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

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 303

RIN 3064–AF54

Branch Application Procedures; Correction

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to the final regulation which was published in the **Federal Register** of November 13, 2020. The regulation to be corrected related to Branch Application Procedures.

DATES: Effective on February 16, 2021.

FOR FURTHER INFORMATION CONTACT: Navid Choudhury, Counsel, Policy Unit, Legal Division, (202) 898–6526, *nchoudhury@fdic.gov*; Patricia A. Colohan, Associate Director, Risk Management Examination Branch; (202) 898–7283, *pcolohan@fdic.gov.*

SUPPLEMENTARY INFORMATION:

Background

The final regulation that is the subject of this correction amends the FDIC's application requirements for the establishment and relocation of branches and offices so that such applications no longer require statements regarding the compliance of such proposals with the National Historic Preservation Act of 1966 and the National Environmental Policy Act of 1969.

Need for Correction

As published, FR Doc. 2020–23529 (85 FR 72551, November 13, 2020) contained an error in the instructions to amend 12 CFR 303.184(a)(2).

List of Subjects in 12 CFR Part 303

Administrative practice and procedure, Bank deposit insurance, Banks, banking, Reporting and recordkeeping requirements, Savings associations.

For the reasons stated in the preamble, the FDIC makes the following correcting amendment to 12 CFR part 303:

PART 303—FILING PROCEDURES

■ 1. The authority citation for part 303 continues to read as follows:

Authority: 12 U.S.C. 378, 478, 1463, 1467a, 1813, 1815, 1817, 1818, 1819 (Seventh and Tenth), 1820, 1823, 1828, 1831i, 1831e, 1831o, 1831p–1, 1831w, 1831z, 1835a, 1843(l), 3104, 3105, 3108, 3207, 5412; 15 U.S.C. 1601–1607.

§ 303.184 [Amended]

■ 2. Amend § 303.184 by:

■ a. Removing paragraphs (a)(2)(iii) and (iv); and

■ b. Redesignating paragraphs (a)(2)(v) and (vi) as paragraphs (a)(2)(iii) and (iv), respectively.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on January 6, 2021.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2021–00371 Filed 2–12–21; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0021; Project Identifier MCAI–2020–01088–R; Amendment 39–21419; AD 2021–03–16]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

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

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Airbus Helicopters Model AS350B, AS350B1, AS350B2, AS350B3, AS350BA, AS350D, AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters. This AD was prompted by the in-flight loss of a sliding door. This AD requires inspecting each sliding door and replacing the upper rail or front roller or removing the front roller from service if necessary. The actions of this AD are intended to address an unsafe condition on these products.

DATES: This AD becomes effective March 3, 2021.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of March 3, 2021.

The FAA must receive comments on this AD by April 2, 2021.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *https://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0021; 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 AD, the European Union Aviation Safety Agency (EASA) AD, any service information that is incorporated by reference, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

For service information identified in this final rule, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone 972–641–0000 or 800–232–0323; fax 972–641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* You may view the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. It is also available on the internet at *https://www.regulations.gov* by

searching for and locating Docket No. FAA–2021–0021.

FOR FURTHER INFORMATION CONTACT: Matt Fuller, AD Program Manager, Operational Safety Branch, Airworthiness Products Section, General Aviation & Rotorcraft Unit, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *matthew.fuller@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0021 and Project Identifier MCAI–2020–01088–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, 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 final rule 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 *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 final rule.

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 AD 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 AD, 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 AD. Submissions containing CBI should be sent to Matt Fuller, AD Program Manager, Operational Safety Branch, Airworthiness Products Section, General Aviation & Rotorcraft Unit, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *matthew.fuller@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.

Discussion

EASA, which is the Technical Agent for the Member States of the European Union, has issued AD No. 2020–0175, dated August 5, 2020 (EASA AD 2020–0175), for all serial-numbered Airbus Helicopters Model AS 350 and AS 355 helicopters if equipped with a left-hand (LH) and/or right-hand (RH) sliding door. EASA advises that an AS 350 B3 helicopter lost the LH door in-flight. The event occurred while flying with the door locked in the open position. The results of the technical analysis of this event indicated that the loss of the sliding door resulted from the disengagement of the roller from the upper rail. This condition, if not detected and corrected, could lead to sliding door in-flight detachment, possibly resulting in damage to the helicopter, and/or injury to persons on the ground. EASA also advises that this scenario may also develop on AS 355 helicopters sliding doors due to design similarity. Accordingly, EASA AD 2020–0175 requires a one-time detailed inspection of the LH and/or RH sliding doors and, depending on findings, accomplishment of applicable corrective actions.

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 of the unsafe condition described in its AD. The FAA is issuing this AD after evaluating all information provided by EASA and determining the unsafe condition exists and is likely to exist or develop on other helicopters of the same type designs.

Related Service Information Under 1 CFR Part 51

Airbus Helicopters has issued Alert Service Bulletin (ASB) No. AS350–52.00.54 and ASB No. AS355–52.00.32, each Revision 1 and each dated July 30, 2020 (ASB AS350–52.00.54 and ASB AS355–52.00.32). ASB AS350–52.00.54 applies to Model AS350-series helicopters and ASB AS355–52.00.32 applies to Model AS355-series helicopters. The ASBs specify inspecting the upper rail and roller of the of the LH and/or RH sliding doors by inspecting the upper rail, and making sure that the parallelism between the sliding door and its frame is correct, that the front roller is in good condition, and that the installation of the front roller is correct. The ASBs also specify notifying Airbus Helicopters if any part is replaced and providing the part number of the part replaced and the serial number and time since new of the helicopter.

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.

AD Requirements

This AD requires, within 30 hours time-in-service (TIS) after the effective date of this AD, inspecting the upper rail of each RH and LH door for parallelism, deformation, corrosion, and cracking and repairing or replacing the upper rail before further flight if necessary; and with each sliding door removed, inspecting the front roller to determine if it is below the minimum diameter and height, if it has any corrosion or flat spot, and if it is correctly installed. If the front roller is below the minimum diameter, below the minimum height, or has any flat spot or corrosion, this AD requires removing the front roller from service before further flight. If the front roller was not correctly installed, this AD requires reinstalling it correctly before further flight.

Differences Between This AD and the EASA AD

Due to a recent additional report of an in-flight door loss, this AD requires compliance within 30 hours TIS after the effective date of the AD; EASA AD 2020–0175 requires compliance within 165 flight hours or 13 months and 6 days, whichever occurs first. The EASA AD requires reporting information to Airbus Helicopters; this AD does not.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 965 helicopters of U.S. Registry and that operators may incur the following costs in order to comply with this AD. Labor costs are $85 per work-hour.

Inspecting each door will take about 2 work-hours for an estimated cost of $170 per helicopter and $164,050 for the U.S. fleet.

Replacing each upper rail, if necessary, will take about 3 work-hours and parts will cost about $3,200, for an estimated cost of $3,455 per door.

Replacing each front roller, if necessary, will take about 1 work-hour and parts will cost about $250 for an estimated cost of $335 per door.

FAA's Justification and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C.) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without seeking comment prior to the rulemaking.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because an initial action is required within 30 hours TIS, which could equate to 1 month in these high usage rotorcraft; and corrective action, if necessary, is required before further flight. Therefore, notice and opportunity for prior public comment are impracticable and contrary to public interest pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the reasons stated above, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

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

For the reasons discussed, I certify that this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866, and

2. Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2021–03–16 Airbus Helicopters: Amendment 39–21419; Docket No. FAA–2021–0021; Project Identifier MCAI–2020–01088–R.

(a) Applicability

This airworthiness directive (AD) applies to Airbus Helicopters Model AS350B, AS350B1, AS350B2, AS350B3, AS350BA, AS350D, AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters, certificated in any category, with any sliding door installed.

(b) Unsafe Condition

This AD defines the unsafe condition as an in-flight loss of a sliding door, which could result in damage to the helicopter or injury to persons on the ground.

(c) Affected ADs

None.

(d) Effective Date

This AD becomes effective March 3, 2021.

(e) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(f) Required Actions

Within 30 hours time-in-service after the effective date of this AD:

(1) Inspect the upper rail of each right hand (RH) and left hand (LH) door for parallelism, deformation, corrosion, and cracking. If necessary, adjust the sliding door, ensuring that the parallelism between the sliding door and its frame does not exceed 1.5 mm (.059 in) on a length of 1,200 mm (47.24 in). The frame includes the sliding door, the overhead panel, and the two rear bulkheads. Repair or replace the upper rail before further flight if there is any deformation, corrosion, or cracking.

(2) With the sliding door removed, inspect the front roller to determine if it is below the minimum diameter of 17.5 mm (0.69 in), below the minimum height of 17 mm (0.67 in), if it has any corrosion or flat spot, and to determine if it is correctly installed per Figure 1 of Airbus Alert Service Bulletin (ASB) No. AS350–52.00.54 or ASB No. AS355–52.00.32, each at Revision 1 and dated July 30, 2020, as applicable to your helicopter model. If the front roller is below the minimum diameter, below the minimum height, or has any flat spot or corrosion, before further flight, remove the front roller from service. If the front roller was not correctly installed, reinstall it correctly before further flight.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Strategic Policy Rotorcraft Section, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Fuller, AD Program Manager, Operational Safety Branch, Airworthiness Products Section, General Aviation & Rotorcraft Unit, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov*.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, the FAA suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

The subject of this AD is addressed in European Union Aviation Safety Agency (EASA) AD No. 2020–0175, dated August 5, 2020. You may view the EASA AD on the internet at *https://www.regulations.gov* by searching for and locating it in Docket No. FAA–2021–0021.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 5210 Passenger/Crew Doors.

(j) Material Incorporated by Reference

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

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

(i) Airbus Helicopters Alert Service Bulletin No. AS350–52.00.54, Revision 1, dated July 30, 2020.

(ii) Airbus Helicopters Alert Service Bulletin No. AS355–52.00.32, Revision 1, dated July 30, 2020.

(3) For Airbus Helicopters service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone 972–641–0000 or 800–232–0323; fax 972–641–3775; or at *https://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 *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on January 29, 2021.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–03063 Filed 2–10–21; 4:15 pm]

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 200

[Release Nos. 33–10913; 34–90787; IA–5656; IC–34151]

Modernization of Delegations of Authority to Commission Staff and Division and Office Descriptions

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (the ''Commission'') is amending its rules delegating authority to the Commission's staff to modernize these rules and more efficiently use the Commission's resources, as well as descriptions of the responsibilities of its divisions and offices.

