agents must have and implement a documented organic control system for intaking and approving or rejecting NOP Import Certificates. This ensures that certifying agents have auditable processes and procedures that NOP can audit to assess certifying agents’ ability to generate and approve NOP Import Certificates.

- AMS removed the requirement that certifying agents must issue NOP Import Certificates within 30 days. This avoids any timing discrepancy between NOP Import Certificate data entry and CBP import filing requirements. AMS does not have authority to change CBP entry requirements. The timing of the NOP Import Certificate data entry into ACE must comply with current CBP import filing requirements for Partner Government Agencies.

- AMS clarified that organic importers must have a documented organic control system to verify NOP Import Certificates and verify no contact with prohibited substances or exposure to ionizing radiation. This is necessary to ensure that organic importers have auditable processes and procedures that certifying agents can review to assess importers’ ability to verify NOP Import Certificates and verify the integrity of imported organic products.

- AMS clarified that organic importers must verify that the NOP Import Certificate data accurately reflects the shipment, which may include verification of quantities and types of product specified on the NOP Import Certificate. This requirement more clearly states the organic importer’s responsibility in assessing and ensuring the integrity of imported products, providing an additional layer of oversight at a critical juncture in organic supply chains.

Summary of Public Comment

The majority of public comments were strongly in support of AMS’s proposed mandatory use of NOP Import Certificates. Many comments discussed or recommended changes to the NOP Import Certificate process, including the timing of NOP Import Certificates, ACE data entry, how the certificate should travel with the import, certifying agent

role and capacity, and how the NOP Import Certificate would function within organic trade arrangements and agreements.

Comments frequently asked AMS to clarify if NOP Import Certificates can be issued before or after shipment. They also noted that the proposed 30-day requirement to issue NOP Import Certificates does not align with the 10-day ACE entry deadline noted in the preamble. Some comments requested that AMS allow up to 30 days to enter NOP Import Certificate data into ACE, while others recommended 10 days or less to help reduce fraud.

Many comments asked AMS to clarify if an NOP Import Certificate must “accompany” an import or be “associated with” an import. Several comments requested that AMS require imports be “accompanied” by an NOP Import Certificate and that the certificate travel with the import and be presented at entry into the United States, claiming that this would help prevent fraudulent organic products from entering the U.S. market. Others stated a preference to allow NOP Import Certificates to “be associated” with shipments, noting that this flexibility is needed to match the frequency and pace of land imports via truck and rail.

Several comments noted that issuing NOP Import Certificates for individual shipments would be difficult for high-volume, high-frequency imports, especially those from Canada and Mexico. These comments asked AMS to consider allowing certifying agents to issue NOP Import Certificates that cover a specific time period (*e.g.*, quarterly), product type, and volume. Comments argued this would reduce administrative burden and cost to both certified operations and certifying agents. A few comments also claimed that some certifying agents may not have the administrative capacity or technical expertise to issue and verify NOP Import Certificates as proposed.

A few comments asked AMS to clarify the definitions and roles of exporters and importers, noting that it is not clear who is responsible for requesting NOP Import Certificates, verifying them upon import, and entering data into ACE. Some comments also asked AMS to further define “equivalent data.”

Finally, some comments requested clarification about the general applicability and use of NOP Import Certificates, including their use for very small or infrequent shipments, use by exporters in a country AMS has a trade arrangement or agreement with, use of electronic vs. paper certificates, and use in trade between two foreign countries.

Responses to Public Comment

Timing of NOP Import Certificates

(*Comment*) AMS received many comments concerning the 30-day time frame for certifying agents to review and issue NOP Import Certificates. Commenters stated that the 30-day timeframe will negatively impact imports of perishable organic product from Canada and Mexico that require a rapid import process.

Other commenters stated that the 30-calendar-day timeframe for certifying agents to review and issue NOP Import Certificates does not align with the existing 10-day requirement to upload the NOP Import Certificate data into the ACE system. Others requested that the 10-day requirement for organic exporters to enter data from an NOP Import Certificates or equivalent into ACE align with the proposed 30-day requirement for certifying agents to issue an NOP Import Certificate or equivalent. Commenters also requested that the 10-day timeframe to enter NOP Import Certificate data be reduced to prevent organic fraud.

More broadly, AMS received comments asking if NOP Import Certificates can be issued both before and after shipment. Additionally, commenters asked if NOP Import Certificates could be issued after the shipment of organic product has already entered the United States.

(*Response*) The timing of the NOP Import Certificate data entry into ACE must comply with current CBP import filing requirements for Partner Government Agencies. AMS does not have authority to change CBP entry requirements.

The certified organic exporter must time the NOP Import Certificate request in such a way that the certifying agent has time to consider the request and generate the NOP Import Certificate, and the exporter has time to deliver it to the importer or Customs broker before the CBP filing requirements for the product.

To address the problem of generating NOP Import Certificates for multiple shipments in short timeframes (*e.g.*, multiple shipments of fresh produce across the border), AMS is granting the certifying agent the authority to determine whether it will issue an NOP Import Certificate for a specific shipment, or for a specific timeframe (*e.g.*, weekly, monthly, season) and amount or volume ceiling. The certifying agent is responsible for ensuring that the issued NOP Import Certificate is only associated with an amount of product that has been verified to be certified organic.

Associated vs. Accompanying

(*Comment*) Several commenters noted that proposed § 205.273(d) states that the organic importer of record must ensure that the shipment is *accompanied* by a verified NOP Import Certificate. This conflicts with the preamble which states that shipments of organic product must be *associated* with a valid NOP Import Certificate.

(*Response*) To clarify the requirement, AMS has removed the term *accompanied* from the rule. The NOP Import Certificate must be *associated* with a shipment. This revision accurately describes AMS’s intent that organic shipments are associated with, and not accompanied by, a valid NOP Import Certificate at the time of entry into the United States.

(*Comment*) Commenters requested that the term *associated*, located in the preamble text, be changed to *accompany* and that AMS require NOP Import Certificates to be available upon entry to the United States, to prevent fraud in the organic market.

(*Response*) USDA is requiring that all organic exports to the United States be associated with a valid NOP Import Certificate. By requiring organic imports to be associated with, and not accompanied by, an NOP Import Certificate, USDA will have access to the import data without restricting or slowing import and trade of organic products.

Certifying Agent Capacity

(*Comment*) AMS received several comments highlighting that organic certifying agents lack the capacity to issue the number of NOP Import Certificates that would be required under the proposed rule at one per shipment. Comments specifically referenced the high-volume of organic products coming by truck and rail from Mexico and Canada.

(*Response*) It is the certifying agent’s responsibility to ensure that the exporting operation has the capacity to produce or handle the product covered by the NOP Import Certificate. When a certifying agent issues a NOP Import Certificate, it is validating that the product is truly organic; therefore, it must have adequate control systems to verify these claims.

To address the problem of generating NOP Import Certificates for multiple shipments in short timeframes (*e.g.*, multiple shipments of fresh produce across the border), AMS is granting the certifying agent the authority to determine whether it will issue an NOP Import Certificate for a specific shipment, or for a specific timeframe

(e.g., weekly, monthly, season) and amount or volume ceiling. The certifying agent is responsible for ensuring that the issued NOP Import Certificate is only associated with an amount of product that has been verified to be certified organic.

(Comment) AMS received several comments that recommended a staggered implementation timeline for the NOP Import Certificate requirement to ensure certifying agents have the administrative capacity to process additional NOP Import Certificates. Several comments also expressed concern about the increased cost associated with issuing NOP Import Certificates. Comments noted that certifying agents would need to hire and train additional technical staff to comply with the proposed requirements for NOP Import Certificates.

(Response) Under the current USDA organic regulations, certifying agents are not allowed to provide certification services that are outside its administrative capacity. While a reasonable implementation period is being provided to fully update the Organic Integrity Database to generate NOP Import Certificates, certifying agents are not to issue any NOP Import Certificates without having adequate expertise and staffing to verify the organic status of products it oversees under the organic program.

(Comment) Commenters asked how certifying agents will verify whether a shipment is compliant with the USDA organic regulations based on an NOP Import Certificate.

(Response) Certifying agents that are overseeing exports of organic products to the United States must have and implement a documented organic control system for intaking and then approving or rejecting an NOP Import Certificate request. The certifying agent is responsible for ensuring that the issued NOP Import Certificate is only associated with an amount of product that has been verified to be certified organic. Certifying agents that are overseeing importers of organic products into the United States must have a system for ensuring that operations receiving organic product are receiving and maintaining NOP Import Certificates, ensuring that importers have met the requirements of this section, and that they are not accepting more product from any providers than is authorized by NOP Import Certificates.

General Applicability

(Comment) AMS received comments asking if NOP Import Certificates would be required for small, retail, and mixed

shipments of organic product imported into the United States.

(Response) NOP Import Certificates will be required for any commodity imported into the United States that is being manifested, sold, marketed, or labeled organic. NOP Import Certificates are required for organic commodities regardless of value or size and is not applicable for any *de minimis* exemptions under current CBP regulations. A very limited number of exemptions will be allowed for items such as, but not limited to, food donations, non-retail samples, and humanitarian efforts.

(Comment) Commenters asked if NOP Form 2110–1, NOP Import Certificate, is mandatory and whether a paper copy would be permitted. Commenters also asked if certifying agents would issue physical or digital copies of NOP–2110–1 to operations.

(Response) Only the NOP Import Certificate and its associated data, generated from the Organic Integrity Database, is a valid NOP Import Certificate. Either a paper-based or electronic NOP Import Certificate may be used. Certifying agents will determine the format it will use to provide the exporter with the NOP Import Certificate data.

ACE Data Entry

(Comment) We received comments requesting AMS clarify the definition of “equivalent data source” by providing additional text in § 205.273(e). Commenters requested the requirement explicitly state that USDA is the sole authority that determines equivalent data sources.

(Response) In the final rule, we have removed the term “equivalent data source.” All NOP Import Certificates will be generated using the Organic Integrity Database. AMS provides multiple ways to upload or enter data into the Organic Integrity Database. We have determined it will be the only data source for NOP Import Certificates because it is a preexisting, proven tool that meets U.S. government security requirements, and a centralized system is needed to facilitate supply chain traceability and to assess authorized import certificate data against actual import data generated by CBP and reported back to AMS. The Organic Integrity Database allows data submittals in multiple formats, such as direct data entry, data spreadsheet uploads, and automated programming interfaces. A data dictionary is also public, allowing external parties to easily map their own systems and data exports to the tool. The Organic Integrity Database is already used and

understood by certifying agents, including many accredited by both the USDA and trade partner countries. It is a system that any government can engage with that minimizes onboarding time and learning curve. Using the Organic Integrity Database as a single source of certification and import data, while allowing multiple data upload methods, will provide secure access to import data that facilitates the use of NOP Import Certificates.

(Comment) We received a number of comments about the respective roles of the exporter and importer with respect to the NOP Import Certificate. Several comments stated that the organic exporter does not have access to the CBP ACE system and is not the party that would enter the required data into ACE. Commenters recommended that the importer of record be the entity responsible for entering data into ACE. Comments stated that the proposed definition of *organic importer of record* is unclear and does not reliably identify the party capable of ensuring each shipment is associated with an NOP Import Certificate.

(Response) NOP Import Certificates must be generated by the certified organic exporter’s certifying agent, using the USDA’s Organic Integrity Database. Only the Organic Integrity Database can be used to generate valid NOP Import Certificates, and only accredited organic certifying agents (USDA or under an organic trade arrangement or agreement) are authorized to use the Organic Integrity Database.

Once the NOP Import Certificate is generated in the Organic Integrity Database, the exporter’s certifying agent provides the NOP Import Certificate, or data set with the NOP Import Certificate number, back to the certified organic exporter who requested the NOP Import Certificate. The certified organic exporter then provides the NOP Import Certificate to the U.S. importer or buyer, who provides it to the specific entity responsible for entering import information into the ACE system. This is typically an importer or designated Customs broker. That importer or Customs broker enters the NOP Import Certificate data into the ACE system as part of its standard import filing processes, including the Entry Summary Process. Organic certifying agents will not have access to ACE; this activity is done by the importer or its Customs broker, using the NOP Import Certificate data provided by the certifying agent to the exporter.

(Comment) Commenters asked how imported organic product would be identified in ACE without an organic

Harmonized Tariff Schedule (HTS) code.

(Response) The NOP Import Certificate in ACE has been programmed to enable NOP Import Certificate entry for a wide range of products, including agricultural products and textiles, not just those with an organic HTS code. An organic HTS code is not required to upload NOP Import Certificate data into ACE.

Trade Arrangements and Agreements

(Comment) AMS received comments requesting that foreign-based certifying agents operating under recognition arrangements be required to list organic operations in the Organic Integrity Database. As noted by commenters, the absence of that data makes it difficult for organizations to verify the certification status of foreign-certified operations.

(Response) AMS is changing access to the Organic Integrity Database to

include organic certifying agents and operations operating under organic trade arrangements or agreements, such as equivalency and recognition arrangements. Certified organic operations covered under trade arrangements or agreements will need to be listed in the Organic Integrity Database by their certifying agents for the certifying agents to be able to generate NOP Import Certificate for valid products entering the United States as organic.

(Comment) We received comments asking how NOP Import Certificates would apply to trade of organic products under, and outside of, an equivalency arrangement. Additionally, commenters requested more information about how NOP Import Certificates would apply to NOP-certified products traded between foreign countries.

(Response) The NOP Organic Import Certificate is required for any product

imported into the United States that is being manifested, sold, marketed, or labeled organic, regardless of the product's country of origin or if that country has an equivalency determination with USDA. Organic products imported from any country with which AMS has an equivalency determination must follow the same NOP Import Certificate requirements outlined in this rule. Other countries may also have their own unique filing requirements for organic products coming into their countries; organic businesses need to consult with their supply chains to determine those requirements.

C. Labeling of Nonretail Containers

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.307	Labeling of nonretail containers. Paragraphs (a) through (c).

Accurate labeling of non-retail containers used to ship or store organic products is critical to organic integrity. Proper labeling reduces misidentification and mishandling, facilitates traceability and product verification, reduces the potential for organic fraud, and allows accurate identification of organic product by customs officials and transportation agents.

Therefore, this rulemaking requires that all nonretail container labels must identify contents as organic and include information linking the container to audit trail documentation. Additionally, audit trail documentation associated with a nonretail container must identify the last certified operation that handled the product. Affected entities may include but are not limited to: certified and noncertified operations that store and transport organic product in nonretail containers; certifying agents; and inspectors.

Background

The organic regulations previously only required a production lot number on nonretail containers labels used to ship or store organic product. Other information—such as identification of the product as organic, and special handling instructions—were optional, but not required on nonretail container labels. Based on the NOP's experience enforcing the organic regulations, this

lack of information created gaps in the organic chain of custody, complicated the verification of organic integrity, and increased the likelihood of organic fraud.

To reduce the prevalence of organic fraud and increase oversight of organic supply chains, nonretail containers are now required to be marked with a statement identifying the product as organic and must include unique information that will link the nonretail containers to audit trail documentation. Unique identifying information could include lot numbers, shipping information, or a unique identifier for that shipment. Accurate labeling will identify contents as organic as a container moves through the supply chain; this will reduce mishandling and help maintain an audit trail and improve traceability.

Nonretail Containers: Description and Use

Nonretail containers are defined under § 205.2 of the USDA organic regulations as “any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.” Nonretail containers are used to ship or store either packaged or unpackaged organic products, and may include the following:

- Produce boxes, totes, bulk containers, bulk bags, flexible bulk containers, harvest crates and bins;
- Boxes, crates, cartons, and master cases of wholesale packaged products; and
- Trailers, tanks, railcars, shipping containers, vessels, cargo holds, freighters, barges, grain elevators, silos, grain bins, or other methods of bulk transport or storage.

Nonretail containers are not used to display organic products for sale to the consumer at retail establishments. Packages that display organic products for retail sale to the consumer must be labeled according to §§ 205.303 and 205.306.

What must be included on nonretail container labels?

Nonretail containers used to ship or store organic products must be clearly labeled with a statement that identifies the product as organic. Clearly visible organic identification alerts handlers that the contents of the nonretail container may require special care, thus reducing accidental mishandling of the product, such as treatment with a prohibited substance or commingling with conventional product during transport and storage. Operations may use abbreviations or acronyms to identify products as organic, provided that they are clear and easily understood. This provides flexibility for

operations to meet the requirements of § 205.307(a)(1) and makes it easier to label containers with limited space or containers that are difficult to label due to their size, shape, material, or use.

Nonretail containers must also be clearly labeled with information that links the container to audit trail documentation (see § 205.2 for definition of *audit trail*). This could be a production lot number, shipping identification, or other unique information that handlers can use to trace the container to its associated audit trail documentation. This creates a clear link between container and audit trail and minimizes the size of labels by allowing some information to be listed in associated documentation, instead of directly on the nonretail container label.

Operations may use temporary labels or signage to meet the requirements of § 205.307(a). This provides additional flexibility for containers that may be difficult to label due to size, shape, material, or use.

Revisions to § 205.307 do not limit the information that can be on a nonretail label. This gives operations the flexibility to include details they deem critical to the integrity of specific products. For example, an operation may opt to include special handling instructions, the USDA organic seal for qualifying products, the operation or certifying agent name, or contact information on the nonretail label.

Nonretail Containers and Audit Trail Documentation

Nonretail containers used to ship or store organic products must be labeled with information that links the container to audit trail documentation (§ 205.307(a)(2)). Such documentation must be sufficient to determine the source, transfer of ownership, and transportation of the product (see definition of *audit trail* in § 205.2) and must identify the last certified operation that handled the product (§ 205.307(b)).

Listing the last certified organic operation provides a point of contact to verify the organic status of a product and supports operations' traceability, recordkeeping, and fraud prevention requirements (§§ 205.103(b)(2)–(3) and 205.201(a)(3)). It also supports on-site inspections and supply chain traceability audits conducted by certifying agents (§§ 205.403(d)(5) and 205.501(a)(21)) by ensuring good recordkeeping of the critical transfers between certified operations.

Exception to Organic Identification on Nonretail Containers

Nonretail containers used to ship or store agricultural products packaged for

retail sale with organic identification visible on the retail label are not required to identify product as organic per § 205.307(a)(1). Examples include master cases and pallets where the organic identification (*e.g.*, the USDA organic seal) of individual retail units is visible. These are exempt from § 205.307(a)(1) because the organic identification is visible on the retail label.

These types of nonretail containers are only excepted from the requirements of § 205.307(a)(1). All nonretail containers must be linked or traceable to audit trail documentation per § 205.307(a)(2); this ensures traceability of the product in the containers and supports organic integrity during transport, storage, and handling.

Summary of Changes to the Final Rule

AMS made several changes to the regulatory text of the SOE proposed rule when writing this final rule. Changes to the proposed rule are discussed below and are followed by specific themes from public comment.

- AMS simplified the requirement to list full organic identification (*e.g.*, “100 percent organic,” or “made with organic . . .”) to “identification of product as organic,” which provides more flexibility to operations and shortens the organic identification statement without changing the statement's intent or its utility as immediate and clear identification of nonretail containers. This change was made in response to public comment.

- AMS revised the requirement to list production lot numbers or shipping identification. This information is now used to link a container to audit trail documentation. To reduce administrative burden and cost to operations, AMS is only requiring the most critical information on nonretail container labels: organic identification and information that links the container to audit trail documentation. This maintains traceability and integrity by requiring nonretail containers to be linked to audit trail documentation, which must identify the last certified operation that handled the product and must be sufficient to determine the source, transfer of ownership, and transportation of the product.

- AMS removed the requirement to identify the product's certifying agent on nonretail labels because this information may be included in audit trail documentation linked to nonretail containers. Removing this requirement limits information on nonretail labels to the most critical information, thereby reducing cost and burden without sacrificing integrity.

- AMS added a requirement that audit trail documentation associated with a nonretail container must identify the last certified operation that handled the product. This allows operations to verify the source of organic products they receive and provides a record trail that certifying agents can use to conduct full supply chain traceability audits and verify organic status.

- The final rule no longer requires organic identification on nonretail containers of retail-labeled products. This avoids undue administrative burden, cost, and redundant information when organic identification is already visible on the products' retail labels.

- AMS removed the list of optional information that may be listed on nonretail container labels. This list is not necessary because operations may optionally include any additional information on nonretail labels if they wish.

Summary of Public Comment

Public comments strongly supported mandatory organic identification on nonretail container labels. However, many comments requested the flexibility to use alternatives like abbreviations and common names. Commenters stated that the proposed rule's requirement to use specific (and sometimes lengthy) statements would add cost and be difficult to apply to containers with limited space. Commenters also requested that AMS require generic product names—*e.g.*, “organic tomatoes”—on labels, claiming that this information is needed to quickly identify the contents of nonretail containers.

Other commenters requested AMS mandate additional information on large nonretail container labels to include country of origin, special handling instructions, and the USDA organic seal. Additionally, comments pointed out that nonretail labels should not be limited to the information explicitly listed in § 205.307, and requested that NOP allow operations to include other types of information on labels.

Responses to Public Comment

(*Comment*) We received comments requesting AMS require all nonretail containers display the information described in § 205.307, regardless of size or type (*i.e.*, not allow exceptions for large nonretail containers used for transport or storage). Additionally, commenters noted that there was no definition or description outlining what type of containers would be exempt from the labeling requirements.

(Response) All nonretail containers of organic products must be labeled with information that links the container to audit trail documentation, regardless of size, shape, or use. This ensures information needed to verify and trace the product is available to those handling the product. Only nonretail containers used to ship or store agricultural products packaged for retail sale with organic identification visible on the retail label are excepted from the requirements of § 205.307(a)(1).

(Comment) Commenters requested the name and contact information of the certified operation be a mandatory field on all nonretail container labels because a certifying agent name alone is not sufficient to match a physical product to an organic certificate. Other commenters also requested that the operation’s address or the NOP operation ID also be included.

(Response) AMS is only requiring the most critical information on nonretail container labels: organic identification and information that links the container to audit trail documentation. This reduces administrative burden and cost to operations. Traceability and integrity are maintained by requiring nonretail containers be linked to audit trail documentation, which must identify the last certified operation that handled the product. Audit trail documentation must be sufficient to determine the source, transfer of ownership, and transportation of the product (see *audit trail* in § 205.2).

(Comment) We received comments requesting that listing the certifying agent be optional because it was redundant for master cases of retail-packaged product and added to the cost of the label.

(Response) AMS does not require listing the certifying agent on nonretail container labels. Such information may be listed in audit trail documentation; operations may choose to do this to verify organic status of the product or determine the source, transfer of ownership, and transportation of the product. Section 205.307(c) excepts nonretail containers of retail-packaged products from listing organic identification if the retail packages clearly identify the product as organic.

(Comment) AMS received comments noting both disagreement and confusion regarding which operation/certifying agent pair is required to be on the nonretail label. Commenters stated that the proposed revision (“producer of the product, or . . . the last handler that processed the product”) may not indicate the appropriate operation for verification purposes or in private labeling scenarios.

(Response) Section 205.307(b) requires that a nonretail container’s audit trail documentation identify the last certified operation that handled the product. The certifying agent that certified this handler may be listed in audit trail documentation; operations may choose to do this to verify organic status of the product or determine the

source, transfer of ownership, and transportation of the product.

(Comment) We received comments stating that special handling instructions are critical to the integrity of organic products in the supply chain and requested that AMS make this information mandatory on all labels. Commenters also inquired about what special handling instructions should include.

(Response) We are not requiring special handling instructions on nonretail container labels; this reduces administrative burden and cost to operations without risking integrity. Operations may include special handling instructions (or other information) on nonretail containers if they deem it necessary.

(Comment) AMS received comments requesting the mandatory use of tamper-evident seals on nonretail containers. Commenters argue that tamper-evident seals may help prevent fraud and mishandling of organic product.

(Response) AMS is not requiring tamper-evident seals on nonretail containers; this avoids potential undue administrative burden and costs to operations. Operations may use tamper-evident seals on nonretail containers if they deem it necessary.

D. On-Site Inspections

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.2	Terms defined. Definition for <i>Unannounced inspection</i> .
205.403	On-site inspections. Paragraphs (b)(1) and (2) and (d)(4) and (5).

On-site inspections of certified organic operations are a critically important tool used to verify an operation’s compliance with the Act and the organic regulations. This rulemaking strengthens the utility of on-site inspections by requiring that certifying agents:

- Conduct a minimum number of unannounced inspections each year.
- Conduct mass-balance audits during on-site inspections.
- Verify traceability of product and ingredients within an operation during on-site inspections.
- Verify traceability of product in an operation’s supply chain back to the last certified operation during on-site inspections.

These requirements will strengthen organic integrity and supply chain

traceability by requiring the use of proven best practices during inspection of organic production and handling. Entities affected by this policy may include certifying agents, certified operations, and operations applying for certification. Organic stakeholders should carefully examine the regulatory text and policy discussion below.

Unannounced Inspections—Background

Unannounced inspections are an effective and useful tool to ensure compliance across certified operations and bolster consumer trust in the organic label. NOP previously issued an instruction (NOP Instruction 2609) on unannounced inspections, which recommends that certifying agents conduct unannounced inspections of

five percent of their total certified operations per year as a tool for ensuring compliance with the regulations.²⁴ This NOP instruction was supported by a recommendation made by the NOSB in December 2011.²⁵ The organic regulations previously allowed for, but did not require, unannounced inspections, leaving this to the discretion of the certifying agent.

²⁴ NOP 2609, Instruction, Unannounced Inspections. September 12, 2012. Available in the NOP Program Handbook: <https://www.ams.usda.gov/sites/default/files/media/2609.pdf>.

²⁵ NOSB Recommendation, Unannounced Inspections. December 2, 2011. Available on the AMS website: <https://www.ams.usda.gov/sites/default/files/media/NOP%20CACC%20Final%20Rec%20on%20Unannounced%20Inspections.pdf>.

Therefore, AMS has codified the requirement for certifying agents to conduct a minimum number of unannounced inspections annually of certified operations.

Use of Unannounced Inspections

To clarify the difference between unannounced inspections and full annual inspections, AMS is defining the term *unannounced inspection* as “The act of examining and evaluating all or a portion of the production or handling activities of a certified operation without advance notice to determine compliance with the Act and the regulations in this part.”²⁶ Note that unannounced inspections are different from a full annual inspection because the scope of the inspection may be limited to a portion of the operation or the operation’s activities, and certifying agents must conduct the inspection without advance notice.

Scope of Unannounced Inspections

Relative to a full annual on-site inspection, an unannounced inspection may be limited in scope, depth, and breadth and may cover only a portion of the operation or the operation’s activities, such as parcels, facilities, products, or a review of records. This allows unannounced inspections to be used as a risk-based tool to address specific needs, such as investigation of a complaint or high-risk area. Inspectors may conduct sampling during an unannounced inspection. Samples collected may count towards the number of samples a certifying agent must collect annually per § 205.670(d) of the organic regulations. Sample collection alone, however, does not qualify as an unannounced inspection.

When unannounced inspections are limited in scope, they are not required to follow the requirements of § 205.403(c)(2), (d), or (e). This means unannounced inspections:

- May be conducted when an authorized representative of the operation is *not* present and the inspector is not trespassing.
- May be conducted at any time of year.
- Do not have to verify all areas or activities of the operation like a full, annual inspection.
- Do not have to include an exit interview with an authorized representative of the operation.

²⁶ Compare to the definition of inspection at 7 CFR 205.2: The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.

An unannounced inspection may fulfill the requirement for a full annual on-site inspection, provided that the inspector meets all requirements for an annual on-site inspection per § 205.403. This includes meeting the timing, scope, exit interview and documentation requirements for annual inspections. The exception is that the inspection would not be scheduled in advance with the operation’s awareness. If an unannounced inspection will serve as the annual inspection, an authorized representative must be present.

Selecting Operations for Unannounced Inspections

To maximize the effectiveness of unannounced inspections, certifying agents are encouraged to select operations from a range of different production and handling types, products, and locations. Operations may be selected randomly, by risk, in response to a complaint or investigation, or other criteria. The number of unannounced inspections to be conducted annually should be calculated by rounding up to the nearest whole number, so that certifying agents with very few certified operations (*e.g.*, under 20 operations) are still required to conduct at least one unannounced inspection per year.

Planning and Scheduling Unannounced Inspections

Unannounced inspections should be conducted without advance notice to the operation. However, some unannounced inspections may require advance notice (*e.g.*, to ensure that portions of an operation are accessible or safe to access). Therefore, a certifying agent may notify an operation up to four hours prior to the inspector arriving onsite. As a best practice, certifying agents are encouraged to disclose their process for unannounced inspections, including a policy on inspector access to certified operations, and to train inspectors to prevent trespassing or breaking laws when accessing an operation. An operation’s refusal to allow an inspector access to any portion of the operation is a violation of § 205.403 and warrants a notification of noncompliance.

Following an unannounced inspection, an inspection report must be written by the inspector and reviewed by the certifying agent. The results of the inspection must be communicated to the inspected operation per § 205.403(f) and the certifying agent’s internal protocols.

Certifying Agent Ability To Conduct Unannounced Inspections

Certifying agents must be able to conduct unannounced inspections of any operation they certify. Therefore, AMS requires that certifying agents only accept applications for certification or continue certification from operations for which the certifying agent is able to conduct unannounced inspections. To ensure consistency, transparency, and accountability, certifying agents are expected to describe the areas where they operate in the written materials they provide to both applicants and certified operations, and review the locations of all operations during their application review or annual review.

A certifying agent that cannot conduct unannounced inspections in an applicant’s or certified operation’s location due to logistical challenges, staffing, security, or other reasons, is considered to not have the administrative capacity for certification activities in that area, consistent with § 205.501(a)(19). In this case, the certifying agent must document the specific reasons it does not have the administrative capacity to certify in that area, and must inform the applicant or certified operation to seek certification from another certifying agent. If new certification is not obtained, the operation’s certification would be suspended/revoked. This process is similar to the current procedures used when a certifying agent surrenders its accreditation or is suspended/revoked.

For additional information about unannounced inspections, certifying agents may refer to NOP Instruction 2609.

Mass-Balance and Traceability Audits During On-Site Inspections

Traceability of organic products is critical to verification of organic integrity. Therefore, AMS requires that certifying agents verify quantities and traceability of organic products produced or handled by an operation through mass-balance and traceability audits. Audit tools are the premier methods to verify organic integrity. The importance of audits has increased because transaction certificates, which certifying agents relied upon in the past to verify the organic status of specific loads or sales or organic products, are neither required by the USDA organic regulations nor universally issued by certifying agents.

Mass-Balance Audits

During on-site inspections, certifying agents must verify that the quantities of organic product and ingredients

produced or purchased by an operation accounts for organic products and ingredients used, stored, sold, or transported by the operation (§ 205.403(d)(4)). Commonly known as a “mass-balance” or “in-out” audit, this verification is an effective method of detecting and discouraging organic fraud.

Mass-balances may be performed on products that are produced on an operation, but then used or stored on-site and not sold (e.g., silage produced on-site as feed for dairy animals). Mass-balance covers quantities of agricultural products; other quantitative assessments such as dry matter intake and stocking rate verification are not mass-balances. To conduct these mass-balance audits, certifying agents may choose a sub-set of products based on risk or other factors. With respect to multi-ingredient products, certifying agents may choose a single ingredient or multiple ingredients to mass-balance. When a single ingredient is selected, a best practice is to choose an ingredient that is high-risk or used in several products.

Mass-balances do not replace the recommended best practice of also conducting yield analyses at producer operations. Yield analysis looks at whether harvested quantities are consistent with expected yields. This is an important tool to assess the potential for commingling of noncertified/nonorganic products with organic products.

Traceability Audits

Successful traceability within organic supply chains requires three basic elements: (1) traceability within a single operation; (2) traceability one step back from an operation in a supply chain; and (3) traceability by a third party along an entire supply chain, source to consumer.

Therefore, during all annual inspections certifying agents must verify the traceability of organic product both within an operation and verify traceability back to an operation’s suppliers (§ 205.403(d)(5)).²⁷ This means that a certifying agent must verify that an operation can trace the products it produces or handles during the full time the operation possesses those products, from time of purchase or acquisition, through production, to sale or transport. This includes ingredients or products that the operation handles but may not own.

²⁷ The third traceability element, traceability along an entire supply chain, is addressed in 7 CFR 205.501(a)(21), and discussed in this rulemaking in Section P, Supply Chain Traceability and Organic Fraud Prevention.

Additionally, certifying agents must verify the traceability of products from an operation’s suppliers (§ 205.403(d)(5)). Because supply chains sometimes include operations that are not certified, certifying agents must verify compliance of organic products back to the last USDA-certified organic operation. Certifying agents may verify compliance back to the last certified operation by inspecting and verifying audit trail documentation and other records kept by the certified operation being inspected. This will ensure oversight of the critical linkages between certified operations and support full traceability and verification of organic products across supply chains.

Certifying agents must also conduct supply traceability chain audits when circumstances meet criteria defined by the certifying agent (§§ 205.501(a)(21) and 205.504(b)(7)). These audits would not be performed at every annual inspection.

Responses to Public Comment Virtual/Remote Inspections

(*Comment*) Several public comments noted that during the COVID–19 pandemic, virtual inspections, or sometimes a hybrid of virtual an on-site inspection, were temporarily used by certifying agents. Several comments asked if AMS intends to allow the use of virtual inspections for operations that have a demonstrated history of compliance or are at low risk of organic fraud.

(*Response*) Virtual and/or remote inspections were not included in the SOE proposed rule and AMS is therefore not setting specific policy related to virtual or remote inspections. The final regulations provide flexibility so that AMS may consider virtual inspection policy options in the future.

Unannounced Inspections

(*Comment*) Several comments asked AMS to increase the minimum number of operations that must receive unannounced inspections beyond the five percent AMS proposed.

(*Response*) AMS is finalizing the proposed requirement that certifying agents must conduct unannounced inspections of at least five percent of the operations they certify. This is consistent with a 2011 NOSB recommendation and a current NOP Instruction document. AMS chose this percentage because the majority of USDA-accredited certifying agents currently complete unannounced

inspections at this frequency.²⁸ Because most certifying agents are already completing unannounced inspections at this level, this percent should be tenable for certifying agents, regardless of size. To justify a higher percentage, AMS would require additional information, industry feedback, and data to assess the potential impact. Comments did not provide justification or data to support a higher inspection percentage. However, certifying agents may choose to conduct a higher percentage of unannounced inspections to supplement their oversight and enforcement of certified operations.

(*Comment*) Some public comments asked if AMS intends to publish criteria for initiating or using unannounced inspections.

(*Response*) AMS is not adding criteria for using or initiating unannounced inspections to the regulations. Unannounced inspections may be triggered and selected by a variety of factors, including at random and in response to complaints or investigations. The regulations provide certifying agents flexibility to use unannounced inspections when and where they are most effective.

Mass-Balances

(*Comment*) Several public comments asked if AMS is requiring one mass-balance per certification scope (i.e., crops, livestock, handling, wild crops) of an operation.

(*Response*) The regulatory text provides certifying agents the flexibility to determine where such audits are most needed within a single inspection.

(*Comment*) Some comments asked AMS if mass-balances should be performed for single-ingredient or multi-ingredient products, and if mass-balances for multi-ingredient products must balance all ingredients in the product.

(*Response*) The final regulatory text provides certifying agents flexibility to perform mass-balance audits of both single- and multi-ingredient products. For multi-ingredient products, the certifying agent may choose to mass-balance one or more of the ingredients.

E. Certificates of Organic Operation

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

²⁸ 42 of the 49 USDA-accredited certifying agents the NOP audited in calendar years 2018 and 2019 completed unannounced inspections for 5% of the operations they certify.

Section	Final regulatory text
205.2	Terms defined.
205.404	Definition for <i>Organic Integrity Database</i> .
	Granting certification. Paragraphs (b) and (c).

Certificates of organic operation are an important tool used by organic stakeholders to communicate information about certified operations. Certifying agents must generate certificates of organic operation electronically using the Organic Integrity Database. Standardized, electronic certificates maintained in a publicly accessible database will help to deter and prevent the use of fraudulent certificates of organic operation. This requirement also ensures that certificates of organic operation have consistent information and format, allowing certifying agents and buyers of organic products to readily validate certificates of organic operation. Certifying agents may add their unique addenda to certificates of organic operation to provide additional details about the certified operation.

Affected entities may include certifying agents, applicants for USDA accreditation, certified operations and entities seeking to validate the certification status of an organic operation. Readers should carefully examine the regulatory text and discussion below to determine if they are affected by this action.

Background

AMS accredits nearly 80 certifying agents; only a few currently create certificates of organic operation using the Organic Integrity Database. As a result, more than 70 distinct formats of certificates of organic operation exist in the market. This variation increases the likelihood of alteration and organic fraud. In addition, AMS consistently cites noncompliances for certifying agents who do not include all of the required information on their certificates of organic operation. Of the 49 USDA-accredited certifying agents audited by the NOP in calendar years 2018 and 2019, 16 were cited for issuing certificates of organic operation not consistent with USDA organic regulations and instruction. The use of a uniform certificate of organic operation generated through the Organic Integrity Database eliminates these inconsistencies and helps avoid noncompliances.

The requirement for uniform certificates of organic operation supports OFPA’s purpose to facilitate interstate commerce of organic foods (7

U.S.C. 6501(3)). This rulemaking also addresses a 2005 NOSB recommendation to standardize information on certificates of organic operation and require certifying agents to issue and maintain certificates of organic operation from a common database.²⁹

Organic Integrity Database and Certificates of Organic Operation

The certificate of organic operation communicates information about the organic certification of an operation. This rulemaking requires certifying agents to provide uniform certificates of organic operation that are electronically generated from the Organic Integrity Database.