DATES: This rule is effective February 16, 2021.

FOR FURTHER INFORMATION CONTACT: J. Matthew DeLesDernier, Assistant Secretary, Office of the Secretary, (202) 551–5400, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–9040.

SUPPLEMENTARY INFORMATION: The Commission is adopting new rules 17 CFR 200.19e (''Article 19e''), 17 CFR 200.30–2 (''Article 30–2''), and 17 CFR 200.30–3b (''Article 30–3b''); we are adding and reserving 17 CFR 200.20a; and we are adopting amendments to:

Commission reference	CFR citation (17 CFR)
Article 10	200.10
Article 11	200.11
Article 13	200.13
Article 13a	200.13a
Article 13b	200.13b
Article 14	200.14
Article 16	200.16
Article 17	200.17
Article 19a	200.19a
Article 19c	200.19c
Article 19d	200.19d
Article 21	200.21
Article 21a	200.21a
Article 23a	200.23a
Article 24	200.24
Article 24a	200.24a
Article 26a	200.26a
Article 27	200.27
Article 30–1	200.30–1
Article 30–3	200.30–3
Article 30–3a	200.30–3a
Article 30–5	200.30–5
Article 30–6	200.30–6
Article 30–7	200.30–7
Article 30–10	200.30–10
Article 30–11	200.30–11
Article 30–13	200.30–13
Article 30–14	200.30–14
Article 30–15	200.30–15
Article 30–16	200.30–16
Article 30–18	200.30–18

I. Discussion

The Commission is amending its rules delegating authority to the Commission's staff. Currently, the Commission delegates to its staff certain authorities that would otherwise be exercised only by the Commission itself. These delegations are codified in our Rules of General Organization,[1] alongside descriptions of the responsibilities of the divisions and offices.[2] We are amending these rules to better reflect the way the Commission conducts its business and to use our resources more efficiently. In some cases, authority previously granted to a particular member of the staff is no longer appropriate, because, for example, the authority references a rule or process that has since been amended or rescinded or because the responsibility for the delegated activity should now rest with another member of the staff. In other instances, authority that is currently exercised only by the Commission could be exercised by the staff with appropriate Commission oversight, thereby preserving the Commission's resources for other activities. In addition, certain of the descriptions are no longer an accurate reflection of the responsibilities of the respective divisions and offices. We have determined, therefore, to make a number of amendments to our rules delegating authority to the staff and to the division and office descriptions, as discussed in detail below.

A. Delegation to the Director and Chief Economist of the Division of Economic and Risk Analysis

We are delegating authority to the Director of the Division of Economic and Risk Analysis (''DERA'') and Chief Economist to update taxonomies and schemas required for use in Commission filings and made available on the Commission's website.[3] DERA maintains on the Commission's website a collection of taxonomies and schemas related to certain Commission structured data reporting requirements.[4] A taxonomy is a list of standardized disclosure elements that covers a variety of concepts, and can contain descriptive labels, definitions, and authoritative references to standards and Commission regulations.[5] Meanwhile, a schema defines the elements and attributes of a structured data report so that the report is appropriately constrained for machine-readability.[6] Updates to these taxonomies and schemas are ministerial in nature. The updates generally reflect changes to the underlying standard—such as to U.S. generally accepted accounting principles—to the underlying technology, to industry practice, or to Commission requirements. We believe that delegating authority for updates to taxonomies and schemas to the Director of DERA and Chief Economist will

[1] Articles 30–1 through 30–19 [17 CFR 200.30–1 through 200.30–19].

[2] Articles 10 through 27 [17 CFR 200.10 through 200.27].

[3] Article 30–2.

[4] Taxonomies; *www.sec.gov/structureddata/data_taxonomies.*

[5] By referencing the same underlying taxonomy, structured data from different filers and over different reporting periods can be instantly aggregated and compared for analysis. Currently, DERA's website hosts the U.S. Generally Accepted Accounting Principles (''GAAP'') eXtensible Business Reporting Language (''XBRL'') Taxonomy, the International Financial Reporting Standards (''IFRS'') Taxonomy, the U.S. Mutual Fund Risk/Return XBRL Taxonomy, the SEC Reporting Taxonomies (''SRT''), the Record of Credit Ratings XBRL Taxonomy, the Draft Closed-End Fund Taxonomy, and the Draft Variable Insurance Product Taxonomy.

[6] Currently, DERA's website hosts the Order Handling Data Schema for Broker-Dealers, the Exchange Transaction Fee Summary Schema for National Market System Stocks, the Draft Volcker Rule Metrics Instructions and Technical Specifications, and the Draft Financial Products Markup Language (''FpML'') and FIXML Schemas for Security-Based Swap Data Repositories.

conserve our resources and increase efficiency, as these updates are ministerial in nature and in the normal course of business. In addition, we are updating the description of the responsibilities of the Director of DERA and Chief Economist in our rules to include that person's current title and responsibilities.[7]

B. Delegation to the Director of the Division of Trading and Markets

We are amending our rules delegating authority to the Director of the Division of Trading and Markets (''TM''), in some instances delegating new authority and, in others, eliminating current authority.

1. Delegation of Advance Notice Authority

We are delegating authority to the Director of TM for the publication of an advance notice (''Advance Notice'') filed by a registered clearing agency designated as systemically important (a ''DCA'') by the Financial Stability Oversight Council;[8] for the issuance of a request that the DCA provide any information necessary to assess the effect a proposed change would have on the nature or level of risks associated with such DCA's payment, clearing, or settlement activities and the sufficiency of any proposed risk management techniques;[9] for the extension of the period of review when the proposed changes in an Advance Notice raise novel or complex issues and publication of notice thereof;[10] and for the publication of a withdrawal of an Advance Notice.[11] The current process associated with Advance Notice processing requires Commission action to, among other things, publish notice of an Advance Notice and any amendments thereto; make an additional information request; extend the period of review of the Advance Notice when the proposed changes in an Advance Notice raise novel or complex issues; or publish notice of a withdrawal of an Advance Notice. These actions do not raise significant issues for Commission consideration and are more administrative in nature in that they provide notice to the public on the status of an Advance Notice proposal and seek public comment for information to assist the Commission as it considers each such action individually.

We believe that delegating authority for Advance Notices will conserve our resources and increase efficiency, as the processing functions for Advance Notices are, in each instance, procedural matters that are ministerial in nature and in the normal course of business. In addition, this delegation will harmonize the staff's authority over issuance of Advance Notices and related self-regulatory organization (''SRO'') rule change filings. Finally, the expedited process that would result from a delegation of authority to affect these matters would provide TM and the Commission additional time to analyze and consider a final determination on an Advance Notice proposal after the comment period has closed.

2. Delegation of Security-Based Swap Authority to the Director of TM and the Director of the Division of Examinations

We are delegating authority to the Director of TM and the Director of the Division of Examinations (''Examinations'')[12] in connection with applications for registration as a security-based swap dealer or major security-based swap participant (''SBS Entities'').[13] We believe that permitting the Director of TM and the Director of Examinations to share this authority will more efficiently allocate agency resources. First, we are delegating authority to authorize issuance of orders granting ongoing registration to SBS Entities pursuant to 17 CFR 240.15Fb2–1(d)[14] under the Securities Exchange Act of 1934 (the ''Exchange Act'').[15] Once an applicant is conditionally registered as an SBS entity, the Commission may grant or deny ongoing registration. The Commission will grant ongoing registration if it finds that the requirements of section 15F(b) of the Exchange Act are satisfied.[16] We believe that delegating the authority to the Director of TM and the Director of Examinations to make the necessary findings and grant ongoing registration will make efficient use of our resources, while still reserving for Commission consideration any recommendation to deny ongoing registration. Similar delegated authority exists for the Director of TM to grant registration as a broker or dealer.[17]

Second, we are delegating authority to the Director of TM and the Director of Examinations to authorize the issuance of orders cancelling registrations of SBS Entities, or pending applications for registration, if such SBS Entities or applicants for registration are no longer in existence or have ceased to do business as an SBS Entity.[18] We believe that delegated authority to cancel the registrations of, or applications for registration by, non-operational SBS Entities will make efficient use of our resources, while still reserving for Commission consideration any recommendation to revoke the registration of an operating SBS Entity. Similar delegated authority exists for staff to cancel registrations of non-operational brokers and dealers.[19]

Third, we are delegating to the Director of TM and the Director of Examinations authority to determine whether notices of withdrawal from registration by SBS Entities shall become effective sooner or later than the default 60-day waiting period.[20] We believe that delegated authority to change the waiting period for withdrawal of registration as an SBS Entity will make efficient use of our resources by allowing staff to determine, and communicate to registrants, the date on which a withdrawal of registration will become effective.

3. Delegation of SBS Entity Application Authority

We are also delegating authority to the Director of TM to grant certain applications made by SBS Entities. Section 201.194 of our Rules of Practice provides for applications by SBS Entities for statutorily disqualified associated persons to effect or be involved in effecting security-based swaps.[21] We are delegating authority to the Director of TM to grant such applications.[22] We believe that delegated authority to grant these applications will make efficient use of the Commission's resources, while still preserving the Commission's ability to deny applications. We have already delegated authority to the Director of TM to grant certain similar applications with respect to an SRO.[23]

[7] Article 23a.

[8] Article 30–3(a)(91).

[9] Article 30–3(a)(93).

[10] Article 30–3(a)(94).

[11] Article 30–3(a)(92).

[12] Examinations was previously known as the Office of Compliance Inspections and Examinations, or ''OCIE.'' *See* Public Statement on the Renaming of the Office of Compliance Inspections and Examinations to the Division of Examinations (Dec. 17, 2020), *available at https://www.sec.gov/news/public-statement/joint-statement-division-examinations.*

[13] *See infra* footnotes 14–20 and accompanying text.

[14] Rule 15Fb2–1(d).

[15] 15 U.S.C. 78a *et seq.;* Article 30–3(a)(86); Article 30–18(m)(1)(i).

[16] 17 CFR 240.15Fb2–1(e).

[17] Article 30–3(a)(3).

[18] Article 30–3(a)(87); Article 30–18(m)(1)(ii).

[19] Article 30–3(a)(3)(ii).

[20] Article 30–3(a)(88); Articles 30–18(m)(1)(iii).

[21] Rule 194 (17 CFR 201.194).

[22] Article 30–3(a)(90).