AMS defines the term *Organic Integrity Database* in § 205.2 as the National Organic Program’s electronic, web-based reporting tool for the submission of data, completion of certificates of organic operation, and other information, or its successors. The Organic Integrity Database may also be referred to as the OID or INTEGRITY. AMS is responsible for the functionality of the Organic Integrity Database and ensuring consistent content and styles of all certificates of organic operation. The general public can view information in the Organic Integrity Database online at: <https://organic.ams.usda.gov/integrity/>

Generating Certificates of Organic Operation in the Organic Integrity Database

Section 205.404(b) requires certifying agents to generate certificates of organic operation in the Organic Integrity Database, making it easier for the certificates to be accessed online by relevant stakeholders in the organic supply chain (e.g., other certifying agents, inspectors). Section 205.501(a)(15) requires certifying agents to maintain current and accurate data on operations they certify in the Organic Integrity Database. Together, sections 205.404(b) and 205.501(a)(15) require certifying agents to input and maintain accurate data on the operations they certify, and to generate certificates of

²⁹ NOSB Recommendation: Information on Certificates of Organic Operation: <https://www.ams.usda.gov/sites/default/files/media/NOSB%20Rec%20Standardize%20Organic%20Certifications%20Certificates.pdf>.

organic operation using the Organic Integrity Database. This applies to all USDA-accredited certifying agents whether foreign- or domestic-based.

Certificates of organic operation generated in the Organic Integrity Database include the required information that stakeholders need to verify organic status of an operation. Users can also access the database to see if an operation’s organic certification has been suspended, revoked, or surrendered. In addition to strengthening organic integrity, standardized certificate format and data fields facilitate and simplify verification of products, ingredients, and suppliers. The Operation Profile feature in the Organic Integrity Database also lists the generic products and services offered by an operation. The accessibility and security of this data will reduce administrative burden on certified operations that purchase organic products and ingredients, as well as certifying agents and inspectors who monitor compliance.

Certifying agents can continue using the data submission template and the web-based form to upload the required data fields into the Organic Integrity Database. Additionally, certifying agents can transfer data from in-house databases to the Organic Integrity Database using an Application Programming Interface (API) to reduce duplicative data entry. AMS provides a data submission API guide for certifying agents on the Organic Integrity Database’s User Resources page.

Addenda to Certificates of Organic Operation

Some certifying agents use certificate addenda to supplement the information on certificates of organic operation with more details about an operation and the products it is certified to produce and/or handle. Certificate addenda may be generated and maintained in the Organic Integrity Database or by certifying agents’ databases. The rulemaking allows certifying agents to continue providing their own certification addenda to communicate additional information about an operation’s certification in a different format than certificates generated by the Organic Integrity Database. For example, an addendum may include information about an operation’s certification to

various international organic standards or the brand names of products that the operation produces and/or handles that are not included on the certificate of organic operation. Certificate addenda may be issued only for a certified operation at an approved location(s).

Section 205.404(c) requires five elements to be on any organic certificate addenda issued by certifying agents to deter organic fraud and provide consistency across certifying agents. Primarily, the addendum requirements are intended to ensure that someone viewing the document is aware that certification may be verified in the Organic Integrity Database. The accuracy of information on addenda, such as products and labeling categories, may also be verified in the Organic Integrity Database (see Operation Profiles). In summary, an addendum must identify the name, location, and contact information of the operation and certifying agent; an operation's unique operation ID from the Organic Integrity Database; addendum issue date; a link to the operation's certificate or profile in the Organic Integrity Database; and a statement citing the Organic Integrity Database for certificate verification. Certifying agents may include other data in addition to the mandatory elements on certificate addenda.

Summary of Changes to the Final Rule

AMS revised § 205.2 to replace the name of the proposed term "INTEGRITY" with "the Organic Integrity Database." Additionally, AMS did not include proposed § 205.404(c)(6) which would have required expiration dates on certificate addenda. Many public comments noted that an addenda expiration date could cause confusion, as it could be mistakenly interpreted as expiration of an operation's certification. Organic certification does not expire; it continues until surrendered, suspended, or revoked—see § 205.404(d). Further, several public comments noted that addenda expiration dates would increase workload for certifying agents, as they would need to update addenda expiration dates even if there are no other changes to a certificate of organic operation. AMS agrees with public

comments and is not finalizing the requirement for addenda expiration dates. This will also encourage stakeholders to adopt the best practice of verifying certification status in the Organic Integrity Database, as this tool will include the most up-to-date operation and certification information (see § 205.201(a)(15)).

Summary of Public Comments

Comments generally supported requirements to including uniform information on certificates of organic operation, noting that this would reduce inconsistencies across the industry on what information is collected and maintained. Comments expressed concern about using the Organic Integrity Database to generate the certificate files and some argued that the proposed changes would instead hinder the process for certificate generation, rather than streamlining it. Some certifying agents noted that they would be more comfortable and efficient using their proprietary databases to generate certificate information and that using the Organic Integrity Database would be additional work to enter duplicative data. Comments requested a method for certifying agents to easily upload or transfer their existing data into the Organic Integrity Database, and to generate a certificate of organic operation. In addition, comments generally opposed including an expiration date on certificates of organic operation because a certificate expiration date could be conflated with an operation's certification status.

Responses to Public Comment

(Comment) Comments requested that NOP change the name of the proposed term *INTEGRITY* to *Organic Integrity Database*. Commenters stated that referring to the database's nickname is not descriptive enough and could lead to confusion between the concept of organic integrity and the database.

(Response) AMS has revised § 205.2 to use the term *Organic Integrity Database* to reduce the possibility of stakeholder confusion by using the full name of the database.

(Comment) Certifying agents stated that entering operation data into their own databases and the Organic Integrity Database is duplicative work and would

be a financial and administrative burden because it will require administrative staff to update both databases. Commenters also expressed concern about whether the Organic Integrity Database would have the functionality and capacity to withstand the number of people who would need to access it regularly, if the Organic Integrity Database is also used to generate certificates of organic operation.

(Response) AMS provides tools for uploading data (data submission template) and transferring data (via an API) into the Organic Integrity Database to reduce duplication. Please see the data submission API guide for certifying agents on the Organic Integrity Database's User Resources page. In addition, generating certificates pulls from the mandatory data that certifying agents must enter into the Organic Integrity Database to comply with § 205.501(a)(15). Section 205.501(a)(15) requires certifiers to enter data into the Organic Integrity Database and states certifying agents must "Maintain current and accurate data in the Organic Integrity Database for each operation which it certifies." Certificate generation does not require additional data. AMS is prepared for the increased usage of the Organic Integrity Database as a result of the rulemaking and will offer outreach to certifying agents to support technology integration.

(Comment) AMS received comments requesting clarification on whether the rule requires operations to receive certificates of organic operation electronically—noting that many operations prefer (or can only receive) paper certificates.

(Response) Section 205.404(b) states that an organic certificate *may* be provided to operations electronically—however, this step occurs after a certificate has been generated electronically and does not affect how a certifying agent transmits certificates to an operation. Anyone may print a certificate from the Organic Integrity Database as needed.

F. Continuation of Certification

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.406	Continuation of certification. Paragraphs (a) and (b).

AMS has amended § 205.406 to clarify the annual update requirements for

organic system plans (OSP) and to specify that certifying agents are

required to conduct inspections of operations they certify at least once per

calendar year. These changes maintain requirements for certified operations to provide certifying agents with updated and accurate information about their organic activities while eliminating duplicative work, and will strengthen oversight of organic operations through regular and timely inspection. Affected entities may include, but are not limited to certifying agents, certified organic operations, and operations seeking organic certification. You should carefully examine the regulatory text to determine if you or your organization may be affected by this action.

Annual Updates of Organic System Plans

Previously, the organic regulations required certified operations to submit an updated OSP in its entirety as part of annual certification renewal. Certifying agents implemented this inconsistently: some required certified operations submit an entire OSP every year, while others required operations only to submit revisions to their OSP. To clarify OSP requirements, this rulemaking revises § 205.406(a) to allow certified organic operations to only submit sections of its OSP that have changed to its certifying agent.

Additionally, the rulemaking removes previous paragraph § 205.406(a)(3), which required that certified operations provide, along with its annual update, an update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification. This requirement was duplicative and unnecessary, as certifying agents (when issuing a notice of noncompliance) must specify a date by which a certified operation must rebut or correct noncompliances (§§ 205.662(a)(3) and 205.404(a)). Removal of this requirement reduces paperwork, simplifies the certification process, and ensures that noncompliances are resolved according to the deadline in the notice, rather than waiting until the next certification cycle.

The NOP previously described this approach in published certifying agent Instructions (NOP 2615 and NOP 2601).³⁰ This change is necessary to ensure legal enforceability, consistent practices between certifying agents, and reduce the paperwork burden of organic certification. This will not impact the requirements for certified operations to

maintain an updated OSP or the requirement for an operation to notify its certifying agent of operational changes that may affect its compliance with organic regulations (§ 205.400(f)). Further, the on-site inspection of an organic operation must verify that the entire OSP is implemented as described.

Frequency and Scheduling for Annual Inspections

Annual inspection cycles are essential to vigilant oversight of organic operations. Inconsistent interpretation of previous § 205.406 regarding inspection timing sometimes resulted in inspection frequencies longer than the annual timeframe specified in OFPA (7 U.S.C. 6506(a)(5)). For example, former § 205.406(b) was sometimes interpreted to mean that an operation may be inspected once every 18 months on an ongoing basis (*i.e.*, two inspections over a 36-month period compared to three inspections if conducted annually). To clarify frequency of on-site inspection, this rulemaking revises § 205.406(b) to simplify the regulatory text and clearly state that inspections are to be conducted at least once per calendar year.

Revised paragraph (b) clarifies that all certified operations must be inspected at least once in a calendar year, regardless of (1) when the certified operation was last inspected and (2) when, or if, the certified operation provided its annual updates. This revision allows certifying agents flexibility to conduct on-site inspections at any time during the year (essential for verifying activities throughout the growing season, for example) to ensure that an inspection is conducted every single calendar year. Additional inspections may be needed to inspect all portions of an operation to assess full compliance of an operation (*e.g.*, during and outside the grazing season for livestock operations). This requirement does not replace the need for additional unannounced inspections.

Summary of Changes to the Final Rule

AMS did not make any revisions to the proposed regulatory text. The policy continues unchanged in this final rule.

Summary of Public Comment

Public comments largely supported changes made in the proposed rule, citing support for reduced paperwork, increased flexibility, and clear enforceability to uphold organic integrity. Some comments questioned the need for the proposed changes, citing that the work of updating an entire OSP is not significantly greater than updating portions of it.

Several comments supported revisions to section 205.406(b), which now requires certifying agents to conduct on-site inspection once per calendar year. However, commenters requested additional flexibility regarding annual inspections requirements in the face of extreme circumstances that may render an in-person inspection unsafe or unfeasible for the inspector or operation. These comments cite the COVID-19 pandemic as an example.

Other comments were generally in support of the flexibility that the revisions provide, particularly allowing inspections to occur when seasonally appropriate (and potentially reducing certifying agents' need to request additional inspections). However, a few commenters noted that the calendar year restriction may cause inspections to occur one closely after another, depending on the type of operation and harvest timeline.

Responses to Public Comment

(Comment) AMS received comments stating that the revisions to OSP submission requirements could lead to inconsistent information across certifying agent databases and the Organic Integrity Database.

(Response) All certifying agents are now required to maintain updated information on operations they certify in the Organic Integrity Database. This requirement will eliminate inconsistencies.

(Comment) Comments asked if certifying agents can still request full updated OSPs from operations they certify, should the certifying agent deem the proposed changes significant.

(Response) The rulemaking does not change or limit the ability of certifying agents to request information, including a full OSP, that is needed to determine an operation's compliance with the organic regulations. Paragraph 205.406(a)(4) of the regulations requires operations to provide certifying agents information that they deem necessary to determine compliance with organic regulations.

(Comment) We received comments requesting more flexibility regarding annual inspections (*e.g.*, allowing the issuance of temporary variances, or allowing for virtual inspections) in the face of extreme circumstances that may render an in-person inspection unsafe or unfeasible for the inspector or operation.

(Response) AMS acknowledges that extreme circumstances may prevent a certifying agent from completing an on-site inspection once per calendar year. In such cases, the certifying agent may

³⁰ NOP 2601 The Organic Certification Process, December 16, 2013: <https://www.ams.usda.gov/sites/default/files/media/2601.pdf>; NOP 2615 Organic System Plans, Organic System Plan Updates, and Notification of Changes, December 16, 2013: <https://www.ams.usda.gov/sites/default/files/media/2615.pdf>.

delay inspection, but the delay should be minimized and explained in the certifying agent’s inspection report and records. A certifying agent’s inability to consistently inspect operations annually due to access, safety, extreme weather, or other issues is a failure to carry out inspection requirements and does not fulfill the general requirements for accreditation (§ 205.501(a)(3)). When the certifying agent is unable to provide adequate oversight and enforcement, the certifying agent should not continue to certify the operation.

(Comment) AMS received comments proposing an inspection window anywhere between 7 and 17 months apart rather than 18 months, thus allowing inspectors to conduct inspections when seasonally appropriate.

(Response) The rulemaking establishes a minimum frequency for on-site inspections—at least once per calendar year—to ensure all certified operations meet OFPA’s requirement for annual inspection. If the certifying agent is unable to complete a full inspection during a time when land, facilities, and

activities that demonstrate compliance can be observed (see § 205.403(c)(2)), then the certifying agent may conduct additional on-site inspections, as allowed in § 205.403(a)(3)(i), to cover unobserved portions and ensure compliance with § 205.403.

G. Paperwork Submissions to the Administrator

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.501	General requirements for accreditation. Paragraph (a)(15).

Accurate and current information about certified operations is critical for commerce and oversight in the organic sector. This rulemaking supports accessible and updated data on organic operations by requiring certifying agents to maintain current data on all operations they certify in the Organic Integrity Database. Certifying agents and certified operations may be affected by these requirements. Readers should carefully review the regulations and policy discussion to determine whether they must comply.

Background

The organic industry, including certifying agents, certified operations, consumers, AMS, and other regulatory agencies use the Organic Integrity Database to confirm the certification status of operations, organic status of products, find contact or product information for specific operations, and obtain data points for investigation and enforcement actions. Timely updates to maintain data on an operation’s current status, including certified products and acreage, is necessary for efficient business transactions and informed oversight. The availability of operation data also reduces the time spent by certifying agents and by AMS responding to inquiries about specific operations because interested parties can independently access the information they need.

Mandatory Reporting in Organic Integrity Database

Certifying agents are required to provide and maintain current mandatory data on operations in the Organic Integrity Database. The required data fields are listed in the INTEGRITY Data Dictionary and defined in the Glossary of Terms which can be

accessed at <https://organic.ams.usda.gov/Integrity/About.aspx>. Some of the data in the Organic Integrity Database is publicly accessible. Examples of mandatory, public data fields include: certification status, scope(s) of certification (e.g., crops, livestock, handling, wild-crop), and the organic commodities produced or handled by the operation. This information is essential for certifying agents and operations to verify the organic status of operations and products and supports efficient business transactions. Organic acreage is an example of mandatory data that will not be publicly available in the Organic Integrity Database.

Update Frequency

Certifying agents are to establish processes for updating data in the Organic Integrity Database in a manner that keeps information current about their certified operations. This is needed to support the industry’s reliance on the Organic Integrity Database for current and accurate information about individual operations. Certifying agents are required in § 205.662(e)(3) to update the Organic Integrity Database within 72 hours of an operation’s suspension, revocation or surrender of certification.

This rule removes the requirement for certifying agents to provide notices of denial of certification to the Administrator following the issuance of a notice of noncompliance to an applicant for certification (formerly § 205.405(c)). In addition, the rule removes the requirement for submission of any notices of denial of certification, notifications of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, or notification of suspension or revocation (formerly

§ 205.501(a)(15)(i)). Also, the rule removes the annual requirement for certifying agents to submit, by January 2, an annual list of operations certified during the preceding year (formerly § 205.501(a)(15)(ii)). Certifying agents’ adherence to noncompliance procedures in the regulations are evaluated during NOP audits, review of appeal cases and relevant complaints. The requirement for certifying agents to list operations in the Organic Integrity Database and their corresponding certification status makes the paperwork submission requirements unnecessary.

Summary of Changes to the Final Rule

AMS renamed the term INTEGRITY in § 205.501(a)(15) to the Organic Integrity Database.

Summary of Public Comment

Comments were largely in support of the proposed revisions, citing that the changes remove an unnecessary and redundant step from certifying agents’ day-to-day operations. Commenters also noted that codifying global use of the Organic Integrity Database and maintaining “accurate and current” data are both critical to ensuring organic integrity. Commenters noted that the regulatory text does not explain how often certifying agents should update operation data.

Responses to Public Comment

(Comment) Comments requested that AMS require certifying agents to upload and maintain data in the Organic Integrity Database on operations that are no longer certified, were denied certification, or withdrew certification with adverse actions on record.

(Response) The Organic Integrity Database can identify applicants for certification that were denied or

withdrew from certification. AMS encourages certifying agents to enter those operations into the Organic Integrity Database, however, this is not a required reporting element. The Organic Integrity Database includes all operations which are no longer certified because they are suspended, revoked, or surrendered.

(Comment) Comments noted that the rule does not describe the data fields that certifying agents are required to complete in the Organic Integrity Database.

(Response) The Data Dictionary provides a list of all data fields for the Organic Integrity Database (<https://organic.ams.usda.gov/Integrity/About.aspx>). The Data Dictionary will

be updated upon implementation of this rulemaking to make all current fields mandatory. AMS may add more mandatory fields in the future based on industry and NOP needs.

(Comment) Comments requested that certifying agents be required to update the Organic Integrity Database within 72 hours of any changes to crops, products, acreage, or certification status.

(Response) The rule does not require certifying agents to update all required data fields within a certain timeframe, as certifiers need flexibility to create their own systems for updating and maintaining current data in the Organic Integrity Database. However, AMS does require certifying agents to update certain data fields within a specified

timeframe. For example, § 205.662(e)(3) requires certifying agents to update the Organic Integrity Database with changes to an operations certification status within 3 business days. The Data Quality Minimum Standards and Best Practices provides recommendations for the minimum frequency to update specific data fields in the Organic Integrity Database.³¹

H. Personnel Training and Qualifications

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.2	Terms defined.
205.501	Definition for <i>Certification review</i> . General requirements for accreditation. Paragraphs (a)(4), (5), and (6).

The USDA organic regulations require that certifying agents use a sufficient number of trained and qualified inspectors and certification review personnel with expertise in organic production and handling. This rulemaking enhances existing requirements with detail about the qualifications that organic inspectors and certification reviewers must have in order to work for certifying agents. By clarifying the necessary technical skills, qualifications, and knowledge needed to conduct organic inspections and certification review, AMS ensures that inspectors and certification reviewers are better prepared to verify organic compliance, which further strengthens organic integrity across all levels of the supply chain and upholds confidence in the organic label among consumers.

The rule adds new requirements for certifying agents, inspectors, and certification personnel:

- Certifying agents must verify that all inspectors and certification personnel they contract with or hire have the minimum required training, skills, and knowledge.
- Inspectors and certification personnel must meet a minimum baseline of knowledge, skills, and experience before beginning inspection or certification review activities.
- Inspectors and certification personnel must meet annual training requirements to continue inspection or certification review activities.

- Certifying agents must conduct periodic observations of inspectors during inspections (“witness inspections”) as a part of their annual evaluation activities.

- Certifying agents must maintain policies, procedures, and records regarding inspector and certification review personnel training and evaluation.

The provisions in this chapter affect current and potential organic inspectors, certification review personnel, and certifying agents who employ or contract with inspectors or certification review personnel. Some provisions apply directly to certifying agents’ hiring and evaluation processes. Others clarify the amount of training inspectors are required to do to maintain compliance to the organic regulations. The following discussion provides further detail on the provisions and AMS’s responses to comments received on the proposed rule.

Background

To continue certification, a certified organic operation must undergo an on-site inspection at least once a year. Organic inspectors visit certified organic operations to thoroughly investigate the operation’s processes, facilities, and records. Inspections vary by type and complexity of operation, but generally an inspector will review fields to investigate pest management, soil fertility management, buffer zones, and

other production techniques; inspect storage and preparation areas for evidence of commingling or contamination with substances prohibited in organic; review records and invoices; conduct mass-balance, traceability, and yield analyses; and interview a representative of the operation. The inspector may also collect samples to test for pesticide residues. The inspector then prepares an inspection report that the certifying agent uses to evaluate the operation’s compliance with the organic regulations. In addition to regular, once-a-year scheduled inspections, organic inspectors also conduct unannounced inspections, which are conducted without advance notice and are often used to target a more limited, but higher-risk, portion of an operation to ensure compliance (see the “On-Site Inspections” portion of this rule for more detail).

Organic inspectors and review staff are therefore the most direct form of enforcement and verification because they inspect certified organic operations onsite and report their findings to certifying agents. Persons performing certification review activities also ensure organic integrity by reviewing these inspection reports along with organic system plans, inputs, and other certification documents that are used to determine compliance with the organic regulations and grant continued certification. The role as inspectors and

³¹ Available in the Organic Integrity Database: <https://organic.ams.usda.gov/integrity/About.aspx>.

reviewers has only grown more critical as organic operations and supply chains become more complex and diverse.

Inspection and certification review are complex professions that require detailed and highly specialized knowledge of organic regulation and agricultural practices and strong observation, communication, and investigation skills. Without highly qualified inspectors and certification review personnel, loss of organic integrity—either unintentional or fraudulent—would go unnoticed and the organic certification system would fail. Therefore, these personnel must adhere to consistent standards of knowledge, skill, and experience, relevant to the scope and complexity of the organic operations they inspect and review. Consistent standards will ensure effective oversight and review of organic operations, catching and preventing mishandling and fraud at critical points in the organic supply chain.

The rapidly increased complexity and scale of the organic market has multiplied opportunities for mishandling of organic products and fraud, especially as supply chains for organic products increasingly depend on imported goods. In its February 2018 recommendation, the NOSB referenced “well-publicized incidents of proven fraudulent imports in the last year” as a compelling reason to ensure the industry has “qualified inspectors experienced in a broad range of operations diverse in scope and scale.”³² For example, a May 2017 *Washington Post* investigation found that millions of pounds of imported corn, soybeans, and ginger had been fraudulently labeled organic, and inconsistent inspection practices were partly to blame.³³ Additionally, public comments from accredited certifying agents and organic inspector associations agreed that minimum training and qualification requirements for inspectors are necessary to detect breach of organic integrity and fraud. AMS recognizes that in a diverse market where operations can choose their own certifiers, one critical element of protecting organic integrity and preventing fraud is ensuring that all organic inspectors and reviewers are

held to the same high standards of training and experience.

The regulations previously lacked specific detail about qualifications, experience, and continual training for inspectors and certification reviewers. Certifying agents currently set their own policies and minimum qualifications to hire inspectors and reviewers, creating inconsistency in on-site inspection and certification review. Further, many inspectors are independent contractors who are responsible for establishing and maintaining their own knowledge base. This diversity of background and training creates an inconsistent baseline of knowledge and skill.

In 2012, NOP issued a memo to clarify that all inspectors and reviewers, whether staff or independent contractors, must possess the expertise and qualifications needed to evaluate compliance with the USDA organic standards.³⁴ Additionally, the NOSB provided recommendations in 2018 to address the need for specific qualification and training requirements for inspectors and persons performing certification review.³⁵ This rulemaking codifies the general policy in the 2012 memo and addresses the NOSB recommendations by describing baseline qualifications for certifying agent personnel.

To clarify the portions of this policy that apply to certification review personnel, AMS defines the term *certification review* as “the act of reviewing and evaluating a certified operation or applicant for certification and determining compliance or ability to comply with the USDA organic regulations.” The term does not encompass performing an inspection, which is separately defined in § 205.2.³⁶ Examples of certification review includes reviewing applications for certification, reviewing certification documents, evaluating qualifications for certification, making recommendations concerning certification, or making certification decisions and implementing measures to correct any deficiencies in certification services. Establishing baseline qualifications for the personnel conducting these activities will lead to greater

consistency in certification review and decision.

General Requirements

Section 205.501(a)(4) requires that certifying agents “continuously use a sufficient number of qualified and adequately trained personnel” to implement and comply with the organic regulations. Certifying agents must maintain adequate staffing levels and the range of expertise needed to perform the full range of certification activities, including inspection and certification review. This includes maintaining an inspection staff to timely complete initial on-site inspections, annual inspections for all operations it certifies, unannounced inspections on a minimum of 5 percent of the operations it certifies annually (see § 205.403(b)), and any other inspections needed to ensure compliance with the regulations.

Certifying agents sometimes use contracted or volunteer personnel (*i.e.*, persons not directly employed by the certifying agent) to inspect operations or complete certification review. Therefore, certifying agents must ensure that all inspectors and certification review personnel—including staff, contractors, and volunteers—meet the requirements of § 205.501(a)(4)–(6). This means that any person performing inspection or certification review activities must meet these requirements, regardless of their work or contractual relationship with the certifying agent. This ensures consistent inspection and certification review by all certifying agents.

Knowledge, Skill, and Expertise

Certifying agents must demonstrate that all personnel they use to conduct inspection and certification review continuously maintain knowledge and skills that qualify them to perform duties as assigned (§ 205.501(a)(4)(i)(A) and (a)(4)(ii)(A)). These paragraphs detail the minimum knowledge and skills that inspectors and certification reviewers must have. Because inspectors and certification reviewers perform different functions, each must meet different baseline criteria, although there is some overlap, such as knowledge and skill of the organic regulations, traceability audits, and mass-balance audits. Certifying agents must demonstrate, as part of their accreditation process, that any inspectors or certification reviewers they use have sufficient knowledge in organic standards and practices to successfully understand, verify, and document an operation’s compliance or noncompliance with the organic regulations.

³² NOSB Formal Recommendation, Inspector Qualifications and Training, May 29, 2018: <https://www.ams.usda.gov/sites/default/files/media/CACSInspectorQualificationsRec.pdf>.

³³ Peter Whoriskey, “The labels said ‘organic.’ But these massive imports of corn and soybeans weren’t.” *Washington Post*, May 12, 2017. https://www.washingtonpost.com/business/economy/the-labels-said-organic-but-these-massive-imports-of-corn-and-soybeans-werent/2017/05/12/6d165984-2b76-11e7-a616-d7c8a68c1a66_story.html?utm_term=.97e7f3942427&itid=ik_inline_manual_7.

³⁴ NOP Memo: Criteria and Qualifications for Organic Inspectors; April 2012: <https://www.ams.usda.gov/sites/default/files/media/NOP-Notice-OrganicInspectorCriteria.pdf>.

³⁵ NOSB Formal Recommendation, Inspector Qualifications and Training, May 29, 2018: <https://www.ams.usda.gov/sites/default/files/media/CACSInspectorQualificationsRec.pdf>.

³⁶ § 205.2 *Inspection*. The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.

The requirements in the rulemaking are based on NOSB recommendations, public comments, and the NOP's own experience auditing certifying agents. AMS chose these specific skills because they are essential to inspection and certification review. These requirements will ensure that inspectors and certification review personnel can accurately interpret the regulations and standards, and consistently apply critical skills when inspecting and assessing compliance. This will address the current regulation's lack of specific qualifications, experience, and continual training for inspectors and reviewers.

Certifying agents must also demonstrate the expertise of all personnel they use to conduct inspection and certification review (§ 205.501(a)(5)). Critically, this means all inspection and review personnel must have expertise in knowledge of certification to the USDA organic standards. Certifying agents must also demonstrate their personnel must have education, training, or professional experience in the fields of agriculture, science, or organic production and handling that relates to assigned duties. This requirement to demonstrate expertise will facilitate more robust accreditation audits of certifying agents and ensure more consistent oversight of certifying agents. Together with the above knowledge and skills, this requirement to maintain adequate expertise will also promote development of a uniform, high-quality base of organic inspectors and certification reviewers.

Training

Organic inspectors and certification reviewers must complete regular training relevant to their duties. Training may include courses, webinars, training sessions, field days, seminars, conferences, shadowing other inspectors on their inspections, and directed readings on relevant topics. Certifying agents may determine if specific trainings fulfill the requirements. Relevant training courses available on the Organic Integrity Learning Center (OILC) may also meet the annual training requirements. When the minimum training hours are completed, certifying agents must still ensure that each inspector and certification reviewer has the training that is sufficient to competently perform assigned inspections or duties.

Sections 205.501(a)(4)(i)(B) and 205.501(a)(4)(ii)(B) require inspectors and certification review personnel with less than one year of experience to complete at least 50 hours of training on

USDA organic standards, inspection protocols, and organic production and handling practices. This requirement will help ensure new inspectors and certification review personnel are adequately prepared for their duties. The proposed rule had included a lower number of hours across all staff, new and experienced. Commenters suggested that less-experienced staff require more hours of training than existing staff. AMS agrees with public comments and has raised the initial training requirement for less-experienced staff to 50 hours, which is a reasonable balance that aligns with industry best practice and will ensure staff are adequately prepared to perform inspection and certification duties.

Onboarding for new inspectors or certification reviewers hired by certifying agents may count towards the 50-hour requirement, as can other qualifying training they complete in their first year performing inspection or certification review duties. Any onboarding that counts towards the training would need to be technical rather than administrative to qualify as relevant training. New inspectors must complete the 50 hours of training, at minimum, before they conduct inspections independently. This allows new inspectors to gain practical training through shadow inspections. Training requirements apply equally to inspectors who are hired as employees and contractors of certifying agents; initial training received must sufficiently address the scope and complexity of work these personnel encounter when performing their duties.

Sections 205.501(a)(4)(i)(B) and 205.501(a)(4)(ii)(B) detail training requirements for inspectors and certification reviewers with more than one year of experience. Inspectors and certification reviewers must complete relevant ongoing training appropriate to their existing skills, expertise, and scope of work. The annual minimum is 10 hours per year for personnel inspecting or reviewing one area of operation (*i.e.*, crops, wild crops, livestock, and handling). Five additional hours of annual training are required for each additional scope or area of operation. For example, an inspector who only inspects crop operations (*i.e.*, a single area of operation) must complete at least 10 hours of annual training; an inspector who inspects crop, livestock, and wild crop operations (*i.e.*, three areas of operation) must complete at least 20 hours of training annually. Because there are four scopes of certification in the USDA organic regulation (crops, livestock, handling, and wild crops), the maximum number

of training hours an inspector would be required to complete annually would be 25 hours (10 hours of training for the first scope of certification, plus 5 hours for each of the additional 3 scopes of certification).

AMS chose these training requirements based on review of public comment and review of established industry norms. AMS agrees with public comments that new inspectors will require more robust initial training and certifying agent personnel may require more or less annual training depending on how many areas of operation they inspect or review. Therefore, relative to the proposed rule, AMS is requiring 50 hours of training for new personnel, and 10 hours plus 5 hours per additional area of operation for more experienced inspectors.

AMS chose the 50-hour requirement for new inspectors because it aligns with industry best practice. Some certifying agents commented that the proposed 20-hour requirement for new inspectors was adequate, while others maintained that 75–100 hours was necessary; 50 hours is a median within that range. The 50-hour requirement also aligns closely with the Accredited Certifier's Association's "Guidance on Organic Inspector Qualifications," which recommends initial inspector training that totals 43–46 hours plus several mentored inspections and monitored reports.³⁷ Finally, many certifying agents currently require new inspectors to complete the International Organic Inspector Association's (IOIA) basic training, a 5-day course requiring approximately 40 hours to complete,³⁸ plus additional field observation and training that together total to 50 hours of training.

AMS chose an annual training requirement of 10 hours plus 5 hours per additional scope for more experienced inspectors because it is consistent with standards established by other agencies or organizations (*e.g.*, Preventive Controls Qualified Individuals per 2011 Food Safety Modernization Act, ISO 9001 Global Certified Lead Auditor), and because it increases flexibility by allowing more or less total annual training hours based on the areas of operations inspected or reviewed. These requirements will ensure that inspectors and reviewers receive annual training that is

³⁷ "Guidance on Organic Inspector Qualifications," Accredited Certifiers Association, Inc., February, 2018, <https://www.accreditedcertifiers.org/wp-content/uploads/2018/02/ACA-Guidance-on-Inspector-Qualifications-with-IOIA-Evaluation-Checklist.pdf>.

³⁸ IOIA Basic Training: <https://www.ioia.net/training-program-overview/>.

appropriate for the level and scope of their duties.

In certain cases, certifying agents may not be able to prescribe specific training to contracted inspectors or certification review personnel. However, certifying agents must use a sufficient number of qualified and trained personnel (§ 205.501(a)(4)) and demonstrate that all persons with inspection and certification review responsibilities have expertise in organic production and handling (§ 205.501(a)(5)). This means that certifying agents must ensure any contractor used to conduct inspection or certification review activities meets the training requirements described in the regulation.

Experience

In addition to training, § 205.501(a)(4)(i)(C) requires that certifying agents demonstrate that the inspectors they use have experience that prepares them to conduct their assigned duties. Certifying agents must demonstrate that inspectors have at least 2,000 hours of relevant experience that prepares them for the areas of operation they will be assigned (*i.e.*, crops, livestock, handling, or wild crops). Both this baseline experience requirement and the 50-hour training requirement must be met before inspectors can independently inspect organic operations. An experienced inspector may advance to inspect more complex operations based on performance.

The proposed rule specified one year of experience. This was consistent with the 2018 NOSB recommendation and generally supported by public comments. However, because public comments noted that “one year” is unclear and can be interpreted differently, AMS has chosen a more specific 2,000-hour requirement. This is equivalent to one year of full-time work (accounting for vacation and time off) and expands the pool of qualifying experiences because the hours can be obtained across multiple years, from one or more jobs, internships, or other qualifying activities.

Eligible types of experience include but are not limited to: work on a farm or ranch; agricultural extension work; agricultural education; internships; apprenticeships; experiential education; 4-H; Future Farmers of America; other inspection or auditing work; management of an organic food handling operation; food processing research; or natural resource management work. Qualifying experience is not restricted to paid work, and may include volunteer work or education.

This minimum experience requirement is supported by § 205.501(a)(5), which requires that certifying agents demonstrate that all persons with inspection or certification review responsibilities have education, training, or professional experience that relates to the duties they will perform.

Field Evaluation of Inspectors

Section 205.501(a)(6) requires certifying agents to ensure that every inspector they use is evaluated while performing an inspection at least every three years. Inspectors with less than three years of organic inspection experience must be evaluated every year. The regulatory text refers to observing an inspector while they are inspecting an operation as a “witness inspection.” This term is used by the International Standards Organization to refer to observations of inspections to ensure proper adherence to inspection procedures and the standards to which the inspection is being made.

The rulemaking’s field evaluation requirements are consistent with a 2016 NOSB proposal and accepted industry guidance from the Accredited Certifiers Association.³⁹ In addition, public comments supported this evaluation frequency, including annual evaluations for inspectors with less than three years of inspection experience. The rulemaking is therefore aligned with industry best practice, and will ensure that the performance of all inspectors is consistently monitored and evaluated by certifying agents.

The above requirement is a minimum and certifying agents have the option of conducting witness inspections more frequently than the above guidelines to verify an inspector’s ability to successfully conduct inspection duties. For example, certifying agents may decide to conduct additional witness inspections if there is a sudden change in the complexity of an operation being inspected, or if inspection reports show deficiencies in an inspector’s skill or knowledge.

To ease the burden on certifying agents and inspectors, certifying agents may share witness inspection reports with each other, but each certifying agent must demonstrate that they have evaluated each inspector’s performance in accordance with their own internal

personnel policies and procedures. Certifying agents may use employees or contractors to perform the witness inspections, provided they are qualified to perform such duties (*e.g.*, a witness inspection for a diversified crop operation should be overseen by an evaluator with adequate experience in inspecting diversified crop operations). A key indicator of an individual’s qualifications to conduct witness inspections is whether that person can perform the type of inspections they are evaluating.

To ensure that witness inspections are effective and consistent, certifying agents must maintain procedures for conducting and documenting them, and maintain records of all witness inspections of inspectors they have conducted (§ 205.501(a)(6)(ii)). These records may include a quantitative or qualitative evaluation of the inspector, along with details on where, when, by whom, and on what area of operation the inspection was conducted. This requirement will facilitate more robust accreditation audits and ensure more consistent oversight of certifying agents.

Witness inspections are intended as one tool to help certifying agents maintain, evaluate and improve inspector quality, but certifying agents are also expected to take corrective action appropriate to remedying gaps and deficiencies in knowledge and skills. For example, if a witness inspection identifies problems with an inspector’s report writing, then a desk audit of additional inspection reports may be appropriate to address any shortcomings. Conversely, if an inspector misses a significant noncompliance while inspecting an operation, the certifying agent may decide to conduct a follow-up witness inspection of the inspector.

Summary of Changes to the Final Rule

AMS made several changes to the proposed regulatory text when writing this final rule. Changes to the final rule are discussed below and are followed by responses to specific themes from public comment.

- In § 205.501(a)(4)(i) and (a)(4)(ii), AMS changed “scale” to “complexity” because public comments noted that scale does not always equate to greater complexity. AMS agrees with public comments and included “complexity” in the rulemaking to highlight its importance in determining appropriate qualifications for inspectors and reviewers.

- In § 205.501(a)(4)(i)(A) and (a)(4)(ii)(A), AMS replaced “auditing” with “traceability audits” and “mass-balance audits.” This addresses public

³⁹ “Personnel Performance Evaluations of Inspectors” proposal, December 13, 2016: <https://www.ams.usda.gov/sites/default/files/media/CACSIInspectorsProposal.pdf>.

The Accredited Certifiers Association, Inc. is a 501(c)(3) non-profit educational organization created to benefit the accredited organic certifying agent community and the organic industry: <https://www.accreditedcertifiers.org/>.

comments that requested additional specificity about the meaning of “audit.” The new language more closely aligns with accepted and well-understood industry terminology and more clearly describes the knowledge and skills that certifying agents must ensure their inspectors and reviewers possess.

- AMS revised the proposed annual training requirement of 20 hours in § 205.501(4)(i)(B) and (4)(ii)(B). Inspectors and reviewers must complete a baseline of 10 hours of training, plus an additional 5 hours for each additional area of operation they inspect or review. Inspectors and reviewers with less than one year of inspection experience must complete 50 hours of training within their first year. This revised requirement is consistent with established industry training standards but is also more flexible because it allows for more or less total annual training hours based on the experience of the inspector or reviewer and the areas of operations they inspect or review. This requirement will ensure that inspectors and reviewers receive annual training that is appropriate for the level and scope of their duties.