[23] Article 30–3(a)(4)(i) (delegating authority to the Director of TM to grant applications with respect to membership in, association with a member of, or

Continued

4. Delegation of Substituted Compliance Authority

We are delegating authority to the Director of TM to authorize the publication in the **Federal Register** of notices that a complete application for substituted compliance has been submitted to the Commission, under 17 CFR 240.0–13.[24] Rule 0–13 provides the procedures for filing applications to request a substituted compliance or listed jurisdiction order under the Exchange Act.[25] We believe that delegating the authority to make the necessary findings will make efficient use of our resources. The action is administrative in nature and provides notice to the public of the completion of an application, beginning the process of seeking public comment for information to assist the Commission as it considers substituted compliance with respect to an application.

5. Eliminated Delegations of Authority

We are eliminating certain current delegations of authority. First, we are eliminating the following delegations of authority because they refer to rules or processes that have themselves been eliminated:

- Authority to grant requests for exemptions from former 17 CFR 240.10a–1(f) (rule 10a–1(f) under the Exchange Act), which we have previously rescinded.[26]
- Authority to publish notice of the filing of a designation plan with respect to national market system securities, or any proposed amendment thereto, and to approve such plan or amendment under former 17 CFR 242.600 (rule 600),[27] which rule has already been amended to eliminate the relevant process.
- Authority to review and, where appropriate, approve the selection by the Municipal Securities Rulemaking Board (''MSRB'') of public representatives to serve on the MSRB under former section 15B(b)(2)(B) of the Exchange Act,[28] which has previously been amended to eliminate the relevant process.
- Authority to grant exemptions from former 17 CFR 240.3b–9 (rule 3b–9 under the Exchange Act),[29] because the rule was rescinded by the Commission after being invalidated by the U.S. Court of Appeals for the District of Columbia Circuit.[30]
- Authority to grant exemptions from 17 CFR 240.17a–23 (Rule 17a–23 under the Exchange Act),[31] which has been rescinded.
- Authority to issue notices related to a transaction fee pilot program that has been vacated.[32]

Second, we are eliminating the following delegations of authority to the Director of TM because the contemplated activities are appropriately within the purview of other divisions and offices:

- Authority to grant or deny exemptions, either unconditionally or on specified terms and conditions, from 17 CFR 240.15c2–12 (Rule 15c2–12 under the Exchange Act),[33] which is similar to authority we are delegating to the Director of the Office of Municipal Securities (''OMS'').[34]
- Authority to grant requests for exemptions from the tender offer provisions of 17 CFR 240.14e–1 (Rule 14e–1 of Regulation 14E under the Exchange Act),[35] which rule is administered by the Division of Corporation Finance (''CF'').[36]
- Authority to designate officers empowered to administer oaths and affirmations, subpoena witnesses, compel their attendance, take evidence, and require the production of any books, papers, correspondence, memoranda, contracts, agreements, or other records in the course of investigations instituted by the Commission under section 21(d) of the Exchange Act,[37] which is similar to authority currently exercised by the Division of Enforcement.[38]
- Authority, in certain nonpublic investigatory proceedings, to grant requests of persons to procure copies of the transcript of their testimony,[39] which is similar to authority currently exercised by the Division of Enforcement.[40]

Finally, we are eliminating current authority to extend trading privileges and to deny applications for unlisted trading privileges (''UTP'') by national securities exchanges under 17 CFR 240.12f–1 (Rule 12f–1 under the Exchange Act), provided that any applicant exchange denied unlisted traded privileges is advised of its right to have such denial reviewed by the Commission.[41] The UTP Act of 1994 changed the way UTP was extended by no longer requiring applications for UTP to be filed with and approved by the Commission. Prior to the enactment of the UTP Act, the Commission received hundreds of applications to extend UTP each year. Although section 12(f)(2) of the Act and Rule 12f–1 are not part of that UTP extension process and instead allow for the suspension and reinstatement of trading for securities that are already trading UTP, the Division has rarely used its delegated authority under these provisions so the delegation is being eliminated.[42]

C. Delegation to the Director of the Office of Municipal Securities

We are delegating additional authority to the Director of OMS to carry out functions—with respect to the Municipal Securities Rulemaking Board (''MSRB''), municipal securities, and municipal securities dealers—that are currently delegated to the Director of TM. These authorities include:

- Authority to publish notices of proposed rule changes filed by the MSRB, to approve such proposed rule changes, to find good cause to approve a proposed rule change earlier than 30 days after publication of such proposed rule change, to disapprove a proposed rule change subject to certain requirements, and related authorities;[43]
- Authority to extend for a period not exceeding 90 days from the date of publication of notice of the filing of a proposed rule change by the MSRB the period during which the Commission must by order approve or disapprove

participation in, a self-regulatory organization and for other relief as to persons who are subject to an applicable disqualification where such relationships or other relief have been approved or recommended by a self-regulatory organization); *see also* 17 CFR 200.30–4(a)(5) [Article 30–4(a)(5)] (delegating authority to the Director of the Division of Enforcement to grant or deny applications made pursuant to 17 CFR 201.193 [Rule 193 of the Commission's Rules of Practice] by barred individuals for consent to associate with other types of registrants); Article 30–1(10) (delegating authority to the Director of CF to grant or deny applications for relief from being considered an ''ineligible issuer'' under 17 CFR 230.403 [Securities Act Rule 405]).

[24] Rule 0–13 under the Exchange Act; Article 30–3(a)(89).

[25] 17 CFR 240.0–13.

[26] Current Article 30–3(a)(15).

[27] Current Article 30–3(a)(37).

[28] Current Article 30–3(a)(40).

[29] Current Article 30–3(a)(45).

[30] *See* Exchange Act Release No. 56502 (Sept. 24, 2007) [72 FR 56562 (Oct. 3, 2007)]; *see also American Bankers Association* v. *SEC,* 804 F.2d 739 (D.C. Cir. 1986).

[31] Current Article 30–3(a)(60).

[32] Current Article 30–3(a)(84).

[33] Current Article 30–3(a)(48).

[34] *See infra* Part II.C.

[35] Current Article 30–3(a)(67).

[36] Article 30–1(f)(16)(ii) [17 CFR 200.30–1(f)(16)(ii)].

[37] Current Article 30–3(b).

[38] Article 30–4(a)(1) [17 CFR 200.30–4(a)(2)].

[39] Current Article 30–3(c).

[40] Article 30–4(a)(2) [17 CFR 200.30–4(a)(2)].

[41] Current Article 30–3(a)(2).

[42] Article 30–3(a)(2) (removed and reserved). We are also making a technical correction to update the name of TM in a delegation. Article 30–3(l). In addition, we are correcting a scrivener's error in a delegation to the Director of TM. Article 30–3(a)(47). We are also making a technical correction to a delegation to the Director of TM. Article 30–3(a)(49).

[43] Article 30–3a(a)(2). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(12).

the proposed rule change or institute proceedings to determine whether the proposed rule change should be disapproved, and related authorities; [44]

- Authority to institute proceedings to determine whether a proposed rule change of the MSRB should be disapproved, to provide to the MSRB notice of the grounds for disapproval under consideration, and to extend for a period not exceeding 240 days from the date of publication of notice of the filing of the proposed rule during which the Commission must issue an order approving or disapproving the proposed rule, and related authorities; [45]
- Authority to temporarily suspend a change in the rules of the MSRB; [46]
- Authority to reduce the period before which a proposed rule change can become operative, and to reduce the period between an MSRB submission of a filing and a pre-filing notification; [47]
- Authority to review and grant or deny exemptions from the rule filing requirements of section 19(b) of the Exchange Act,[48] in a case where the MSRB elects to incorporate by reference one or more rules of another self-regulatory organization, subject to certain terms and conditions; [49]
- Authority to issue orders granting registration of municipal securities dealers within 45 days of the filing of an application for registration; [50]
- Authority to grant, deny, and revoke applications for confidential treatment filed pursuant to section 24(b) of the Exchange Act and 17 CFR 240.24b–2 (rule 24b–2 thereunder); [51]
- Authority to notify and consult with the appropriate regulatory agency about a registered municipal securities dealer whose appropriate regulatory agency is not the Commission prior to any examination of that registered municipal securities dealer; [52]
- Authority to notify such an appropriate regulatory agency about any examination of such a registered municipal securities dealer by the Commission; [53]
- Authority to request from such an appropriate regulatory agency a copy of the report of any examination it conducted of any such registered municipal securities dealer and any data supplied to it in connection with such examination; [54]
- Authority to furnish to such an appropriate regulatory agency on request a copy of the report of any examination of any such municipal securities dealer conducted by the Commission and any data supplied to it in connection with such examination; [55]
- Authority to grant or deny exemptions, either unconditionally or on specified terms and conditions, from Rule 15c2–12 under the Exchange Act; [56]
- Authority to administer the provisions of 17 CFR 240.24c–1 (Rule 24c–1 under the Exchange Act); [57]
- Authority to administer the provisions of section 24(d) of the Exchange Act; [58] and
- Authority to consult on behalf of the Commission pursuant to section 18(t)(1) of the Federal Deposit Insurance Act [59] with respect to matters described in Article 19a.[60]

We believe it is appropriate for the Director of OMS—like the Director of TM—to exercise such functions and that delegating this authority will conserve our resources and improve efficiency. In addition, we are updating the description of the responsibilities of the Director of OMS in our rules to include that person's current responsibilities.[61]

D. Delegation to the Director of the Division of Investment Management

The Commission is eliminating a current delegation to the Director of the Division of Investment Management (''IM''). The Commission previously delegated to the Director of IM the same authority with respect to certain rules under the Securities Act of 1933 (''Securities Act'') [62] that it also delegated to each Regional Director.[63] This delegation to the Director of IM refers to the delegation to each Regional Director that has since been eliminated by the Commission.[64] We are therefore eliminating the delegation to the Director of IM that refers to the previously eliminated delegation to each Regional Director.[65]

E. Delegation to the Chief Accountant

The Commission is delegating authority to its Chief Accountant to share with certain specified persons nonpublic information and files with the concurrence of the head of the division or office responsible for such information and files.[66] Rule 24c–1 under the Exchange Act provides that the Commission may, in its discretion and upon a showing that such information is needed, provide nonpublic information in its possession to certain persons if they provide such assurances of confidentiality as the Commission deems appropriate.[67] The Commission has previously delegated similar authority to several other divisions and offices.[68] The Chief Accountant's responsibilities related to the Public Company Accounting Oversight Board (the ''PCAOB'') occasionally requires the sharing of nonpublic information. We believe that providing the Chief Accountant with the same authority delegated to other divisions and offices will make

[44] Article 30–3a(a)(7). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(31).