- AMS updated proposed § 205.501(a)(4)(i)(C) from “field-based experience related to both the scope and scale of operations they will inspect” to “experience relevant to the scope and complexity of operations they will inspect.” We removed “field-based” because that term was unclear and could be interpreted too narrowly. Using “scope and complexity” focuses the requirement on experience relevant to the type of inspections to be performed.

- AMS changed the one-year experience requirement in § 205.501(a)(4)(i)(C) to 2,000 hours in response to comments that requested more specificity and a clear metric for verifying compliance. A 2,000-hour requirement is clearer, will promote consistent implementation among certifying agents, will allow inspectors to combine qualifying experience from more than one activity, and was supported by public comments.

- In § 205.501(a)(6), AMS added “witness inspection” to refer to certifying agents observing inspectors as they inspect an operation. This change aligns with industry and international convention and more clearly describes the requirement.

- AMS revised § 205.501(a)(6) to clarify that certifying agents must conduct annual witness inspections of inspectors with fewer than three years of experience. This change is consistent with industry best practice and will

ensure that the performance of new inspectors is consistently monitored and evaluated by certifying agents.

Summary of Public Comment

Many public comments focused on the proposed number of required hours of continuing education, with a mix of comments that believed that 20 hours annually is sufficient, and others arguing that 20 hours would not be sufficient. A few comments requested flexibility in how inspectors meet the education requirements, suggesting that added flexibility would help them complete the education more easily and reduce costs for certifying agents.

Some comments expressed concern that the proposed requirement of one-year of field-based experience was restrictive, and that the proposed rule was not specific enough about what types of experience would qualify. AMS also received several comments noting that using years as a metric is not an adequate measure for experience; several comments suggested a minimum number of hours per year as an alternative.

Several comments discussed inspector evaluations, with most of these comments supporting in-person evaluations once every three years, and others recommending more frequent evaluations for new or inexperienced inspectors.

Responses to Public Comment

Specified Additional Knowledge, Skills, and Experience

(*Comment*) One comment stated that labor laws prevent certifying agents from requiring contract inspectors to undertake specific training.

(*Response*) The regulations do not require contract inspectors to complete training specified by certifying agents; however, certifying agents must demonstrate that all inspectors, including contract inspectors, complete training that is relevant to inspection. Certifying agents can recommend or offer courses to contract inspectors, but may not be able to require completion of specific training courses. Certifying agents should review inspector training logs or other records to ensure that the inspector has completed the required number of hours and that the training is appropriate to inspectors’ skill and role.

(*Comment*) Comments expressed concern that a list of skills, knowledge, and experience detailed in § 205.501(a)(4)(i)(A) may limit the pool of organic inspectors, and thus limit the capacity of certifying agents to inspect operations. Comments stated that specific qualifications should be based

on the scope of inspections performed by individual inspectors.

(*Response*) The list of qualifications specified in this section are not unique to any specific type of organic operation, but are important for all inspection and certification review activities, regardless of area of operation. All inspectors must meet the general qualifications listed in § 205.501(a)(4)(i)(A). Specific qualifications should be based on the scope of inspections performed—§ 205.501(a)(4) requires certifying agents to demonstrate that inspectors have qualifications to inspect the scope and complexity of the operations assigned.

(*Comment*) Comments recommended including recordkeeping, mass-balance audits, traceability/trace-back audits, DMI calculations, biosecurity, cultural training, and internal control systems for producer groups as areas where inspectors must demonstrate adequate knowledge and skills.

(*Response*) AMS expanded the list of qualifications in the rulemaking to include mass-balance audits and traceability audits. These additions support changes to the USDA organic regulations for supply chain traceability and on-site inspections as a result of this rulemaking. DMI calculations, biosecurity, and internal control systems for producer groups are specific to particular types of operations, and AMS is not mandating these topics for general organic inspector qualifications. Although knowledge of recordkeeping is not explicitly included, some certifying agent personnel may need this knowledge if it pertains to their duties (e.g., personnel who conduct supply chain traceability audits).

(*Comment*) Comments recommended requiring special qualifications or experience for inspectors who inspect high-risk operations, including special training requirements for producer group operations.

(*Response*) AMS is not including special training requirements for inspectors of high-risk operations or producer group operations. Section 205.501(a)(4)(i) requires certifying agents to demonstrate that their inspectors are qualified to inspect the operations of the scope and complexity assigned. If an inspector is to inspect high-risk operations or producer groups, then they must be qualified to inspect those types of operations.

(*Comment*) Comments recommended clarifying that import/export skills are needed only if relevant, as not all certifying agents deal with import or export of organic products.

(*Response*) AMS is keeping import/export requirements in the knowledge

areas required for all inspectors. Because this rule requires an NOP Import Certificate for each organic shipment imported to the United States, all inspectors must have knowledge of import and/or export requirements and how they are implemented. Inspectors who regularly inspect importing or exporting operations, or operations adjacent in the supply chain, may require more advanced import/export expertise.

Training Requirements

(Comment) Some comments stated that an annual training requirement violates labor laws regarding contractors. Commenters claimed certifying agents cannot provide the training to contract inspectors, so these inspectors will need to pay for the training, which could lead to higher inspection fees.

(Response) All inspectors must meet the hourly annual requirements for training that is relevant to their inspection work. While certifying agents cannot require inspectors to complete trainings, certifying agents must ensure all contract inspectors they use meet the training requirement. The rulemaking adds clarifying detail to existing training requirements to ensure consistent implementation by certifying agents. In addition, there are various trainings available for free, such as the online Organic Integrity Learning Center, which offers 33 courses averaging 3–4 hours per course. Additional no-cost resources that could qualify for training include resources published by universities, the USDA, or other organic experts (*e.g.*, plant identification databases, university extension courses, recorded lectures, informational web pages) and organic farming conferences. Furthermore, certifying agents commonly offer no-cost activities that can count as training, such as updates to inspection procedure, overviews of changes in organic regulation, supervised inspections, or field visits. Because of the wide availability of no-cost training, and because the rule's hourly training requirement is consistent with what the industry already practices, AMS does not believe this requirement will result in additional costs for inspectors beyond what is accounted for in the rule's economic analysis, or affect the cost of inspection.

(Comment) Comments stated that the number of required training hours should depend on how many different types of operations are inspected by a particular inspector.

(Response) AMS revised the training hour requirements in the rulemaking

based on the types of operations inspected—see § 205.501(a)(4)(i)(B) and (a)(4)(ii)(B).

(Comment) Comments showed concern that a specific numerical training requirement is not appropriate. They stated that the required content in the training is critical, not the number of training hours.

(Response) The annual training minimum is required to ensure the regulation's specified knowledge, skills, and experience requirements are effectively implemented. Establishing a minimum number of training hours sets a clear baseline for inspector and certification reviewer knowledge that promotes consistent implementation of the regulation by certifying agents.

Experience Requirements

(Comment) Comments opposed the requirement that inspectors have one year of field-based experience, asserting it was difficult to interpret and may limit the pool of potential inspectors.

(Response) AMS agrees that the proposed use of “field-based” experience may be interpreted narrowly (*e.g.*, only farming and organic inspection experience) and that this may limit the pool of potential new organic inspectors. The final rule is updated to reference “relevant” rather than “field-based” experience. This change supports the use of a broader pool of qualified candidates, such as persons with auditing or food handling experience.

(Comment) Comments recommended changing the proposed requirement for one year of experience to a specific number of hours of related experience.

(Response) AMS incorporated this recommendation into the final rule. Inspectors are required to have at least 2,000 hours of relevant experience prior to conducting their first inspection. This is equivalent to one year of full-time work, and can be obtained across multiple years, from one or more jobs, internships, or other qualifying activities. This clarifies the requirement and expands the pool of qualifying experiences across an individual's career and education.

(Comment) Comments recommended AMS adopt a “mentoring and evaluation system” for inspectors in lieu of a one-year field-based experience requirement because the proposed requirement was vague. Comments stated requiring experience based on scope and scale was seen as overly prescriptive and would limit the pool of qualified inspectors.

(Response) The rulemaking does not codify an inspector mentoring program. However, a mentorship program may be

used by a certifying agent to improve the quality and proficiency of their inspectors. Mentorships may also count towards the 2,000-hour minimum experience requirement, provided that the certifying agent can demonstrate that the mentorship provided experience relevant to inspection.

Field Evaluation of Inspectors/Witness Inspections

(Comment) Several comments recommended that witness inspections occur more frequently than once every three years, or that NOP issue guidance for how to determine when witness inspections should be more frequent.

(Response) Certifying agents may conduct witness audits more frequently than once every three years “if warranted.” However, certifying agents must also maintain documented policies, procedures, and records for annual performance evaluations and witness inspections (§ 205.501(a)(6)). This means that a certifying agent may choose to conduct witness inspections more frequently than required by the regulation (*e.g.*, to monitor inspectors with performance issues), but that the reason for more frequent witness audits should be justified and documented in the certifying agent's policies and procedures.

Additionally, AMS increased the frequency of witness inspections for inspectors with less than three years of experience from once per three years to annually. This change was made to ensure that the performance of new inspectors is consistently monitored and evaluated by certifying agents.

(Comment) Comments recommended allowing virtual or remote witness inspections.

(Response) Virtual and/or remote witness inspections were not included in the SOE proposed rule and AMS is therefore not setting specific policy related to virtual or remote witness inspections. The final regulations provide flexibility so that AMS may consider virtual witness inspection policy options in the future.

(Comment) Comments recommend allowing certifying agents to share inspector evaluation reports with other certifying agents following witness inspections.

(Response) AMS has addressed this recommendation in the rulemaking. Certifying agents may share witness inspections reports with each other. However, certifying agents using an inspector performance evaluation or witness inspection report from another certifying must demonstrate that they have evaluated the inspector's performance in accordance with their

own internal personnel policies and procedures.

(Comment) Several comments expressed concern that the proposed language would not allow contractors of a certifying agent to perform witness inspections.

(Response) Certifying agents may use contractors to perform witness inspections. However, the contracted personnel performing the witness

inspection must be qualified to evaluate the inspector (§ 205.501(a)(6)(i)).

(Comment) One comment stated that new inspectors should be shadowed on 10 inspections during their first year, in addition to the proposed 20-hour training requirement.

(Response) AMS has not included this recommendation in the rulemaking. Witness inspections will assess inspectors as they perform their duties, with more frequent witness inspections

of less experienced inspectors. Comments did not demonstrate the benefit of shadowing, although certifying agents may use this method if it is documented in their policies and procedures for witness inspections.

I. Oversight of Certification Activities

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.2	Terms defined. Definition for <i>Certification activity</i> and <i>Certification office</i> .
205.501	General requirements for accreditation. Paragraph (a)(22).
205.665	Noncompliance procedure for certifying agents. Paragraph (a).

This rulemaking revises the USDA organic regulations at §§ 205.2, 205.501(a)(22) and 205.665(a) to clarify AMS’s authority to oversee the activities of certifying agents. Certifying agents must notify AMS when opening any certification office that conducts certification activities. In addition, this rulemaking clarifies that AMS may issue notices of noncompliance to certifying agents based on the certification activities of a party working on behalf of a certifying agent.

Certifying agents, applicants for accreditation, and certified operations may be affected by these requirements. Readers should carefully review the regulations and policy discussion to determine if they may be affected by this action.

Background

Certifying agents commonly have multiple offices to ensure they provide adequate services to their clients. However, certifying agents sometimes open new certification offices without reporting this to AMS. Some certification offices operate independently and in different countries or regions than a certifying agent’s main office. AMS cannot provide oversight (regular audits and reviews) or enforcement of offices of which it is not aware. This can lead to inconsistent application and enforcement of the regulations across certifying agents. To address these gaps in oversight, the 2018 Farm Bill amended OFPA to require certifying agents to report new certification offices to AMS within 90 days of opening.⁴⁰

AMS also needs clear authority to initiate enforcement against parties acting on behalf of a certifying agent (e.g., a subcontractor) or individual certification offices. The use of subcontractors is common in the organic industry and effective enforcement depends on oversight of all persons involved in the certification of organic operations. Uncertainty about whether AMS can target a certification office or contractor for enforcement action interferes with precise and expedited enforcement. Therefore, AMS revised the organic regulations to clarify that entities acting on behalf of a certifying agent are subject to oversight and enforcement.

90-Day Notification of New Certification Offices

To support the consistent application of the organic regulations across all certifying agents, § 205.501(a)(22) requires certifying agents to notify AMS within 90 calendar days of the opening of any office performing certification activities. A *certification office* is defined as any site or facility where certification activities take place, except for activities that take place at certified operations or other specialized facilities, such as inspection, sampling, and testing. This notification requirement applies to any facility or location that meets the definition of certification office, regardless of how the office is classified by a certifying agent (e.g., “central” vs. “satellite” offices).

Notification of a new office opening must include basic information to support effective oversight of the certification office, including the countries serviced, location and nature of the certification activities, and the qualifications of the personnel that will

provide the certification activities. Information on the location of new offices allows AMS to efficiently use personnel and travel resources to schedule on-site audits, and to be precise in any adverse action that may affect only a portion of certifying agent’s accreditation, e.g., a certification office or activities in a specific country or region. Information on the types of certification activities being conducted allows AMS to better evaluate the need for additional oversight; for instance, a new office located in a high-risk area with a history of organic fraud may require additional oversight.

Authority To Issue Notices of Noncompliance

AMS is clarifying its authority to issue notices of noncompliance to certifying agents based on the activities of persons acting on behalf of a certifying agent, the activities of a certification office, or the activities in a specific country. AMS added the term *certification activity* to § 205.2 of the organic regulations to define activities that are essential to the function of a certifying agent and therefore subject to NOP oversight. *Certification activity* is any business conducted by a certifying agent, or by a person acting on behalf of a certifying agent (e.g., a specific office operating in specific countries, or a subcontractor or subcontractor organization). Any business activity conducted by a certifying agent as it implements the USDA organic regulations is considered a certification activity, including review, inspection, and certification of organic operations. The definition includes a non-exhaustive list of certification activities that fall under AMS oversight authority.

⁴⁰ See section 10104(d) of the Agriculture Improvement Act of 2018, Public Law No: 115–334, available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf> (7 U.S.C. 6515(j)).

AMS's authority to initiate enforcement action for a portion of a certifying agent's operation is reinforced in § 205.665(a)(1). This states that AMS may send notifications of noncompliance to a certifying agent based upon review of the certification activities of:

- A person acting on behalf of the certifying agent or
- A certification office.

This means that AMS may issue notices of noncompliance to a certifying agent based on the activity of certifying agent subcontractors, or an individual certification office(s) that may be in a different location from the certifying agent's main office. Further, AMS may suspend or revoke a portion of accreditation for activities in a specific certification office, country, or region.

Summary of Changes to the Final Rule

AMS made no changes to the proposed regulatory text in §§ 205.2, 205.501(a)(22), and 205.665(a) with respect to oversight of certification activities and has finalized the proposed requirements.

Summary of Public Comment

The majority of public comments supported AMS's proposed clarification. Commenters were primarily concerned that the proposed definition of certification office would subject remote staff and home offices to NOP audits. Commenters stated that NOP audits of home offices and remote workers does

not align with NOP's intent for adding the term certification office. Comments suggested excluding home offices and telework locations from the definition for certification office, and some explained that certifying offices which solely operate virtually should qualify as a certification office and individual workers working remotely on a temporary basis should not be subject to NOP audits.

Commenters were also concerned that the 90-day timeframe for certifying agents to notify AMS of new offices conducting certification activities is too long.

Responses to Public Comment
Definition of Certification Office

(Comment) AMS received comments requesting that the definition of certification office exclude home offices and remote workers. Commenters asserted that if home offices for remote staff are included in the definition of certification offices, they will be subject to audits, which would be unreasonable.

(Response) Home offices are not excluded in the definition of certification office because some certifying agents may maintain home offices as their primary location or certification office from which they conduct certification activities.

90-Day Notification of New Offices

(Comment) We received comments stating that the 90-day timeframe for

certifying agents to notify AMS of new offices conducting certification activities is too long. Some suggested that timeframes of 30 or 45 days would be more appropriate.

(Response) The 2018 Farm Bill established the 90-day timeframe. Section 10104 (j) of the 2018 Farm Bill and 7 U.S.C. 6515(j) state "Not later than 90 days after the date on which a new certifying office performing certification activities opens, an accredited certifying agent shall notify the Secretary of the opening." While certifying agents may choose to notify AMS earlier, AMS is retaining the 90-day notification requirement in the organic regulations.

(Comment) Commenters asked what office types (e.g., satellite offices or main offices) would require a certifying agent to notify AMS.

(Response) Certifying agents must notify AMS of the opening of any type of office where certification activities take place. This requirement for notification is based on the activities of an office not the type.

J. Accepting Foreign Conformity Assessment Systems

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.2	Terms defined.
205.511	Definitions for <i>Conformity assessment system</i> and <i>Technical requirements</i> .
205.511	Accepting foreign conformity assessment systems. Entire section.

AMS has added a new section to the USDA organic regulations, § 205.511, on accepting foreign conformity assessment systems that oversee organic certification in foreign countries. Section 205.511 replaces former § 205.500(c).

Affected entities may include, but are not limited to:

- Trade partners who have established an organic equivalence determination or are interested in establishing an equivalence determination with the United States.
- Foreign certifying agents and certified operations not accredited or certified by the USDA.
- Foreign organic producers who export products to the United States.

The above list is a general description of entities likely to be affected by this action. Other types of entities could also

be affected. You should carefully examine the regulatory text to determine if you or your organization may be affected by this action.

Background

The OFPA, under 7 U.S.C. 6505(b), allows imported organic products to be sold or labeled in the United States as organically produced if the Secretary determines that the products have been produced and handled under an organic certification program with requirements and oversight determined to be at least equivalent to those described in the OFPA. Under this authority, the U.S. government, including the USDA and the U.S. Trade Representative, work closely together to implement processes that determine the equivalence of foreign organic certification programs

and then negotiate an arrangement or agreement as appropriate.

USDA organic regulations formerly addressed USDA's authority to make equivalence determinations in general terms under § 205.500(c), but did not describe the criteria, scope, and other parameters to establish, oversee, or terminate such equivalence determinations, which are critical to the enforcement of organic imports. This new § 205.511 does not change current policy or add new requirements. It codifies existing practices and clarifies the procedures followed when determining organic equivalence, which strengthens oversight and enforcement capacity of organic imports by supporting the government's authority to reassess, continue, and terminate equivalence determinations, as

necessary. Without this clear implementation of Federal authority in the USDA organic regulations, the government could face challenges establishing and enforcing terms under current and future equivalence determinations that are critical to ensuring the integrity of imported organic products.

Definitions

The rulemaking adds two new terms in § 205.2: *conformity assessment system* and *technical requirements*. These terms are defined to ensure that the process and requirements described in § 205.511 are clear. The rulemaking defines *conformity assessment system* as all activities, including oversight, accreditation, compliance review, and enforcement, undertaken by a government to ensure that the applicable technical requirements for the production and handling of organic agricultural products are fully and consistently applied. The rulemaking defines *technical requirements* as a system of relevant laws, regulations, regulatory practices, standards, policies, and procedures that address the certification, production, and handling of organic agricultural products.

Foreign Product Certification

Section 205.511(a) describes the U.S. government's authority under OFPA to make equivalence determinations and explains the conditions in which foreign-produced product can be labeled and sold as organic in the United States.

Equivalency Determination Request

Section 205.511(b) describes the process used by the U.S. government and other foreign governments for initiating a request for an equivalence determination. Since there are several factors that may impact whether the U.S. government moves forward to review an equivalence determination request (e.g., agency resources, capacity to oversee the potential trade arrangement or agreement, relative benefits for the U.S. organic sector), this section clarifies that the U.S. government will determine if it can proceed with the evaluation process on a case-by-case basis.

Equivalency Reviews and Reassessments

Section 205.511(d) lays out the current process that AMS and other foreign governments use to monitor equivalence determinations that have been made. The section provides some flexibility in the timing of reviews to accommodate unavoidable factors in both countries that can impact timing

(e.g., federal budgets, election cycles, growing seasons).

Equivalence Termination Procedures

Section 205.511(e) describes the conditions under which the U.S. government may terminate equivalence determinations. These conditions for termination are commonly accepted among countries that maintain equivalence determinations and are based upon the core concepts underlying equivalence. The U.S. government must be able to terminate equivalence determinations under these conditions in order to fulfill its statutory obligation to assure that organic products sold in the United States are compliant with OFPA and the USDA organic regulations and maintain a level playing field for U.S. farms and businesses.

In addition to the conditions described in § 205.511(e), the U.S. government may also terminate an equivalence determination "for other good cause." This includes risks that may negatively affect the integrity of organic products imported from a country with which the U.S. government has an equivalence determination, policy changes, or resource constraints that impact either government. Examples include:

- Repeated cases of organic fraud that are not corrected by a foreign government;
- Increasing levels of organic fraud that a foreign government is unable or unwilling to address;
- Political instability, safety concerns, or limitations on access that make it impossible for USDA to travel to and assess a foreign government's equivalence determination;
- Reduction in funding or other resources that compromises a foreign government's or USDA's ability to operate its organic program and oversee the equivalence determination; or
- Changes in a foreign government's unilateral equivalence determination with the USDA that may restrict domestic producers' access to foreign markets.

In all cases, the U.S. government would provide notice and justification to the foreign government prior to termination, and give notice to affected organic stakeholders along with a reasonable timeline to transition.

Summary of Changes to the Final Rule

AMS made several revisions to the proposed regulatory text when writing this final rule. Changes to the proposed rule are discussed below and are followed by responses to specific themes from public comment.

- AMS added "oversight, accreditation, compliance review, and enforcement" to the definition of *conformity assessment system* to clarify the scope of the assessment of a foreign organic certification system's eligibility for an equivalence determination.

- AMS added "standards, policies" and "certification" to the definition of *technical requirements* to clarify the scope of this term and to ensure that the definition covers all parts of a country's framework for regulating organic products.

- AMS corrected the syntax of § 205.511(a) and (b) to state that foreign product "may be sold, labeled, or represented in the United States as organically produced." This accurately reflects the intent to allow foreign organic product to be exported to the United States and sold as organic, but does not allow foreign organic product to be labeled as domestically produced in the United States.

- AMS removed the reference to a two-year review cycle in § 205.511(d) and replaced with a statement explaining how AMS will determine the timing and scope of reviews of equivalence determinations. This gives AMS the flexibility to determine timelines for audits and reassessments of equivalence determinations, and allows AMS to accommodate unavoidable factors when scheduling audits and reassessments of equivalence determinations.

Summary of Public Comment

Public comments showed overall support for codifying AMS's existing practices for determining organic equivalence, agreeing that the proposed updates would strengthen the integrity of imported organic products.

Several of these comments largely focused on how the specifics of the proposed § 205.511 would improve the transparency and oversight of equivalence determinations and recognition agreements. Some of these comments recommended requiring certified foreign operations to be listed in the Organic Integrity Database and for NOP to investigate any countries with equivalence determinations found to be noncompliant. Some comments expressed opinions in opposition to some existing trade arrangements, and/or suggested that USDA not allow equivalence determinations and require direct certification via USDA-accredited certifying agents instead. Some comments were also uncertain the proposed requirements of § 205.511 apply to recognition agreements.

Several comments expressed concern that the proposed § 205.511(a) and (b)

would allow organic products produced under foreign equivalence determinations to be sold as “produced in the United States.” Some comments pointed out that the two and five-year inspection timelines may conflict with other regulations.

Responses to Public Comment

Definition of Conformity Assessment Systems

(Comment) AMS received comments requesting that several activities be included in the definition of *conformity assessment systems*. Commenters stated that it is critical to ensure that foreign governments have sufficient oversight, accreditation, compliance, and enforcement mechanisms in place to ensure that organic technical requirements are being enforced.

(Response) The definition of *conformity assessment systems* has been modified from the proposed rule to include the following activities: oversight, accreditation, compliance review, and enforcement. The additional activities were added to the definition of *conformity assessment systems* to clarify the scope of the assessment of a foreign organic certification system’s eligibility for an equivalence determination.

Definition of Technical Requirements

(Comment) We received comments requesting that the definition of *technical requirements* include the terms standards, policies, and certification. Commenters stated that it was important that these terms be added to ensure that the definition covers all

parts of a country’s framework for regulating organic products.

(Response) The terms standards, policies, and certification have been added to the definition of *technical requirements*. The new terms were added to ensure that the definition covers all parts of a country’s framework for regulating organic products.

Labeling of Foreign Product Origin

(Comment) Comments noted that § 205.511(a) could be interpreted to allow labeling of foreign-produced organic product as “produced in the United States.”

(Response) The final rule corrects the syntax of § 205.511(a) to state foreign organic product “. . . may be sold, labeled, or represented in the United States as organically produced.” This accurately reflects the intent to allow foreign organic product to be exported to the United States and sold as organic, but does not allow foreign organic product to be labeled as domestically produced in the United States.

Equivalence Reviews and Reassessments

(Comment) We received comments requesting AMS clarify its timeline for audits and reassessments of equivalence determinations. Additionally, commenters noted the difference between proposed § 205.511(d), which requires a two-year midcycle review, and the proposed rule preamble, which states, “The review cycles mirror ISO standards, which include a five-year reassessment cycle and mid-cycle reviews.”

(Response) The final rule has been revised to allow AMS additional flexibility to determine timelines for audits and reassessments of equivalence determinations. The final rule replaces “two-year cycle” and “five years” with the phrase “regular reviews and reassessments.” The new regulatory language allows AMS to accommodate unavoidable factors when scheduling audits and reassessments of equivalence determinations.

(Comment) AMS received comments asking if recognition agreements would be subject to AMS audits and reassessments per new § 205.511.

(Response) Recognition agreements will be subject to AMS audits and reassessments of equivalence per § 205.511.

Equivalence Determination Procedures

(Comment) We received comments requesting AMS describe in § 205.511(e) the criteria used to determine termination of an equivalence determination.

(Response) Each equivalence determination is unique and is assessed using the general criteria described in § 205.511. To ensure fair assessment of each unique equivalence determination, AMS has not codified specific criteria used to determine termination of equivalence.

K. Compliance and Noncompliance Procedures

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.660	General.
205.661	Paragraph (c). Investigation.
205.100	Change section heading only. What has to be certified.
205.662	Paragraph (c). Noncompliance procedure for certified operations. Paragraphs (e)(3), (f)(1), and (g)(1).

Authority To Pursue Enforcement Action Against Any OFPA Violator

The NOP currently pursues enforcement actions against uncertified parties when AMS has evidence of OFPA violations. In 2021, more than half of the complaints received by the NOP alleging violations of OFPA involved uncertified operations representing products as organic. Continued AMS enforcement against uncertified operations is central to the effective administration of the OFPA.

The rulemaking updates the USDA organic regulations by adding new paragraph (c) to § 205.660, to clarify that the NOP Program Manager may initiate an enforcement action against any violator of OFPA, regardless of certification status. Consistent with the new paragraph (c) to § 205.660, to clarify that the NOP Program Manager may initiate an enforcement action against any violator of the OFPA, AMS changed the title of § 205.661 from “Investigation of Certified Operations” to “Investigation.”

Enforcement Action Against Responsibly Connected Persons

Person(s) responsibly connected to a violator of the OFPA may be complicit in the OFPA violation(s) because of their association to the violator. Because of this, the rulemaking clarifies at §§ 205.100 and 205.662 that any person who is responsibly connected to an operation that violates OFPA or the USDA organic regulations may be subject to a suspension of certification, civil penalties, or criminal charges and/

or may be ineligible to receive certification. This clarification strengthens AMS's enforcement capacity by ensuring that enforcement actions and penalties for violations of the OFPA extend to all accountable parties.

Responsibly connected persons who are suspended or revoked may request to have their certification reinstated, if suspended, or their eligibility to become certified reinstated, if revoked. AMS has published guidance for Reinstating Suspended Operations (NOP 2605), which applies to both suspended and revoked operations that want to become certified again.⁴¹

Timely Updates to the Organic Integrity Database

Timely updates to the Organic Integrity Database (OID) are critical to inform other certifying agents, operations in the supply chain, and consumers when an operation is no longer certified and can help prevent noncompliant products from entering or continuing in the stream of commerce. At § 205.662(e)(3) of the regulations, AMS requires certifying agents to provide timely updates on the status of an operation that has been suspended or revoked (or that has surrendered its organic certification). These updates should be viewable in the Organic Integrity Database within three business days of issuing a notification of suspension or revocation, or from the effective date of a surrender. This publicly available information helps businesses in the supply chain confirm that an operation from which they purchase or receive organic products has a valid organic certification.

In most cases, the effective date of an operation's surrender means that the certifying agent has received notification from the operation and confirmed the surrender status. AMS recognizes that in some cases the effective date of the surrender may date prior to certifying agent confirmation of surrender and the Organic Integrity database updates will extend past the three-day window.

Federal Civil Penalty Inflation Adjustment

Finally, AMS amended § 205.662(g)(1) of the regulations to update the citation which specifies the maximum civil penalty amount for violations of the OFPA. Title 7 CFR 3.91(b)(1)(xxxvi) provides the civil penalty amount for each violation of

OFPA. This amendment aligns with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74, sec. 701.⁴²

Changes From Proposed to Final Rule

AMS made one change to the proposed regulatory text when writing this final rule:

- Removed the phrase “directly or indirectly” from 205.660(c) because its meaning was confusing. The intent of 205.660(c) is to clarify the scope of potential enforcement actions which may include blatant and subtle false labeling and representation of nonorganic products as organic.

No other changes were made to the proposed regulatory text in §§ 205.100(c), 205.660(c), 205.662(e)(3), and 205.662(f)(1) and AMS has finalized the proposed requirements with respect to AMS's authority to enforce against any OFPA violator and all responsibly connected persons connected to a violator. AMS also made no changes to proposed requirement to timely update the Organic Integrity Database.

Summary of Public Comments

In general, most public comments supported the proposed revisions to clarify AMS's authority to enforce against any violator of the OFPA and the organic regulations. Many comments also discussed the revisions in detail and offered recommendations or changes to the proposed policy.

Many comments discussed the proposed three-day timeframe to submit updates to the Organic Integrity Database (§ 205.662(e)(3)). Some comments describe the requirement as too burdensome, while some support the three-day timeframe. Comments opposing the proposed requirement recommended alternatives ranging from 7 to 30 days. Other comments state that updates should be immediate, or made within 48 hours, so that noncompliant products do not continue in the stream of commerce.

Several comments also claim that identifying and tracking all responsibly connected persons would be difficult, and requested more guidance on how this should be done. A few comments asked AMS if revocation of an operation's certification should also result in the revocation of all

responsibly connected persons' certification.

Some comments also asked AMS to clarify the phrase “or submit a request for eligibility to be certified” in § 205.662(f)(1). A few comments also asked if this applies to persons responsibly connected to a suspended operation. One comment also asked if this section applies to revocation of certification.

Responses to Public Comment

Timely Updates to the Organic Integrity Database

(Comment) AMS received comments that the three-day requirement to update the Organic Integrity Database is too burdensome. Commenters did not quantify negative impacts to certifying agents, nor did they clearly explain why this would be burdensome for certifying agents. Others supported the three-day timeframe or recommended that updates should be immediate or within 48 hours, so that noncompliant products do not continue in the stream of commerce. Other commenters recommended alternatives ranging from 7 to 30 days.

(Response) Certifying agents will have a one-year implementation period before this requirement takes effect. During the implementation period, there is no fixed time frame for updating data in the Organic Integrity Database. This requirement is limited in scope and applies when an operation is suspended, revoked, or has surrendered organic certification. Public accessibility of an operation's correct certification status is essential for movement of products in organic supply chains. AMS believes that three days for certification status updates is adequate and supports organic verification across supply chains of different speeds. Extending the deadline beyond three days may interfere with the timely verification of an operation's accurate certification status. This is critical data and inaccurate information can delay legitimate transactions and fail to prevent sales of products from suspended or revoked operations. Further, AMS provides certifying agents with an API to upload data to the Organic Integrity Database, which reduces redundant or duplicative work for certifying agents.

Enforcing Against Responsibly Connected Persons

(Comment) AMS received comments stating that identifying and tracking all responsibly connected persons would be difficult because these entities are not listed in the Organic Integrity

⁴¹ Instruction NOP 2605, Reinstating Suspended Operations: <https://www.ams.usda.gov/sites/default/files/media/2605.pdf>.

⁴² <https://www.govinfo.gov/content/pkg/PLAW-114publ74/html/PLAW-114publ74.htm>. As of the publication of this rule the civil penalty amount is \$20,130 per violation of OFPA occurring on or after February 15, 2022. The civil penalty amount will be adjusted in the future so readers should refer to 7 CFR 3.91(b)(1)(xxxvi) for the current amount.

Database. Commenters requested guidance on how this should be accomplished.

(Response) AMS is not specifying how certifying agents must identify responsibly connected persons, nor are we requiring responsibly connected persons to be listed and searchable as such in the Organic Integrity Database. Obtaining responsibly connected persons from organic system plans and/or identifying all known responsibly connected persons in adverse action letters are best practices that certifying agents should pursue.

Use of Term “Indirectly” in 205.660(c)

(Comment) Commenters requested clarification of what is meant by a label or information which “indirectly” implies that product was produced with organic methods if product was

produced in violation of the OFPA or the organic regulations.

(Response) AMS removed the phrase “directly or indirectly” from 205.660(c) because its meaning was confusing. The intent of 205.660(c) is to clarify the scope of potential enforcement actions which may include blatant and subtle false labeling and representation of nonorganic products as organic.

Civil Penalty Citation

(Comment) For civil penalty fines, commenters requested AMS cite the regulation, not the amount, since the latter changes and becomes outdated.

(Response) The proposed and final rules cite the regulation that sets the civil penalty amount.

Documented Delivery Confirmation

(Comment) Commenters requested AMS allow “documented delivery

confirmation” to accommodate electronic communication rather than only certified paper mail.

(Response) AMS accepts that “dated return receipts,” which are required when certifying agents or NOP sends an adverse action notice to an operation, may include electronic communications. This means that the adverse action notices may be sent electronically to the recipient and delivery confirmation may include, for example, confirmation that an email has been delivered.

L. Mediation

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.504	Evidence of expertise and ability. Introductory text and paragraph (b)(8).
205.663	Mediation. Entire section.

Background

AMS revised § 205.663 to improve the general readability of this section and to more clearly explain how mediation may be used in noncompliance procedures. When successful, mediation is an efficient way to bring operations into compliance and resolve conflicts among certifying agents and operations. The USDA organic regulations require that certifying agents and State organic programs provide applicants for certification and certified operations the right to request mediation when they issue a denial of certification, notice of proposed suspension, or proposed revocation of certification (§§ 205.405(d) and 205.662(c)). Section 205.663 provides requirements for requesting mediation, responding to a mediation request, the time frame for reaching an agreement, and what happens when mediation is unsuccessful.

The USDA organic regulations require certifying agents and State organic programs to notify operations of the option to request mediation as an alternative dispute resolution to resolve noncompliance findings that have led to a proposed suspension, revocation, or denial of certification. This will facilitate resolution of these issues before they escalate to an appeal to AMS or a State organic program.

Mediation Is a Collaborative Process

The requirements for mediation support a process that is efficient and accessible to producers and handlers who want to resolve a denial of certification, proposed suspension, or revocation of certification. Mediation is a collaborative process between a certifying agent and an operation or applicant for certification. A successful mediation addresses the noncompliance(s) and leads to full compliance with the USDA organic regulations. To ensure that mediation is readily accessible, certifying agents and certified operations or applicants may engage in mediation without a third-party mediator, provided that all parties agree upon the person who will serve as the mediator.

Mediation Must Be Requested in Writing

After a certifying agent issues a denial of certification, proposed suspension, or revocation of certification, a certified operation and certifying agent may discuss the option of mediation prior to receiving a request for mediation. However, for mediation to proceed as a form of alternative dispute resolution, an operation must request mediation in writing to the certifying agent. The request for mediation must be submitted to the certifying agent within 30 calendar days from the date of the proposed adverse action or denial of

certification (§ 205.663(b)(1)). This aligns with the length of time provided to submit an appeal of a proposed adverse action.

Mediation Acceptance Criteria

A certifying agent determines whether to accept or reject a written request for mediation. Certifying agents must include mediation acceptance decision criteria as part of the administrative policies and procedures which certifying agents are required to submit to demonstrate their ability to comply with the certification program (§ 205.504(b)(8)). The mediation acceptance criteria must be fair and reasonable and not arbitrary. The criteria must be based on factors that will likely determine potential success or failure of the mediation process. The certifying agent must document how it applied the criteria to accept or reject requests for mediation. Parties to the mediation may develop conditions, such as cost, timeframes to reach a settlement agreement within the allowed maximum of 30 days, and any incremental steps, only after a certifying agent accepts a mediation request. A certifying agent must not impose any preconditions for the acceptance of mediation (*i.e.*, the certifying agent cannot require that the operation take a specific action—other than submitting a written request for mediation—before it will consider mediation).

If a certifying agent decides to reject a request for mediation, based on its criteria for acceptance of mediation, it must inform the operation in writing, with the justification for the rejection. That notification must explain that the operation has the right to appeal the rejection of mediation (§ 205.663(b)(3)). While an operation appeals a rejection of mediation, the proposed suspension or revocation which led to the request for mediation must not be finalized (§ 205.663(b)(4)). The date that the notification is received by the operation is important because it starts the 30-day window for filing an appeal and may be used to determine whether an appeal has been timely filed. Likewise, when mediation is unsuccessful, the certifying agent must inform the operation in writing to document the start of the 30-day window for filing an appeal. This means that certifying agents must send rejection and termination of mediation notices using a method with delivery confirmation.

Use of Settlement Agreements

In accepting mediation, a certifying agent may also, at its discretion, offer a settlement agreement for an operation to consider (§ 205.663(e)). The outcome of successful mediation is a settlement agreement that brings an operation into compliance with the USDA organic regulations. A settlement agreement must clearly describe the corrective actions and timeframes for implementing corrective actions, and may impose additional actions (e.g., unannounced inspections, sampling for residue testing) to ensure the operation maintains compliance. A settlement agreement may also include a suspension of organic certification.

A settlement offer may be useful when the corrective action(s) is clear and the noncompliance(s) is not recurrent. As part of the mediation, an operation may accept or reject the settlement agreement, negotiate the terms with the certifying agent, or request a mediator to try and reach a settlement agreement.

Use of a Third-Party Mediator

This rule clarifies that mediation does not require a third-party mediator to reach a settlement agreement (§ 205.663(c)). The certifying agent and operation may agree that mediation will be between only those two parties. For example, mediation may consist of a phone call or series of phone calls between the operation and the certifying agent to discuss the terms of a settlement offer prior to signing the agreement.

In some cases, the use of a third-party mediator may be appropriate, either because the operation initially requested this, or the operation rejected a settlement offer and then requested a mediator. To demonstrate their ability to comply with the certification program, each certifying agent must submit a process to identify a qualified mediator and set the time and location of mediation session(s), mediation format (in-person, video, phone), and mediation fees and payment (§ 205.504(b)(8)).

Role of the Program Manager

The Program Manager does not require, manage, or otherwise participate in mediation between operations and certifying agents or State organic programs. The Program Manager may review an agreement that results from the mediation for conformity to the OFPA and the USDA organic regulations and reject any nonconforming provision or agreement (§ 205.663(f)). The Program Manager may direct the certifying agent or State organic program to revise any nonconforming provisions, and the operation would have a new opportunity to accept or reject the revised settlement agreement.

Mediation under the USDA organic regulations is an alternative dispute resolution mechanism, conducted between a certified operation or applicant for certification and a certifying agent or State organic program. The Program Manager is not involved in determining the outcome of a mediation, notwithstanding his or her authority to review dispute resolution terms for conformity with the OFPA and the USDA organic regulations.

This does not affect AMS's ability to carry out oversight, compliance, and enforcement activities on behalf of the Program Manager. For example, AMS may conduct informal mediation, at its discretion, and enter into mutually agreeable settlement agreements with parties that receive a proposed adverse action (§ 205.663(g)).

Changes From Proposed to Final Rule

AMS made minor revisions to the proposed regulatory text when writing this final rule. Changes to the final rule are discussed below and are followed by specific themes from public comment.

- AMS added the words "of receipt" to § 205.663(b)(3) and (e) so that the 30-day time frame for requesting an appeal when mediation is rejected or terminated provides adequate due process and aligns with the appeal filing time frame for other adverse action notices.

- AMS added a requirement for termination of mediation to be documented in a written notice so it is clear when an operation may exercise its right to file an appeal.

- AMS revised the introductory paragraph at § 205.504 to include the cross-reference to § 205.663 because certifying agents must submit mediation procedures as part of the evidence of their ability to comply with and implement mediation requirements.

- AMS relocated the requirement to submit mediation policies and procedures from § 205.663(a) to § 205.504(b), where requirements for certifying agents' policies and procedures are identified.

- AMS added a requirement that certifiers document the reason for denying mediation. If the rejection is appealed, this will allow the Administrator to determine whether the rejection was reasonable and consistent with the certifier's criteria for rejection.

- AMS added the word "reasonable" to § 205.504(b)(8) to describe parameters for the criteria that certifiers must set for accepting mediation. This supports fair and consistent decisions on requests for mediation across certifying agents.

- AMS revised § 205.663(e) to require that a settlement agreement be reached within 30 days from the start of mediation. This clarifies when the 30-day timeframe begins and supports timely resolution of compliance issues.

- AMS added a new provision at § 205.663(b)(4) to clarify that an adverse action (e.g., proposed suspension or revocation) must not be finalized during the appeal proceeding. This clarification supports the right to adequate due process before an adverse action takes effect.

Responses to Public Comment

Settlement Agreements

(Comment) Several commenters asked questions about the management of settlement agreements.

(Response) AMS is not addressing questions about management of settlement agreements in this rule because they are beyond the scope of this rule. More information on settlement agreements is available through the Organic Integrity Learning Center and annual training for certifying agents.

Mediation

(Comment) AMS received a comment stating certifying agents should be allowed to propose mediation and offer settlement agreements.

(Response) The regulations do not prohibit a certifying agent from

informing an operation of its willingness to engage in mediation prior to an operation requesting mediation. In addition, the regulations do not prohibit a certifying agent from offering a settlement agreement as part of mediation to resolve an adverse action.

(Comment) AMS received a comment to replace the terms “mediation session” with “mediation” to allow informal mediation at § 205.663(e).

(Response) AMS replaced “mediation session” with “mediation” to account for informal mediation which may not use the same format as formal mediation.

(Comment) AMS received a comment to change the deadline to submit a request for mediation from “30 days from receipt” to “30 days from date of issue.”

(Response) AMS is declining to make this change, in order to align with

USDA’s Office of Administrative Hearings and Appeals, which uses date of receipt and not date of issue. This practice preserves due process rights of operations being notified of adverse actions. AMS believes that the use of electronic communications and the availability of electronic delivery confirmation will make this requirement less burdensome.

(Comment) Comments requested that AMS align language for timeframes for requesting mediation and requesting an appeal.

(Response) AMS agrees that the timeframes for requesting mediation and requesting an appeal when mediation fails should be consistent. We changed § 205.663(b)(3) to state that an operation has 30 days from receipt of the rejection of request for mediation to file an appeal. We also changed § 205.663(e) to state that an operation has 30 days from

receipt of a written notice of termination of mediation to file an appeal. These changes make the timeframes to file an appeal consistent whether mediation is rejected or terminated.

(Comment) AMS received a comment that both parties agreeing on the person conducting mediation should only apply to formal mediation.

(Response) AMS disagrees that consensus on the person conducting mediation should only apply for formal mediation. Informal mediation also requires that parties agree on who will facilitate the mediation, even when the parties to the mediation facilitate the process themselves.

M. Adverse Action Appeal Process

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.2	Terms defined. Definition for <i>Adverse action</i> .
205.680	Adverse Action Appeal Process—General. Entire section.
205.68	Adverse Action Appeal Process—Appeals. Paragraphs (a), (a)(2), (b), (c), and (d)(1) and (2).

General Appeals

AMS revised parts of the adverse action appeals process in §§ 205.680 and 205.681. These changes clarify which actions can be appealed, recognize the use of alternative dispute resolution in lieu of a formal administrative proceeding to resolve an appeal, and reinforce that appeal submissions need to comply with the basic requirements in the regulations.

The OFPA calls for an expedited appeals procedure that gives persons affected by a proposed adverse action the opportunity to appeal that action (7 U.S.C. 6520). All appealed adverse actions are expeditiously reviewed and decided in an unbiased manner by persons that are not involved in the initial decision to issue an adverse action. In December 2014, AMS issued guidance to explain how it administers the adverse action appeal process, the status of an appellant during an appeal, and the possible outcomes of an appeal in NOP 4011, Adverse Action Appeal Process.⁴³

The original USDA organic regulations described how certified operations, accredited certifying agents, and applicants for certification or

accreditation may appeal a noncompliance decision that would affect their certification or accreditation status or eligibility to become certified or accredited (§ 205.680(a)). The regulations explained when an appeal may be submitted, how it must be submitted, and what the appeal submission must contain. Specifically, appeals of noncompliance decisions of a certifying agent or NOP are appealable to the AMS Administrator, or to the State organic program if the appellant is in a State with an approved State organic program. A decision to sustain an appeal will result in a favorable action with respect to the appellant’s certification or accreditation. Following a decision to deny an appeal, AMS will initiate a formal administrative proceeding (*i.e.*, a hearing), unless the parties resolve the issue through settlement, or the appellant waives the hearing. If an appeal is not timely filed, the adverse action which led to the appeal will be final and cannot be appealed further.

Adverse Action Defined

The new term *adverse action* clarifies which actions may be appealed under the USDA organic regulations. *Adverse action* replaces the use of “noncompliance decision” throughout this section. *Adverse action* is defined

as a noncompliance decision that adversely affects certification, accreditation, or a person subject to the Act, including a proposed suspension or revocation; a denial of certification, accreditation, or reinstatement; a cease-and-desist notice; or a civil penalty.

Option To Request Mediation or Appeal of an Adverse Action Issued by a Certifying Agent or State Organic Program

When a certifying agent or State organic program issues a proposed suspension or revocation, operations have the option to request mediation or appeal the proposed adverse action. Mediation is covered in more detail in § 205.663. The mediation process can be a viable path to resolve noncompliances that are correctable and are not willful or recurrent. If mediation is rejected or is not successful, the operation maintains the right to appeal. The time frame for filing an appeal is calculated from receipt of the notice of rejection or termination of mediation (§ 205.663(b)(3) and (e)).

Administrative Requirements

Appeals must be properly filed as described in paragraphs (c) and (d) of § 205.681. This means that an appeal must be:

⁴³ NOP 4011, Adverse Action Appeal Process. December 23, 2011: <https://www.ams.usda.gov/sites/default/files/media/4011.pdf>.

- Filed in writing within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later.
- Sent to the correct physical or email address:
 - 1400 Independence Ave. SW, Room 2642, Stop 0268, Washington, DC 20250.
 - NOPAppeals@usda.gov.
- Include a copy of the adverse action and explain why the adverse action is incorrect.

An adverse action will become final and nonappealable unless an appeal is timely filed. Appeals will be considered “filed” on the date received by the Administrator or by the State organic program.

Denied Appeals

AMS supports the use of alternative means, such as mediation and settlement agreements to expedite resolution of an adverse action dispute while preserving due process and avoiding prolonged formal proceedings. When an appeal is denied, AMS offers the appellant the option to waive further hearing. When an appellant waives a hearing, the appeal decision is final and takes effect. Failing to timely submit a request for hearing is regarded as a waiver of hearing. In some cases, when an appeal is denied, AMS may pursue a settlement agreement in lieu of initiating a formal administrative proceeding. AMS assesses the potential for a settlement agreement on a case-by-case basis and will exercise this option when a settlement may offer a viable route for the operation to come back into compliance or to exit the organic sector. Even when an appellant requests a hearing, AMS and the appellant may enter into a settlement agreement prior to the hearing. This provides flexibility to resolve appeals outside of a lengthy formal administrative process. The appellant reserves the right to an administrative hearing. Entering into a settlement agreement is an optional, not compulsory, alternative to a hearing.

Changes From Proposed to Final Rule

AMS made several revisions to the proposed regulatory text when writing

this final rule, including revising § 205.681(a)(2) and (b)(2) to state that the Administrator will initiate a formal proceeding and identify the conditions when that would not occur, *i.e.*, the parties settle beforehand, or the appellant waives its right to a hearing. These sections explain that failing to timely request a hearing constitutes a waiver of hearing. AMS also deleted “policies and procedures” from 205.681(d)(3) to clarify that the USDA organic regulations are the basis for enforcement.

Summary of Public Comments

Comments were generally supportive of the clarifications to the appeals sections of the USDA organic regulations. The main concern in comments was the revision to state that AMS “may” rather than “will” initiate a formal administrative proceeding if the Administrator denies an appeal. The comments stated that this change removes due process rights of an appellant and should not be at the discretion of AMS. Other comments requested changes to appeal filing timeframes and delivery confirmation.

Responses to Public Comment

(Comment) Comments opposed the change to not require AMS to initiate the hearing process following an appeal denial.

(Response) AMS made changes to § 205.681(a)(2) and (b)(2) to state that AMS will begin formal administrative proceedings once an appeal is denied. Those sections also explain that an administrative proceeding would not begin if the appellant waives or fails to timely request a hearing or AMS and the appellant reach a settlement agreement. This revision does not change AMS’s intent that appellants always have the right to request a hearing following a denial of an appeal; it only provides options for a more expedient resolution in lieu of a hearing if the appellant consents to that outcome.

(Comment) AMS received comments stating that the proposed revisions to § 205.681(b) do not clearly provide appeal rights for certifying agents.

(Response) Person, as defined in the regulations at § 205.2, includes certifying agents and § 205.681(b) allows persons to appeal an adverse action by the NOP Program Manager. Further, § 205.681(b)(1) explains what happens to accreditation when an appeal is sustained.

(Comment) AMS received comments suggesting that dated return receipts should be replaced with documented delivery confirmation.

(Response) AMS interprets dated return receipts to include electronic confirmation of electronic delivery, such as registered email which shows that a message has been delivered to recipient’s email and the date of delivery.

(Comment) AMS received comments that appeals should be filed within 30 days of date of notice rather than date of receipt of notice.

(Response) AMS is not making this change because it could interfere with due process rights of an appellant. We believe that appellant should have the full 30 days to appeal from the time that they receive the notice and not lose time due to possible delays in the mail or delivery service. Therefore, we are keeping this timeframe to 30 days from the date of receipt of notice to ensure that appellants have 30 days to review the notice and to decide how to respond.

(Comment) Comments requested that NOP timely respond to appeals because operations are allowed to remain certified during the appeal process and any subsequent hearing proceeding.

(Response) AMS has procedures to thoroughly and efficiently evaluate NOP appeals. AMS generally resolves appeals within 6 months of receipt. AMS also frequently uses settlement agreements to resolve appeals which decreases the number of appeals that may potentially proceed to a hearing.

N. Producer Group Operations

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.2	Terms defined. Definitions for <i>Producer group member</i> , <i>Producer group operation</i> , <i>Producer group production unit</i> , and <i>Internal control system</i> .
205.201	Organic production and handling system plan. Paragraph (c).
205.400	General requirements for certification. Paragraph (g).
205.403	On-site inspections. Paragraph (a)(2).

The organic industry has a longstanding practice of certifying groups of producers. This practice helps small farmers access the organic market and enables handlers to source products that are not produced in the United States. Compared with traditional producers and handlers, these groups of producers have unique needs in quality control and compliance. AMS is establishing requirements for producer group operations that promote consistent certification practices and ensure their continued viability and integrity. This rule codifies key provisions of the 2002 and 2008 NOSB recommendations on producer group certification, including:

- Establishing eligibility criteria for operations to qualify as producer group operations.
- Clarifying the function and responsibilities of Internal Control Systems (ICS).
- Clarifying inspection requirements for producer group operations.

Additionally, this rule builds upon the NOSB recommendations with additional detail based on public comment and NOP's programmatic experience auditing certifying agents and witnessing producer group inspections. These additions include requirements for more specific ICS requirements, more specific member and group information in OSPs, and an improved inspection sampling rate.

This rule strengthens the oversight of organic supply chains by enabling certifying agents to more readily assess a producer group operation's compliance with the USDA organic regulations. Certifying agents and operations that are certified as part of a producer group may be affected by these requirements. Readers should carefully review the regulatory text and policy discussion to determine if the requirements apply to them.

Background

Producer group operations export important organic agricultural products to the United States, such as coffee, cocoa, bananas, tea, and spices.⁴⁴ Globally, there are about 2.6 million organic producers organized across 5,900 producer group operations in 58 countries (mainly in Africa, Asia, and Latin America), managing a total area of

about 4.5 million hectares (11 million acres) of certified organic land.⁴⁵

Producer group operations present unique certification challenges. Producer groups may have thousands of members spread across a large area. The collection, handling, and processing of crops may be centralized, and these groups may also rely on centralized input procurement, training, and marketing to sell their product. These centralized practices can introduce risks to traceability and organic integrity due to producer group operations' unique structure, size, and reliance upon internal quality control systems (the ICS) as the first layer of oversight. Through certification audits and field visits, USDA has witnessed many of the common problems created by the lack of a codified producer group standard.

The most common, and difficult to address, challenge is lack of a well-functioning ICS. The ICS is the first line of oversight and enforcement and is responsible for critical functions such as education and inspection of members, and ensuring adherence to the organic regulations. A poorly functioning ICS often leads to poorly trained members who do not understand basic organic principles, and the ICS's lack of effective oversight means members' mistakes go unreported, resulting in a breakdown of the basic oversight necessary to ensure that products meet the USDA organic standard. As a result, NOP audits have uncovered issues such as application of prohibited synthetic fertilizers and pesticides, mixing of conventional and organic products, decentralized storage that causes mixing and contamination, and poor or nonexistent recordkeeping that makes traceability and verification of integrity difficult. These issues sometimes persist because the current regulations lack ICS responsibilities and NOP therefore has no mechanism or basis for citing noncompliance.

Conflict of interest can also become a challenge if not specifically addressed by the ICS. Often, ICS personnel are relatives or friends of the members and may withhold or obscure evidence of noncompliance or fraud. In other cases, the influence of a buyer or exporter will lead members to compromise organic

integrity in order to meet specific quality or volume targets.

In addition to the ICS, the lack of general criteria that producer groups must meet creates challenges for certifying agents. This is most often seen as an absence of critical information about the producer group and its members. Producer groups often do not provide certifying agents with basic information, such as accurate maps, location of plots, acreage, and production practices and inputs. During inspection, certifying agents commonly cannot locate members, plots, boundaries, or central distribution points, making it difficult to complete basic audit techniques such as yield analysis or mass balance.

The unique conditions of producer group production mentioned above, when combined with poor oversight and enforcement mechanisms at the ICS level, create an environment where loss of organic integrity and organic fraud are more likely to occur. The organic regulation currently does not have the specificity to address these unique challenges, making it challenging to both discover and correct issues that are prevalent in producer groups. The provisions in this rule codify specific eligibility criteria, ICS requirements, and inspection techniques to address these challenges, and the rule will give certifying agents the ability to successfully certify and oversee producer group operations and the products they produce.

The International Federation of Organic Agriculture Movements (IFOAM)⁴⁶ started developing criteria for producer group certification in 1994, and in 2003 published its position on "Small Holder Group Certification for organic production and processing" to support the concept.⁴⁷ The criteria formed the basis for acceptance of producer group certification in the European Union (EU) and the United States. Producer group operation certification is also used by other standards organizations, such as the International Accreditation Forum and Global G.A.P., to provide small-holder farming operations access to markets, expand consumer choices, and ensure the integrity of the supply chain.⁴⁸

⁴⁴ Producer groups may also be called "grower groups." The latter term is commonly used when certification of group operations is limited to the production or harvest of crops or wild crops.

⁴⁵ Florentine Meinshausen, Toralf Richter, Johan Blockeel and Beate Huber Project: Consolidation of the Local Organic Certification Bodies—ConsCert (2014–2018)/March 2019 <https://orgprints.org/id/eprint/35159/7/fibl-2019-ics.pdf>.

⁴⁶ <https://www.ifoam.bio/>.

⁴⁷ https://www.ifoam-eu.org/sites/default/files/page/files/small_holder_group_certification_0.pdf.

⁴⁸ https://www.iaf.nu/sites//www.globalgap.org/uk_en/.

Organic certification standards for producer group operations support strong and consistent oversight and enforcement of producer group operations. This final rule addresses 2002 and 2008 NOSB recommendations on producer group certification and adds detail about documentation requirements and inspection methods in response to public comments to the proposed rule.⁴⁹ While there are only a few known producer groups in the U.S. at this time, setting requirements for producer groups may help U.S. producer group members access the organic cost-share program and crop insurance. These regulations support the legitimate status of U.S. producer group members as part of an organic operation.

Qualifying as a Producer Group Operation

Certifying agents must assess whether operations that apply for or maintain producer group certification meet the characteristics in the definitions for *producer group member*, *producer group operation*, and *producer group production unit* and the qualifications for certification as producer group operations in 205.400(g). Operations that do not meet all criteria must not be certified as a producer group operation.

The smallest unit of a producer group operation is a *producer group member*. A producer group member is an individual engaged in the activity of producing or harvesting agricultural products as a member of a producer group operation. The practices of each producer group member must align with the organic system plan (OSP) of the producer group. Each member must use practices that comply with the requirements for producers and handlers in the USDA organic regulations. Some requirements may be met collectively by the producer group operation, such as submitting an organic system plan.

Producer group members are organized into production units. A *producer group production unit* is a defined subgroup of producer group members in geographic proximity within a single producer group

operation that use shared practices and resources to produce similar agricultural products. Each producer group operation determines the producer group production units in its operation and must identify these in the organic system plan per § 205.201(c)(4).

A *producer group operation* is a producer, organized as a person, consisting of producer group members and production units in geographic proximity governed by an internal control system under one organic system plan and certification. A producer group operation must define its geographic proximity criteria for its producer members and production units § 205.201(c)(4). The site-specific conditions of an operation, such as infrastructure, topography, common soil, water source, and products produced will affect “geographic proximity.” Therefore, AMS is requiring that certifying agents document and adopt their own criteria or guidelines for internal consistency when establishing acceptable distances or evaluating the geographic reach of a producer group operation.

Producer group operations may be certified for crops, wild crops, livestock, and handling. The requirements for production and handling operations in the USDA organic regulations also apply to producer group operations.

Structure and Organization of Producer Group Operations

A producer group operation must be organized as a person (§ 205.400(g)(1)). Organization as a person provides a path to certification because OFPA and the USDA organic regulations apply to a person as the basic regulatory unit. The definition for *person* at 7 U.S.C. 6502(16) and § 205.2 includes groups (*e.g.*, “. . . association, cooperative, or other entity”). Therefore, certification may be granted to the producer group operation, rather than individual producer group members.

A producer group operation must use centralized processing, distribution, and marketing facilities and systems (§ 205.400(g)(2)). A group may have several facilities for aggregating the products of producer group members and production units and moving into commerce.

An internal control system (ICS) is a defining component of producer group operations and is critical for management of the operation. The ICS is an additional tier of oversight and enforcement between the producer group members and the certifying agent. All producer group operations must have an ICS that implements the practices and procedures described in

the organic system plan (§ 205.400(g)(4)). Further ICS requirements are discussed in the following section.

All products sold, labeled, or represented as organic by a producer group operation must be produced or harvested only by producer group members on land and using facilities that are included in the producer group operation’s certification (§ 205.400(g)(5)). This means that, for example, a producer group member from one operation (A) must not use a handling facility owned by another producer group operation (B) unless the facility is included in the organic system plan and the producer group operation’s (A) certification. A producer group operation must not buy products from non-member producers and sell, label, or represent them as organic using the producer group certification. Likewise, producer group members must not sell, label, or represent their products as organic outside of the producer group operation unless they are individually certified (§ 205.400(g)(6)). This accommodates producer group operations with members of varying production levels where some members have the capacity and need for marketing channels in addition to the producer group operation. When this occurs, clear and careful recordkeeping is essential for successful mass-balance audits.

Producer group operations must provide a comprehensive inventory of the producer group operation and its capacity to the certifying agent. Specifically, the operation must provide the name and location of each producer group member and producer group production unit(s), and identify all products produced, estimated yield(s), and the sizes of the production and harvesting areas (§ 205.400(g)(7)). Producer group operations must provide this information to the certifying agent at least annually and should inform the certifying agent more frequently of changes that may affect its compliance with OFPA or the USDA organic regulations, *e.g.*, additional crops produced, inclusion of new land area and producer group members.

Producer group operations must also show evidence of compliance with the USDA organic regulations through internal inspections and reporting sanctions imposed on producer group members. It is not feasible for certifying agents to inspect each producer member annually, due to the number of members in any one producer group operation. However, the producer member must attend the internal inspection to provide complete information about their

⁴⁹NOSB Recommendation: Criteria for Certification of Grower Groups. October 20, 2002: <https://www.ams.usda.gov/sites/default/files/media/Rec%20Criteria%20of%20Certification%20of%20Grower%20Groups.pdf>.

NOSB Recommendation: Certifying Operations with Multiple Production Units, Sites, and Facilities under the National Organic Program. November 19, 2008: <https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Certifying%20Operations%20with%20Multiple%20Sites.pdf>.

production activities (§ 205.400(g)(8)). Internal inspections must include mass-balance audits and reconciliation of each producer group member's and each producer group production unit's yield and group sales. Records are critical to demonstrate compliance and producer group operations must maintain a recordkeeping system so that products are traceable from producer group members' individual production parcel to aggregation and handling at the production unit and through sale or transport when the products leave the custody and ownership of the producer group operation (§ 205.400(g)(9)).

Internal Control Systems

Pursuant to the 2002 NOSB recommendation "Criteria for Certification of Grower Groups"⁵⁰ and an August 2020 IFOAM position paper,⁵¹ all producer group operations must have an *internal control system* (ICS). The *internal control system* is an internal quality management system that establishes and governs the review, monitoring, training, and inspection of the producer group operation, and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations. The ICS consists of both the personnel and the procedures that form a producer group's internal governance, verification, and enforcement system. The ICS is responsible for the overall governance and compliance of the producer group operation and verifies each member's adherence to the organic system plan and USDA organic regulations.

ICS Functions

A producer group operation must have an OSP that meets the requirements for all operations in § 205.201(a) and additionally must describe its ICS procedures and practices. Section 205.201(c) describes the OSP requirements that are specific to producer group operations. The OSP for a producer group operation needs to include a description of the ICS and how it verifies the operation's compliance with the USDA organic regulations. This includes defining the organizational structure, roles, qualifications, and responsibilities of all ICS personnel (§ 205.201(c)(1)).

Personnel qualifications could include, for example, knowledge of local production practices, organic production and handling practices, ICS procedures, USDA organic regulations, and fluency in the language(s) of the producer group operation.

The ICS must also describe and prevent conflicts of interest between ICS personnel and the producer group operation that it oversees (§ 205.201(c)(3)). The USDA organic regulations identify conflict of interest scenarios for certifying agent and operations (§ 205.501(a)(11)). The ICS personnel-producer member relationship is different than the certifying agent-certified operation relationship so these criteria are not wholly applicable to producer group operations. For example, certifying agents are not permitted to consult with operations to overcome obstacles to certification. However, ICS personnel are required to provide training, education, and resources to assist producer members with awareness of, and compliance with, organic requirements. A generally accepted criteria for conflict of interest is whether an oversight entity, e.g., the ICS, has a financial interest in the regulated party or likely bias based on familial relations. For example, internal inspectors should not inspect family members or production units where the inspector is a member.

The oversight function of the ICS places its personnel at a higher risk for retribution from producer group operations. To support the integrity of ICS oversight, the ICS must also describe how it will protect ICS personnel from retaliation for carrying out their responsibilities, and, in particular, finding and reporting noncompliances (§ 205.201(c)(3)). This could include obtaining a written guarantee from the producer group operation that ICS personnel will not be subject to retribution and requiring ICS personnel to disclose any conflicts of interest prior to internal inspections or review.

The ICS must document and apply procedures for adding new members to a producer group operation (§ 205.201(c)(5)). These procedures must cover how each new member will be inspected by the ICS and evaluated to determine whether they can fully comply with the organic production and handling requirements before they are added as a producer member.

Producer group members use common practices to produce, harvest, and handle their collective products and common inputs. Shared farming or harvesting practices could include

fertility and pest management, procurement of inputs (including seeds or soil amendments), and shared resources could include post-harvest handling facilities. The ICS must describe how shared resources, including production practices and inputs, are procured and provided to all producer group members and personnel (§ 205.201(c)(7)). Shared practices and inputs are critical to fostering compliance among many individual farmers and documenting these practices is an important indicator of compliance for the entire operation. Training, education, and technical assistance are critical practices to support consistent and compliant practices among producer members and the description of the ICS must explain how these resources are provided (§ 205.201(c)(8)).

Internal Oversight

The ICS is the first line of oversight of a producer group operation and is responsible for assessing the compliance of producer group members. The USDA organic regulations include several requirements to ensure that the ICS provides competent and thorough oversight. More generally, the ICS must have documented clear policies and procedures to verify the producer group operation's and producer group members' compliance with the USDA organic regulations (§ 205.201(c)).

The ICS must identify criteria for high-risk producer group members and production units (§ 205.201(c)(6)). Certifying agents must also determine which producer members are high risk. Examples of risk factors that may be used by both the ICS and the certifying agent are listed below in the discussion of on-site inspection by the certifying agent.

Clear and comprehensive records are a critical component of an ICS. They help certifying agents understand how the operation is implementing its organic system plan and complying with the USDA organic regulations. The organic system plan must describe the system of records maintained by the ICS (§ 205.201(c)(9)). The system of records must show how records will support and be used for mass-balance calculations and traceability throughout the operation. For full traceability, records would need to cover the purchase, acquisition, or production of products for each producer member through sale or transport.

The description of the ICS must explain internal monitoring, surveillance, sanctions, inspection, and auditing methods used to assess compliance of all producer group

⁵⁰ NOSB Formal Recommendation, Criteria for Certification of Grower Groups, October 20, 2002: <https://www.ams.usda.gov/sites/default/files/media/Rec%20Criteria%20for%20Certification%20of%20Grower%20Groups.pdf>.

⁵¹ "Internal Control Systems (ICS) for Group Certification," IFOAM Organics International, August 2020, <https://www.ifoam.bio/our-work/how/standards-certification/internal-control>.

members (§ 205.201(c)(10)). As a best practice, internal monitoring and surveillance should cover critical organic control points may include, for example, buffer areas, condition of crops and/or wild crops and animals, soil quality indicators, handling practices, input and equipment use and storage areas. A description of sanctions may cover the review of internal inspection results to determine member compliance; and the processes to address noncompliances, impose sanctions, remove noncompliant producer group members and reporting noncompliances to the certifying agent. A description of the auditing methods could cover mass-balance audits to reconcile the expected and actual yields and sales of producer members, producer group production units, and producer group operations.

On-Site Inspections by the Certifying Agent

Certifying agents are the second tier of oversight for producer group operations. Certifying agents, in addition to verifying that producer group operations

are fully compliant with the eligibility, certification and ICS requirements, must follow specific requirements for on-site inspections of producer group operations. Initial and annual on-site inspections of producer group operations must comply with the general requirements for inspections in § 205.403. During annual on-site inspections of producer group operations, certifying agents are required to evaluate the ICS, review internal inspections conducted by the ICS of individual members, and observe ICS personnel conducting internal inspections (§ 205.403(a)(2)(i)–(ii)). At least one producer group member from each producer group production unit must be inspected, and each handling facility, including all collection sites, must be inspected (§ 205.403(a)(2)(iii)–(iv)). Collection sites, where the harvest from multiple producer group members is stored before transport, are handling facilities, and are inspected by certifying agents. USDA organic regulations do not set a minimum number or percentage of witness inspections that a certifying agent must conduct at each producer

group operation inspection. Witness inspections are a key component of assessing the ICS and certifying agents will need to ensure that the number of witness inspections at a given operation is sufficient to evaluate ICS rigor.

During on-site inspections, certifying agents must inspect at least 1.4 times the square root or 2% of the total number of producer group members, whichever is higher (§ 205.403(a)(2)(iii)).⁵² The square root sampling rate aligns with industry practice. Two sampling rates are provided because the power of the square root sampling power begins to decline when operations exceed 5,000 members so that a smaller proportion of members are inspected relative to the total number of members. The addition of the 2% rate more evenly distributes the number of external inspections across producer groups regardless of the number of members as shown in Table 1. For each producer group operation, certifying agents need to calculate the number of members to inspect using the square root method and the 2% rate and use the higher number.

TABLE 1—CERTIFYING AGENT ICS INSPECTION SAMPLING RATES

Producer group members (N)	Square root method	Flat 2%	Final rule
		2%	Greater of 1.4 * √N or 2%
N	1.4 * √N		
50	10	1	10
100	14	2	14
250	23	5	23
500	32	10	32
1000	45	20	45
5000	99	100	100
7500	122	150	150
10000	140	200	200

The number of producer group members inspected by the certifying agent must include all high-risk members (§ 205.403(a)(2)(iii)). Certifying agents must inspect at least one producer group member in each production unit (as defined in § 205.2) to ensure all producer group production units are inspected, as well as each handling facility. As a best practice, AMS recommends that certifying agents also select members from across the risk spectrum—including lower-risk members—so that the same producer members are not inspected year after year. This may require a sample size larger than the minimum required (*i.e.*, more than 1.4 times the square root or more than 2% of the number of

producer group members). All numbers must be rounded up to the next whole number (*e.g.*, using square root method, 50 members = 10 inspections, 100 members = 14 inspections, 500 members = 31 inspections, and 1,000 members = 44 inspections). The certifying agent has the discretion to inspect more producer group members than the minimum indicated by the calculation.

Risk-based inspections rely upon certifying agents having policies and procedures to determine the risk factors associated with producer group operations. While the ICS determines which producer members and production units are high-risk according to their criteria, the certifying agent needs to independently determine

which members are high-risk (§ 205.403(a)(2)(iii)). The certifying agent should apply the risk assessment procedures to determine and instruct the inspector on which producer group members to inspect during the annual inspection. After all risk-based and other inspection selection criteria are satisfied, certifying agents should randomly select the remaining member inspections so that different lower-risk producer group members are inspected each year.

Risk factors may include, but are not limited to, producer group administrative capacity, organization complexity, and variations in members and production units (such as product quantity and value, member size,

⁵² The square root sampling scheme was developed in the 1920s as a sampling scheme for agricultural regulatory inspectors. The formula used

was the square root (Sqrt) of the lot size (N) + 1. Blanck, F.C. (1927). "Report of the Committee on

Sampling." J. Assoc. Official Agricultural Chemists, 10, 92–98.

number of products), rate of growth, and compliance and enforcement history. For example, a producer group member selling products outside of the producer group or a producer group member that is considerably larger than the other producer group members in a production unit represent compliance risks to the overall producer group operation. When assessing the risks of the producer group operation to determine which producer group members to inspect, examples of risk factors that the certifying agent may consider include, but are not limited to:

- Noncompliance history of overall producer group and of individual members;
- The criteria used to designate a collection of producer group members as a single producer group production unit;
- High-risk members identified in the ICS and producer groups member with noncompliances;
- Application of prohibited materials adjacent to member fields;
- Split or parallel operations (*i.e.*, operations that are also producing nonorganic agricultural products);
- Producer group members with incomes greater than \$5,000 USD per year;
- The procurement, availability, and distribution of inputs and resources to members;
- The prevalence of nonorganic production of similar products and crops in the region;
- Post-harvest handling practices designed to prevent commingling and contact with prohibited substances;
- New producer group members;
- Size of producer group member's production or gathering areas; and
- Significant expansion of a producer group member's production area.

As a best practice, the inspection of the ICS should also include: document review; auditing of production and sales/distribution records; reconciliation of product inventory; review of procurement and distribution of inputs; review of the inspections conducted by the ICS; review of ICS personnel qualifications and training; witness audits to observe ICS inspectors; review of noncompliance actions for producer group members; examination of organic control points and high-risk areas; interviews with managers responsible for the OSP, governance of the ICS, and producer group members and individuals overseen by the ICS; and review of training provided to ICS staff and producer group members.

Summary of Changes to Final Rule

AMS made several changes to the proposed regulatory text when writing this final rule. Changes to the final rule are discussed below and are followed by responses to specific themes from public comment.

- AMS revised the definitions of *producer group member*, *producer group operation*, *producer group production unit* and *internal control system* to allow livestock production and to clarify that the operation is regulated as a person. Use of the term "individual" in *producer group member* and "person" in *producer group operation* more clearly indicates that the operation is the legal regulated entity, which is consistent with current regulation and ties to the existing defined term *person* (see § 205.2).

- AMS replaced "crop/wild-crop" with "agricultural product" throughout so that livestock and livestock products are not excluded from producer group operation production. Public commenters argued that a prohibition on livestock in producer group certification may disproportionately affect poor and small-scale farmers that depend on producer groups to access the organic market. Livestock production in producer group certification is consistent with EU organic standards, IFOAM, the 2008 NOSB recommendation, and current practice in the organic industry. Allowing livestock production avoids market disruption and negative impact to operations that depend on producer group certification for market access.

- AMS added more specificity to the description of the ICS in the organic system plan, including: describing qualifications of ICS personnel; procedures for approving new members; policies to protect ICS personnel from retribution; description of technical assistance to members; and a system of records that covers each member and support mass-balance audits and traceability. Public comments stressed the importance of the ICS and suggested modifications to strengthen the ICS's ability to enforce the organic regulations and maintain organic integrity. AMS agrees with public comments and has revised ICS requirements to be more specific because this is necessary to bolster the oversight and enforcement of producer groups.

- AMS clarified that producer group operations must only sell products from the land and facilities included in the certification. The proposed text only specified "from grower group members." Additionally, requiring that producer groups only sell products

produced using land and facilities within the certified operation improves oversight because these facilities and land are routinely inspected by the ICS and the certifying agent.

- AMS added a requirement that producer group operations must maintain an ICS as described in the organic system plan. Although it was implied, proposed § 205.400(g) did not include an explicit requirement to maintain an ICS and did not reference the ICS requirements (§ 205.201(c)). Adding this explicit requirement makes an ICS a clear condition of certification that must be included as part of an organic system plan.

- AMS clarified that producer group members must be present during internal inspections. Having producer group members present during onsite internal inspections is necessary so that ICS personnel can interact with and ask questions of the members to ensure a full understanding of the activities on the members' production sites.

- AMS removed a redundant requirement from § 205.400(g) that the producer group operation must document and report the use of sanctions; the description and implementation of a system of sanctions is covered in §§ 205.201(c)(10) and 205.400(g)(4) and (10).

- AMS adjusted the sampling rates certifying agents must use when inspecting producer groups to 1.4 times the square root or 2% of the total number of producer group members, whichever is higher. The proposed inspection rate of 1.4 times the number of members is a digressive rate, which samples a smaller percentage of members as a group grows larger. Combining this with a linear 2% sampling rate ensures that larger producer groups (those with more than 5,000 members) are inspected at a similar rate as smaller groups.

- AMS revised § 205.403(a)(2)(iii) to clarify that a certifying agent must inspect all producer group members determined to be high-risk by the certifying agent. The proposed rule had stated that high-risk members should be chosen based on the ICS's risk criteria. This change improves oversight by ensuring that a certifying agent conducts independent risk assessments based on their own risk criteria, rather than relying only on the ICS's assessment.

Summary of Public Comments

The majority of public comments received supported AMS's codification of producer group standards in the USDA organic regulations. Many comments provided suggestions and

recommendations to the proposed policy.

Many comments strongly opposed the proposed prohibition of livestock production within producer groups, requesting that AMS revise the standard to allow “scope neutrality” and the production of livestock and livestock products. Several commenters stated that many certified producer groups already produce livestock and livestock products, and that prohibiting livestock would negatively impact these operations.