[45] Article 30–3a(a)(11). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(57).

[46] Article 30–3a(a)(12). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(58).

[47] Article 30–3a(a)(13). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(59).

[48] 15 U.S.C. 78s(b).

[49] Article 30–3a(a)(14). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(76).

[50] Article 30–3a(a)(3). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(13).

[51] Article 30–3a(a)(4). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(19).

[52] Article 30–3a(a)(5). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(23).

[53] Article 30–3a(a)(6)(i). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(24)(i).

[54] Article 30–3a(a)(6)(ii). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(24)(ii).

[55] Article 30–3a(a)(6)(iii). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(24)(iii).

[56] Article 30–3a(a)(8). This authority is current delegated to the Director of TM, but we are transferring it to the Director of OMS. *See* current Article 30–3(a)(48). *See supra* Part II.B.

[57] Article 30–3a(a)(9). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(53).

[58] Article 30–3a(a)(10). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(a)(54).

[59] 12 U.S.C. 1828(t)(1).

[60] Article 30–3a(c). This authority is similar to authority already delegated to the Director of TM. *See* Article 30–3(g).

[61] Article 19d.

[62] 15 U.S.C. 77a *et seq.*

[63] Current article 30–5(h)(1).

[64] *Id.* (providing that Director of the Division of Investment Management shall have the same authority with respect to the Securities Act of 1933 and 17 CFR 230.251 through 230.262 (rules 251 through 263 thereunder) as that delegated to each Regional Director in Article 30–6(b) and (c)).

[65] *See* article 30–5(h)(1) (removed and reserved).

[66] Article 30–11(c).

[67] 17 CFR 240.24c–1(b).

[68] Article 30–1(f)(14) (delegating similar authority to the Director of the Division of Corporate Finance); article 30–3(a)(53) (delegating similar authority to the Director of the Division of Trading and Markets); article 30–4(a)(7) (delegating similar authority to the Director of the Division of Enforcement); article 30–5(c–1)(3) (delegating similar authority to the Director of the Division of Investment Management); article 30–15(m)(1) (delegating similar authority to the General Counsel of the Commission); article 30–18(a) (delegating similar authority to the Director of the Office of Compliance Inspections and Examinations).

coordination with the PCAOB more efficient.

F. Delegation to the General Counsel

The Commission is clarifying a delegation of authority to the General Counsel. We have previously delegated to the General Counsel authority to approve non-expert, non-privileged, factual testimony by present or former staff members, and the production of non-privileged documents, when validly subpoenaed, and to assert governmental privileges on behalf of the Commission in litigation where the Commission appears as a party or in response to third party subpoenas.[69] Our rules specify, however, that those functions are not delegated to the General Counsel with respect to proceedings in which the Chairman or the General Counsel determines that separation of functions requirements or other circumstances would make inappropriate the General Counsel's exercise of such delegated functions.[70] Rather, with respect to such proceedings, such functions had been delegated to the Executive Assistant to the Chairman.[71] The Executive Assistant to the Chairman is a position that is no longer in use. We are therefore removing and reserving the provisions relating to description of and delegation to the Executive Assistant to the Chairman.[72] We have determined, instead, to delegate such functions in those circumstances to the Secretary of the Commission.[73] This delegation is similar to a prior delegation that we made to the Secretary for functions otherwise carried out by the General Counsel when the Chairman or General Counsel determines that separation of functions requirements or other circumstances would make exercise of the delegated functions by the General Counsel inappropriate.[74]

G. Delegation to the Director of the Division of Examinations

The Commission is eliminating certain current delegations of authority to the Director of Examinations that Examinations does not use. The Commission has previously delegated to the Director of Examinations authority to grant, deny, and revoke applications for confidential treatment filed pursuant to section 24(b) of the Exchange Act and rule 24b–2 thereunder;[75] to administer the provisions of section 24(d) of the Exchange Act;[76] to notify the Securities Investor Protection Corporation (''SIPC'') of facts concerning the activities and the operational and financial condition of any registered broker or dealer which is or appears to be a member of SIPC and which is in or approaching financial difficulty within the meaning of section 5 of the Securities Investor Protection Act of 1970, as amended;[77] to delay certain inspections of certain newly registered broker-dealers under section 15(b)(2)(C) of the Exchange Act;[78] and, in certain circumstances, to grant or deny exemptions from 17 CFR 240.17a–25 (rule 17a–25 under the Exchange Act), among other authorities.[79] The Commission is also eliminating a duplicative delegation that authorizes the issuance of orders canceling registrations or pending applications of registration of certain investment advisers.[80] We understand that the Director of Examinations does not exercise the above authorities, and we have determined that it is appropriate to eliminate them. In addition, we are updating the name and description of the responsibilities of the Director of Examinations in our rules to include the current name and the responsibilities related to security-based swaps.[81]

H. Delegation to the Director of the Office of Credit Ratings

The Commission is delegating authority to the Director of the Office of Credit Ratings (''OCR'') for functions that are currently delegated to the Director of TM and others. First, we are delegating authority to grant and deny applications for confidential treatment filed under section 24(b) of the Exchange Act,[82] and to revoke a grant of confidential treatment for any such application.[83] The authority to grant and deny applications for confidential treatment and revoke a grant of confidential treatment is delegated to several members of our staff.[84] Second, we are delegating authority to administer the provisions of rule 24c–1 under the Exchange Act,[85] which the Commission has previously delegated to other members of the staff.[86] Finally, we are delegating authority to administer the provisions of section 24(d) of the Exchange Act,[87] which the Commission has similarly delegated to other members of the staff.[88] We believe it is appropriate for the Director of OCR to exercise such functions and that delegating this authority will conserve our resources and improve efficiency. In addition, we are adding a description of the responsibilities of the Director of OCR in our rules.[89]

I. Additional Amendments to Division and Office Descriptions and Delegations

We are also amending the description for certain other divisions and offices to better reflect the current name or duties of those divisions and offices.[90] In addition, we are amending a number of our division and office descriptions and delegations to remove gender-specific language from them.[91]

[69] Article 30–14(g).

[70] Article 30–14(i).

[71] Current Article 30–14(i).

[72] Article 16 (removed and reserved); Article 30–16 (removed and reserved).

[73] Article 30–14(i).

[74] Article 30–14(k). In addition, we are correcting a typographical error in the rules delegating authority to the General Counsel. Article 30–14(b).

[75] Current Article 30–18(b).

[76] Current Article 30–18(e) (providing for administration of provisions related to certain records obtained from foreign securities authorities).

[77] 15 U.S.C. 78aa *et seq.*; current Article 30–18(f). Currently, rather than exercising this authority directly, it is Examinations's practice to notify the Division of Trading and Markets, which will then determine whether to exercise its Director's authority to notify SIPC. *See* Article 30–3(d) (delegating similar authority to the Director of Trading and Markets).

[78] Current Article 30–18(g).

[79] Current Article 30–18(h).

[80] Current Article 30–18(k)(2). We believe that this authority is duplicative of authority separately delegated to the Director of Examinations to authorize the issuance of orders cancelling registration or applications for registration of certain investment advisers. Article 30–18(i)(1). As discussed above, we are also delegating authority to the Director of Examinations that is similar to the authority delegated to the Director of TM concerning security-based swaps. Article 30–18(m); *see also supra* footnotes 14–20 and accompanying text.

[81] Article 19c.

[82] 15 U.S.C. 78x(b).

[83] Article 30–3b(a).

[84] *See* Article 30–1(f)(3) (delegating similar authority to the Director of CF); Article 30–3(a)(19) (delegating similar authority to the Director of TM); Article 30–5(c–1)(4) (delegating similar authority to the Director of IM).

[85] Article 30–3b(b)(1).

[86] *See* Article 30–1(f)(14) (delegating similar authority to the Director of CF); Article 30–3(a)(53) (delegating similar authority to the Director of TM); Article 30–4(a)(7) (delegating similar authority to the Director of the Division of Enforcement); Article 30–5(c–1)(3) (delegating similar authority to the Director of IM); Article 30–11(d) (delegating similar authority to the Chief Accountant); Article 30–14(m)(1) (delegating similar authority to the General Counsel); Article 30–18(a) (delegating similar authority to the Director of Examinations).

[87] 15 U.S.C. 78x(d).

[88] *See* Article 30–1(f)(15) (delegating similar authority to the Director of CF); Article 30–3(a)(54) (delegating similar authority to the Director of TM); Article 30–4(a)(9) (delegating similar authority to the Director of the Division of Enforcement); Article 30–5(c–1)(4) (delegating similar authority to the Director of IM); Article 30–14(m)(2) (delegating similar authority to the General Counsel); Article 30–17(b) (delegating similar authority to the Director of the Office of International Affairs).

[89] Article 19e.

[90] Article 11; Article 13; Article 13b; Article 24a; Article 26a; Article 27. We have also determined to eliminate the description of the Chief Management Analyst position, as this position is no longer in use. Article 17 (removed and reserved).

[91] Article 10; Article 11; Article 13a; Article 13b; Article 14; Article 21; Article 21a; Article 24;

II. Administrative Law Matters

The Commission finds, in accordance with the Administrative Procedure Act (''APA''), that these amendments relate solely to agency organization, procedure, or practice.[92] Accordingly, the APA's provisions regarding notice of rulemaking and opportunity for public comment are not applicable. These changes are therefore effective on February 16, 2021. In accord with the APA, we find that there is good cause to establish an effective date less than 30 days after publication of these rules.[93] These rules do not substantially affect the rights or obligations of non-agency parties and pertain to increasing efficiency of internal Commission operations. For the same reasons, the provisions of the Small Business Regulatory Enforcement Fairness Act are not applicable.[94] Additionally, the provisions of the Regulatory Flexibility Act,[95] which apply only when notice and comment are required by the APA or other law, are not applicable.[96] These amendments do not contain any collection of information requirements as defined by the Paperwork Reduction Act of 1995.[97] Further, because these amendments impose no new burdens on private parties, the Commission does not believe that the amendments will have any impact on competition for purposes of section 23(a)(2) of the Exchange Act.[98]

III. Statutory Authority

This rule is adopted pursuant to statutory authority granted to the Commission, including section 19 of the Securities Act of 1933, 15 U.S.C. 77s; sections 4A, 4B, and 23 of the Exchange Act, 15 U.S.C. 78d–1, 78d–2, and 78w; section 38 of the Investment Company Act of 1940, 15 U.S.C. 80a–37; section 211 of the Investment Advisers Act of 1940, 15 U.S.C. 80b–11; and section 3 of the Sarbanes-Oxley Act of 2002, 15 U.S.C. 7202.

Article 27; Article 30–1; Article 30–3; Article 30–3a; Article 30–5; Article 30–6; Article 30–7; Article 30–10; Article 30–11; Article 30–13; Article 30–14; Article 30–15; Article 30–18. In addition, we are correcting certain outdated statutory references. Article 30–1; Article 30–2; Article 30–3; Article 30–5; Article 30–6; Article 30–7; Article 30–10.

[92] 5 U.S.C. 553(b)(3)(A).

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

[94] *See* 5 U.S.C. 804(3)(C) (the term ''rule'' does not include ''any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties'').

[95] 5 U.S.C. 60 *et seq.*

[96] *See* 5 U.S.C. 601(2).

[97] *See* 5 CFR 1320.3.

[98] 15 U.S.C. 78w(a)(2).

List of Subjects in 17 CFR Part 200

Administrative practice and procedure, Authority delegations (Government agencies).

Text of Rule Amendments

For the reasons set out in the preamble, the Commission is amending title 17, chapter II of the *Code of Federal Regulations* as follows:

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

Subpart A—Organization and Program Management

■ 1. The authority citation for part 200, subpart A, continues to read in part as follows:

Authority: 15 U.S.C. 77c, 77o, 77s, 77z–3, 77sss, 78d, 78d–1, 78d–2, 78o–4, 78w, 78*ll*(d), 78mm, 80a–37, 80b–11, 7202, and 7211 *et seq.,* unless otherwise noted.

* * * * *

Sections 200.27 and 200.30–6 are also issued under 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77q, 77u, 78e, 78g, 78h, 78i, 78k, 78m, 78o, 78o–4, 78q, 78q–1, 78t–1, 78u, 77hhh, 77uuu, 80a–41, 80b–5, and 80b–9.

Section 200.30–1 is also issued under 15 U.S.C. 77f, 77g, 77h, 77j, 78c(b) 78*l,* 78m, 78n, 78*o*(d).

Section 200.30–3 is also issued under 15 U.S.C. 78b, 78d, 78f, 78k–1, 78q, 78s, and 78eee.

Section 200.30–5 is also issued under 15 U.S.C. 77f, 77g, 77h, 77j, 78c(b), 78*l,* 78m, 78n, 78o(d), 80a–8, 80a–20, 80a–24, 80a–29, 80b–3, 80b–4.

* * * * *

■ 2. Section 200.10 is revised to read as follows:

§ 200.10 The Commission.

The Commission is composed of five members, not more than three of whom may be members of the same political party. The members are appointed by the President, with the advice and consent of the Senate, for 5-year terms, one term ending each year. The Chairman is designated by the President pursuant to the provisions of section 3 of Reorganization Plan No. 10 of 1950 (3 CFR, 1949–1953 Comp., p. 1006). The terms Chair, Chairperson, Chairman, Chairwoman, and the like may be used interchangeably. The Commission is assisted by a staff, which includes lawyers, accountants, engineers, financial security analysts, investigators, and examiners, as well as administrative and clerical employees.

■ 3. Section 200.11 is amended by revising paragraph (a)(2) to read as follows:

§ 200.11 Headquarters Office—Regional Office relationships.

(a) * * *

(2) Each Regional Director is responsible for the direction and supervision of the Regional Director's work force and for the execution of all programs in the Regional Director's office's region as shown in paragraph (b) of this section, in accordance with established policy, and reports, on enforcement matters, to the Director or Deputy Director of the Division of Enforcement who is responsible for Regional Office enforcement matters and, on examination matters, to the Director of the Division of Examinations.

* * * * *

■ 4. Section 200.13 is amended by revising paragraphs (a), (d)(1), (e), and (f) to read as follows:

§ 200.13 Chief Operating Officer.

(a) The Chief Operating Officer is responsible for developing and executing the overall management policies of the Commission for all its operating divisions and staff offices. The Chief Operating Officer also provides executive direction to, and exercises administrative control over, the Office of Human Resources, the Office of Acquisitions, the Office of Financial Management, the Office of Support Operations, the EDGAR Business Office, and the Office of Information Technology.

* * * * *

(d) * * *

(1) Implementing the goals of the Chairman and the mission of the Commission;

* * * * *

(e) Overseeing Commission-specific application of performance measures, procurement reforms, personnel reductions, financial management improvements, telecommunications and information technology policies, and other Government-wide systems reforms; and

(f) Reforming the Commission's management practices.

■ 5. Section 200.13a is amended by revising paragraphs (a) and (c) to read as follows:

§ 200.13a The Secretary of the Commission.

(a) The Secretary of the Commission is responsible for the preparation of the daily and weekly agendas of Commission business; the orderly and expeditious flow of business at formal Commission meetings; the maintenance of the Official Minute record of all actions of the Commission; and the

service of all instruments of formal Commission action. The Secretary is custodian of the official seal of the Commission, and also has the responsibility for authenticating documents.

* * * * *

(c) In addition, the Secretary administers the Commission's Library.

■ 6. Section 200.13b is revised to read as follows:

§ 200.13b Director of the Office of Public Affairs.

The Director of the Office of Public Affairs is the chief public information officer for the Commission, and oversees activities that communicate the Commission's actions to those interested in or affected by them. The Director's responsibilities include serving as liaison with the news media, dissemination of information to the news media and to the general public, supervision of internal and some external publications and of audio-visual presentations. Responsibilities of the Director, and of the Director's staff, include special projects that may be deemed appropriate to communicate information on Commission actions.

■ 7. Section 200.14 is amended by revising paragraph (b) to read as follows:

§ 200.14 Office of the Administrative Law Judges.

* * * * *

(b) The Chief Administrative Law Judge performs the duties of an Administrative Law Judge under the Administrative Procedure Act and the duties delegated to the Chief Administrative Law Judge by the Commission that are compatible with those duties. The Chief Administrative Law Judge is responsible for the orderly functioning of the Office of Administrative Law Judges apart from the conduct of administrative proceedings and acts as liaison between that Office and the Commission.

§ 200.16 [Removed and Reserved]

■ 8. Section 200.16 is removed and reserved.

§ 200.17 [Removed and Reserved]

■ 9. Section 200.17 is removed and reserved.

■ 10. Section 200.19c is revised to read as follows:

§ 200.19c Director of the Division of Examinations.

The Director of the Division of Examinations (''Examinations'') is responsible for the compliance inspections and examinations relating to the regulation of exchanges, national securities associations, clearing agencies, securities information processors, the Municipal Securities Rulemaking Board, brokers and dealers, municipal securities dealers, municipal advisors, security-based swap data repositories, security-based swap dealers, major security-based swap participants, transfer agents, investment companies, and investment advisers, under sections 13(n)(2), 15B, 15C(d)(1), 15F, and 17(b) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(n)(2), 78*o*–4, 78*o*–5(d)(1), 78*o*–10, and 78q(b)), section 31(b) of the Investment Company Act of 1940 (15 U.S.C. 80a–30(b)), and section 204 of the Investment Advisers Act of 1940 (15 U.S.C. 80b–4).

■ 11. Section 200.19d is revised to read as follows:

§ 200.19d Director of the Office of Municipal Securities.

The Director of the Office of Municipal Securities is responsible to the Commission for the administration and execution of the Commission's programs under the Securities Exchange Act of 1934 relating to the registration and regulation of municipal advisors, the practices of municipal securities brokers and dealers, and oversight of the Municipal Securities Rulemaking Board. The functions involved include recommending the adoption and amendment of Commission rules, reviewing proposed rule changes of the Municipal Securities Rulemaking Board, and responding to interpretive and no-action requests.

■ 12. Section 200.19e is added to read as follows:

§ 200.19e Director of the Office of Credit Ratings.

The Director of the Office of Credit Ratings is responsible to the Commission for the administration and execution of the Commission's programs under the Securities Exchange Act of 1934 relating to the registration and regulation of nationally recognized statistical rating organizations. The functions involved in the regulation of such entities include compliance inspections and examinations, recommending the adoption and amendment of Commission rules, and responding to interpretive and no-action requests.

§ 200.20a [Added and Reserved]

■ 13. Add reserved § 200.20a.

■ 14. Section 200.21 is revised to read as follows:

§ 200.21 The General Counsel.

(a) The General Counsel is the chief legal officer of the Commission. The General Counsel is responsible for the representation of the Commission in judicial proceedings in which it is involved as a party or as amicus curiae, for directing and supervising all civil litigation involving the Commission in the United States District Courts, except for law enforcement actions filed on behalf of the Commission, for directing and supervising the Commission's responsibilities under the Bankruptcy Code and all related litigation, and for representing the Commission in all cases in appellate courts. The General Counsel is responsible for the review of cases which the Division of Enforcement recommends be referred to the Department of Justice with a recommendation for criminal prosecution. In addition, the General Counsel is responsible for advising the Commission at its request or at the request of any division director or office head, or on the General Counsel's own motion, with respect to interpretations involving questions of law; for the conduct of administrative proceedings relating to the disqualification of lawyers from practice before the Commission; for conducting preliminary investigations, as described in 17 CFR 202.5(a), into potential violations of 17 CFR 201.102(e) by attorneys; for the preparation of the Commission comments to the Congress on pending legislation; and for the drafting, in conjunction with appropriate divisions and offices, of legislative proposals to be sponsored by the Commission. The General Counsel is responsible for providing advice to Commission attorneys on professional responsibility issues relating to their official duties. The General Counsel is further responsible for investigating allegations of professional misconduct by Commission staff and, where appropriate, making referrals to state professional boards or societies. The General Counsel is also responsible for the review and clearance of the form and content of articles, treatises, and prepared speeches and addresses by members of the staff relating to the Commission or to the statutes and rules administered by the Commission. The General Counsel also is responsible for coordinating and reviewing the interpretive positions of the various divisions and offices. In addition, the General Counsel is responsible for appropriate disposition of all Freedom of Information Act and Privacy Act appeals pursuant to the authority delegated in § 200.30–14, and is the

Commission's advisor with respect to legal problems arising under the Freedom of Information Act, the Privacy Act, the Federal Reports Act, the Federal Advisory Committee Act, the Civil Service laws and regulations, the statutes and rules applicable to the Commission's procurement, contracting, fiscal and related administrative activities, and other statutes and regulations of a similar nature applicable to a number of Government agencies.