Several comments suggested AMS add more specificity to the proposed ICS requirements to ensure the ICS can manage the unique challenges of producer groups. Commenters requested more detail about conflict of interest, training, risk assessment, inspections, recordkeeping, personnel qualifications, protections for farmers, and evaluation of the ICS by the certifying agent. Commenters pointed to specific details found in the preamble describing organic system plans and the internal control system and requested these be added to the final rule to support clarity and consistency.

The proposed rule asked if producer group risk should be managed by placing limits on scale (*e.g.*, number of members, size of individual members, geographic distribution of members). Most commenters agreed that the risks of uncontrolled size or scale should be addressed but felt prescriptive limits may arbitrarily exclude members, disrupt well-functioning groups, restrict economic opportunity, or force producers to revert to conventional methods. The majority of commenters advocated for “scale neutrality” and requested NOP develop alternate strategies to manage the risks of large producer group operations.

Several comments requested that AMS require the use of risk criteria and assessment to control issues of scale. Others recommended that AMS develop a separate scope of accreditation specifically for producer groups, arguing that certification of these operations requires specialized skill and oversight. A few comments noted the difficulty of identifying producer groups in the Organic Integrity Database, and asked for identification to be mandatory. Some comments noted differences between the proposed policy and other international standards, and asked AMS to align its producer group standards with EU and IFOAM. Finally, a few comments expressed concern that the producer group standard may be used by large livestock or poultry cooperatives in the United States, which they argue is against the intent of the

standard to support opportunity and growth for very small organic farmers.

Responses to Public Comments

(Comment) Some commenters recommended specific limits on parcel size and number of members in a producer group operation because a lack of controls on scale could lead to inadequate and inconsistent enforcement. Commenters mentioned that an ICS could be reluctant to enforce against a large producer member without which the producer group could fail.

(Response) AMS is not setting size limitations, in terms of land area or number of members, on producer group operations. The ICS requirements support effective oversight of producer group operations regardless of their size.

(Comment) Comments opposed the proposed prohibition of livestock producer group operations. Commenters argued that this may disproportionately affect poor and small-scale farmers that depend on producer groups to access the organic market. Some comments mentioned that livestock producer group operations are already certified for beef and honey production.

(Response) AMS revised the proposed rule to allow the certification of livestock production as producer group operations. This allowance aligns with the EU organic standards for producer group operations and the 2008 NOSB recommendation, which did not restrict producer group certification to crop and wild crop operations. Livestock producer group operations may be more complex and higher risk than crop and wild crop producer group operations. In practice, this will require careful oversight of the ICS and qualifications of ICS inspectors and personnel. Further, some types of livestock production may be unsuitable for group certification (*e.g.*, intensive livestock farming, variability between producer members) because it is more difficult for them to meet the requirements for certification as a producer group operation.

(Comment) Comments requested a separate scope of accreditation for producer group certification to ensure that certifying agents are sufficiently qualified to certify producer groups.

(Response) Establishing a separate scope of accreditation would require more input and assessment of impacts, as this was not included in the proposed rule. This type of certification is complex and presents higher risks for organic integrity. AMS will assess certifying agents’ oversight of and qualifications for producer group certification through rigorous audits.

(Comment) Comments suggested that the ICS should describe the qualifications of all ICS personnel and the procedure to ensure the availability of a sufficient number of qualified personnel. Comments specified that the ICS should describe how ICS personnel are familiar with the local production practices, general organic production and handling practices, the USDA organic regulations, ICS procedures and regulations, and be fluent in the language(s) of the producer group members and the ICS.

(Response) The description of the ICS must describe the qualifications and responsibilities of ICS personnel. AMS has identified examples of the knowledge qualifications for ICS personnel, but is not adding these as required to give flexibility to certifying agents to determine the suitable qualifications on specific operations.

(Comment) Comments asserted that producer group operations must ensure that all group members understand and can comply with the USDA organic regulations. Commenters urged that the ICS should describe how the training, education, and technical assistance that is provided to producer group members and ICS personnel ensures their understanding of and compliance with internal control system’s policies, the organic system plan, and the USDA organic regulations.

(Response) Producer group operation compliance requires that each member understand the required and prohibited practices for organic production and handling. AMS has added a requirement for the ICS to include training, education, and technical assistance to producer members (205.201(c)(8)). Given that producer group operations are located in areas with varying language and literacy proficiency, it is the responsibility of the operation to effectively communicate this information to all members on an ongoing basis.

(Comment) Comments stated that the ICS should explain how it manages conflicts of interest by addressing or prohibiting internal inspectors from inspecting or acting as buying officers for their own relatives. Comments also requested guidance around conflict-of-interest scenarios and that internal inspectors are not restricted from providing training, education, or technical assistance to producer group members.

(Response) The description of the ICS must explain how it will prevent potential conflicts of interest. The development of guidance on specific examples of conflict of interest needs further public input and discussion and

that level of detail was not included in the scope of this rule. Certifying agents will review the ICS to determine if known potential conflicts of interest are identified and prevented. AMS agrees that internal inspectors inspecting or procuring products from their relatives would be potential conflicts of interest because the relationship may compromise the inspector's objectivity in assessing compliance.

(Comment) Comments stressed that group members need to be present during their internal inspection and that more guidance is needed to ensure the ICS is addressing noncompliances and reporting major noncompliances to the certifying agent.

(Response) AMS has added the requirement for producer members to be present at the inspection of their production site(s). Maintaining an organized, transparent, and equitable system of sanctions is critical for producer group certification. The ICS must have procedures for implementing a system of sanctions, and the producer group operation must report sanctions for noncompliant members to the certifying agent. The requirements for recordkeeping that covers internal inspection reports, sanctions, and corrective actions plus the external inspection requirements will help certifying agents to assess whether the ICS is reporting noncompliances and sanctions to the certifying agent.

(Comment) Comments supported that the ICS describe the recordkeeping system that must cover signed member agreements, internal inspection reports, documents related to internal sanctions and corrections, and formal agreements for each producer group member that commits them to complying with ICS,

OSP, and USDA organic regulations, along with all training records for members and personnel. The ICS procedures should state how lists of individual members, locations, products, acreage, copies of inspection reports, sanctions, and corrections are stored and made available during inspection by the certifying agent.

(Response) The USDA organic regulations require a description and implementation of the recordkeeping system. The critical objective of recordkeeping is to support traceability of production, inputs, and transactions throughout the producer group operation. Information about sanctions and internal inspection reports are required by separate provisions.

(Comment) Comments requested clarification about what types of noncompliances (*i.e.*, major vs minor) must be reported to the certifying agent.

(Response) The requirement to report noncompliances to the certifying agent enables the certifying agent to assess ICS oversight. It also leaves flexibility for the ICS to describe different timing and reporting methods for noncompliances of varying scope and severity. Noncompliances that may result in removal of the member(s) from the producer group, for example, application of prohibited substances, warrant timely notification to the certifying agent. In contrast, maintaining records of correctable noncompliances for the certifying agent to review during external inspections would be acceptable.

(Comment) Comments stated that the use of 1.4 times the square root of the number of members is not adequate for external inspections. They explained that this inspection rate is either too low for a producer group with more than

5,000 members, resulting in potentially inadequate oversight of very large groups, or the inspection rate is too high and burdensome for small producers, resulting in pressure to grow larger to reduce certification costs. Comments suggested other rates including a flat percentage rate of 2–3%, a combination of square root and flat rate methods, or a minimum of 10% of producer group members.

(Response) The external inspection sampling rate should be equally stringent for producer member operations regardless of size. The USDA organic regulations specify that certifying agents must use the higher result of 2 sampling rates to set the minimum number of producer members that need to be inspected. Setting 2 rates is necessary because the square root sampling power begins to decline when producer groups are larger than 5,000 members. The use of 1.4 times the square root or 2% of the total number of producer members is a minimum and does not prevent certifying agents from using sampling sizes that exceed the results of those rates. Higher levels of inspection rates may be warranted when necessary if a producer group operation has a history of inadequate internal controls and poorly trained personnel with ineffective policies, procedures, or sanctions, and is failing to enforce against noncompliant members, failing to inspect all members, or is not completing mass-balance audits.

O. Calculating the Percentage of Organically Produced Ingredients

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.302	Calculating the percentage of organically produced ingredients. Paragraphs (a)(1), (2), and (3).

This rulemaking revises § 205.302(a) to clarify that the percentage of organic ingredients in multi-ingredient products should be calculated by dividing the weight or volume of the organic ingredients at formulation by the total weight or volume of the product at formulation, with water and salt added as ingredients at formulation excluded from the calculation.

This policy may affect certified operations, noncertified operations that process products containing organic ingredients, applicants for organic certification, and certifying agents. The

reader should carefully examine the regulatory text and discussion below.

Background

Section 205.301 of the organic regulations classify products containing organic ingredients into several categories based on percent composition—*e.g.*, “100 percent organic,” “organic,” “made with organic (specified ingredients or food group(s)).” Clear and easily understood instructions for calculating product composition are needed to ensure consistent classification by the organic industry.

Previous policy had sometimes caused inconsistent implementation because it required calculation based on “total weight of the finished product.” It was unclear if this meant products before or after processing. Because processing (*e.g.*, cooking, baking, dehydrating, freeze drying) often causes water loss from ingredients, using the total weight of the product after processing sometimes resulted in inflated percent organic content calculations. This rulemaking clarifies that organic content must be calculated from the weight of ingredients at formulation (*i.e.*, *before* processing such

as baking or cooking). This will ensure correct calculation of organic content so that labels on multi-ingredient organic products are accurately listed. This requirement also addresses an existing point of confusion and will increase the consistency of organic labeling claims in processed organic products. This policy is consistent with both an April 2013 NOSB recommendation⁵³ and NOP 5037 Draft Guidance published by AMS in December 2016.⁵⁴

Calculating Percentage of Organic Ingredients

To calculate the percentage of organic ingredients in a multi-ingredient product, divide the weight or volume of the organic ingredients at formulation by the total weight or volume of the product at formulation. If water and salt are added as ingredients, these must be excluded from the calculation. If a multi-ingredient product contains only liquids, volume must be used for calculation. If a product contains both solid and liquid ingredients, weight must be used for calculation. Please see

Table 2, below, for an example of how to calculate the percentage organic content of a multi-ingredient product.

Liquid ingredients being reconstituted from concentrates should be calculated based on single-strength concentrations. The term “single-strength” is defined by the Food and Drug Administration (21 CFR 101) as equivalent to the Brix value of 100 percent juice. Brix is a measurement referring to the percent, by mass, of soluble solids (generally sugar) in a solution. Brix is a useful reference in identifying single-strength identities of juices (see 21 CFR 101.30(h)(1)) as the mass of sugar and other soluble solids is not affected by the concentration process (*i.e.*, the same mass of sugar will be present in 1 liter of apple juice measured at 11.5 Brix, as is present in 0.5 liters of concentrated apple juice measured at 23 Brix). Reconstitution is taking a concentrated juice product and adding water to dilute the concentrated juice back to single-strength values. Using the previous example, if a producer starts with 0.5 liters of concentrated apple juice, they could

add water to increase the total volume to 1 liter, bringing the juice back to the original Brix value of 11.5. Allowing for reconstituting concentrated juice gives producers flexibility in shipping, storage, and use of juice products in organic production.

For products that have ingredients composed of multiple ingredients (also referred to as “multi-ingredient ingredients”), the exact organic content should be obtained of that multi-ingredient ingredient when calculating the total organic content of the final organic product. In this case, the calculation should identify the organic and nonorganic parts of the multi-ingredient ingredient and supporting documentation should be available for the certifying agent to review. Alternatively, these ingredients should be calculated as contributing either 95% organic content or 70% organic content depending on how the product is classified (*i.e.*, either “organic” or “made with organic (specified ingredients or food groups)” respectively).

TABLE 2—CALCULATING PERCENT ORGANIC OF A SOY BEVERAGE

Ingredient	Weight of ingredient at formulation (lbs.)	% Organic content of ingredient	% In formulation	Actual organic %
Organic Soy Base	1,100	100	16.42	16.4200
Organic Cane Sugar	5,288	100	78.94	78.9400
Organic Vanilla Extract	60	95	0.89	0.8455
Vitamins	50	0	0.74	0.0000
Calcium Phosphate	100	0	1.49	0.0000
Carrageenan	100	0	1.49	0.0000
Added Water	10,000			
Added Salt	5			
Total weight (excluding added salt and water)	6,698			
Total % Organic				96.2055

Summary of Changes to the Final Rule

AMS replaced the parenthetical statements “(excluding water and salt)” with the single statement “Water and salt added as ingredients at formulation are excluded from the calculation.” This more clearly states NOP’s intent and will result in more consistent calculation of organic content across the industry.

Summary of Public Comment

In general, almost all public comments supported AMS’s clarification that percent organic

content must be calculated based on weights/volumes at formulation. However, many comments noted that the proposed text could be interpreted to mean that salt and water must be excluded from each ingredient during calculation. Commenters explained this would be difficult and unnecessary to calculate the amount of water and salt in some ingredients and asked that AMS revise § 205.302(a) to state that only water and salt added as ingredients should be excluded from calculation. However, several comments also asked AMS to clarify that water and salt added to individual ingredients (*e.g.*, broth or

tea) should be excluded from calculation.

Responses to Public Comment

(*Comment*) Many comments noted that the proposed text could be interpreted to mean that salt and water must be excluded from individual ingredients during calculation. Commenters explained this would be difficult and unnecessary to calculate the amount of water and salt in some ingredients, and asked that AMS revise § 205.302(a) to state that only water and salt added as ingredients should be excluded from calculation.

⁵³ NOSB Recommendation, Calculating Percentage Organic in Multi-Ingredient Products, April 11, 2013: <https://www.ams.usda.gov/sites/>

[default/files/media/NOP%20ACC%20Final%20Rec%20Calculating%20Percentage.pdf](https://www.ams.usda.gov/sites/default/files/media/NOP%20ACC%20Final%20Rec%20Calculating%20Percentage.pdf).

⁵⁴ The draft guidance and comments can be viewed at <https://www.regulations.gov/>

[document?D=AMS-NOP-16-0085-0001](https://www.ams.usda.gov/sites/default/files/media/NOP5037DraftGuidancePercentCalculations.pdf) and in the NOP Program Handbook: <https://www.ams.usda.gov/sites/default/files/media/NOP5037DraftGuidancePercentCalculations.pdf>.

(Response) AMS has replaced the parenthetical statements “(excluding water and salt)” with the single statement “Water and salt added as ingredients at formulation are excluded from the calculation.” This clearly states that only water and salt added as ingredients are excluded from calculation.

(Comment) Several comments asked NOP to clarify how to calculate percentage organic content when ingredients are composed of more than one ingredient (a “multi-ingredient ingredient”).

(Response) The exact organic content of a multi-ingredient ingredient should be used when calculating the total

organic content of the final organic product.

P. Supply Chain Traceability and Organic Fraud Prevention

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.2	Terms defined.
205.103	Definitions for <i>Organic fraud</i> and <i>Supply chain traceability</i> .
205.201	Recordkeeping by certified operations. Paragraphs (b)(2), and (3).
205.501	Organic production and handling system plan. Paragraph (a)(3).
205.504	General requirements for accreditation. Paragraphs (a)(10), (13), and (21).
205.504	Evidence of expertise and ability. Paragraphs (b)(4) and (7).

Traceability and fraud prevention are essential in complex organic supply chains. Because protecting and verifying organic integrity is a responsibility shared by many participants in the organic industry, this rulemaking requires certified operations and certifying agents to incorporate supply chain traceability and organic fraud prevention into their practices. These actions will strengthen organic integrity and reinforce trust in the USDA organic label.

- Certified organic operations must:
- Maintain records of their activities that span the time of purchase or acquisition, through production, to sale or transport;
 - Maintain records that trace back to the last certified operations in their supply chain;
 - Maintain audit trail documentation to facilitate supply chain traceability, including identification of agricultural products as organic on audit trail documents; and
 - Describe in their organic system plan the monitoring practices and procedures used to prevent organic fraud and verify suppliers and organic product status.

- Certifying agents must:
- Conduct risk-based supply chain traceability audits of products they certify to verify compliance;
 - Maintain procedures for identifying high-risk operations and agricultural products, conducting risk-based supply chain audits, and reporting credible evidence of organic fraud to the USDA; and
 - Share information with other certifying agents to conduct investigations, conduct supply chain traceability audits, and verify compliance of organic products.

These requirements may affect certified organic operations, certifying agents, and operations applying for organic certification. Organic stakeholders should carefully examine the regulatory text and policy discussion below.

Background

Because organic products are credence goods, the organic system relies upon on trust between entities in organic supply chains.⁵⁵ Therefore, traceability and verification of organic products are essential to the function of a healthy organic market. This is especially true of modern organic supply chains, which have grown longer and more complex. Organic products and ingredients are often handled by dozens of operations, including uncertified entities, on their way to the consumer. A robust system of traceability and fraud prevention can help reduce the risks of complex supply chains and minimize fraud.

The length and complexity of modern supply chains present many risks to organic integrity. Activities that can compromise organic integrity and void the use of the USDA organic label include physical risks such as contact with substances prohibited in organic production (e.g., pesticides, fumigants, or cleaning agents) and mixing or commingling of organic and nonorganic products. Integrity can also be compromised if a nonorganic product is mistakenly labeled or identified as organic, or if poor recordkeeping cannot demonstrate that a product was produced on a certified farm and

handled according to the organic regulations. Additionally, fraud can occur through falsification of records and labeling to claim that a nonorganic product is certified organic. Breach of integrity can occur at any point in a supply chain, from production to final sale. In addition, the prevalence in organic supply chains of uncertified operations, who do not have direct *USDA* or *certifying agent oversight*, increases the chance that loss of integrity may occur and/or go unreported.

Organic products therefore require additional care to verify organic status and ensure that products bought and sold are genuinely organic and have not been compromised. Because full visibility across an entire supply chain is difficult, this rule focuses on using critical information at control points where risk is highest to verify chain of custody and confirm organic integrity. This is primarily done by building a record of product transaction and movement that demonstrates proper handling and maintenance of integrity. Without a verified transaction record, operations (and by extension, consumers) don’t have a full picture of a product’s history, and breaches of integrity can go unnoticed, allowing compromised product to continue along a supply chain to the consumer.

The current USDA organic regulations require general recordkeeping and verification of organic integrity, but the requirements are not specific and lack key types of information and practices that are necessary to prove the integrity of products from long, complex supply chains. This lack of recordkeeping information often leads to incomplete audit trails, and operations and

⁵⁵ A credence good is something with value or qualities that cannot be easily determined by the consumer before, or even after, purchase.

certifying agents are often unable to verify product origin or organic integrity. The specific recordkeeping, auditing, and fraud prevention procedures in this rule will augment existing practice to ensure more complete visibility into organic supply chains. This visibility will allow operations and certifying agents to complete more rigorous verification of organic products and identify and stop loss of organic integrity before it moves further into organic supply chains.

All successful systems of traceability include three common elements: (1) traceability within a single operation; (2) traceability one step forward and one step back from an operation in a supply chain; and (3) bidirectional traceability along a supply chain by a third party. This rulemaking supports traceability by clarifying who is responsible for each element: certified organic operations are responsible for traceability within their operation, back to their suppliers, and forward to their customers; certifying agents are responsible for verifying and tracing products along a supply chain and assessing a certified operation's system of traceability.

Fraud is also a significant risk to organic integrity; this rulemaking therefore focuses effort on its prevention. To clarify what this means, § 205.2 of the organic regulations includes a definition of *organic fraud*: deceptive representation, sale, or labeling of nonorganic products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” This broad definition helps clarify portions of this rulemaking's policy (e.g., §§ 205.201(a)(3) and 205.504(b)(7)), but is not intended to be used as a mechanism or criterion for enforcement.

Certified Operations

Recordkeeping

Section 205.103 of the organic regulations describes the recordkeeping responsibilities of certified operations. Records are used by operations, certifying agents, the USDA, and others to verify the compliance of organic operations and products. Clear and auditable records also support traceability. This rulemaking clarifies recordkeeping requirements to support the traceability of organic products both within and between operations.

General Recordkeeping Requirements

Section 205.103(b)(2) specifies that a certified operation's records must describe all activities and transactions of the operation. This includes physical and financial possession, production,

handling, title, and contractual oversight responsibilities of the organic products and ingredients the operation produces or handles. Such records must span the time of purchase or acquisition, through production, to sale or transport. This requirement supports “internal” traceability, or the ability to track the movement, handling, and organic status of products within a single operation. These records are needed to verify the compliance of an organic operation and its products, and supports on-site inspections by providing information for mass-balance audits and traceability verification by certifying agents (see § 205.403(d)(4)–(5)).

Section 205.103(b)(2) also requires that an operation's records must be sufficient to trace products back through a supply chain to the last certified operation. Keeping “external” records back to the last certified operation is needed to verify the source of organic products. Note that records must reach back to the last *certified* operation. Operations receiving organic products from uncertified suppliers (e.g., an exempt wholesaler) must keep records demonstrating how the uncertified operation maintained organic product integrity. This may require keeping records from several uncertified operations in sequence; in all cases the records must show an audit trail back to the last certified operation. Operations can demonstrate an audit trail by using various types of documentation that are typically used during sale, purchase, and transfer, such as receipts, invoices, shipping or receiving manifests, shipping logs, bills of lading, or transaction certificates. The organic industry creates and transfers this documentation (almost always electronically) in the usual course of business, and sales contracts often list this documentation as a condition of the sale. Typically, handling entities along a supply chain (such as a transporter, broker, or storage facility) will send electronic documentation directly to the buyer either before or at receipt of a product. A buyer may also obtain additional documents or records directly from the certified operation that sold the product.

Maintaining records back to the last certified operation will support supplier verification and fraud prevention plans (§ 205.201(a)(3)). Such records will also ensure certifying agents have the information they need to verify the compliance of products during on-site inspections (§ 205.403(d)(5)) and during supply chain traceability audits (§ 205.501(a)(21)).

Section 205.103(b)(2) describes a certified operation's minimum recordkeeping requirements. Certified operations may need to keep additional records beyond the scope of § 205.103(b)(2) to comply with other portions of the organic regulations and the Act. For example, to comply with § 205.236, Origin of livestock, livestock operations must maintain records demonstrating that animals were organically managed from the last third of gestation, which may include place and date of birth. This may require records that trace purchased animals back to the operation where the animal was born to prove origin and organic management (i.e., the records must trace *beyond* the last certified operation to prove compliance).

Audit Trail Documentation

Certified operations must keep audit trail documentation for all organic products they produce or handle. Audit trail documents are records used to determine the source, transfer of ownership, and transportation of organic products (see definition of *audit trail* in § 205.2). For the purpose of audit trail documentation, the “source” of organic products is the certified operation that supplied the product to the operation. Examples of audit trail documentation may include but are not limited to receipts, invoices, shipping or receiving manifests, shipping logs, bills of lading, and transaction certificates. Audit trails must document the history of organic products back to the last certified operation (per § 205.103(b)(2)).

Audit trail documentation must identify organic products as “100% organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” as appropriate. Operations may use abbreviations or acronyms to identify products, provided that the abbreviations or acronyms are easily understood. Certified operations should consider describing use of any abbreviations or acronyms in their OSP; this will facilitate on-site inspections and record audits by certifying agents, and help ensure that records are “readily understood and audited” (§ 205.103(b)(2)).

Explicit identification of products as organic is required for audit trail records (i.e., “transaction” or “external” records). “Internal” records do not need to provide explicit organic identification (e.g., “100 percent organic”). However, all systems of records must be “in sufficient detail as to be readily understood and audited” to meet the requirements of § 205.103(b)(2). This means that operations must be able to identify products they produce or

handle as organic, even if records do not explicitly state “organic.” For example, an operation may use an inventory management system that uses lot codes, batch numbers, or other designation system that indicates organic status. Such designation systems must be clear and auditable to facilitate on-site inspection and verification of compliance.

Audit trail documentation that clearly identifies organic products will support an operation’s verification of suppliers and implementation of fraud prevention plans. They will also allow certifying agents to verify compliance of suppliers and products during on-site inspections (§ 205.403(d)(5)) and supply chain traceability audits (§ 205.501(a)(21)).

Fraud Prevention Plans

Section 205.201(a)(3) requires all certified operations to maintain and implement practices to verify the organic status of suppliers and products in their supply chain and to prevent organic fraud. Often called “fraud prevention plans,” these procedures and practices support early detection, prevention, and mitigation of fraud, and strengthen integrity across organic supply chains.

A fraud prevention plan must be included in an operation’s OSP. This allows certifying agents to assess the effectiveness of certified operations’ anti-fraud practices and compliance with the organic regulations. A fraud prevention plan must be appropriate to the activities, scope, and complexity of the operation, and should be sufficient to address the verification and anti-fraud needs of the particular operation. This means not all fraud prevention plans will be alike. For example, a producer who does not handle another operation’s organic products may develop a simple fraud prevention that verifies purchased inputs comply with organic regulation. In contrast, a processor that receives many organic ingredients from numerous suppliers should develop a fraud prevention plan that describes practices to detect, prevent, minimize, and mitigate organic fraud risks in lengthy supply chains.

Because fraud prevention plans must verify the organic status of suppliers and organic products, they should include a description of how an operation verifies organic status back to the last certified operation in the supply chain. This supports recordkeeping and audit trail requirements at § 205.103(b)(2) and (3) and allows certifying agents to verify compliance during on-site inspections and supply chain traceability audits.

As a best practice, a robust plan for supply chain oversight and organic fraud prevention may include:

- A map or inventory of the operation’s supply chain that identifies suppliers;
- Identification of critical control points in the supply chain where organic fraud or loss of organic status are most likely to occur;
- A vulnerability assessment to identify weaknesses in the operation’s practices and supply chain;
- Practices for verifying the organic status of any product they acquire and/or use;
- A process to verify suppliers and minimize supplier risk to organic integrity;
- Mitigation measures to correct vulnerabilities and minimize risks;
- Monitoring practices and verification tools to assess the effectiveness of mitigation measures; and
- A process for reporting suspected organic fraud to certifying agents and the NOP.

Certifying Agents

Supply Chain Traceability Audits

Traceability of organic products across multiple operations in a supply chain is an effective strategy to detect fraud, conduct investigations, and verify compliance of products and operations. Therefore, § 205.501(a)(21) of the organic regulations requires certifying agents to conduct risk-based supply chain traceability audits of products and operations they certify.

What is a supply chain traceability audit?

A supply chain traceability audit (SCT audit) is the process of identifying and tracking the movement, sale, custody, handling, and organic status of a product along a supply chain. The objective of a supply chain audit is to verify a product’s compliance with the organic regulations. SCT audits can be used to investigate evidence or suspicion of fraud, verify compliance of high-risk products, investigate patterns of activity, trace the source of products contaminated with prohibited substances, surveil high-risk supply chains, or for other compliance-related reasons.

Criteria and Procedures for Supply Chain Traceability Audits

Certifying agents must maintain criteria and procedures that describe the use of risk-based SCT audits. This must include (1) criteria used to identify high-risk operations and products for SCT audits, and (2) procedures used to

conduct SCT audits. SCT audits conducted by the certifying agent must be based on these criteria and procedures. To ensure that AMS is made aware of organic fraud when it is discovered, certifying agents must also maintain procedures to report credible evidence of fraud to the USDA. Copies of these procedures and criteria should be kept by the certifying agent to demonstrate its expertise and ability (§ 205.504(b)(7)); this allows AMS to review and evaluate use of SCT audits during regular accreditation audits.

SCT audits should be initiated by events or criteria chosen and described by the certifying agent. For example, SCT audits may be initiated to investigate evidence or suspicion of fraud, verify compliance of an organic product, investigate patterns of activity, trace the source of positive residue testing, surveil high-risk supply chains or products, or to address any other compliance-related risk, activity, or need identified by the certifying agent.

Use of Supply Chain Traceability Audits

The length, extent, and frequency of an SCT audit may vary and should be determined by the objective of the audit (*i.e.*, an SCT audit ends when its objective is achieved). SCT audits may trace back to the origin (production site) of a product, or until a noncompliance is verified or cleared. For example, if a certifying agent’s objective is to verify the production origin of an ingredient, the SCT audit should trace the ingredient through the entire supply chain to the farm or ranch where the ingredient was produced. In contrast, if an SCT audit is initiated to determine the source of a positive residue test, the SCT audit may conclude when the source of the contamination is identified (which may only be several “steps” back in the supply chain).

The number, frequency, type, and extent of SCT audits should be appropriate to the number, scope, and complexity of operations the certifying agent certifies.

Information Sharing

To facilitate supply chain traceability audits, investigations, and verification of organic status, AMS requires certifying agents share compliance- and enforcement-related information with each other. Per § 205.501(a)(10), certifying agents must maintain strict confidentiality with respect to its clients and not disclose business-related information to third parties that are not involved in the regulation or certification of operations, as required by the OFPA (7 U.S.C. 6515(f)).

Certifying agents must exchange information that is credibly needed to determine an operation's compliance with the USDA organic regulations, including assessment of applications for certification, noncompliance investigations, suspension/revocation of certification, supply chain traceability audits, verification of audit trail documentation, and verification of the organic status of products represented as organic (see § 205.501(a)(10)(ii) and (a)(13)).

Section 205.501(a)(10)(iii) requires that compliance-related proprietary business information exchanged between certifying agents must remain proprietary, and that all certifying agents involved in the exchange must preserve the confidentiality of the information during and after the exchange. Certifying agents must maintain copies of the procedures used to exchange information and maintain confidentiality of information (§ 205.504(b)(4)). These requirements will ensure confidentiality of information during compliance activities that span multiple certified operations and certifying agents, such as supply chain traceability audits and investigations.

Conclusion

The traceability and fraud prevention requirements discussed above are part of a holistic organic control system that enhances the oversight, enforcement, and integrity of organic products. Many other sections of this rule support and facilitate traceability and fraud prevention; stakeholders should read the following sections to better understand how to implement this rule's traceability and fraud prevention requirements:

- Section III. A: Applicability and Exemptions from Certification;
- Section III. B: Imports to the United States;
- Section III. C: Labeling of Nonretail Containers;
- Section III. D: On-Site Inspections;
- Section III. G: Paperwork Submissions to the Administrator; and
- Section III. H: Personnel Training and Qualifications.

Summary of Changes to the Final Rule

AMS made several changes to the proposed regulatory text when writing this final rule. Changes to the proposed rule are discussed below and are followed by responses to specific themes from public comment:

- AMS revised the definition of *organic fraud* to remove “intentional” and “for illicit economic gain.” “Intentional” is not needed because this

defined term is not used for enforcement; it is used to help explain the objective of this rulemaking and many of its provisions. AMS removed the phrase “for illicit economic gain” because not all fraud results in or is motivated by economic gain. The final defined term is more flexible than proposed and encompasses a broader range of potential fraud types.

- AMS added the new term *supply chain traceability audit*. A similar definition was used in the preamble of the proposed rule to help stakeholders understand the rule and its objectives. AMS added this new term to more formally clarify its purpose and objective, and to more clearly define the expectations of traceability audits by certifying agents (see § 205.501(a)(21)).

- AMS removed the requirement in § 205.103(b)(2) to identify specific labeling categories (e.g., “100% organic”) in records. Removing this requirement avoids the potential for additional recordkeeping burden that some comments noted the proposed rule could unintentionally create, and gives operations more flexibility in how they keep records.

- AMS specified the scope of recordkeeping in § 205.103(b)(2) to more clearly indicate the types of records that operations should keep, and what timeframe they should span. This presents clear expectations that support traceability and verification of organic products, but also puts clear boundaries on the scope of records to control burden and cost to operations.

- AMS added a requirement to identify organic status (e.g., “100 organic”) in audit trail documentation at § 205.103(b)(3) and added “or similar terms, as applicable.” The proposed rule had included this at (b)(2) as a general requirement for all records; the rulemaking only requires such identification on audit trail documentation (see *audit trail* at § 205.2). This change will avoid the potential for additional recordkeeping burden that some comments noted the proposed rule could unintentionally create, but still ensures that this critical information is available to trace organic products between operations and to verify integrity.

- AMS revised § 205.201(a)(3) to clarify that fraud prevention plans must be appropriate to an operation's activities, scope, and complexity. This change responds to public comments that were concerned about disproportionate burden (i.e., greater cost) on small operations, especially small producers. This change may allow operations with less complex activities and/or a more limited scope to write

and implement simpler fraud prevention plans.

- AMS removed “back to the source” in § 205.501(a)(21) because public comments indicated this phrase was unclear and that the length of supply chain traceability audits varies. The new term *supply chain traceability audit* states the objective of such an audit—to verify an organic product's compliance—and therefore serves to clarify that the length and extent of supply chain traceability audits will vary depending on the objective and findings of the process.

- In § 205.501(a)(15), AMS added references to § 205.504(b)(7) and § 205.501(a)(13). This more clearly specifies that certifying agents are to use their own criteria for identifying high-risk operations and conducting supply chain traceability audits, and that they are to share information with other certifying agents to conduct audits and verify compliance.

- AMS added the term *supply chain traceability audit* to § 205.504(b)(7) to more clearly state the need for and objectives of the risk criteria and procedures in this paragraph.

- AMS did not change § 205.501(a)(10), § 205.501(a)(13), or § 205.504(b)(4).

Summary of Public Comment

The majority of public comments supported AMS's proposed revisions to recordkeeping requirements for certified operations. Many comments noted that including a description of full organic status (e.g., “100 percent organic . . .”) on all records may be burdensome and suggested that AMS allow the use of abbreviations, acronyms, or shorthand when identifying organic ingredients. Other comments asked for additional clarity about the definition of *audit trail* and what types of documentation are needed to meet the requirements of § 205.103(b)(3). Finally, a few comments claimed that keeping full organic identification on all records may be burdensome and asked that AMS not finalize this requirement in cases where inventory management systems can indicate organic status via lot codes or batch numbers.

Comments largely supported AMS's proposed use of fraud prevention plans by certified operations. However, many comments requested additional specificity about what should be included in fraud prevention plans. Other comments noted that fraud prevention plans may be difficult for very small businesses to write and implement and recommended AMS develop templates, examples, and

generic forms for small operations to use.

AMS received many comments about the proposed definition of *organic fraud*. Some comments requested that AMS remove “illicit” and from the definition, arguing that fraud may not always constitute illegal activity. Others suggested removing “intentional,” citing the difficulty of proving intent. Several comments also suggested AMS harmonize the proposed definition with existing definitions from other organizations such as GFSI, the EU, ISO, and FDA.

Public comment generally supported the proposed use of supply chain traceability audits. Many comments asked AMS to clarify the requirements of and extent of supply chain traceability audits, particularly how far back an audit should trace a product. Others suggested adding a definition of supply chain audit or traceability. Opinions varied widely on the number of supply chain traceability audits to be conducted, with many comments suggesting a minimum percentage of operations or a risk-based selection. Many comments also discussed the administrative impacts of supply chain traceability audits: a few comments claimed some certifying agents may not have the capacity of expertise to conduct audits; others highlighted challenges with information sharing and coordination among certifying agents. A few comments expressed a desire for AMS to coordinate supply chain traceability audits.

Finally, some comments suggested alternatives to AMS’s proposed traceability and fraud prevention strategy, including trusted trader programs, increased surveillance by AMS, and exemptions for businesses that already participate in other traceability programs.

Responses to Public Comment

Definition of Organic Fraud

(Comment) Comments asked AMS to use “willful” instead of “intentional” in the definition of *organic fraud*.

(Response) The rulemaking does not use “willful” or “intentional” in the final definition. This allows for a more flexible definition that encompasses a broader range of potential fraud types. “Willful” and “intentional” are not needed because *organic fraud* is not used for enforcement; it is used to help explain the objective of this final rule and many of its provisions.

(Comment) Comments asked AMS to remove “for illicit economic gain,” claiming that not all fraud is illicit or economic in nature. Comments also

asked AMS to harmonize the definition of *organic fraud* with terms used by other standards organizations such as ISO, GFSI, FDA, and the EU.

(Response) Many of the organizations mentioned in public comment focus on “economic gain” as a key factor in defining fraud. The final rule does not include the phrase “for illicit economic gain” because not all fraud results in or is motivated by economic gain. This definition is more flexible and encompasses a broader range of potential fraud types than terms used by other standards organizations.

Recordkeeping

(Comment) Comments requested that the regulatory text explicitly allow use of abbreviations for indicating organic status on records.

(Response) AMS amended § 205.103(b)(3) to allow use of similar terms such as acronyms or abbreviations for identifying organic status on audit trail documentation. Abbreviations or acronyms should be easily understood to meet the requirement that all records “be readily understood and audited” (§ 205.103(b)(2)).

(Comment) Comments are concerned that the requirement to identify organic products as such on all records will add an unnecessary recordkeeping burden that duplicates existing recordkeeping or inventory management systems.

(Response) The requirement to identify products as “100% organic,” “organic,” or “made with organic (specified ingredients or food group(s))” has been revised to apply only to audit trail documentation. Other records should also indicate organic status to meet the requirement that all records “be readily understood and audited” (§ 205.103(b)(2)). However, operations may use a system of recordkeeping or inventory management system that uses lot codes, batch numbers, or other designation system that indicates organic status, as long as such designations are clear and auditable.

(Comment) Commenters requested clarity on the use of “internal” vs. “external” records for purposes of supply chain traceability.

(Response) The requirements of § 205.103(b)(2) applies to broadly all records maintained by an operation, including both “external” and “internal” records. Section 205.103(b)(3) applies only to audit trail documentation, *i.e.*, “external” or “transaction” records.

Fraud Prevention Plans

(Comment) Comments asked AMS for more detail about the scope of fraud

prevention plans and what elements should be included in them.

(Response) The preamble of this rulemaking describes best practices that operations may use to develop and implement fraud prevention plans. The final regulatory text does not include specific practices or requirements; this provides maximum flexibility for operations and certifying agents to determine what is appropriate for individual operations. A fraud prevention plan must describe the operation’s monitoring practices and procedures they use to verify suppliers, verify products received, and prevent organic fraud. The plan must be appropriately tailored to the activities, scope, and complexity of the operation.