(b)(1) The General Counsel is also responsible for assisting members of the Commission in the preparation of the opinions of the Commission, and for the preparation of opinions and decisions on motions and certifications of questions and rulings by administrative law judges in the course of administrative law proceedings, except:

(i) In cases where, pursuant to a waiver by the parties of separation of function requirements, another Division or Office of the Commission's staff undertakes to prepare an opinion or decision, in which cases the General Counsel may assist in such preparation; and

(ii) With respect to administrative proceedings against lawyers under § 201.102(e) of this chapter (Rule 102(e) of the Commission's Rules of Practice) or other cases in which the Chairman or the General Counsel has determined that separation of function requirements or other circumstances would make inappropriate the exercise of such functions by the General Counsel.

(2) The General Counsel deals with general problems arising under the Administrative Procedure Act, including the revision or adoption of rules of practice. The General Counsel is also responsible for the exercise of such review functions with respect to adjudicatory matters as are delegated to the General Counsel by the Commission pursuant to 101 Stat. 1254 (15 U.S.C. 78d–1, 78d–2) or as may be otherwise delegated or assigned to the General Counsel.

(c) The General Counsel also is responsible to the Commission for the administration of the Government in the Sunshine Act for publicly certifying, pursuant to § 200.406, that, in the General Counsel's opinion, particular Commission meetings may properly be closed to the public. In the absence of the General Counsel, the Solicitor to the Commission shall be deemed the General Counsel for purposes of § 200.406. In the absence of the General Counsel and the Solicitor, the most senior Associate General Counsel available shall be deemed the General Counsel for purposes of § 200.406. In the absence of the General Counsel, the Solicitor, and every Associate General Counsel, the most senior Assistant General Counsel available shall be deemed the General Counsel for purposes of § 200.406. In the absence of the General Counsel, the Solicitor, every Associate General Counsel and every Assistant General Counsel, such attorneys as the General Counsel may designate (in such order of succession as the General Counsel directs) shall exercise the responsibilities imposed by § 200.406.

■ 15. Section 200.21a is amended by revising paragraph (a) to read as follows:

§ 200.21a The Ethics Counsel.

(a) The Ethics Counsel is responsible for administering the Commission's Ethics Program and for interpreting subpart M of this part and 5 CFR part 2635. The Ethics Counsel serves as Counselor to the Commission and its staff with regard to ethical and conflicts of interest questions and acts as the Commission's liaison on such matters with the Office of Human Resources, the Office of Government Ethics, the Office of the Inspector General, and the Department of Justice. When appropriate and subject to the authority of, and in consultation with, the Inspector General, the Ethics Counsel shall inquire into alleged violations of subparts C, F, and M of this part, and 5 CFR part 2635.

* * * * *

■ 16. Section 200.23a is revised to read as follows:

§ 200.23a Director of the Division of Economic and Risk Analysis and Chief Economist.

The Director of the Division of Economic and Risk Analysis and Chief Economist serves as economic advisor to the Commission and its staff and is responsible to the Commission for sound economic analysis of market events and conditions; economic analysis in support of Commission rulemaking; economic and risk analysis to inform and support the Commission's enforcement actions and its examination program; development of financial and market data analysis tools; preparation of economic statistics; promotion of data standards; review and guidance of staff research and publications; and assisting the Commission and its staff in responding to policy, legislative, or international issues relating to securities markets.

■ 17. Section 200.24 is revised to read as follows:

§ 200.24 Office of Financial Management.

This Office, under the direction of the Chief Financial Officer, is responsible to the Chief Operating Officer, Chairman and Commission for the internal financial management and programming functions of the Securities and Exchange Commission. These functions include: Budgeting, accounting, payroll and administrative audit. The Chief Financial Officer, and the Chief Financial Officer's designees, serve as liaison to the Commission before the Office of Management and Budget and Congressional Appropriations Committees on appropriation matters, and the Treasury Department and the General Accounting Office on financial and programming matters.

■ 18. Section 200.24a is revised to read as follows:

§ 200.24a Director of the Office of Investor Education and Advocacy.

The Director of the Office of Investor Education and Advocacy is responsible to the Chairman for the Commission's investor education and investor assistance programs. These programs include, but are not limited to:

(a) Educating investors through in-person outreach, digital and social media, and other communication channels, including the Commission's website for individual investors, *Investor.gov*, by preparing and distributing to the public educational content describing the operations of the securities markets, developing strategies for prudent investor behavior, and increasing public knowledge of the functions of the Commission.

(b) Implementing and administering a nationwide system for resolving investor complaints against individuals and entities regulated by the Commission by processing complaints received from individual investors and seeking to ensure that regulated individuals and entities process and respond to such complaints.

(c) Providing information to investors and others who inquire about individuals and entities regulated by the Commission, the operation of the securities markets, or the functions of the Commission.

(d) Advising the Commission and its staff, and exchanging information with domestic and international regulators and self-regulatory organizations, about problems frequently encountered by investors and possible solutions to them.

(e) Transmitting to other offices and divisions of the Commission information provided by investors which concerns the responsibilities of these offices and divisions.

(f) Providing for greater investor input in Commission rulemaking proceedings.

■ 19. Section 200.26a is revised to read as follows:

§ 200.26a Office of Information Technology.

The Office of Information Technology is responsible for the analysis, design programming, operation, and maintenance of all agency information systems; developing and implementing long-range technology plans and programs; coordinating all information systems analysis activities being considered or carried out by other divisions and offices, and furnishing such organizations with appropriate assistance and support; providing technical advice to the staff in connection with development of Commission rules and regulations having technology implications; providing expert advice on the Commission's surveillance of technology in the securities industry; evaluating and recommending new technology concepts and capabilities for application within the Commission; and developing technology and automation capabilities and support within the Commission.

§ 200.27 [Amended]

■ 20. Section 200.27 is revised by:

■ a. Removing the words ''his or her'' and adding in their place the words ''the Regional Director's'';

■ b. Removing the words ''by the Deputy Director of the Division of Enforcement who is responsible for Regional Office enforcement matters'' and adding in their place the words ''by the Director or Deputy Director of the Division of Enforcement''; and

■ c. Removing the words ''Office of Compliance Inspections and Examinations'' and adding in their place the words ''Division of Examinations''.

■ 21. Section 200.30–1 is amended by:

■ a. Revising the introductory text and paragraph (a)(3);

■ b. In paragraph (f)(2)(i), removing the word ''ommission'' and adding in its place the word ''omission''; and

■ c. Revising paragraphs (f)(5) and (g)(2).

The revisions read as follows:

§ 200.30–1 Delegation of authority to the Director of the Division of Corporation Finance.

Pursuant to sections 4A and 4B of the Securities Exchange Act of 1934, as amended (15 U.S.C. 78d–1, 78d–2), the Securities and Exchange Commission hereby delegates, until the Commission orders otherwise, the following functions to the Director of the Division of Corporation Finance, to be performed by the Director or under the Director's direction by such person or persons as may be designated from time to time by the Chairman of the Commission:

(a) * * *

(3) To grant applications for confidential treatment of contract provisions pursuant to § 230.406 of this chapter (Rule 406 under the Act); to issue orders scheduling hearings on such applications and to deny any such application as to which the applicant waives the applicant's right to a hearing, provided such applicant is advised of the applicant's right to have such denial reviewed by the Commission.

* * * * *

(f) * * *

(5) To grant or deny applications filed pursuant to section 12(g)(1) of the Act (15 U.S.C. 78l(g)(1)) for extensions of time within which to file registration statements pursuant to that section, provided the applicant is advised of the applicant's right to have any such denial reviewed by the Commission.

* * * * *

(g) * * *

(2) In any case in which the Director of the Division of Corporation Finance believes it appropriate, the Director may submit the matter to the Commission.

* * * * *

■ 22. Section 200.30–2 is added to read as follows:

§ 200.30–2 Delegation of authority to the Director of the Division of Economic and Risk Analysis and Chief Economist.

Pursuant to sections 4A and 4B of the Securities Exchange Act of 1934, as amended (15 U.S.C. 78d–21, 78d–22), the Securities and Exchange Commission hereby delegates, until the Commission orders otherwise, the following functions to the Director of the Division of Economic and Risk Analysis and Chief Economist, to be performed by that person or under that person's direction by such person or persons as may be designated from time to time by the Chairman of the Commission:

(a) To update taxonomies and schemas required for use in Commission filings and made available on the Commission's website.

(b) [Reserved]

■ 23. Section 200.30–3 is amended by:

■ a. Revising the introductory text;

■ b. Removing and reserving paragraph (a)(2);

■ c. In paragraphs (a)(5), (8), and (9), removing the word ''his'' and adding in its place the words ''the applicant's'';

■ d. Removing and reserving paragraphs (a)(15), (37), and (40);

■ e. In paragraph (a)(43), removing the citation ''Pub. L. 87–592, 76 Stat. 394'' and adding in its place the citation ''sections 4A and 4B of the Securities Exchange Act of 1934, as amended'';

■ f. Removing and reserving paragraph (a)(45);

■ g. Revising paragraph (a)(47);

■ h. Removing and reserving paragraph (a)(48);

■ i. In paragraph (a)(49):

■ i. Removing ''Rule 609 thereunder (17 CFR 242.609)'' and adding in its place ''17 CFR 242.609 (Rule 609 thereunder)''; and

■ ii. Removing the words ''that section and any rules or regulations promulgated thereunder'' and adding in their place ''Rule 609'';

■ j. Removing and reserving paragraphs (a)(60), (67), and (84);

■ k. Adding paragraphs (a)(86) through (94);

■ l. Removing and reserving paragraphs (b) and (c); and

■ m. Revising paragraph (l).

The revisions and additions read as follows:

§ 200.30–3 Delegation of authority to Director of the Division of Trading and Markets.

Pursuant to sections 4A and 4B of the Securities Exchange Act of 1934, as amended (15 U.S.C. 78d–1, 78d–2), the Securities and Exchange Commission hereby delegates, until the Commission orders otherwise, the following functions to the Director of the Division of Trading and Markets to be performed by the Director or under the Director's direction by such person or persons as may be designated from time to time by the Chairman of the Commission:

(a) * * *

(47) Pursuant to section 15(a)(2) of the Act, 15 U.S.C. 78o(a)(2), to review and, either unconditionally or on specified terms and conditions, grant exemptions from the broker-dealer registration requirements of section 15(a)(1) of the Act, 15 U.S.C. 78o(a)(1), to Government securities brokers or Government securities dealers that have registered with the Commission under section 15C(a)(2) of the Act, 15 U.S.C. 78o–5(a)(2), solely with respect to effecting any transactions in, or inducing or attempting to induce the purchase or sale of, any security principally backed by a guaranty of the United States.

* * * * *

(86) To authorize the issuance of orders granting on-going registration to security-based swap dealers and major security-based swap participants based on the security-based swap dealer's or major security-based swap participant's application, pursuant to § 240.15Fb2–1(e) of this chapter (Rule 15Fb2–1(e)).

(87) To authorize the issuance of orders canceling the registration of security-based swap dealers and major security-based swap participants registered pursuant to § 240.15Fb2–1 of this chapter (Rule 15Fb2–1) if such persons are no longer in existence or have ceased to do business as security-based swap dealers or major security-based swap participants, pursuant to § 240.15Fb3–3(a) of this chapter (Rule 15Fb3–3(a)).

(88) To determine by order, pursuant to § 240.15Fb3–2(b) of this chapter (Rule 15Fb3–2(b)), whether notices of withdrawal of registration filed by security-based swap dealers or major security-based swap participants pursuant to section 15F(b) of the Securities Exchange Act of 1934 (15 U.S.C. 78o–10(b)) shall become effective sooner than the normal 60 day period provided in Rule 15Fb3–2(b) (§ 240.15Fb3–2(b) of this chapter).

(89) To authorize the publication in the **Federal Register** of notices that a complete application for substituted compliance has been submitted to the Commission, pursuant to § 240.0–13 of this chapter (Rule 0–13).

(90) To grant applications made pursuant to § 201.194 of this chapter (Rule 194 of the Commission's Rules of Practice).

(91) Pursuant to section 19(b) of the Act, 15 U.S.C. 78s(b), and § 240.19b–4(n) of this chapter (Rule 19b–4), to publish notices of advance notices filed by designated clearing agencies.

(92) Pursuant to section 19(b) of the Act, 15 U.S.C. 78s(b), and § 240.19b–4(n) of this chapter (Rule 19b–4), to publish notices of withdrawals of advance notices filed by designated clearing agencies.

(93) Pursuant to section 806(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010, 12 U.S.C. 5465(e)(1)(D), to require a designated clearing agency to provide any information necessary to assess the effect the proposed change would have on the nature or level of risks associated with the designated clearing agency's payment, clearing, or settlement activities and the sufficiency of any proposed risk management techniques.

(94) Pursuant to section 806(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010, 12 U.S.C. 5465(e)(1)(H), to extend the review period for an additional 60 days for proposed changes that raise novel or complex issues and provide the designated clearing agency with prompt written notice of such extension.

* * * * *

(l) Notwithstanding anything in paragraphs (a) through (k) of this section, in any case in which the Director of the Division of Trading and Markets believes it appropriate, the Director may submit the matter to the Commission.

■ 24. Section 200.30–3a is amended by:

■ a. In the introductory text, removing the words ''him or under his'' and adding in their place ''the Director or under the Director's'';

■ b. Adding paragraphs (a)(2) through (14);

■ c. Redesignating paragraph (b) as paragraph (c); and

■ d. Adding new paragraph (b).

The additions read as follows.

§ 200.30–3a Delegation of authority to the Director of the Office of Municipal Securities.

* * * * *

(a) * * *

(2) Pursuant to section 19(b) of the Act, 15 U.S.C. 78s(b), and § 240.19b–4 of this chapter (Rule 19b–4), to publish notices of proposed rule changes filed by the Municipal Securities Rulemaking Board and to approve such proposed rule changes, and to find good cause to approve a proposed rule change earlier than 30 days after the date of publication of such proposed rule change and to publish the reasons for such finding. Pursuant to section 19(b) of the Act, 15 U.S.C. 78s(b), and Rule 19b–4 (§ 240.19b–4 of this chapter), to disapprove a proposed rule change, provided that, with respect to a particular proposed rule change, if two (2) or more Commissioners object in writing to the Director within five (5) business days of being notified by the Director that the Office intends to exercise its authority to disapprove that particular proposed rule change, then the delegation of authority to approve or disapprove that proposal is withdrawn, and the Director shall either present a recommendation to the Commission or institute pursuant to delegated authority proceedings to determine whether the proposed rule change should be disapproved. In addition, pursuant to section 19(b)(10) of the Act, 15 U.S.C. 78s(b)(10), to notify the Municipal Securities Rulemaking Board that a proposed rule change does not comply with the rules of the Commission relating to the required form of a proposed rule change, and to determine that a proposed rule change is unusually lengthy and complex or raises novel regulatory issues and to inform the Municipal Securities Rulemaking Board of such determination.

(3) Pursuant to section 15B(a) of the Act [15 U.S.C. 78o–4(a)], to authorize the issuance of orders granting registration of municipal securities dealers within forty-five days of the filing of an application for registration as a municipal securities dealer (or within such longer period as to which the applicant consents).

(4)(i) To grant and deny applications for confidential treatment filed pursuant to section 24(b) of the Act (15 U.S.C. 78x(b)) and § 240.24b–2 of this chapter (Rule 24b–2 thereunder);

(ii) To revoke a grant of confidential treatment for any such application.

(5) Pursuant to section 17(b) of the Act (15 U.S.C. 78q(b)), prior to any examination of a registered municipal securities dealer whose appropriate regulatory agency is not the Commission, to notify and consult with the appropriate regulatory agency for such municipal securities dealer.

(6) Pursuant to section 17(c)(3) of the Act, 15 U.S.C. 78q(c)(3), in regard to municipal securities dealers for which the Commission is not the appropriate regulatory agency:

(i) To notify the appropriate regulatory agency of any examination conducted by the Commission of any such municipal securities dealer;

(ii) To request from the appropriate regulatory agency a copy of the report of any examination of any such municipal securities dealer conducted by such appropriate regulatory agency and any data supplied to it in connection with such examination; and

(iii) To furnish to the appropriate regulatory agency on request a copy of the report of any examination of any such municipal securities dealer conducted by the Commission and any data supplied to it in connection with such examination.

(7) Pursuant to section 19(b)(2)(A) of the Act, 15 U.S.C. 78s(b)(2)(A), to extend for a period not exceeding 90 days from the date of publication of notice of the filing of a proposed rule change by the Municipal Securities Rulemaking Board pursuant to section 19(b)(1) of the Act, 15 U.S.C. 78s(b)(1), the period during which the Commission must by order approve or disapprove the proposed rule change or institute proceedings to determine whether the proposed rule change should be disapproved and to determine whether such longer period is appropriate and publish the reasons for such determination.

(8) Pursuant to 17 CFR 15c2–12(e) (Rule 15c2–12(e)), to grant or deny exemptions, either unconditionally or on specified terms and conditions, from Rule 15c2–12.

(9) To administer the provisions of § 240.24c–1 of this chapter; provided that access to nonpublic information as defined in § 240.24c–1 shall be provided

only with the concurrence of the head of the Commission division or office responsible for such information or the files containing such information.

(10) To administer the provisions of section 24(d) of the Act (15 U.S.C. 78x(d)).

(11) Pursuant to section 19(b)(2) of the Act, 15 U.S.C. 78s(b)(2), and section 19(b)(3) of the Act, 15 U.S.C. 78s(b)(3), to institute proceedings to determine whether a proposed rule change of the Municipal Securities Rulemaking Board should be disapproved and to provide to the Municipal Securities Rulemaking Board notice of the grounds for disapproval under consideration. If the Commission has not taken action on a proposed rule change for which delegated authority has been withdrawn under paragraph (a)(12) of this section prior to the expiration of the applicable time period specified in section 19(b)(2) of the Act, 15 U.S.C. 78s(b)(2), then the Director shall institute pursuant to delegated authority proceedings to determine whether the proposed rule change should be disapproved. In addition, pursuant to section 19(b)(2)(B) of the Act, 15 U.S.C. 78s(b)(2)(B), to extend for a period not exceeding 240 days from the date of publication of notice of the filing of a proposed rule change pursuant to section 19(b)(1) of the Act, 15 U.S.C. 78s(b)(1), the period during which the Commission must issue an order approving or disapproving the proposed rule change and to determine whether such longer period is appropriate and publish the reasons for such determination.

(12) Pursuant to section 19(b)(3)(C) of the Act, 15 U.S.C. 78s(b)(3)(C), to temporarily suspend a change in the rules of the Municipal Securities Rulemaking Board.

(13) Pursuant to § 240.19b–4(f)(6)(iii) of this chapter (Rule 19b–4(f)(6)(iii)), to reduce the period before which a proposed rule change can become operative, and to reduce the period between an Municipal Securities Rulemaking Board submission of a filing and a pre-filing notification.

(14) Pursuant to section 36 of the Act (15 U.S.C. 78mm), to review and grant or deny exemptions from the rule filing requirements of section 19(b) (15 U.S.C. 78s(b)) of the Act, in a case where the Municipal Securities Rulemaking Board elects to incorporate by reference one or more rules of another self-regulatory organization, provided that the following specified terms and conditions are met:

(i) The Municipal Securities Rulemaking Board, when electing to incorporate rules of another self-regulatory organization, has requested to incorporate rules other than trading rules (*e.g.,* the Municipal Securities Rulemaking Board has requested to incorporate rules such as margin, suitability, arbitration);

(ii) The Municipal Securities Rulemaking Board, when electing to incorporate rules of another self-regulatory organization has requested to incorporate by reference categories of rules (rather than to incorporate individual rules within a category); and

(iii) The Municipal Securities Rulemaking Board has reasonable procedures in place to provide written notice to its members each time a change is proposed to the incorporated rules of another self-regulatory organization.

(b) To consult on behalf of the Commission pursuant to section 18(t)(1) of the Federal Deposit Insurance Act (12 U.S.C. 1828(t)(1)) with respect to matters described in § 200.19a.

* * * * *

■ 25. Section 200.30–3b is added to read as follows:

§ 200.30–3b Delegation of authority to Director of the Office of Credit Ratings.