(Comment) Comments stated that the fraud prevention plan requirement would cause a disproportionate burden (*i.e.*, greater cost) on small operations, especially small producers.

(Response) The final rule regulatory text and the preamble explain that an operation’s fraud prevention plan must be appropriate to the operation’s complexity, scope, and activities. This may allow operations with less complex activities and/or a more limited scope to write and implement simpler fraud prevention plans.

Supply Chain Traceability Audits

(Comment) Comments requested greater clarity about the proposed rule’s use of the terms traceback, mass-balance, and supply chain audits.

(Response) Verification of traceability back to the last certified operation and mass-balance audits are routine practice during on-site inspection of certified operations. Section 205.403(d)(4)–(5) describe the use of these mechanisms. In contrast, supply chain traceability audits are triggered by criteria defined by the certifying agent. A supply chain traceability audit generally encompasses at least a portion of a supply chain and is conducted to verify the compliance of a product with the organic regulations and the Act.

“Traceback” is a term commonly used in the organic industry. However, this term was used inconsistently in public comment and there was no clear preference for how to define it. Therefore, AMS has avoided using this term in the final rule. AMS defines and uses the term *supply chain traceability audit* to describe certain activities, and the regulatory text clarifies the extent of other traceability requirements (*e.g.*, § 205.103(b)(2)) requires that an operation’s records must be traceable back to the last certified operation).

(Comment) Comments asked AMS for clarification about the phrase “back to

the source” in the proposed rule’s revision to § 205.501(a)(21).

(Response) This phrase is not used in the SOE final rule. The length and extent of supply chain traceability audits will vary depending on the objective and findings of the process. Some supply chain traceability audits may extend back to the site of production, while others may only go a few steps back in a supply chain; the audit ends when its objective (e.g., verification of compliance) is achieved.

(Comment) Many comments discussed the administrative impacts of

supply chain traceability audits: a few comments claimed some certifying agents may not have the capacity or expertise to conduct audits; others highlighted challenges with information sharing and coordination among certifying agents.

(Response) Supply chain audits are an important tool for oversight in the organic market. AMS has added flexibility for certifying agents to define the conditions for when supply chain audits are necessary. Further, there are other requirements in this rule that will

support supply chain audits: certification of additional handlers in supply chains, mandatory NOP Import Certificates, identifying organic products on audit trail documentation, and information sharing among certifying agents.

Q. Technical Corrections

The table below includes the regulatory text related to this section of the rule. A discussion of the policy follows.

Section	Final regulatory text
205.301	Product composition. Paragraphs (f)(2) and (3).
205.400	General requirements for certification. Paragraph (b).
205.401	Application for certification. Paragraph (a).

AMS has revised § 205.301 to correct a technical error in the description of the prohibition of ionizing radiation and sewage sludge. A previous technical correction (80 FR 6429) contained an error in the language used to describe the prohibition on ionizing radiation and sewage sludge. The terms “produced” and “processed” were erroneously used to describe the use of ionizing radiation and sewage sludge, respectively, in the current regulatory text. This action corrects the language at paragraphs (f)(2) and (f)(3) to clarify that all products labeled as “100% organic” or “organic” and all ingredients identified as organic in the ingredient statement of any product must not be processed using ionizing radiation or produced using sewage sludge.

AMS also revised §§ 205.400(b) and 205.401(a) to correct the references to organic system plans (§ 205.201), which was incorrectly cited in the previous organic regulation.

R. Additional Amendments Considered But Not Included in This Rule

The Strengthening Organic Enforcement proposed rule asked the public for feedback on two additional subjects: packaged product labeling and expiration of certification. AMS did not propose amending the portions of the USDA organic regulations that relate to these subjects. The specific questions asked in the proposed rule were meant to elicit feedback from stakeholders about the two topics for possible future consideration. AMS has summarized the public comment received below.

Summary of Public Comments: Packaged Product Labeling

Processed and/or packaged food products are often manufactured or packaged by one business and labeled for sale/distribution by another business. This type of relationship, sometimes called contract manufacturing and private labeling, is common in both the organic and nonorganic markets. This rulemaking does not change how such products are labeled for retail sale. However, in the proposed rule AMS asked for public comment on private-labeled product labeling, prompting feedback about preferred terminology and which businesses should be listed on labels.

Overall, there was no consensus among comments about issues of organic private-labeled products, including who should be certified, what terminology to use, and which operations and certifying agents should be listed on labels. Because private label and brand/contract relationships are on a contract-by-contract basis to protect proprietary information, some comments argued that creating a single set of rules to govern these relationships may change how private labels operate in the future. The comments received reflect this, and include a variety of opinions based on a commenter’s position in the organic supply chain. Responses from public comments are summarized below along with background information to provide context and help explain comments.

Preferred Terminology To Describe Private Label Products and Parties

Throughout the supply chain there are many steps where brand companies can leverage contracted companies to produce items for sale under the brand. After raw material sourcing, there are opportunities for a company to contract out steps such as manufacturing, packaging, and distribution.

Because of the variable use and function of contracted organizations in organic production, it is important to use common terminology to refer to organic operations and their certifying agents. Many comments requested consistent regulatory terminology to categorize these operations in relation to the organic supply chain, but there was no clear preference for certain terminology. Terms and relationships between contract food producers and brand owners are highly variable in the organic industry, but comments highlighted opportunities to align with commonly used and understood terminology. Comments suggested terms that could be consistently used to prevent confusion about which companies should appear on product labels, including contract manufacturer or “co-man,” contract packer or “co-packer,” external distributors, Private label entities/owners, and brand owners.”

Listing Contract Manufacturers on Labels

The SOE proposed rule asked the public if private label products or brands that use contract manufacturers should list those manufacturers on the product label. The majority of

comments supported optionally listing contract manufacturers. Those who did not agree with this opinion requested that products should list the brand name and the contract manufacturer. Currently, it is mandatory for some product categories such as meat, poultry, and dairy to have an Establishment Number that can trace back to the facility where it was processed. For other products that are not currently mandated to provide this information, identity of the contract manufacturer is often considered proprietary information, and in some instances, there could be multiple contract manufacturers operating at the direction of one brand owner.

Commenters were concerned that listing contract manufacturers would result in a loss of competitiveness; mandatory listings would expose proprietary information and undercut the success of these relationships. For brand owners that use several contracted companies, their products would need multiple versions of labels and traceability would become more complex. Comments also questioned the purpose of listing contract manufacturers on labels, some arguing that it would not improve organic integrity or traceability, especially because certifying agents are already listed on products. Some comments discussed that certifying agent information is enough to trace the product back to the manufacturer, making the listing of contract manufacturers unnecessary.

Listing Certified Operations on Private-Label Packaged Products

The organic regulations currently require listing a certified operation on branded products. The proposed rule asked commenters which certified operations should be added to the packaging of private label products, in the interest of furthering traceability. Many comments recommend the brand owner/distributor and their certifying agent be listed on retail labels, with some comments stating no preference. Some commenters stated listing the brand owner would require companies to impose traceability standards on the contract companies they use.

Some individuals recommend listing the last certified operation in the supply chain, to improve clarity and traceability, while others contradict this point by discussing the confidentiality concerns of listing the contract manufacturer. Commenters noted that distributors may be the best certified operation to list because they are often the last step in the organic handling process and can trace a product back

through manufacturing and sourcing. Conversely, others noted that not all companies handle distribution internally (choosing instead to use a contracted company).

Other comments claim that listing co-packers on labels is not necessary if brand owners are certified; however, some comments indicated it is unclear if brand owners need to be certified. Finally, a few comments recommended AMS assess the labeling requirements' alignment with the FDA.

Listing Certifying Agents on Private-Label Packaged Products

Multiple certifying agents are typically involved in the production and processing of organic products (from raw materials to material refining, manufacturing, and distribution); each assures that an individual process or step meets the organic standard. In the case of brand companies with contract manufacturers, comments did not clearly agree on which certifying agent (that of the brand company or that of the contract manufacturer) to list on the product label. Many individuals supported listing the certifying agent of the brand owner/distributor, but the brand owner may not be certified. For example, some comments pointed out that retailers are often the brand owners/distributors of organic products, but they are often exempt from organic certification. In this case, some commenters recommended listing the contract manufacturer's certifying agent.

Others recommended listing the certifying agent that certified that last handling operation in the supply chain, arguing that this would aid traceability. However, due to the variety of different manufacturing/branding relationships, this could be either the certifying agent of the brand owner or the manufacturer.

Matching the Certifying Agent to the Listed Operation

Organic product labels currently must include both a certifying agent and an operation. Commenters generally agreed that if a specific operation is listed (*i.e.*, contract manufacturer), that the certifying agent on the label should match. Comments explained that matching the two organizations would make it easier to contact a responsible party or file a complaint. Commenters on the proposed rule also agree that a label that lists the brand name next to the contract manufacturer's certifying agent would be confusing. However, given that some brand owners may not be certified, commenters noted this mismatch may already be happening in the marketplace.

Summary of Public Comments: Expiration of Certification

Under current USDA regulation, organic certification continues until surrendered, revoked, or suspended (§ 205.404(c)). Certified operations must undergo an annual recertification process (§ 205.406), but certification does not expire after one year. While developing the SOE proposed rule, AMS considered, but did not propose, adding a mechanism where certification would expire if an operation did not complete the annual recertification process timely.

The proposed rule included specific questions about expiration of certification and asked the public to comment on the subject. At this time, AMS has chosen not to pursue a policy of expiration of certification. The following is a summary of public comments received in response to the questions AMS asked the public in the SOE proposed rule.

Potential Improvements to Organic Integrity

The SOE proposed rule asked the public how annual expiration of certification could improve organic integrity. Some comments suggested that expiration could be an incentive for operations to punctually renew. Some comments adverted that it may help address the common incident of adverse action circumstances by encouraging operations to update their (organic system plan) OSP and pay fees on time. Commenters expressed if operations understood the annual expiration date, operations with unresolved noncompliances would risk losing certification via expiration. Those who did not agree indicated that current regulation specifies that operations are certified unless suspended or revoked. The annual expiration would disrupt this current system of recertification.

Limitations of Expiration of Certification

The proposed rule requested the public to comment on what the limitations of requiring expiration of certification may be. Commenters forecast potential negative effects such as marketplace disruption, communication burdens and administrative burdens. Commentators mentioned that expiration may negatively impact the status of inventory of operations who allowed their certification to expire. One remark stated that the requirement could place additional administrative burden on the certifying agent: expiration of certification would result in the

certifying agent having to update systems, train staff, educate operations on the policy change, and frequently remind operations of the upcoming expiration date.

Minimum Requirement for Renewing Certification

The SOE proposed rule asked for comments on what the minimum requirement for renewing certification should be. Many commenters recommended the following process: submit required paperwork, pay annual fee, and confirm interest in renewing. It was also recommended that on-site inspection should not be a requirement for recertification.

Operations With Adverse Actions

The proposed rule asked the public if an operation with adverse actions that are in the appeals process could renew certification. Comments expressed contrasting views on this matter, some finding that operations should be able to renew, and some communicating that those operations should not have the flexibility to renew their certification. Some comments pointed out that the appeal process for a proposed suspension is lengthy, and that not allowing an operation with pending adverse actions to renew certification would promptly remove them from the system and prevent potentially noncompliant product from entering the market. Some individuals stated that depending on the severity of the pending adverse action, AMS should administer a system that would not block an operation from renewing its certification due to minor non-compliances. Others asked that if an operation has a record of failing to address certain adverse actions, then the system should prevent them from renewing their certification.

Grace Period for Renewing Certification

The SOE proposed rule asked commenters if a grace period would be appropriate for operations that failed to renew by the expiration date. Commenters were also asked what the length of the grace period should be. Overall, comments proffered a 30- or 90-day grace period or mentioned that the current system already has a grace period built into the timeline. Some individuals suggested that a grace

period would improve assurance among farmers.

Process of Regaining Certification

The SOE proposed rule asked the public to express their opinion on what process should exist for an operation to regain organic certification should they allow it to expire. Many individuals communicated that the process of regaining an expired certification should be different than regaining a suspended/revoked certification. They stated the process should also be dependent on the presence and severity of adverse actions and there should be leniency within the duration. Some commentators proposed that operations with expired certification should apply as a new applicant, unless applying within the grace period. However, a commenter identified a potential loophole in tracking pending adverse actions of operations with expired certification; they recommended a system that would keep a record of operations with any pending adverse actions.

Notification of Upcoming Expiration of Certification

The SOE proposed rule asked the public if certified agents should notify certified operations of their upcoming expiration of certification. Commenters clarified that notifying certified operations is currently a widespread practice. Moreover, a commenter suggested that notification should be sent from the Organic Integrity Database, which may normalize the process.

IV. Regulatory Analyses

A. Summary of Economic Analyses

Executive Orders 12866 and 13563 control regulatory review.⁵⁶ Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives, and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential

⁵⁶ Executive Order 12866, Regulatory Planning and Review, September 30, 1993: <https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf>.

Executive Order 13563, Improving Regulation and Regulatory Review: <https://www.federalregister.gov/documents/2011/01/21/2011-1385/improving-regulation-and-regulatory-review>.

economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The Regulatory Flexibility Act (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.

This rulemaking amends amending several portions of the USDA organic regulations (7 CFR part 205) to strengthen oversight and enforcement of the production, handling, sale, and marketing of organic agricultural products in the United States. The amendments address gaps in the organic standards to deter organic fraud and create a level playing field for farms and businesses. This reinforces the value of the organic label by assuring consumers and stakeholders that organic products meet a robust and consistent standard.

The revised organic standards in this rule affect: certifying agents; certified operations (farms, processors, and handlers); and certain operations that are currently excluded or exempt from organic certification (e.g., certain brokers, traders, importers, exporters).

The following discussion summarizes the economic analysis AMS performed to estimate the impacts of this rule. A complete economic analysis of this rulemaking is available at <https://www.regulations.gov/>. You can access the economic analysis by searching for document number AMS–NOP–17–0065.

B. Regulatory Impact Analysis

The costs of this rule are primarily due to new or additional reporting and recordkeeping (paperwork) activities. In addition, there is cost for some currently excluded and exempt operations to become certified to handle organic products. AMS estimated the benefits of this rule by quantifying the organic fraud that will be prevented by implementation of the rule. The estimated benefits are expected to outweigh the estimated costs. Total estimated costs and benefits of the rule are summarized below.

COSTS AND BENEFITS OF RULEMAKING DISCOUNTED AT 3% AND 7%

Amendments	Average annual cost ^a		Total cost ^b	
	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate
Domestic Certifying Agents				
Imports to the United States	\$50,247	\$37,534	\$753,710	\$563,016
Certificates of Org. Operation & Cont. of Certification	22,742	21,892	341,130	328,377
Personnel Training & Qualifications	144,661	108,061	2,169,922	1,620,918
On-Site Inspections	96,402	72,012	1,446,031	1,080,176
Supply Chain Traceability & Organic Fraud Prevention	4,089	3,054	61,333	45,815
Mediation	139	134	2,091	2,013
Domestic Excluded Handlers				
Applicability and Exemptions	8,349,390	6,236,939	125,240,844	93,554,079
Imports to the United States	369,807	276,243	5,547,100	4,143,647
Domestic Certified Operations				
Labeling of Nonretail Containers	901,966	673,763	13,529,496	10,106,444
Supply Chain Traceability & Organic Fraud Prevention	609,066	454,968	9,135,993	6,824,526
Total Costs and Benefits, Discounted Over 15 Years				
Total Expected Domestic Costs	10,548,510	7,884,601	158,227,651	118,269,011
Total Expected Foreign ^c Costs	8,769,681	6,550,892	131,545,210	98,263,398
Total Expected Domestic & Foreign Costs	19,318,191	14,435,494	289,772,861	216,532,409
Total Expected Benefit of Rulemaking	32,944,811	24,272,099	494,172,179	364,081,491

^a These are the estimated annual averages of the 15-year Net Present Value domestic costs discounted at 3 and 7 percent.

^b These are the estimated total domestic costs for affected industry in Net Present Value of the stream of future costs, discounted at 3 and 7 percent.

^c AMS assumes all foreign costs will pass through to U.S. consumers and therefore includes these costs in the final rule. See the full Regulatory Impact Analysis for more detail.

Estimation of Benefits

AMS expects that this rule will reduce organic fraud in the U.S. market. Therefore, AMS quantified the estimated benefits of the rulemaking as the value of the projected reduction in organic fraud in the U.S. organic marketplace following implementation. AMS reviewed economic studies that identify and quantify fraudulent activity in retail food markets. AMS then used these estimates of fraud as a benchmark to quantify the benefits of the rulemaking.

Based on analysis of these food fraud studies, AMS estimated that 2 percent of organic products sold in the United States are currently subject to some form of fraud. This estimate aligns with rates of food fraud reported in multiple studies. Therefore, AMS estimated the total value of organic fraud in the United States as 2 percent of the total annual organic premiums for domestic organic production and organic imports, or approximately \$109 million annually. AMS chose to use organic premiums (the cost difference between organic and nonorganic products) to estimate fraud because this more accurately measures the value lost to fraud than total sales value (i.e., a fraudulent organic product only loses the value of its organic

attributes, not its entire value as a food product).

AMS expects the changes from this rule will reduce the amount of organic fraud (estimated at \$109 million annually) by half (an estimated \$54 million). However, it is unclear what proportion of this \$54-million fraud reduction translates directly into social welfare loss. For example, some certified operations and other compliant entities in organic supply chains may unknowingly experience some economic gain from fraud elsewhere in the supply chain. Additionally, AMS cannot accurately predict how fraud reduction efforts would impact organic prices, and hence premiums. Given this uncertainty about the true value of social welfare loss, AMS reduced the estimated \$54 million fraud reduction by half for an estimated social welfare gain (benefit) of \$27 million in the first year following implementation of the rule. Estimated over a 15-year period, and accounting for projected future annual growth rates of the U.S. organic market, annual benefits from fraud reduction are estimated to reach \$57 million in year 2036. When discounted over the 15-year period, total economic benefits of the rulemaking range from \$364 to \$494 million. When averaged,

the economic benefits range from \$24.3 to \$32.9 million annually.

Estimation of Costs

The costs of this rule are driven primarily by new or additional reporting and recordkeeping (paperwork) activities. AMS estimated additional paperwork cost for each provision of the rule by identifying the affected population (e.g., number of producers affected by a change), estimating the time for each affected entity to comply with a new change, and assigning an appropriate labor category and wage rate. This accounting of new reporting and recordkeeping costs is discussed in more detail in the Paperwork Reduction Act section of this rulemaking.

This rule would also require some currently excluded and exempt operations to become certified to handle organic products. AMS predicts that these businesses fall within NAICS categories 425 (*Wholesale Electronic Markets and Agents and Brokers*) and 4244 (*Grocery and Related Product Merchant Wholesalers*). These categories are very broad and include mostly businesses that do not handle organic products. Therefore, AMS used participation rates in the organic sector to estimate that 1,985 domestic businesses would need to become

certified organic. Using historic knowledge of certification costs, AMS estimated that each of the affected 1,985 domestic businesses would spend \$2,000 to become certified organic.

AMS also estimated the cost of this rule to foreign entities, including both paperwork and recordkeeping burden and costs for certain businesses to obtain certification. AMS assumes that all foreign costs will be passed along to U.S. consumers. This may create some tendency to overstate U.S.-borne costs, as competitive pressures will lead some compliance costs to be absorbed by businesses and other entities as the cost of doing business.

Alternatives

AMS also considered three alternatives when developing this rulemaking.

1. *Make no change to the organic regulations.* This option would not implement this rulemaking and leave the organic regulation as-is. AMS did not select this option because it does not address organic fraud or other issues affecting organic integrity. AMS considers this a costly alternative because it forgoes the fraud reduction benefits of the rulemaking. Regulatory inaction would create social costs that increase over time. AMS believes the rulemaking will mitigate social welfare losses by approximately half through the use of practical, risk-based oversight and enforcement.

2. *Require NOP Import Certificates for individual imported shipments of organic product.* The rulemaking will allow NOP Import Certificates to be issued for multiple shipments over a time span to be determined at the discretion of each certifying agent. In contrast, this alternative would require the use of NOP Import Certificates for each physical shipment of organic products imported into the United States. AMS found this alternative to be inferior to the rulemaking because it would create greater cost with limited additional benefit. AMS believes that the rulemaking's option to issue NOP Import Certificates on a periodic basis is the most practical, effective, and cost-sensitive means to address fraudulent imported organic products.

3. *Require less-stringent data reporting and training requirements for certifying agents.* AMS also considered a less-stringent alternative to the rulemaking to assesses if this could lower costs while maintaining the effectiveness of the rulemaking. Relative to the rulemaking, this alternative would (1) omit the requirement for certifying agents to issue standardized certificates of organic operation

generated in the USDA Organic Integrity Database; and (2) reduce the annual training hours that must be completed by organic inspectors and certification review personnel. AMS chose not to pursue this alternative because it would weaken other critical, interdependent amendments in the rulemaking. AMS predicts any cost reduction of this alternative would be accompanied by a significant reduction in effectiveness of the rulemaking.

Regulatory Flexibility Act

AMS also performed additional analysis to determine the rule's impact to domestic small businesses. This analysis revealed that small businesses producing, selling, handling, and marketing organic products would not be adversely affected by the amendments in this rule. AMS expects that most of the entities affected by this rule are small businesses as defined by Small Business Administration criteria. For each category of affected entity (certifying agents, certified operations, and exempt or excluded operations that need to become certified), AMS estimates that the costs of the rule for each business type will be less than one percent of the annual revenue.

A full economic analysis of this rulemaking is available at <https://www.regulations.gov/>. You can access this rule and the economic analysis by searching for document number AMS-NOP-17-0065.

C. 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 rule cannot be applied retroactively. States and local jurisdictions are preempted under the 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 USDA to be accredited as a certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under sections 6503 through 6507 of the OFPA 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.

Pursuant to section 6507(b)(2) of the OFPA, a state organic certification program that has been approved by the Secretary may 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 under certain circumstances. Such additional requirements must (a) further the purposes of the OFPA, (b) not be inconsistent with the 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 section 6519(c)(6) of the OFPA, this rulemaking 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. 301–399), nor the authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136–136(y)).

OFPA at 7 U.S.C. 6520 provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

D. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA), AMS is requesting OMB approval for a new information collection totaling 368,321 hours for the reporting and recordkeeping requirements contained in this rulemaking. OMB previously approved information collection requirements associated with NOP and assigned OMB control number 0581–0191. AMS intends to merge this new information collection (0581–0321), upon OMB approval, into the approved 0581–0191 collection. Below, AMS has described and estimated the annual burden (*i.e.*, the amount of time and cost of labor), for entities to prepare and maintain information to participate in this voluntary labeling program. The Organic Foods Production Act of 1990

(OFPA) provides authority for this action.⁵⁷

Title: National Organic Program.
OMB Control Number: 0581–0321.

Expiration Date of Approval: 3 years from OMB date of approval.

Type of Request: New collection.

Abstract: Information collection and recordkeeping are necessary to implement reporting and recordkeeping necessitated by amendments to §§ 205.2, 205.100, 205.101, 205.103, 205.201, 205.273, 205.300–205.302, 205.310, 205.307, 205.310, 205.400, 205.403–205.404, 205.406, 205.500–501, 205.504, 205.511, 205.660–205.663, 205.665, 205.680, and 205.681 of the USDA organic regulations. The rulemaking will protect organic product integrity and build consumer and industry trust in the USDA organic label by strengthening organic control systems, improving organic import oversight, clarifying organic certification standards, and enhancing farm to market traceability.

This rulemaking amends several sections of the USDA organic regulations, 7 CFR part 205, to strengthen the NOP's ability to oversee and enforce the production, handling, marketing, and sale of organic agricultural products as established by the OFPA. The rule will improve organic integrity throughout the organic supply chain and benefit stakeholders at all levels of the organic industry. The amendments will close gaps in the current regulations to build consistent certification practices, deter organic fraud, and improve transparency and product traceability. NOP identified the need for many of the amendments as part of its direct experience in administering this program, particularly via complaint investigation and audits of certifying agents. Other amendments are based on changes to the OFPA included in the Agriculture Improvement Act of 2018;⁵⁸ the recommendations of a 2017 Office of Inspector General audit;⁵⁹ the

recommendations of the National Organic Standards Board (a federal advisory committee to NOP); and industry stakeholder feedback.

This rulemaking strengthens enforcement with amendments to the USDA organic regulations and modifies the reporting and recordkeeping burdens as summarized below.

1. Reduces the types of uncertified handling operations in the organic supply chain that operate without USDA oversight.⁶⁰ The amendments require certification of operations that facilitate the sale or trade of organic products, including but not limited to certain brokers, importers, and traders. These handlers must obtain organic certification and develop an organic system plan (OSP) to describe the practices and procedures used in their operations. Certifying agents customize the format of the OSP to cover standards applicable to operations seeking certification. Because traders and brokers do not farm or manufacture organic products, the OSPs for traders and brokers will address fewer sections of the organic regulations than OSPs for operations that farm or manufacture organic products. Therefore, uncertified traders and brokers will take 40 hours in the first year after the rule going into effect to prepare an initial OSP. In subsequent years, AMS estimates each of these entities will incur a recordkeeping burden of 10 hours annually, and a reporting burden of 20 hours annually, to update their OSP (§§ 205.2, 205.100, 205.101, and 205.103).

Burden is increased in the rulemaking due to refinements in NAICS code 425 and the addition of operations from NAICS code 4244 in response to public comment. The 2018 Farm Bill mandates that NOP reduce the number of operations excluded from certification at § 205.101. AMS's revised estimate indicates 1,985 formerly excluded domestic operations now require organic certification. This includes 855 operations in NAICS code 425 (*Wholesale Electronic Markets and Agents and Brokers*) and 1,130 operations in NAICS code 4244 (*Grocery and Related Product Merchant Wholesalers*). See the accompanying Regulatory Impact Analysis (RIA) for more information. AMS assumes the 1,985 domestic excluded operations represent 59 percent of the global total of excluded handlers (using a benchmark 59 percent to 41 percent ratio of domestic to foreign operations). Therefore, AMS estimates there are an

additional 1,379 foreign formerly excluded operations, for a total of 3,364 new handlers that will need organic certification.

2. Requires all currently certified organic operations and new applicants to describe their procedures for monitoring, verifying, and demonstrating the organic status of their suppliers and products received to prevent organic fraud. Operations will include this information as a supplemental part of the OSP; therefore, AMS allocates the time to develop these procedures separately from the initial 40 hours to develop an OSP. AMS estimates that each currently certified operation and applicant seeking certification will need 30 minutes to describe the supply chain verification procedures and monitoring practices required by this regulation (§§ 205.103 and 205.201). Burden is increased in the rulemaking due to industry growth.

3. Mandates the use of NOP Import Certificates. Each shipment of organic products imported into the United States must be declared as organic to U.S. Customs and Border Protection (CBP) and associated with a valid NOP Import Certificate (currently form NOP 2110–1).⁶¹ The NOP Import Certificate contains specific information about the quantity and source of a shipment of imported organic products. NOP Import Certificates are currently used for organic products imported from countries with which NOP has trade arrangements. This rulemaking will expand and make compulsory the use of NOP Import Certificates, regardless of an imported product's country of origin.

In response to public comments, the final rule allows NOP Import Certificates to be issued for a given time period (e.g., quarterly) rather than with every shipment as proposed. AMS estimates that NOP Import Certificates will be issued quarterly, as this will reduce costs and limit disruption to the speed of imports. Additionally, the estimated number of annual shipments has increased from 67,023 in 2017 to 80,109 in 2020 due to industry growth.⁶² Therefore, AMS estimates 3,856 exporters will request from their certifying agents an annual total of 15,424 NOP Import Certificates,

⁶¹ Office of Management and Budget (OMB) approved form NOP 2110–1 NOP Import Certificate. <https://www.ams.usda.gov/resources/nop-2110-1>.

⁶² Data source: USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS). Select: Partners, World Total, Product Type, Imports—General, Products: All Aggregates; Product Groups: Organic—Selected: <https://apps.fas.usda.gov/gats/default.aspx>.

⁵⁷ The Organic Foods Production Act of 1990, 7 U.S.C. 6501–6524, is the statute from which the Agricultural Marketing Service derives authority to administer the NOP, and authority to amend the regulations as described in this rulemaking. This document is available at: <https://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter94&edition=prelim>.

⁵⁸ The Agriculture Improvement Act of 2018 (Public Law No: 115–334), commonly known as the “2018 Farm Bill,” is available at <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>. Organic certification is discussed in Title X, Section 10104.

⁵⁹ The National Organic Program International Trade Arrangements and Agreements Audit Report 01601–0001–21, September 2017: <https://www.usda.gov/sites/default/files/01601-0001-21.pdf>.

⁶⁰ Mandated by the Agriculture Improvement Act of 2018. See section 10104(a).

covering 80,109 annual shipments.⁶³ AMS estimates each exporter and certifying agent will spend an average of 30 minutes to request and approve each NOP Import Certificate. This estimate accounts for some learning within the first year, as well as the option to issue a single NOP Import Certificate for multiple shipments over a specific timeframe and amount or volume. Additionally, AMS estimates that importers and their certifying agents will need an average of one tenth (0.1) of an hour, or 6 minutes, to compare the shipping manifest of each shipment with its respective NOP Import Certificate to verify the accuracy and organic compliance of each shipment.

Further, certifying agents must have and implement a documented organic control system for intaking and approving or rejecting the validity of an NOP Import Certificate request, and importers must have and implement a documented organic control system to verify that shipments of organic products are accompanied by accurate NOP Import Certificate data and have not had contact with prohibited substances or ionizing radiation (§§ 205.273 and 205.300).

4. Clarifies nonretail containers used to ship or store organic products must display organic identification and information that links the container to audit trail documentation. This will help maintain the integrity of organic products by reducing misidentification and mishandling, facilitating traceability through the supply chain, reducing organic fraud, and allowing accurate identification of organic product by customs officials and transportation agents.

The rulemaking reduces burden because the revised regulation requires less information on nonretail container labels and provides exceptions for certain types of containers in response to public comment. AMS estimates that 35,698 producers and/or processors will need one tenth (0.1) of an hour, or 6 minutes, to add the required information to the labels that are displayed on the nonretail containers of an estimated 275,596 annual shipments (§ 205.307).⁶⁴

⁶³ NOP International Division reports that 3,303 organic exporters are certified by foreign (non-USDA) certifiers. Plus, the Organic Integrity Database shows that 553 foreign-based handlers are certified by USDA-accredited certifying agents. The total number of NOP Import Certificates assumes each exporter is issued NOP Import Certificates quarterly (four annually).

⁶⁴ 29,929 (existing and new domestic operations and traders) certified operations will be modifying how they label 195,387 nonretail shipments and 5,769 (existing, new, and domestic operations and traders) certified operations will be modifying how

5. Codifies current practices for the certification of producer group operations (groups of producers organized and certified as a single operation).⁶⁵ The rulemaking describes the criteria to qualify as a producer group, how producer group operations must comply with the USDA organic regulations, and how certifying agents should inspect these operations. It also sets a risk-based benchmark to determine how many producer group members in an operation need to be inspected by certifying agents annually.

In response to public comment, AMS expects that these requirements will add 11,800 hours of one-time paperwork burden for 5,900 producer group operations⁶⁶ to prepare a detailed Internal Control System for their OSP, including procedures to address conflicts of interest and manage the unique challenges of producer group oversight. In addition, AMS estimates 5 hours to prepare and deliver training, outreach and technical assistance to ICS personnel and producer group members, leading to a total annual burden of 29,500 hours of burden annually (§§ 205.201, 205.400(g) and 205.403).

6. Clarifies how certified operations may submit annual updates to their OSP. This includes the option to only submit practices or procedures that have changed since their last approved OSP, rather than submitting an OSP in its entirety. This will reduce unnecessary paperwork without compromising oversight because operations will continue to maintain an OSP that accurately reflects current practices and procedures of the operation. This codifies current policy and does not modify the paperwork burden (§ 205.406).

7. Requires certifying agents to issue standardized certificates of organic operation generated from the USDA's publicly available Organic Integrity Database (OID).⁶⁷ This will require an initial upload of mandatory data for each operation and maintenance to ensure that data in OID are current and accurate. Currently, all certifying agents have voluntarily uploaded data and maintain an estimated 50% or more data

they label 80,109 nonretail shipments exported to the US.

⁶⁵ NOP Policy Memo 11–10. Grower Group Certification, October 31, 2011: <https://www.ams.usda.gov/sites/default/files/media/NOP-11-10-GroupGrowerCert.pdf>.

⁶⁶ Meinshausen F., Richter, T., Blockeel, J., and Huber, B., Group Certification: Internal Control Systems in Organic Agriculture: Significance, Opportunities and Challenges, Research Institute of Organic Agriculture FiBL, March 2019.

⁶⁷ Organic Integrity Database: <https://organic.ams.usda.gov/integrity>. Accessed September 2021.

on all certified operations per the recommendations found in the NOP's Data Quality Best Practices.⁶⁸

These amendments will require a new, one-time burden of reporting hours for certifying agents to upload existing data pertaining to currently certified operations into OID for the first time. It is estimated that uploading these data into OID will require 30 minutes for each operation and will be performed by administrative support personnel who have a lower wage rate than review and compliance staff. The rulemaking's burden increases slightly due to industry growth.

These amendments will simultaneously eliminate the requirement to physically mail the Administrator or State organic program paper copies of: (1) the list of operations certified annually; (2) notifications of proposed adverse actions, approvals, or denials of corrective actions; and (3) notifications of executions of adverse actions regarding certified operations or operations applying for certification (§§ 205.405 and 205.501). AMS is not modifying the estimate of paperwork burden associated with these changes in requirements because any change will be very small, and these activities and tasks are still occurring electronically as a part of maintaining the data on all operations over time.

8. Requires certifying agents to develop procedures to: (1) identify high-risk operations and agricultural products; (2) conduct supply chain traceability audits, (3) share information with other certifying agents to verify supply chains and conduct investigations, and (4) report credible evidence of organic fraud to the USDA. Due to the complexity of these procedures, AMS estimates each certifying agent will spend two hours documenting these procedures (§§ 205.501 and 205.504) rather than one hour as proposed. The rulemaking's burden increases due to an increase in time for preparing procedures despite a net loss of certifying agents since 2017 (the net value reflects that while some certifiers have been suspended or have surrendered, others have been newly accredited).

9. Requires certifying agents to submit their decision criteria for acceptance of mediation, and a process for identifying personnel to conduct mediation and set up mediation sessions with its administrative policies and procedures required by § 205.504(b). AMS estimates each certifying agent will spend one

⁶⁸ Data Quality Best Practices: <https://www.ams.usda.gov/sites/default/files/media/INTEGRITY%20Data%20Quality.pdf>.

hour documenting these procedures, which they are already implementing. The rulemaking's burden changes due to the net loss of 3 certifying agents since 2017.

10. Requires certifying agents to establish procedures to conduct inspector field evaluations ("witness inspections"), demonstrate that they are sufficiently staffed with qualified personnel, and demonstrate that all inspectors, certification reviewers, and in-field evaluators meet knowledge, skills, and experience qualifications. AMS estimates that each certifying agent will spend 60 minutes to draft policies and procedures for conducting inspector field evaluations. Further, certifying agents must observe an inspector performing an on-site inspection at least once every three years (or annually for inspectors with fewer than three years of experience).

The rulemaking's burden is reduced due to narrowed training requirements and the net loss of 3 certifying agents since 2017. AMS estimates each certifying agent will conduct an average of two field evaluations of an inspector and certification review personnel per year, rather than four as proposed, and that this activity will require 7.5 hours per evaluation (§§ 205.2 and 205.501).

11. Requires some additional training of new inspectors and certification review personnel. Inspectors and certification review personnel play a crucial role in determining whether an operation is granted organic certification initially and whether certified operations comply with the USDA organic regulations. Certification review personnel may also serve as inspectors. Through insight gained during regular audits of certifying agents, AMS estimates that inspectors and certification review staff currently receive at least 10 hours of training per year from certifying agents on topics related to the USDA organic regulations.

In response to public comment, 40 hours of additional training is required for inspectors and certification review personnel with less than one year of experience.⁶⁹ Based on an estimated separation rate of 14 percent,⁷⁰ AMS

estimates that certifying agents will annually hire 35 new certification review staff and hire or contract with 35 inspectors with less than one year of experience to replace the certification review staff and inspectors that exit the labor pool. Training offered by NOP through its online Organic Integrity Learning Center (OILC) and training provided by the certifying agents or other providers may qualify towards the minimum annual training requirements (§§ 205.2 and 205.501).

12. Requires that certifying agents conduct unannounced inspections of at least 5 percent of the operations they certify, which is the current recommended practice in NOP Instruction 2609.⁷¹ For the purposes of estimating paperwork impacts, AMS expects that half of the unannounced inspections (2.5% of total inspections) will meet the requirement for a full annual inspection and will not impact current paperwork burden. The remaining half of the unannounced inspections (2.5% of total inspections) will be limited in scope and target high-risk operations and will not count as a full annual inspection. Examples of targeted, limited-scope unannounced inspections include but are not limited to verifying livestock on pasture or performing targeted mass-balance or traceability audits. AMS estimates that the paperwork impacts associated with these unannounced inspections will average inspectors 5 hours per inspection; half of the estimated 10 hours for a full annual inspection (§ 205.403).

13. Clarifies the process for accepting foreign conformity assessment systems that oversee organic certification in foreign countries.⁷² The OFPA (7 U.S.C. 6505(b)) and the USDA organic regulations provide the authority to establish organic equivalency. The revised regulations describe the criteria, scope, and other parameters for ongoing peer review audits of foreign organic conformity systems to determine whether the United States should continue, revise, or terminate such equivalence determinations. These peer review audits of equivalence determinations occur as needed and will result in new periodic paperwork impacts for foreign governments. The

rulemaking's burden is reduced because AMS estimates it will review one foreign government conformity assessment system per year. AMS estimates the reporting impacts for foreign governments when USDA reviews the applicable trade arrangement or agreement to be 60 hours. Since recordkeeping is ongoing requirement, recordkeeping is calculated as 10 hours per year per foreign government. These impacts are comparable to the estimated paperwork impacts for AMS audits of certifying agents (§ 205.511).

Respondents

AMS has identified four primary types of entities (respondents) that will need to submit and maintain information as a result of this rulemaking: certified organic operations; accredited certifying agents; organic inspectors; and foreign governments. Three respondent types—certified operations (producers and handlers), certifying agents, and inspectors—have been identified in a currently approved information collection (0581–0191). To implement a 2018 Farm Bill mandate, AMS is requiring certification of additional types of operations in the organic supply chain and regular audits of trade arrangements or agreements with foreign governments.⁷³ This adds new types of handlers as a subcategory of certified operations and foreign governments as a new type of respondent.

To more precisely understand the paperwork impacts of this rulemaking, AMS has divided the categories of respondents into domestic and foreign, as appropriate, to show the potential impacts on domestic-based versus foreign-based USDA-accredited certifying agents, inspectors, and certified operations, along with foreign-accredited certifying agents, and foreign governments serving as accrediting bodies. For each type of respondent, we describe the general paperwork submission and recordkeeping activities and estimate: (1) the number of respondents; (2) the hours they spend, annually, creating and storing records to meet the paperwork requirements of the organic labeling program; and (3) the costs of those activities based on prevailing domestic and foreign wages and benefits.

Certifying Agents

Certifying agents are State, private, or foreign entities accredited by the USDA,

⁶⁹Ten hours of training are accounted for in the 2020 Information Collections Renewal for NOP (AMS–NOP–19–0090; OMB Control Number: 0581–0191). Our internal on-site accreditation audit checklist used by our accreditation audit team includes a question on training. With the implementation of this rule, the specific hours of training offered by the 75 certifying agents will be documented.

⁷⁰The US Bureau of Labor and Statistics reports that the average separation rate (which captures both labor force exits and transfers in occupation) for agricultural inspectors is 14 percent. <https://www.bls.gov/news.release/jolts.t16.htm>.

⁷¹NOP 2609, Instruction, Unannounced Inspections. September 12, 2012. Available in the NOP Program Handbook: <https://www.ams.usda.gov/sites/default/files/media/2609.pdf>.

⁷²Currently, the United States has established organic trade arrangements with Canada, the European Union, the United Kingdom, Israel, Japan, New Zealand, South Korea, Taiwan, and Switzerland.

⁷³See Section 10104(a) of the Agriculture Improvement Act of 2018, Public Law No: 115–334, available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>.

or by accreditation bodies of foreign governments with which USDA has a trade arrangement or agreement. Certifying agents certify domestic and foreign producers and handlers as organic in accordance with the OFPA and the USDA organic regulations. Certifying agents determine whether a producer or handler meets the organic requirements, using detailed information from the operation about its specific practices and on-site inspection reports from organic inspectors.

Currently, there are 75 USDA-accredited certifying agents (down from 78 in 2017) 45 are based in the United States and 30 are headquartered in foreign countries. Both domestic- and foreign-based USDA-accredited certifying agents certify operations based in the United States and abroad. AMS assumes all currently accredited certifying agents evaluate all types of production and handling operations for compliance with the USDA organic regulations and will be subject to the reporting and recordkeeping burdens of this rulemaking. In addition, AMS assumes there are 30 foreign government-accredited foreign-based certifying agents that certify handlers in accordance with the USDA organic regulations and that will issue NOP Import Certificates for organic product shipments to the United States.⁷⁴

Certifying agents of operations that export to the United States must issue NOP Import Certificates for all shipments of organic products being exported. The USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS) showed 80,109 shipments of organic product coming into the United States in 2020 (up from 67,023 in 2017 due to

⁷⁴ An estimate based on the number of foreign-based USDA-accredited certifying agents.

industry growth).⁷⁵ In response to public comments, AMS estimates that NOP Import certificates will be issued seasonally (*e.g.*, quarterly) rather than with every shipment as proposed. AMS estimates that 3,856 foreign exporters will request from their certifying agents an annual total of 15,424 NOP Import Certificates, covering 80,109 annual shipments.⁷⁶ AMS estimates each exporter and certifying agent will spend 30 minutes to request and approve each NOP Import Certificate.

Thirty (30) USDA-accredited certifying agents based in foreign countries certify 92% of the foreign operations certified under USDA organic standards. Of the 45 domestic-based USDA accredited certifying agents, 15 certifying agents certify 8% of the foreign operations certified under USDA.⁷⁷ This means that 30 domestic-based USDA-accredited certifying agents only certify domestic-based operations that do not import foreign organic products or ingredients. AMS estimates there are 30 foreign-accredited certifying agents that certify foreign operations under trade arrangements.⁷⁸

AMS will review documents regarding imports during the

⁷⁵ Data source: USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS). Select: Partners, World Total, Product Type, Imports—General, Products: All Aggregates; Product Groups: Organic—Selected: <https://apps.fas.usda.gov/gats/default.aspx>.

⁷⁶ NOP International Division reports that 3,303 organic exporters are certified by foreign (non-USDA) certifiers. Plus, the Organic Integrity Database shows that 553 foreign-based handlers are certified by USDA-accredited certifying agents. The total number of NOP Import Certificates assumes each exporter is issued NOP Import Certificates quarterly (four annually).

⁷⁷ Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>.

⁷⁸ An estimate based on the number of foreign-based USDA-accredited certifying agents.

accreditation audits of USDA-accredited certifying agents. AMS estimates 30 minutes for the 3,856 exporters and their certifying agents to prepare and approve each of the 15,424 NOP Import Certificates and one tenth of an hour, or 6 minutes, for importers to verify and reconcile all 80,109 subsequent associated shipments exported to the United States.⁷⁶ USDA-accredited domestic-based certifying agents must work with their foreign-based operations to verify their associated shipments for 8%, or 6,409, of 80,109 annual shipments. USDA-accredited foreign-based certifying agents must work with their foreign-based operations to verify their associated shipments for 46%, or 36,850, of 80,109 annual shipments. Foreign-accredited certifying agents must work with their foreign-based operations to verify 46% of 80,109 annual shipments.

In addition, this rulemaking reduces the current paperwork burden of accredited certifying agents by eliminating the need to provide notices of approval or denial of certification to the Administrator following the issuance of a notice of noncompliance or adverse action to an applicant for certification. Also, the rulemaking removes the annual requirement for certifying agents to submit by January 2 an annual list of operations certified. Certifying agents will instead be required to update data in OID for each operation they certify. AMS is not modifying the estimate of paperwork burden with these changes in requirements because any change will be very small. These activities and tasks are still occurring electronically as a part of maintaining the data on all operations over time. Certifying agents must issue organic certificates generated in OID.

In addition, all USDA-accredited certifying agents must write detailed procedures to identify high-risk operations and products they certify and procedures to conduct supply-chain traceability audits. Certifying agents must write fraud prevention and reporting procedures, and mediation procedures per § 205.504(b). Certifying agents must write procedures to demonstrate how they are sufficiently staffed and that all persons who perform certification review activities and on-site inspections (inspectors) are qualified and complying with training requirements for their new certification review personnel. AMS estimates that 14 percent, or 35, new certification review staff with less than one year of experience must complete 40 hours of training in their first year in addition to the baseline training requirement of 10

hours annually already accounted for in the overall program ICR (0191).^{79 80}

This rulemaking increases the overall reporting and recordkeeping burden for certifying agents (See Summary Table 1: *Certifying Agents*). AMS estimates the annual collection cost per domestic-based USDA-accredited certifying agents will be \$13,511.⁸¹ This cost is based on an estimated 109.23 labor hours per certifying agent per year for staff with certification review responsibilities at \$47.97 per labor hour, including 31.7% benefits, for a total salary component of \$5,229 per year.⁸² The estimated cost for domestic certifying agents also includes 332.55 labor hours per certifying agent per year for administrative support staff to upload data about certified operations to OID at \$24.90 per labor hour, including

31.7% benefits, for a total salary component of \$8,282 per year.⁸³

In addition, AMS estimates the annual collection cost for all domestic-based USDA-accredited certifying agents will be \$608,001. This cost is based on a total of 4,915 hours for all staff with certification review responsibilities at \$47.87 per labor hour, including 31.7% benefits, for a total salary component of \$235,313 for all staff with certification review and procedure writing responsibilities of all domestic-based USDA-accredited certifying agents. The estimated cost for all domestic-based certifying agents also includes 14,965 hours total hours for administrative support staff uploading data about certified operations to OID at \$24.90 per labor hour, including 31.7% benefits for a total salary component of \$372,688.

SUMMARY TABLE 1—CERTIFYING AGENTS

Respondent categories	Number of respondents	Wages + benefits	Hours per respondent	Cost per respondent type	Total all hours	Total all costs
US Based USDA Certifying Agents	45	\$47.87	109.23	\$5,229.17	4,915.36	\$235,312.78
US Based USDA Certifying Agents—data entry	45	24.90	332.55	8,281.95	14,964.69	372,687.76
<i>Subtotal U.S.-Based USDA Certifying Agents</i>	45	441.78	13,511.12	19,880.05	608,000.54
Foreign-Based USDA Certifying Agents	30	34.40	653.80	22,493.03	19,614.07	674,791.04
Foreign-Based USDA Certifying Agents—data entry	30	17.90	346.64	6,203.93	10,399.19	186,118.00
<i>Subtotal Foreign-Based USDA Certifying Agents</i>	30	1,000.44	28,696.97	30,013.26	860,909.04
Total USDA Accredited Certifying Agents	75	42,208.09	49,893.31	1,468,909.58
Foreign (Non-USA) Accredited Certifying Agents	30	34.40	614.17	21,129.51	18,425.07	633,885.38
All Certifying Agents	105	68,318.38	2,102,794.96

For foreign-based USDA-accredited certifying agents, AMS estimates the annual cost per certifying agent will be \$28,697 per year. This cost is based on an estimated 653.80 labor hours for staff with certification review and procedure writing responsibilities at \$34.40 per labor hour, including 34.63% benefits, for a total salary component of \$22,493 per foreign-based USDA-accredited certifying agent per year. These estimated costs primarily pertain to the issuance and review of NOP Import Certificates. The estimated cost for

foreign-based USDA-accredited certifying agents also includes 346.64 labor hours per certifying agent per year for administrative support staff to upload data about certified operations to OID at \$17.90 per labor hour, including 34.63% benefits, for a total salary component of \$6,204 per year.^{84 85}

AMS estimates the annual collection cost for all foreign-based USDA accredited certifying agents will total \$860,909. This cost is based on a total of 19,614.07 hours for all staff with certification review responsibilities at

\$24.90 per labor hour, including 34.63% benefits, for a total salary component of \$674,791 for staff with certification review and procedure writing responsibilities of all foreign-based USDA-accredited certifying agents. The estimated cost for all foreign-based USDA-accredited certifying agents also includes 10,399.19 hours total hours for administrative support staff uploading data about certified operations to OID at \$17.90 per labor hour, including 34.63%

⁷⁹Ten hours of training are accounted for in the 2020 Information Collections Renewal for the NOP (AMS–NOP–19–0090; OMB Control Number: 0581–0191). Our internal onsite accreditation audit checklist used by our accreditation audit team includes a question on training. With the implementation of this rule, the specific hours of training offered by our 75 certifying agents will be documented.

⁸⁰The US Bureau of Labor and Statistics reports that the average separation rate (which captures both labor force exits and transfers in occupation) for agricultural inspectors is 14 percent. <https://www.bls.gov/news.release/jolts.t16.htm>.

⁸¹In this assessment, all domestic labor rates are sourced from the U.S. Bureau of Labor Statistics National Compensation Survey, Occupational

Employment and Wages, May 2020: https://www.bls.gov/oes/current/oes_nat.htm. Domestic benefits are based on a Bureau of Labor Statistics News Release on Employer Costs for Employee Compensation, which states that benefits account for 31.7% of total average employer compensation costs, December 17, 2020.

⁸²The labor rate for certification review staff is based on Occupational Employment Statistics group 13–1041, *Compliance Officers*. Compliance officers examine, evaluate, and investigate eligibility for or conformity with laws and regulations governing contract compliance of licenses and permits, and perform other compliance and enforcement inspection and analysis activities not classified elsewhere. Compliance Officers (*bls.gov*).

⁸³The labor rate for *administrative support staff* is based on Occupational Employment Statistics group 43–9199, *Office and Administrative Support Workers*, who support general office work and data entry functions. Office and Administrative Support Workers, All Other (*bls.gov*).

⁸⁴The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents, which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>.

⁸⁵Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

benefits, for a total salary component of \$186,118.^{86 87}

For foreign-accredited certifying agents (non-USDA accredited), AMS estimates the annual cost will be \$21,130 per certifying agent. This cost is based on an estimated 614.17 labor hours per year for staff to issue and review NOP Import Certificates, at \$34.40 per labor hour plus 34.63% benefits. The total for all foreign-accredited certifying agents is estimated to be \$633,885. The cost is based on an estimated 18,425 total hours for all staff involved in the issuance and review of NOP Import Certificates, at \$34.40 per labor hour plus 34.63% benefits.^{88 89}

The total cost for all certifying agents—including the 75 USDA-accredited certifying agents, domestic- and foreign-based, and the estimated 30 foreign-accredited (non-USDA) certifying agents who certify operations

that export products to the U.S.—is \$2,102,795. This cost is based on 68,318.38 total hours at their respective wage rates and benefits to comply with the rulemaking’s requirements.

Organic Inspectors

Inspectors conduct on-site inspections of certified operations and operations applying for certification and report the findings to the certifying agent. Inspectors may be independent contractors or employees of certifying agents. Certified operations must be inspected annually, and a certifying agent may call for additional inspections or unannounced inspections on an as-needed basis (§ 205.403(a)). Any individuals who apply to conduct inspections of operations will need to submit information documenting their qualifications to the certifying agent (§ 205.504(a)(3)).

Inspectors provide an inspection report to the certifying agent for each operation inspected (§ 205.403(e)) but are not expected to store the record. Currently, AMS estimates that inspectors spend 10 hours on average to complete an inspection report for a full annual inspection of an organic operation. The additional unannounced inspections required by this rulemaking are likely to be more limited in scope (such as pasture or dairy surveillance, or mass-balance and supply chain traceability audits). AMS projects, on average, that inspectors will spend 5 hours to complete an inspection report for an unannounced targeted-scope inspection. Organic inspectors do not have recordkeeping obligations; certifying agents maintain the records of inspection reports (see Summary Table 2: *Inspectors*).

SUMMARY TABLE 2—INSPECTORS

Respondent categories	Number of respondents	Wages + benefits	Hours per respondent	Cost per respondent type	Total all hours	Total all costs
USDA US based Inspectors	148	\$30.79	30.86	\$950.20	4,567.17	\$140,629.94
USDA Foreign based inspectors	102	22.13	31.12	688.53	3,173.80	70,229.73
All USDA Inspectors	250	7,740.97	210,859.67

According to the International Organic Inspectors Association (IOIA), there are approximately 250 inspectors currently inspecting crop, livestock, handling, and/or wild crop operations that are certified or have applied for certification. To comply with this rulemaking, AMS estimates that 14 percent, or 35, new inspectors with less than one year of experience must complete 40 hours of training in their first year in addition to the baseline training requirement of 10 hours annually already accounted for in the overall program ICR (0191).^{90 91}

AMS estimates that 148 inspectors are working for USDA-accredited certifying agents in the United States. For the

additional training of new inspectors, and for conducting unannounced targeted-scope inspections, AMS estimates the annual paperwork impact cost per domestic-based inspector is \$950.20. This is based on an estimated 30.86 labor hours per year at \$30.79 per labor hour, including 31.7% benefits. The total annual cost for all domestic-based inspectors is \$140,630. This cost is based on 4,567 total hours for all domestic based inspectors at \$30.79 per labor hour, including 31.7% benefits.⁹²

AMS estimates that 102 inspectors are working for USDA-accredited certifying agents in foreign countries. AMS estimates the annual paperwork impact cost per foreign-based inspector is

\$688.53. This estimate is based on an estimated 31.12 labor hours per year at \$22.13 per labor hour, including 34.63% benefits for the additional training of new inspectors and for conducting unannounced targeted-scope inspections. This rule does not impose additional recordkeeping costs for inspectors. The total annual cost for all foreign-based inspectors is \$70,230 at \$31.12 per labor hour, including 34.63% benefits. The total annual cost for all inspectors working for USDA-accredited certifying agents is \$210,860, at their respective wage rates and benefits.^{93 94}

⁸⁶ The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>.

⁸⁷ Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

⁸⁸ The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>.

⁸⁹ Benefits are based on a review of data from the Organisation for Economic Co-Operation and

Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

⁹⁰ Ten hours of training are accounted for in the 2020 Information Collections Renewal for the NOP (AMS-NOP-19-0090; OMB Control Number: 0581-0191). Our internal onsite accreditation audit checklist used by our accreditation audit team includes a question on training. With the implementation of this rule, the specific hours of training offered by our 75 certifying agents will be documented.

⁹¹ The US Bureau of Labor and Statistics reports that the average separation rate (which captures both labor force exits and transfers in occupation) for agricultural inspectors is 14 percent. <https://www.bls.gov/news.release/jolts.t16.htm>.

⁹² The labor rate for inspectors is based on Occupational Employment Statistics group 45–

2011, *Agricultural Inspectors*. Agricultural inspectors inspect agricultural commodities, processing equipment, facilities, and fish and logging operations to ensure compliance with regulations and laws governing health, quality, and safety.

⁹³ The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>.

⁹⁴ Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

Producers and Handlers

Domestic and foreign producers and handlers seeking organic certification must submit an OSP that details the practices and activities specific to their operation. Once certified, operations are required to update any changes in their operation or practices to their certifying agent at least annually.

Uncertified Handlers. This rulemaking requires that operations that facilitate the sale or trade of organic products—including, but not limited to, certain brokers, importers, and traders—obtain organic certification and submit and maintain an OSP. AMS estimates that 1,985 domestic ⁹⁵ and 1,379 foreign-

based ⁹⁶ operations will need to become certified as a result of the rule. Traders and brokers do not farm or manufacture organic products, so the OSPs for traders and brokers will address fewer sections of USDA organic regulations than OSPs for operations that produce or manufacture organic products. Certifying agents customize the format of the OSP to cover standards applicable to the operations seeking certification. Therefore, AMS estimates that preparation of an initial OSP will require 40 reporting hours, plus 10 hours of annual recordkeeping. The estimated annual reporting burden for each entity to update its OSP in future

years is 20 hours (See Summary Table 3a: *Uncertified Handlers*).

All operations that export organic products to the United States must request an NOP Import Certificate from their certifying agent. Further, operations that import organic products must verify and reconcile each shipment with its associated NOP Import Certificate and verify that organic integrity was maintained throughout the import process. In addition, domestic and foreign handlers that must obtain organic certification as a result of this rulemaking will also need to comply with the labeling requirements for nonretail containers.

SUMMARY TABLE 3a—UNCERTIFIED HANDLERS

Respondent categories	Number of respondents	Wages + benefits	Total hours per respondent	Total cost per respondent type	Total all hours	Total all costs
Formerly Excluded Handlers—Domestic	1,985	\$48.64	50.97	\$2,478.80	101,166.47	\$4,920,414.48
Formerly Excluded Handlers—Foreign	1,379	34.95	53.42	1,867.02	73,660.94	2,574,623.40
All Uncertified Handlers	3,364	174,827.41	7,495,037.88

AMS estimates the annual paperwork impact for each domestic handler to prepare their initial organic system plan, verify and reconcile imported shipments with their respective NOP Import Certificates, and verify that the organic integrity of the product was maintained through shipping is 2,478.80. This is based on an estimated 50.97 labor hours at \$48.64 per labor hour, including 31.7% benefits. The total cost to all previously uncertified domestic handlers is \$4,920,415. This cost is based on 101,166.47 total labor hours at \$48.64 per labor hour, including 31.7% benefits.⁹⁷

AMS estimates the annual paperwork impact for each foreign-based handler to prepare their initial organic system plan and to work with their certifying agent to prepare NOP Import Certificates for the products they export is \$1,867.02. This is based on an estimated 53.42 labor hours per year at \$34.95 per labor

hour, which includes 34.63% for benefits. The total cost to all previously uncertified foreign handlers is \$2,574,623.40. This cost is based on 73,660.94 total labor hours at \$34.95 per labor hour, which includes 34.63% for benefits. Total costs to the 3,364 previously uncertified handlers, domestic and foreign, is \$7,495,038, based on 174,827 total labor hours at their respective domestic and foreign wage rates and benefits. This cost is to prepare and keep initial OSPs and related records, and to prepare, verify, and reconcile NOP Import Certificates for compliance.^{98 99}

Certified Operations and New Applicants under Current Rules. There currently are 44,725 organic operations worldwide that are certified to the USDA organic standards. Over the next 12 months, AMS expects 2,639 operations will seek organic certification, based on the 5.9% rate of

growth in number of operations observed in the last 12 months under current rules. Therefore, AMS estimates that 27,945 operations based in the United States, and 19,419 operations based in foreign countries, including the respective applicants for certification, will be impacted by this rulemaking.¹⁰⁰

All currently certified organic operations and projected new applicants must describe in their OSP their procedures for monitoring, verifying, and demonstrating the organic status of their suppliers and products received to prevent organic fraud. All certified organic operations must also comply with revised nonretail container labeling requirements and must maintain all records about their organic production and/or handling for five years (§ 205.103(b)(3)).

⁹⁵ Please refer to the “Applicability and Exemptions from Certification (§§ 205.100–101)” chapter in the Regulatory Impact Analysis (RIA) for an explanation of how previously excluded domestic handlers were estimated.

⁹⁶ AMS assumes the 1,985 domestic excluded operations represent 59% of the global total benchmarked 59%/41% ratio of domestic to foreign operations and certifying agents. Therefore, AMS estimate there are an additional 1,379 foreign

formerly excluded operations, for a total of 3,364 new handlers that will need organic certification.

⁹⁷ For uncertified handlers, AMS chose to use the same labor rate as certified producers and handlers: Occupational Employment Statistics group 11–9013, *Farmers, Ranchers, and Other Agricultural Managers*.

⁹⁸ The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of

U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD.agents>; <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>.

⁹⁹ Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

¹⁰⁰ Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>.

In addition, AMS estimates a one-time paperwork burden of 11,800 hours for 5,900 producer group operations to prepare a detailed Internal Control System (ICS) for their OSP, including

procedures to address conflicts of interest and manage the unique challenges of producer group oversight. In addition, training requirements for ICS personnel and producer group

members are expanded to 29,500 hours annually (§§ 205.201, 205.400(g) and 205.403).¹⁰¹

SUMMARY TABLE 3b—CERTIFIED ORGANIC OPERATIONS AND NEW APPLICANTS

Respondent categories	Number of respondents	Wages + benefits	Total hours/respondent	Total cost/respondent type	Total all hours	Total all costs
Certified Producers & Handlers—New and Existing Domestic	27,945	\$48.64	1.67	\$81.07	46,579.60	\$2,265,483.08
Certified Producers & Handlers—New and Existing Foreign	19,419	34.95	3.44	120.39	66,888.32	2,337,904.67
All New and Existing Producers & Handlers	47,364	113,467.92	4,603,388.08

AMS estimates that the average annual paperwork impact for domestic USDA-certified organic producers and handlers to develop fraud prevention procedures and to comply with nonretail container labeling requirements is \$81.07. This is based on an estimated 1.67 labor hours at \$48.64 per labor hour, including 31.7% benefits. The total cost for all domestic certified organic producers and handlers to comply with these new requirements is \$2,265,483.08. This cost is based on 46,579.60 labor hours at \$48.64 per labor hour, including 31.7% benefits.¹⁰²

AMS estimates the average annual paperwork impact for foreign-based USDA-certified organic producers and handlers to create fraud prevention procedures and to comply with nonretail container labeling requirements is \$120.39. This is based on an estimated 3.44 labor hours per year at \$34.95 per labor hour, including 34.63% benefits. The total cost for all foreign producers and handlers certified to the USDA organic standards is \$2,337,904.67. This cost is based on 66,888.32 labor hours year at \$34.95 per labor hour, including 34.63% benefits. The total cost for the 47,364 current and projected certified organic producers and handlers, domestic and foreign, is \$4,603,388. This cost is based on 113,467.92 labor hours at their respective domestic and foreign wages and benefits.^{103 104}

Foreign Governments

The U.S. government, including the USDA and the U.S. Trade

Representative, work closely together to implement processes that determine the equivalence of foreign organic certification programs and then negotiate an arrangement or agreement as appropriate.¹⁰⁵ Formerly, the organic regulations only addressed this authority in general terms under § 205.500(c) but did not describe the criteria, scope, and other parameters to establish, oversee, or terminate such arrangements or agreements. The rulemaking describes equivalence determinations in more detail; this creates a new type of PRA respondent category. The rulemaking allows an equivalence determination if the U.S. government determines that the technical requirements and conformity assessment system under which foreign products labeled as organic are produced and handled are at least equivalent to the requirements of the OFPA and the USDA organic regulations. The rulemaking requires periodic assessment.

AMS expects these periodic peer review assessments will be similar in depth and frequency to the audits of USDA-accredited certifying agents and estimates a comparable level of reporting and recordkeeping burden by foreign governments with which USDA has negotiated trade arrangements or agreements. AMS estimates the collection cost for the periodic review of a single foreign government is \$602. This cost is based on 7.5 reporting labor hours averaged as needed and an estimated 10 hours of annual recordkeeping per foreign government

per year at \$24.59 per labor hour, including 34.63% benefits, for a total salary component of \$602.06 per year reviewed. The total cost for foreign governments to be assessed for a trade arrangement or agreement is \$4,816. This cost is averaged as 140 total labor hours for all foreign governments at \$24.59 per labor hour, including 34.63% benefits.^{106 107}

Total (Domestic and Foreign) Information Collection Cost (Reporting and Recordkeeping) of Rulemaking: \$14,416,897 (Also, see Summary Table 4: All Reporting and Recordkeeping Hours and Costs, and All Domestic Reporting and Recordkeeping Hours and Costs).

Total All Reporting Burden Cost: \$12,454,097.

Estimate of Burden: Public reporting burden for the collection of information is estimated to average 0.56 hours per year per response.

Respondents: Certifying agents, certified operations, inspectors, and foreign governments.

Estimated Number of Reporting Respondents: 51,091.

Estimated Number of Reporting Responses: 566,387.

Estimated Total Annual Burden on Reporting Respondents: 318,859 hours.

Estimated Total Annual Reporting Responses per Reporting Respondents: 11.09 reporting responses per reporting respondents.

Total All Recordkeeping Burden Cost: \$1,962,800.

Estimate of Burden: Public recordkeeping burden is estimated to be

¹⁰¹ Meinshausen F., Richter, T., Blockeel, J., and Huber, B., *Group Certification: Internal Control Systems in Organic Agriculture: Significance, Opportunities and Challenges*, Research Institute of Organic Agriculture FiBL, March 2019.

¹⁰² The labor rate for producers and handlers is based on Occupational Employment Statistics group 11–9013, *Farmers, Ranchers, and Other Agricultural Managers*, who plan, direct, or coordinate the management or operation of farms, ranches, or other agricultural establishments.

¹⁰³ The source of the data is based on average World Bank wage rates for countries with USDA-

accredited certifying agents which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>.

¹⁰⁴ Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

¹⁰⁵ The United States currently has organic trade arrangements with Canada, the European Union, the United Kingdom, Israel, Japan, New Zealand, South Korea, Taiwan, and Switzerland.

¹⁰⁶ The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>.

¹⁰⁷ Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

an annual total of 0.90 hours per year per respondent.

Respondents: Certifying agents, certified operations, and foreign governments.

Estimated Number of Recordkeeping Respondents: 50,811.

Estimated Total Recordkeeping Burden on Respondents: 45,636 hours.

Estimated Total Recordkeeping Responses per Recordkeeping Respondents: 1 recordkeeping response per recordkeeping respondents.

Total Domestic Only Information Collection Cost (Reporting and Recordkeeping) of Rulemaking: \$7,934,528.

Total Domestic Only Reporting Burden Cost: \$6,627,301.

Estimate of Burden: Public domestic only reporting burden is estimated to be an annual total 0.43 hours per year per domestic respondent.

Respondents: Certifying agents, certified operations, and inspectors.

Estimated Number of Domestic Reporting Respondents: 30,123.

Estimated Number of Domestic Reporting Responses: 334,168.

Estimated Total Annual Reporting Burden on Domestic Respondents: 145,315 hours.

Estimated Total Domestic Reporting Responses per Reporting Respondents: 11.09 reporting response per reporting respondents.

Total Domestic Only Recordkeeping Burden Cost: \$1,307,227.

Estimate of Burden: Public domestic only recordkeeping burden is estimated to be an annual total of 1 hours per year per respondent.

Respondents: Certifying agents and certified operations.

Estimated Number of Domestic Recordkeeping Respondents: 29,975.

Estimated Total Annual Recordkeeping Burden on Domestic Respondents: 26,878 hours.

Estimated Number of Domestic Recordkeeping Responses: 29,929.

Estimated Total Domestic Recordkeeping Responses per Recordkeeping Respondents: 1 recordkeeping response per recordkeeping respondents.

SUMMARY TABLE 4—ALL HOURS AND COSTS, ALL DOMESTIC HOURS AND COSTS, AND ALL FOREIGN HOURS AND COSTS

	Hours	Costs	Number of respondents	Respondent types
Total for All (Reporting & Recordkeeping)	364,495	\$14,416,897	51,091	Certifying agents, certified operations, inspectors, and foreign governments.
All Reporting	318,859	12,454,097	51,091	Certifying agents, certified operations, inspectors, and foreign governments.
All Recordkeeping	45,636	1,962,800	50,811	Certifying agents, certified operations, and foreign governments.
Just Domestic—All (Reporting & Recordkeeping).	172,193	7,934,528	30,123	Certifying agents, certified operations, and inspectors.
Just Domestic Reporting	145,315	6,627,301	30,123	Certifying agents, certified operations, and inspectors.
Just Domestic Recordkeeping	26,878	1,307,227	29,975	Certifying agents and certified operations.
Just Foreign—All (Reporting & Recordkeeping).	192,301	6,482,369	20,968	Certifying agents, certified operations, inspectors, and foreign governments.
Just Foreign Reporting	173,543	5,826,795	20,968	Certifying agents, certified operations, inspectors, and foreign governments.
Just Foreign Recordkeeping	18,758	655,573	20,836	Certifying agents, certified operations, and foreign governments.

E. Executive Order 13175

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments, or proposed legislation. Additionally, other policy statements or actions that have substantial direct effects on one or more Indian Tribes, the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes also require consultation.

AMS hosted a virtual tribal listening session on April 9, 2020, to discuss the Strengthening Organic Enforcement proposed rule and upcoming public comment opportunity. AMS has not received comments from Tribes during the rulemaking process. AMS conducted an analysis of possible Tribal impacts and determined that any impact is most likely to be positive. AMS finds oversight protections and fraud deterrence actions that will have

positive benefits for organic producers extend to any Tribal organic producers. Further, the specific provisions related to grower groups may benefit small producers in a Tribe who wish to join together under a shared certification for market development purposes.

If a tribe requests consultation in the future, AMS will work with the Office of Tribal Relations to ensure meaningful consultation is provided. AMS also stands ready to provide technical assistance to Tribes and operators wishing to participate in the organic certification process.

F. Executive Order 13132

Executive Order 13132 mandates that federal agencies consider how their policymaking and regulatory activities impact the policymaking discretion of States and local officials and how well such efforts conform to the principles of federalism defined in said order. This executive order only pertains to regulations with clear federalism implications.

AMS has determined that this rulemaking conforms with the principles of federalism described in

E.O. 13132. The rule does not impose substantial direct costs or effects on States, does not alter the relationship between States and the federal government, and does not alter the distribution of powers and responsibilities among the various levels of government. States had the opportunity to comment on the proposed rule. No States provided public comment on the federalism implications of this rule. Therefore, AMS has concluded that this rulemaking does not have federalism implications.

G. Civil Rights Impact Analysis

AMS has reviewed this rulemaking in accordance with the Department Regulation 4300–4, Civil Rights Impact Analysis, to address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule’s intent and provisions, AMS determined that this rule will affect certifying agents and organic inspectors, handlers of organic products, and organic producers. AMS also determined that this rule has no

potential for affecting producers, handlers, certifying agents, or inspectors in protected groups differently than the general population of producers, handlers, certifying agents, or inspectors.

Protected individuals have the same opportunity to participate in NOP as non-protected individuals. The USDA organic regulations prohibit discrimination by certifying agents. Specifically, § 205.501(d) of the current regulations for accreditation of certifying agents provides that “No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.” Section 205.501(a)(2) requires “certifying agents to demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart” including the prohibition on discrimination. The granting of accreditation to certifying agents under § 205.506 requires the review of information submitted by the certifying agent and an on-site review of the certifying agent’s client operation. Further, if certification is denied, § 205.405(d) requires that the certifying agent notify the applicant of their right to file an appeal to the AMS Administrator in accordance with § 205.681.

These regulations provide protections against discrimination, thereby permitting all producers, regardless of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status, who voluntarily choose to adhere to the rule and qualify, to be certified as meeting NOP requirements by an accredited certifying agent. This action in no way changes any of these protections against discrimination.

H. Related Documents

Documents related to this rule include the Organic Foods Production Act of 1990, as amended, (7 U.S.C. 6501–6524) and its implementing regulations (7 CFR part 205). On August 5, 2020, AMS published the proposed rule (85 FR 47536) to notify the public of and request comments on the potential changes to the organic regulations discussed in this rulemaking.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agricultural Commodities, Agriculture, Animals, Archives and

records, Fees, Imports, Labeling, Livestock, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 205 as follows:

PART 205—NATIONAL ORGANIC PROGRAM

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

Authority: 7 U.S.C. 6501–6524.

- 2. Section 205.2 is amended by:
■ a. Adding in alphabetical order the terms “Adverse action”, “Certification activity”, “Certification office”, “Certification review”, and “Conformity assessment system”;
■ b. Revising the terms “Handle”, “Handler”, and “Handling operation”;
■ c. Adding in alphabetical order the terms “Internal control system”, “Organic exporter”, “Organic fraud”, “Organic importer”, “Organic Integrity Database”, “Producer group member”, “Producer group operation”, “Producer group production unit”, and “Retail establishment”;
■ d. Removing the terms “Retail food establishment”; and
■ e. Adding in alphabetical order the terms “Supply chain traceability audit”, “Technical requirements”, and “Unannounced inspection”.

The revisions and additions read as follows:

§ 205.2 Terms defined.

Adverse action. A noncompliance decision that adversely affects certification, accreditation, or a person subject to the Act, including a proposed suspension or revocation; a denial of certification, accreditation, or reinstatement; a cease and desist notice; or a civil penalty.

Certification activity. Any business conducted by a certifying agent, or by a person acting on behalf of a certifying agent, including but not limited to: certification management; administration; application review; inspection planning; inspections; sampling; inspection report review; material review; label review; records retention; compliance review; investigating complaints and taking adverse actions; certification decisions; and issuing transaction certificates.

Certification office. Any site or facility where certification activities are conducted, except for certification

activities that occur at certified operations or applicants for certification, such as inspections and sampling.

Certification review. The act of reviewing and evaluating a certified operation or applicant for certification and determining compliance or ability to comply with the USDA organic regulations. This does not include performing an inspection.

Conformity assessment system. All activities, including oversight, accreditation, compliance review, and enforcement, undertaken by a government to ensure that the applicable technical requirements for the production and handling of organic agricultural products are fully and consistently applied.

Handle. To sell, process, or package agricultural products, including but not limited to trading, facilitating sale or trade on behalf of a seller or oneself, importing to the United States, exporting for sale in the United States, combining, aggregating, culling, conditioning, treating, packing, containerizing, repackaging, labeling, storing, receiving, or loading.

Handler. Any person that handles agricultural products, except final retailers of agricultural products that do not process agricultural products.

Handling operation. Any operation that handles agricultural products, except final retailers of agricultural products that do not process agricultural products.

Internal control system. An internal quality management system that establishes and governs the review, monitoring, training, and inspection of the producer group operation, and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations.

Organic exporter. The final certified exporter of the organic agricultural product, who facilitates the trade of, consigns, or arranges for the transport/shipping of the organic agricultural product from a foreign country to the United States.

Organic fraud. Deceptive representation, sale, or labeling of nonorganic agricultural products or ingredients as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

Organic importer. The operation responsible for accepting imported organic agricultural products within the United States and ensuring NOP Import Certificate data are entered into the U.S. Customs and Border Protection import system of record.

Organic Integrity Database. The National Organic Program's electronic, web-based reporting tool for the submission of data, completion of certificates of organic operation, and other information, or the tool's successors.

* * * * *

Producer group member. An individual engaged in the activity of producing or harvesting agricultural products as a member of a producer group operation.

Producer group operation. A producer, organized as a person, consisting of producer group members and production units in geographic proximity governed by an internal control system under one organic system plan and certification.

Producer group production unit. A defined subgroup of producer group members in geographic proximity within a single producer group operation that use shared practices and resources to produce similar agricultural products.

* * * * *

Retail establishment. Restaurants, delicatessens, bakeries, grocery stores, or any retail business with a restaurant, delicatessen, bakery, salad bar, bulk food self-service station, or other eat-in, carry-out, mail-order, or delivery service of raw or processed agricultural products.

* * * * *

Supply chain traceability audit. The process of identifying and tracking the movement, sale, custody, handling, and organic status of an agricultural product along a supply chain to verify the agricultural product's compliance with this part.

* * * * *

Technical requirements. A system of relevant laws, regulations, regulatory practices, standards, policies, and procedures that address the certification, production, and handling of organic agricultural products.

* * * * *

Unannounced inspection. The act of examining and evaluating all or a portion of the production or handling activities of a certified operation without advance notice to determine compliance with the Act and the regulations in this part.

* * * * *

■ 3. Section 205.100 is amended by revising paragraph (a) and paragraph (c) introductory text to read as follows:

§ 205.100 What has to be certified.

(a) Except for the exempt operations described in § 205.101, each operation or portion of an operation that produces or handles agricultural products intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

* * * * *

(c) Any person or responsibly connected person that:

* * * * *

■ 4. Revise § 205.101 to read as follows:

§ 205.101 Exemptions from certification.

The following operations in paragraphs (a) through (h) of this section are exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part, the applicable labeling requirements of subpart D of this part, and any requirements described in paragraphs (a) through (i) of this section.

(a) A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually.

(b) A retail establishment that does not process organically produced agricultural products.

(c) A retail establishment that processes, at the point of final sale, agricultural products certified under this part as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

(d) A handling operation that only handles agricultural products that contain less than 70 percent organic ingredients (as described in § 205.301(d)) or that only identifies organic ingredients on the information panel.

(e) An operation that only receives, stores, and/or prepares for shipment, but does not otherwise handle, organic agricultural products that:

(1) Are enclosed in sealed, tamper-evident packages or containers prior to being received or acquired by the operation; and

(2) Remain in the same sealed, tamper-evident packages or containers

and are not otherwise handled while in the control of the operation.

(f) An operation that only buys, sells, receives, stores, and/or prepares for shipment, but does not otherwise handle, organic agricultural products already labeled for retail sale that:

(1) Are enclosed in sealed, tamper-evident packages or containers that are labeled for retail sale prior to being received or acquired by the operation; and

(2) Remain in the same sealed, tamper-evident packages or containers that are labeled for retail sale and are not otherwise handled while in the control of the operation.

(g) A Customs broker (per 19 CFR 111.1) that only conducts customs business but does not otherwise handle organic agricultural products.

(h) An operation that only arranges for the shipping, storing, transport, or movement of organic agricultural products but does not otherwise handle organic products.

(i) Recordkeeping by exempt operations.

(1) Exempt operations described in paragraphs (a) and (c) through (f) of this section must make available to representatives of the Secretary, upon request, records that:

(i) Demonstrate that agricultural products identified as organic were organically produced and handled; and

(ii) Verify quantities of organic agricultural products received and shipped or sold

(2) All records described in this section must be maintained for no less than 3 years beyond their creation, and the operations must allow representatives of the Secretary and the applicable State organic programs' governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

■ 5. Section 205.103 is amended by:

- a. Revising paragraph (b)(2);
- b. Redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5); and
- c. Adding new paragraph (b)(3).

The revision and addition read as follows:

§ 205.103 Recordkeeping by certified operations.

* * * * *

(b) * * *

(2) Fully disclose all activities and transactions of the certified operation, in sufficient detail as to be readily understood and audited; records must span the time of purchase or acquisition, through production, to sale

or transport and be traceable back to the last certified operation;

(3) Include audit trail documentation for agricultural products handled or produced by the certified operation and identify agricultural products on these records as "100% organic," "organic," or "made with organic (specified ingredients or food group(s))," or similar terms, as applicable;

* * * * *

- 6. Section 205.201 is amended by:
- a. Removing the words "or excluded" in paragraph (a) introductory text;
- b. Revising paragraph (a)(3); and
- c. Adding paragraph (c).

The revision and addition to read as follows:

§ 205.201 Organic production and handling system plan.

(a) * * *

(3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented. This must include a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status of agricultural products received, and to prevent organic fraud, as appropriate to the certified operation's activities, scope, and complexity;

* * * * *

(c) In addition to paragraph (a) of this section, a producer group operation's organic system plan must describe its internal control system. The description of the internal control system must:

- (1) Define the organizational structure, roles, and responsibilities of all personnel;
- (2) Identify producer group production units and locations;
- (3) Describe measures to protect against potential conflicts of interest and protect internal control system personnel from retribution;
- (4) Define geographic proximity criteria for producer group members and producer group production units;
- (5) Describe procedures for accepting new members into the producer group operation, including initial inspection and compliance determination;
- (6) Describe characteristics of high-risk producer group members and producer group production units;
- (7) Describe how shared resources, including production practices and inputs, are procured and provided to all producer group members and personnel;
- (8) Describe how training, education, and technical assistance is provided to producer group members and internal control system personnel;

(9) Describe the system of records used to demonstrate compliance with this part, including traceability and mass-balance audits; and

(10) Describe how internal monitoring, surveillance, inspection, sanctions, and auditing are used to assess the compliance of all producer group members.

- 7. Add § 205.273 to subpart C to read as follows:

§ 205.273 Imports to the United States.

Each shipment of organic agricultural products imported into the United States must be certified pursuant to subpart E of this part, labeled pursuant to subpart D of this part, be declared as organic to U.S. Customs and Border Protection, and be associated with valid NOP Import Certificate data.

(a) Persons exporting organic agricultural products to the United States must request an NOP Import Certificate from a certifying agent prior to their export. Only certifying agents accredited by the USDA or foreign certifying agents authorized under an organic trade arrangement or agreement may issue an NOP Import Certificate.

(b) The certifying agent must review an NOP Import Certificate request and determine whether the export complies with the USDA organic regulations. The certifying agent must have and implement a documented organic control system for intaking and approving or rejecting the validity of an NOP Import Certificate request. The certifying agent shall issue the NOP Import Certificate through the Organic Integrity Database only if the export complies with the USDA organic regulations.

(c) Each compliant organic import must be declared as organic to U.S. Customs and Border Protection by entering NOP Import Certificate data into the U.S. Customs and Border Protection's Automated Commercial Environment system. Organic imports must be clearly identified and marked as organic on all import documents including but not limited to invoices, packing lists, bills of lading, and U.S. Customs and Border Protection entry data. Only NOP Import Certificate data generated by the Organic Integrity Database are valid.

(d) Upon receiving a shipment with organic agricultural products, the organic importer must ensure the import is accompanied by accurate NOP Import Certificate data and must verify that the shipment has had no contact with prohibited substances pursuant to § 205.272 or exposure to ionizing radiation pursuant to § 205.105, since export. The organic importer must have

a documented organic control system to conduct this verification.

- 8. Amend § 205.300 by revising paragraph (c) to read as follows:

§ 205.300 Use of the term, "organic."

* * * * *

(c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part, labeled pursuant to this subpart D, and must comply with the requirements in § 205.273.

* * * * *

- 9. Amend § 205.301 by revising paragraphs (f)(2) and (3) to read as follows:

§ 205.301 Product composition.

* * * * *

(f) * * *

(2) Be processed using ionizing radiation, pursuant to § 205.105(f);

(3) Be produced using sewage sludge, pursuant to § 205.105(g);

* * * * *

- 10. Amend § 205.302 by revising paragraphs (a)(1) through (3) to read as follows:

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) * * *

(1) Dividing the total net weight of the combined organic ingredients at formulation by the total weight of all ingredients of the product at formulation. Water and salt added as ingredients at formulation are excluded from the calculation.

(2) Dividing the total fluid volume of the combined organic ingredients at formulation by the total fluid volume of all ingredients of the product at formulation if the product and ingredients are liquid. Water and salt added as ingredients at formulation are excluded from the calculation. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made based on single-strength concentrations of all ingredients.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined net weight of the solid organic ingredients and the net weight of the liquid organic ingredients at formulation by the total weight of all ingredients of the product at formulation. Water and salt added as ingredients at formulation are excluded from the calculation.

* * * * *

- 11. Revise § 205.307 to read as follows:

§ 205.307 Labeling of nonretail containers.

(a) Nonretail containers used to ship or store certified organic agricultural products must display:

- (1) Identification of the product as organic; and
- (2) The production lot number, shipping identification, or other unique information that links the container to audit trail documentation.

(b) Audit trail documentation for nonretail containers must identify the last certified operation that handled the agricultural product.

(c) Paragraph (a)(1) of this section does not apply to nonretail containers used to ship or store agricultural products packaged for retail sale with organic identification visible on the retail label.

(d) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled in accordance with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer: Provided, that, the shipping containers and shipping documents accompanying such organic products are clearly marked "For Export Only" and: Provided further, that proof of such container marking and export must be maintained by the handler in accordance with recordkeeping requirements for exempt operations under § 205.101.

■ 12. Section 205.310 is amended by revising the section heading and paragraphs (a) and (b) to read as follows:

§ 205.310 Agricultural products produced or processed by an exempt operation.

(a) An agricultural product organically produced or processed by an exempt operation must not:

- (1) Display the USDA seal or any certifying agent's seal or other identifying mark which represents the exempt operation as a certified organic operation; or
- (2) Be represented as a certified organic product or certified organic ingredient to any buyer.

(b) An agricultural product organically produced or processed by an exempt operation may be identified as an organic product or organic ingredient in a multi-ingredient product produced by the exempt operation. Such product or ingredient must not be identified or represented as "organic" in a product processed by others.

* * * * *

■ 13. Section 205.400 is amended by:

- a. Removing "§ 205.200" and adding in its place "§ 205.201" in paragraph (b); and

- b. Adding paragraph (g).
The addition reads as follows:

§ 205.400 General requirements for certification.

* * * * *

(g) In addition to paragraphs (a) through (f) of this section, a producer group operation must:

- (1) Be organized as a person;
- (2) Use centralized processing, distribution, and marketing facilities and systems;
- (3) Be organized into producer group production units;
- (4) Maintain an internal control system to implement the practices described in § 205.201(c) and ensure compliance with this part;
- (5) Ensure that all agricultural products sold, labeled, or represented as organic are produced only by producer group members using land and facilities within the certified operation;
- (6) Ensure that producer group members do not sell, label, or represent their agricultural products as organic outside of the producer group operation unless they are individually certified;
- (7) Report to the certifying agent, at least annually, the name and location of all producer group members and producer group production units, the agricultural products produced, estimated yields, and size of production areas;

(8) Conduct internal inspections of each producer group member, at least annually, by internal inspectors with the member present, which must include mass-balance audits and reconciliation of each producer group member's and each producer group production unit's yield and group sales;

(9) Implement recordkeeping requirements to ensure traceability from production at each producer group member and production unit through handling to sale and transport;

(10) Implement procedures to ensure all production and handling by the producer group operation is compliant with the USDA organic regulations and the Act; and

(11) Address any other terms or conditions determined by the Administrator to be necessary to enforce compliance with the USDA organic regulations and the Act.

§ 205.401 [Amended]

■ 14. Amend § 205.401 in paragraph (a) by removing "§ 205.200" and adding in its place "§ 205.201".

■ 15. Section 205.403 is amended by:

- a. Redesignating paragraph (a)(2) as paragraph (a)(3);

- b. Adding new paragraph (a)(2);

- c. Redesignating paragraphs (b) through (e) as paragraphs (c) through (f);

- d. Adding new paragraph (b);

- e. In newly redesignated paragraph (d)(2), removing "§ 205.200" and adding in its place "§ 205.201"; and

- f. Adding paragraphs (d)(4) and (5).
The additions read as follows:

§ 205.403 On-site inspections.

(a) * * *

(2) Inspections of a producer group operation must:

(i) Assess the internal control system's compliance, or ability to comply, with the requirements of § 205.400(g)(8). This must include review of the internal inspections conducted by the internal control system.

(ii) Conduct witness audits of internal control system inspectors performing inspections of the producer group operation.

(iii) Individually inspect at least 1.4 times the square root or 2% of the total number of producer group members, whichever is higher. All producer group members determined to be high risk by the certifying agent must be inspected. At least one producer group member in each producer group production unit must be inspected.

(iv) Inspect each handling facility.

* * * * *

(b) *Unannounced inspections.* (1) A certifying agent must, on an annual basis, conduct unannounced inspections of a minimum of five percent of the operations it certifies, rounded up to the nearest whole number.

(2) Certifying agents must be able to conduct unannounced inspections of any operation they certify and must not accept applications or continue certification with operations located in areas where they are unable to conduct unannounced inspections.

* * * * *

(d) * * *

(4) Mass-balances, in that quantities of organic product and ingredients produced or purchased account for organic product and ingredients used, stored, sold, or transported (that is, inputs account for outputs); and

(5) That organic products and ingredients are traceable by the operation from the time of purchase or acquisition through production to sale or transport; and that the certifying agent can verify compliance back to the last certified operation.

* * * * *

■ 16. Section § 205.404 is amended by revising paragraph (b), redesignating paragraph (c) as paragraph (d), and adding a new paragraph (c).

The revision and addition read as follows:

§ 205.404 Certificates of organic operation.

* * * * *

(b) The certifying agent must issue a certificate of organic operation. The certificate of organic operation must be generated from the Organic Integrity Database and may be provided to certified operations electronically.

(c) In addition to the certificate of organic operation provided for in paragraph (b) of this section, a certifying agent may issue its own addenda to the certificate of organic operation. If issued, any addenda must include:

- (1) Name, address, and contact information for the certified operation;
- (2) The certified operation's unique ID number/code that corresponds to the certified operation's ID number/code in the Organic Integrity Database;
- (3) A link to the Organic Integrity Database or a link to the certified operation's profile in the Organic Integrity Database, along with a statement, "You may verify the certification of this operation at the Organic Integrity Database," or a similar statement;
- (4) Name, address, and contact information of the certifying agent; and
- (5) "Addendum issue date."

* * * * *

§ 205.405 [Amended]

- 17. Amend § 205.405 by removing paragraph (c)(3).
- 18. Amend 205.406 by revising paragraphs (a) and (b) to read as follows:

§ 205.406 Continuation of certification.

(a) To continue certification, a certified operation must annually pay the certification fees and submit the following information to the certifying agent:

- (1) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the organic system plan submitted during the previous year;
- (2) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to § 205.201;
- (3) Any additions to or deletions from the information required pursuant to § 205.401(b); and
- (4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

(b) The certifying agent must arrange and conduct an on-site inspection, pursuant to § 205.403, of the certified operation at least once per calendar year.

* * * * *

§ 205.500 [Amended]

- 19. Amend § 205.500 by removing paragraph (c).
- 20. Section 205.501 is amended by:
 - a. Revising paragraphs (a)(4), (5), (6), (10), (13), and (15);
 - b. Redesignating paragraph (a)(21) as paragraph (a)(23); and
 - c. Adding new paragraph (a)(21) and paragraph (a)(22).

The revisions and additions read as follows:

§ 205.501 General requirements for accreditation.

- (a) * * *
- (4) Continuously use a sufficient number of qualified and adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the USDA organic standards.
 - (i) Certifying agents must demonstrate that all inspectors, including staff, volunteers, and contractors, have the relevant knowledge, skills, and experience required to inspect operations of the scope and complexity assigned and to evaluate compliance with the applicable regulations of this part.

(A) Certifying agents must demonstrate that inspectors continuously maintain adequate knowledge and skills about the current USDA organic standards, production and handling practices, certification and inspection, import and/or export requirements, traceability audits, mass-balance audits, written and oral communication skills, sample collection, investigation techniques, and preparation of technically accurate inspection documents.

(B) All inspectors must demonstrate successful completion of training that is relevant to inspection. Inspectors with less than one year of inspection experience must complete at least 50 hours of training within their first year and prior to performing inspections independently. Inspectors with one or more years of inspection experience must annually complete at least 10 hours of training if inspecting one area of operation (as defined at § 205.2) and an additional 5 hours of training for each additional area of operation inspected.

(C) Certifying agents must demonstrate that inspectors have a minimum of 2,000 hours of experience relevant to the scope and complexity of operations they will inspect before assigning initial inspection responsibilities.

- (ii) Certifying agents must demonstrate that all certification review

personnel, including staff, volunteers, or contractors, have the knowledge, skills, and experience required to perform certification review of operations of the scope and complexity assigned and to evaluate compliance with the applicable regulations of this part.

(A) Certifying agents must demonstrate that all certification review personnel continuously maintain adequate knowledge and skills in the current USDA organic standards, certification and compliance processes, traceability audits, mass-balance audits, and practices applicable to the type, volume, and range of review activities assigned.

(B) All certification review personnel must demonstrate successful completion of training that is relevant to certification review. Certification review personnel with less than one year of certification review experience must complete at least 50 hours of training within their first year performing certification review. Certification review personnel with one or more years of certification review experience must annually complete at least 10 hours of training if conducting certification review related to one area of operation and an additional 5 hours of training for each additional area of operation.

(iii) Certifying agents must maintain current training requirements, training procedures, and training records for all inspectors and certification review personnel.

(5) Demonstrate that all persons with inspection or certification review responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. Sufficient expertise must include knowledge of certification to USDA organic standards and evidence of education, training, or professional experience in the fields of agriculture, science, or organic production and handling that relates to assigned duties.

(6) Conduct an annual performance evaluation of all persons who conduct inspections, certification review, or implement measures to correct any deficiencies in certification services.

(i) Witness inspections—certifying agents must ensure that each inspector is evaluated while performing an inspection at least once every three years, or more frequently if warranted. Inspectors with less than three years of inspection experience must undergo a witness inspection annually. Witness inspections must be performed by certifying agent personnel who are qualified to evaluate inspectors.

(ii) Certifying agents must maintain documented policies, procedures, and

records for annual performance evaluations and witness inspections.

* * * * *

(10) Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (except for the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except:

(i) For information that must be made available to any member of the public, as provided for in § 205.504(b)(5);

(ii) For enforcement purposes, certifying agents must exchange any compliance-related information that is credibly needed to certify, decertify, or investigate an operation, including for the purpose of verifying supply chain traceability and audit trail documentation; and

(iii) If a certified operation's proprietary business information is compliance-related and thus credibly needed to certify, decertify, or investigate that operation, certifying agents may exchange that information for the purposes of enforcing the Act, but the information in question still retains its proprietary character even after it is exchanged and all of the certifying agents that are involved in the exchange still have a duty to preserve the confidentiality of that information after the exchange.

* * * * *

(13) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to § 205.500. Certifying agents must provide information to other certifying agents to ensure organic integrity or to enforce organic regulations, including to verify supply chain integrity, authenticate the organic status of certified products, and conduct investigations;

* * * * *

(15) Maintain current and accurate data in the Organic Integrity Database for each operation which it certifies;

* * * * *

(21) Conduct risk-based supply chain traceability audits as described in the criteria and procedures for supply chain audits, per § 205.504(b)(7), and share audit findings with other certifying agents as needed to determine compliance, per paragraph (a)(13) of this section.

(22) Notify AMS not later than 90 calendar days after certification activities begin in a new certification office. The notification must include the

countries where the certification activities are being provided, the nature of the certification activities, and the qualifications of the personnel providing the certification activities.

* * * * *

■ 21. Section 205.504 is amended by revising the introductory text and paragraph (b)(4) and adding paragraphs (b)(7) and (8) to read as follows:

§ 205.504 Evidence of expertise and ability.

A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§ 205.100 and 205.101, 205.201 through 205.203, 205.300 through 205.303, 205.400 through 205.406, and 205.661 through 205.663; and its ability to comply with the requirements for accreditation set forth in § 205.501:

* * * * *

(b) * * *

(4) A copy of the procedures to be used for sharing information with other certifying agents and for maintaining the confidentiality of any business-related information as set forth in § 205.501(a)(10);

* * * * *

(7) A copy of the criteria to identify high-risk operations and agricultural products for supply chain traceability audits; and procedures to conduct risk-based supply chain traceability audits, as required in § 205.501(a)(21); and procedures to report credible evidence of organic fraud to the Administrator.

(8) A copy of reasonable decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation.

* * * * *

■ 22. Add § 205.511 to subpart F to read as follows:

§ 205.511 Accepting foreign conformity assessment systems.

(a) Foreign product may be certified under the USDA organic regulations by a USDA-accredited certifying agent and imported for sale in the United States. Foreign product that is produced and handled under another country's organic certification program may be sold, labeled, or represented in the United States as organically produced if the U.S. Government determines that such country's organic certification program provides technical

requirements and a conformity assessment system governing the production and handling of such products that are at least equivalent to the requirements of the Act and the regulations in this part.

(b) Countries desiring to establish eligibility of product certified under that country's organic certification program to be sold, labeled, or represented in the United States as organically produced may request equivalence determinations from AMS. A foreign government must maintain compliance and enforcement mechanisms to ensure that its organic certification program is fully meeting the terms and conditions of any equivalence determination provided by the U.S. Government pursuant to this section. To request an equivalence determination, the requesting country must submit documentation that fully describes its technical requirements and conformity assessment system. If the U.S. Government determines it can proceed, AMS will assess the country's organic certification program to evaluate if it is equivalent.

(c) USDA, working with other Federal agencies, will describe the scope of an equivalence determination.

(d) AMS will conduct regular reviews and reassessments of countries deemed equivalent to verify that the foreign government's technical requirements and conformity assessment system continue to be at least equivalent to the requirements of the Act and the regulations of this part, and will determine if the equivalence determination should be continued, amended, or terminated. AMS will determine the timing and scope of reviews and re-assessments based on, but not limited to, factors such as: the terms of the equivalence determination, changes to the foreign country's technical requirements or conformity assessment system, the results of previous reviews and re-assessments, instances of suspected or verified noncompliance issues, the volume of trade, and other factors contributing to the risk level of the equivalence determination.

(e) The U.S. Government may terminate an equivalence determination if the terms or conditions established under the equivalence determination are not met; if AMS determines that the country's technical requirements and/or conformity assessment program are no longer equivalent; if AMS determines that the foreign government's organic control system is inadequate to ensure that the country's organic certification program is fully meeting the terms and conditions under the equivalence determination; or for other good cause.

■ 23. Amend § 205.660 by redesignating paragraphs (c) and (d) as paragraphs (d) and (e) and adding new paragraph (c).

The addition reads as follows:

§ 205.660 General.

* * * * *

(c) The Program Manager may initiate enforcement action against any person who sells, labels, or provides other market information concerning an agricultural product if such label or information implies that such product is produced or handled using organic methods, if the product was produced or handled in violation of the Organic Foods Production Act or the regulations in this part.

* * * * *

■ 24. Amend § 205.661 by revising the section heading to read as follows:

§ 205.661 Investigation.

* * * * *

■ 25. Section 205.662 is amended by:

■ a. Adding paragraph (e)(3);

■ b. Revising the first sentence of paragraph (f)(1); and

■ c. Revising paragraph (g)(1).

The addition and revisions read as follows:

§ 205.662 Noncompliance procedure for certified operations.

* * * * *

(e) * * *

(3) Within 3 business days of issuing a notification of suspension or revocation, or the effective date of an operation's surrender, the certifying agent must update the operation's status in the Organic Integrity Database.

(f) * * *

(1) A certified operation or a person responsibly connected with an operation whose certification has been suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification, or submit a request for eligibility to be certified. * * *

* * * * *

(g) * * *

(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than the amount specified in 7 CFR 3.91(b)(1)(xxxvi) per violation.

* * * * *

■ 26. Revise § 205.663 to read as follows:

§ 205.663 Mediation.

(a) A certifying agent must submit with its administrative policies and procedures: decision criteria for

acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions per § 205.504(b)(8).

(b) A certified operation or applicant for certification may request mediation to resolve a denial of certification or proposed suspension or proposed revocation of certification issued by a certifying agent or State organic program.

(1) A certified operation or applicant for certification must submit any request for mediation in writing to the applicable certifying agent or State organic program within 30 calendar days of receipt of the notice of proposed suspension or proposed revocation of certification or denial of certification.

(2) A certifying agent or State organic program may accept or reject a request for mediation based on the decision criteria required in paragraph (a) of this section. Certifying agents must document these criteria and how the certifying agent applied the criteria to the request.

(3) If a certifying agent rejects a mediation request, it must provide this rejection, in writing to the applicant for certification or certified operation. The rejection must include the right to request an appeal, pursuant to § 205.681, within 30 calendar days of the date of receipt of the written notification of rejection of the request for mediation.

(4) When an operation appeals a rejection of mediation, the adverse action which is contested must not be finalized during the appeal proceeding.

(c) Both parties must agree on the person conducting the mediation.

(d) If a State organic program is in effect, the parties must follow the mediation procedures established in the State organic program and approved by the Secretary.

(e) The parties to the mediation have a maximum of 30 calendar days from the start of mediation to reach an agreement. Successful mediation results in a settlement agreement agreed to in writing by both the certifying agent and the certified operation. If mediation is unsuccessful, the applicant for certification or certified operation has 30 calendar days from receipt of a written notice of termination of mediation to appeal the denial of certification or proposed suspension or revocation pursuant to § 205.681.

(f) Any settlement agreement reached through mediation must comply with the Act and the regulations in this part. The Program Manager may review any mediated settlement agreement for conformity to the Act and the

regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.

(g) The Program Manager may propose mediation and enter into a settlement agreement at any time to resolve any adverse action notice.

■ 27. Amend § 205.665 by revising paragraph (a) to read as follows:

§ 205.665 Noncompliance procedure for certifying agents.

(a) *Notification.* (1) A written notification of noncompliance will be sent to the certifying agent when:

(i) An inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part; or

(ii) The Program Manager determines that the certification activities of the certifying agent, or any person performing certification activities on behalf of the certifying agent, are not compliant with the Act or the regulations in this part; or

(iii) The Program Manager determines that the certification activities at a certification office, and/in specific countries, are not compliant with the Act or the regulations in this part.

(2) Such notification must provide:

(i) A description of each noncompliance;

(ii) The facts upon which the notification of noncompliance is based; and

(iii) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible.

* * * * *

■ 28. Revise § 205.680 to read as follows:

§ 205.680 General.

(a) Persons subject to the Act who believe they are adversely affected by an adverse action of the National Organic Program's Program Manager may appeal such decision to the Administrator.

(b) Persons subject to the Act who believe they are adversely affected by an adverse action of a State organic program may appeal such decision to the State organic program's governing State official, who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary.

(c) Persons subject to the Act who believe they are adversely affected by an adverse action of a certifying agent may appeal such decision to the Administrator, *Except*, that, when the person is subject to an approved State

organic program, the appeal must be made to the State organic program.

(d) Persons subject to the Act who believe they are adversely affected by an adverse action of a certifying agent or a State organic program may request mediation as provided in § 205.663.

(e) All appeals must comply with the procedural requirements in § 205.681(c) and (d).

(f) All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts.

(g) All appeals must be reviewed, heard, and decided by persons not involved with the adverse action being appealed.

■ 29. Amend § 205.681 by revising paragraph (a) introductory text and paragraphs (a)(2), (b), (c), and (d)(1) and (3) to read as follows:

§ 205.681 Appeals.

(a) *Adverse actions by certifying agents.* An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or proposed revocation of certification to the Administrator, *Except*, that, when the applicant or certified operation is subject to an approved State organic program, the appeal must be made to the State organic program which will carry out

the appeal pursuant to the State organic program's appeal procedures approved by the Secretary.

* * * * *

(2) If the Administrator or State organic program denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification unless the parties resolve the issues through settlement, or the appellant waives or does not timely request a hearing. Such proceeding must be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, subpart H, or the State organic program's rules of procedure.

(b) *Adverse actions by the NOP Program Manager.* A person affected by an adverse action, as defined by § 205.2, issued by the NOP Program Manager, may appeal to the Administrator.

(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, a certifying agent will continue its accreditation, or an operation will continue its certification, a civil penalty will be withdrawn, and a cease and desist notice will be withdrawn, as applicable to the operation.

(2) If the Administrator denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the accreditation or certification and/or levy civil penalties unless the parties resolve the issues through settlement, the appellant

waives a hearing, or the appellant does not timely request a hearing. Such proceeding must be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, subpart H.

(c) *Filing period.* An appeal must be filed in writing within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or by the State organic program. An adverse action will become final and nonappealable unless an appeal is timely filed.

(d) * * *

(1) Appeals to the Administrator and Requests for Hearing must be filed in writing and addressed to: 1400 Independence Ave. SW, Room 2642, Stop 0268, Washington, DC 20250, or electronic transmission, *NOPAppeals@usda.gov*.

* * * * *

(3) All appeals must include a copy of the adverse action and a statement of the appellant's reasons for believing that the action was not proper or made in accordance with applicable program regulations.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2023-00702 Filed 1-18-23; 8:45 am]

BILLING CODE 3410-02-P

Reader Aids

Federal Register

Vol. 88, No. 12

Thursday, January 19, 2023

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	202-741-6000
Laws	741-6000
Presidential Documents	
Executive orders and proclamations	741-6000
The United States Government Manual	741-6000
Other Services	
Electronic and on-line services (voice)	741-6020
Privacy Act Compilation	741-6050

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: www.govinfo.gov.

Federal Register information and research tools, including Public Inspection List and electronic text are located at: www.federalregister.gov.

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to <https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to <http://listserv.gsa.gov/archives/publaws-l.html> and select *Join or leave the list (or change settings)*; then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: fedreg.info@nara.gov

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, JANUARY

1-288	3
289-738	4
739-948	5
949-1132	6
1133-1322	9
1323-1496	10
1497-1972	11
1973-2174	12
2175-2500	13
2501-2794	17
2795-3282	18
2795-3282	18
3283-3628	19

CFR PARTS AFFECTED DURING JANUARY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

2 CFR	354	2798
	362	2798
Proposed Rules:	412	2798
3474 95		
3 CFR		
Administrative Orders:		
Memorandums:		
Memorandum of		
January 6, 2023	2795	
Proclamations:		
10510	739	
10511	741	
10512	743	
10513	3283	
10514	3285	
5 CFR		
532	1133	
2634	1139	
2636	1139	
6 CFR		
5	2797	
27	2175	
Proposed Rules:		
19	2395	
7 CFR		
9	1862	
205	3548	
701	1862	
760	1862	
1400	1862	
1416	1862	
1437	1862	
1450	1862	
Proposed Rules:		
16	2395	
905	2862	
920	16	
985	18	
3560	1149	
8 CFR		
270	2175	
274a	2175	
280	2175	
Proposed Rules:		
103	402, 1172	
106	402, 1172	
204	402, 1172	
212	402, 1172	
214	402, 1172	
240	402, 1172	
244	402, 1172	
245	402, 1172	
245a	402, 1172	
264	402, 1172	
274a	402, 1172	
9 CFR		
352	2798	
	354	2798
	362	2798
	412	2798
Proposed Rules:		
1	1151	
2	1151	
3	1151	
71	3320	
77	3320	
78	3320	
86	3320	
10 CFR		
2	2187, 2188	
13	2188	
52	3287	
72	949	
207	2190	
218	2190	
429	2190, 3234	
430	3234	
431	2190	
490	2190	
501	2190	
601	2190	
810	1973	
820	2190	
824	2190	
851	2190	
1013	2190	
1017	2190	
1050	2190	
Proposed Rules:		
30	25	
40	25	
50	25	
70	25	
72	25, 1010	
430	790, 1638	
431	1722	
1021	2029	
12 CFR		
19	289	
109	289	
201	2194	
204	2195	
263	1497	
622	2197	
747	1323	
1083	1	
1411	2812	
Proposed Rules:		
1610	1154	
14 CFR		
13	1114	
21	2813	
23	2813	
25	2813	
29	2813	
33	2813	
36	2813	

39.....1981, 1983, 1984, 2199, 2202, 2501	4.....2175	1903.....2210	38 CFR
47.....2813, 2815	20 CFR	4071.....1991	17.....2526
49.....2813	10.....974	4302.....1991	21.....2831
60.....2813	401.....1326	Proposed Rules:	36.....985, 2537
61.....2813	403.....1326	2.....2395	42.....985
67.....2813	422.....1326	30 CFR	Proposed Rules
71.....1987, 2204, 2205, 2503, 2504, 2506, 2815, 2816, 2818, 2820	423.....1326	100.....2210	17.....2038
73.....2813	429.....1326	1241.....2520	50.....2395
91.....2813	655.....2210	31 CFR	61.....2395
97.....1988, 2813	702.....2210	501.....2229	62.....2395
101.....2813	725.....2210	510.....2229	39 CFR
107.....2813	726.....2210	535.....2229	111.....758
121.....2813	Proposed Rules:	536.....2229	233.....1513
125.....2813	726.....3349	539.....2229	273.....1513
129.....2813	21 CFR	541.....2229	3035.....3313
135.....2813	1.....1503	542.....2229	Proposed Rules:
141.....2813	101.....6	544.....2229	111.....2046, 2047
183.....2813	172.....745	546.....2229	40 CFR
383.....1114	862.....2518	547.....2229	19.....986
406.....1114	870.....975	548.....2229	52.....291, 773, 1515, 2243, 2245, 2538, 2541, 2834, 2839
440.....2813	874.....977	549.....2229	62.....2543
Proposed Rules:	876.....8	551.....2229	81.....775, 1515
5.....1932	882.....749, 2222	552.....2229	120.....2878
21.....1932	888.....751, 753, 979	553.....2229	180.....990
39.....1520, 2029, 2032, 2035, 2273, 2276, 2279, 2283, 2286, 2292, 2295, 2558, 3330	890.....981, 983	560.....2229	Proposed Rules:
71.....2561, 2867, 2869, 2870	22 CFR	561.....2229	49.....2298
91.....1932	35.....1505	566.....2229	52.....1341, 1454, 1533, 1537, 2050, 2303, 2873, 2876
119.....1932	103.....1505	570.....2229	60.....2563
121.....1932	127.....1505	576.....2229	61.....2057
135.....1932	138.....1505	578.....2229	62.....2564
61.....34	Proposed Rules:	583.....2229, 2522	63.....805, 2057
63.....34	205.....2395	584.....2229	81.....1543
65.....34	24 CFR	588.....2229	180.....38
15 CFR	Proposed Rules:	589.....2229	721.....41
6.....3	5.....321, 2395	590.....2229	41 CFR
734.....2821	1006.....328	591.....1507	50-210.....2210
736.....2821	25 CFR	592.....2229	105-70.....2247
740.....2507, 2821	Proposed Rules:	594.....2229	301.....2843
742.....2507, 2821	226.....2430	597.....2229	302.....2843
744.....2821	26 CFR	598.....2229	303.....2843
762.....2821	301.....755, 756	599.....2229	304.....2843
772.....2821	27 CFR	1010.....3311	305.....2843
774.....2507, 2821	5.....2224	Proposed Rules:	306.....2843
922.....953	16.....2228	208.....1336	307.....2843
Proposed Rules:	Proposed Rules:	601.....2871	308.....2843
922.....3334	6.....1171	32 CFR	309.....2843
16 CFR	8.....1171	199.....1992	310.....2843
Ch. II.....2206	10.....1171	269.....2239	311.....2843
1.....1499	11.....1171	33 CFR	312.....2843
305.....1135	28 CFR	27.....2175	313.....2843
Proposed Rules:	Proposed Rules:	100.....291	314.....2843
1.....2562	16.....1012	147.....1511	315.....2843
456.....248	38.....2395	165.....756, 1141, 1145, 2002, 2241, 2523, 2829	316.....2843
910.....3482	545.....1331	277.....2525	317.....2843
17 CFR	29 CFR	328.....2878	318.....2843
143.....1501	5.....2210	401.....1114	319.....2843
18 CFR	500.....2210	Proposed Rules:	320.....2843
250.....1989	501.....2210	100.....3366	321.....2843
385.....1989	503.....2210	165.....35, 1528	322.....2843
Proposed Rules:	530.....2210	203.....1340	323.....2843
50.....2770	570.....2210	334.....1532, 3372	324.....2843
240.....128	578.....2210	34 CFR	325.....2843
242.....128	579.....2210	Proposed Rules:	326.....2843
380.....2770	801.....2210	75.....2395	327.....2843
19 CFR	810.....2210	76.....2395	328.....2843
Ch. I.....2517	825.....2210	685.....1894	329.....2843
		36 CFR	330.....2843
		Proposed Rules:	331.....2843
		13.....1176	332.....2843

333.....2843	410.....297, 2546	506.....1517	236.....1114
334.....2843	411.....297	Proposed Rules:	237.....1114
335.....2843	412.....297	8.....1547	238.....1114
336.....2843	413.....297	197.....1547	239.....1114
337.....2843	414.....2546	47 CFR	240.....1114
338.....2843	416.....297	1.....783	241.....1114
339.....2843	419.....297	54.....2248	242.....1114
340.....2843	424.....297	73.....10, 2550, 2551	243.....1114
341.....2843	485.....297	Proposed Rules:	244.....1114
342.....2843	489.....297	9.....2565	272.....1114
343.....2843	43 CFR	25.....2590	386.....1114
344.....2843	10.....3315	54.....1035, 2305	578.....1114
345.....2843	Proposed Rules:	73.....42, 1038, 2595	831.....2858
346.....2843	10.....1344	49 CFR	1002.....299
347.....2843	11.....3373	107.....1114	1011.....700
348.....2843	2800.....2304	171.....1114	1022.....2268
349.....2843	2860.....2304	190.....1114	1108.....700
350.....2843	2880.....2304	209.....1114	1111.....299
351.....2843	2920.....2304	213.....1114	1114.....299
352.....2843	45 CFR	214.....1114	1115.....299,700
353.....2843	3.....1134	215.....1114	1244.....700
354.....2843	1149.....2004	216.....1114	1503.....2175
355.....2843	1158.....2004	217.....1114	Proposed Rules:
356.....2843	1302.....993	218.....1114	386.....830
357.....2843	Proposed Rules:	219.....1114	387.....830
358.....2843	87.....2395	220.....1114	50 CFR
359.....2843	88.....820	221.....1114	17.....2006
360.....2843	2525.....1021	222.....1114	218.....604
361.....2843	2526.....1021	223.....1114	635.....786
362.....2843	2527.....1021	224.....1114	648.....11, 788, 2271, 2551,
363.....2843	2528.....1021	225.....1114	2859, 3317
364.....2843	2529.....1021	227.....1114	679.....789, 2271, 2861, 3318
365.....2843	2530.....1021	228.....1114	Proposed Rules:
366.....2843	46 CFR	229.....1114	17.....2597
367.....2843	221.....1114	230.....1114	217.....916, 3146, 3375
368.....2843	307.....1114	231.....1114	223.....1548
369.....2843	340.....1114	233.....1114	224.....1548
370.....2843	356.....1114	234.....1114	660.....1171, 2061
42 CFR		235.....1114	
88.....2845			
405.....297			

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion

in today's **List of Public Laws**.

Last List January 10, 2023

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly

enacted public laws. To subscribe, go to https://portalguard.gsa.gov/__layouts/PG/register.aspx.

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.