Pursuant to the provisions of Public Law 100–181, 101 Stat. 1254, 1255 (15 U.S.C. 78d–1, 78d–2), the Securities and Exchange Commission hereby delegates, until the Commission orders otherwise, the following functions to the Director of the Office of Credit Ratings to be performed by the Director or under the direction of the Director by such person or persons as may be designated from time to time by the Chairman of the Commission:

(a) With respect to the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*):

(1) To grant and deny applications for confidential treatment filed pursuant to section 24(b) of the Act (15 U.S.C. 78x(b)) and § 240.24b–2 of this chapter (Rule 24b–2 thereunder);

(2) To revoke a grant of confidential treatment for any such application.

(b) With respect to the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*):

(1) To administer the provisions of § 240.24c–1 of this chapter; provided that access to nonpublic information as defined in § 240.24c–1 shall be provided only with the concurrence of the head of the Commission division or office responsible for such information or the files containing such information.

(2) To administer the provisions of section 24(d) of the Act (15 U.S.C. 78x(d)).

§ 200.30–5 [Amended]

■ 26. Section 200.30–5 is amended by:

■ a. In the introductory text:

■ i. Removing the citation ''Pub. L. 87–592, 76 Stat. 394'' and adding in its place the citation ''sections 4A and 4B of the Securities Exchange Act of 1934, as amended,''; and

■ ii. Removing the words ''him or under his'' and adding in their place the words ''the Director or under the Director's'';

■ b. In paragraph (a)(4)(ii), removing the word ''he'' and adding in its place the words ''the applicant'';

■ c. In paragraph (b–1)(1), removing the word ''him'' and adding in its place the words ''the Director'';

■ d. In paragraph (b–1)(2):

■ i. Removing the word ''he'' and adding in its place the words ''the Director''; and

■ ii. Removing the word ''him'' and adding in its place the words ''the Director'';

■ e. Removing and reserving paragraph (h)(1); and

■ f. In paragraph (h)(2), removing the word ''he'' and adding in its place the words ''the Director''.

■ 27. Section 200.30–6 is amended by:

■ a. In the introductory text:

■ i. Removing ''the provisions of Pub. L. 87–592, 76 Stat. 394'' and adding in its place ''sections 4A and 4B of the Securities Exchange Act of 1934, as amended (15 U.S.C. 78d–1, 78d–2)''; and

■ ii. Removing the words ''him or under his'' and adding in their place the words ''the Regional Director or under the Regional Director's''; and

■ b. Revising paragraph (e).

The revision reads as follows:

§ 200.30–6 Delegation of authority to Regional Directors.

* * * * *

(e) Notwithstanding anything in paragraphs (a) through (d) of this section, in any case in which the Regional Director believes it appropriate, the Regional Director may submit the matter to the Commission.

§ 200.30–7 [Amended]

■ 28. Section 200.30–7 is amended by:

■ a. In the introductory text:

■ i. Removing ''the provisions of Pub. L. 87–592, 76 Stat. 394 (15 U.S.C. 78d–1)'' and adding in its place ''sections 4A and 4B of the Securities Exchange Act of 1934, as amended (15 U.S.C. 78d–1, 78d–2)''; and

■ ii. Removing the words ''him or under his'' and adding in their place the words ''the Secretary or under the Secretary's'';

■ b. In paragraph (d):

■ i. Removing the citation ''§ 200.30–14(i)'' and adding in its place the citation ''§ 200.30–14(h) and (j)''; and

■ ii. Removing the citation ''§ 200.30–14(j)'' and adding in its place the citation ''§ 200.30–14(i) and (k)''; and
■ c. In paragraph (e):
■ i. Removing the words ''the foregoing'' and adding in their place ''paragraphs (a) through (d) of this section''; and
■ ii. Removing the words ''he or she'' and adding in their place the words ''the Secretary''.

§ 200.30–10 [Amended]

■ 29. Section 200.30–10 is amended by:
■ a. In the introductory text:
■ i. Removing ''the provisions of Pub. L. 87–592, 76 Stat. 394'' and adding in its place ''sections 4A and 4B of the Securities Exchange Act of 1934, as amended''; and
■ ii. Removing the word ''his'' and adding in its place ''the Chief Administrative Law Judge's'';
■ b. In paragraph (a)(6):
■ i. Removing the word ''subpenas'' and adding ''subpoenas''; and
■ ii. Removing ''Rule 232 of the Commission's Rules of Practice, 201.232 of this chapter'' and adding in its place ''§ 201.232 of this chapter (Rule 232 of the Commission's Rules of Practice)''; and
■ c. In paragraph (c):
■ i. Removing the words ''the foregoing'' and adding in their place ''paragraphs (a) and (b) of this section''; and
■ ii. Removing the words ''he or she'' and adding in their place ''the Chief Administrative Law Judge''.

■ 30. Section 200.30–11 is amended by:
■ a. In the introductory text, removing the words ''him or her or under his or her'' and adding in their place the words ''the Chief Accountant or under the Chief Accountant's'';
■ b. In paragraph (a)(4):
■ i. Removing the words ''he or she'' and adding in their place the words ''the Chief Accountant''; and
■ ii. Removing the citation ''§ 202.140'' and adding in its place ''§ 202.140 of this chapter'';
■ c. In paragraph (b)(2), removing the words ''his or her'' and adding in their place the words ''the Chief Accountant's'';
■ d. Redesignating paragraph (c) as paragraph (d);
■ e. Adding new paragraph (c); and
■ f. In newly redesignated paragraph (d):
■ i. Removing the words ''the foregoing'' and adding in their place ''paragraphs (a) through (c) of this section''; and
■ ii. Removing the words ''he or she'' and adding in their place the words ''the Chief Accountant''.

The addition reads as follows:

§ 200.30–11 Delegation of authority to the Chief Accountant.

* * * * *

(c) To administer the provisions of § 240.24c–1 of this chapter; provided that access to nonpublic information as defined in § 240.24c–1 shall be provided only with the concurrence of the head of the Commission division or office responsible for such information or the files containing such information.

* * * * *

§ 200.30–13 [Amended]

■ 31. Section 200.30–13 is amended by:
■ a. In the introductory text, removing the words ''him or her, or under his or her'' and adding in their place the words ''the Chief Financial Officer or under the Chief Financial Officer's''; and
■ b. In paragraph (c), removing the words ''his or her'' and adding in their place the words ''the Secretary of the Treasury's''.

§ 200.30–14 [Amended]

■ 32. Section 200.30–14 is amended by:
■ a. In the introductory text, removing the words ''him or her or under his or her'' and adding in their place the words ''the General Counsel or under the General Counsel's'';
■ b. In paragraph (b), removing the words ''and amicus curiae'' and adding in their place the words ''an amicus curiae'';
■ c. In paragraph (h)(1)(iii), removing the word ''his'' and adding in its place the word ''an'';
■ d. In paragraph (i):
■ i. Removing the words ''paragraph (g) of this section, the functions described in paragraph (g)'' and adding in their place the words ''paragraph (h) of this section, the functions described in paragraph (h)'';
■ ii. Removing the words ''Executive Assistant to the Chairman'' and adding in its place the words ''Secretary of the Commission''; and
■ iii. Removing the citation ''§ 200.30–16'' and adding in its place the citation ''§ 200.30–7''; and
■ e. In paragraph (l):
■ i. Removing the citation ''paragraphs (g) or (i)'' and adding in its place ''paragraph (h) or (j)''; and
■ ii Removing the words ''he or she'' and adding in their place the words ''the General Counsel''.

§ 200.30–15 [Amended]

■ 33. Section 200.30–15 is amended by removing the words ''him or her or under his or her'' and adding in their place the words ''the Chief Operating Officer or under the Chief Operating Officer's''.

§ 200.30–16 [Removed and Reserved]

■ 34. Section 200.30–16 is removed and reserved.

■ 35. Section 200.30–18 is amended by:
■ a. Revising the section heading and introductory text;
■ b. Removing and reserving paragraphs (b), (e) through (h), and (k)(2);
■ c. In paragraph (l)(1), removing the words ''him or her'' and adding in their place the words ''the member'';
■ d. Redesignating paragraph (m) as paragraph (n);
■ e. Adding new paragraph (m); and
■ f. In newly redesignated paragraph (n):
■ i. Removing the words ''the foregoing'' and adding in their place ''paragraphs (a) through (m) of this section''; and
■ ii. Removing the words ''the OCIE'' and adding in their place the word ''Examinations''.

The addition and revisions read as follows:

§ 200.30–18 Delegation of authority to Director of the Division of Examinations.

Pursuant to the provisions of Public Law 100–181, 101 Stat. 1254, 1255 (15 U.S.C. 78d–1, 78d–2), the Securities and Exchange Commission hereby delegates, until the Commission orders otherwise, the following authority to the Director of the Division of Examinations (''Examinations'') to be performed by the Director or by such other person or persons as may be designated from time to time by the Chairman of the Commission:

* * * * *

(m) With respect to the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*):

(1) Under section 15F(b) of the Act (15 U.S.C. 78o–10(b)):

(i) To authorize the issuance of orders granting on-going registration to security-based swap dealers and major security-based swap participants based on the security-based swap dealer's or major security-based swap participant's application, pursuant to § 240.15Fb2–1(e) of this chapter (Rule 15Fb2–1(e));

(ii) To authorize the issuance of orders canceling the registration of security-based swap dealers and major security-based swap participants registered pursuant to § 240.15Fb2–1 of this chapter (Rule 15Fb2–1) if such persons are no longer in existence or have ceased to do business as security-based swap dealers or major security-based swap participants, pursuant to § 240.15Fb3–3(a) of this chapter (Rule 15Fb3–3(a)); and

(iii) To determine by order, pursuant to § 240.15Fb3–2(b) of this chapter (Rule 15Fb3–2(b)), whether notices of withdrawal of registration filed by

security-based swap dealers or major security-based swap participants pursuant to section 15F(b) of the Securities Exchange Act of 1934 (15 U.S.C. 78o–10(b)) shall become effective sooner than the normal 60 day waiting period provided in Rule 15Fb3–2(b) (§ 240.15Fb3–2(b) of this chapter).

* * * * *

By the Commission.

Dated: December 22, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–28819 Filed 2–12–21; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 342

[Docket No. RM20–14–000]

Five-Year Review of the Oil Pipeline Index

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Order establishing index level.

SUMMARY: The Federal Energy Regulatory Commission (Commission) issues this Final Order concluding its five-year review of the index level used to determine annual changes to oil pipeline rate ceilings. The Commission establishes an index level of Producer Price Index for Finished Goods plus 0.78% (PPI–FG+0.78%) for the five-year period commencing July 1, 2021.

DATES: This order is effective February 16, 2021.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

1. On June 18, 2020, the Commission issued a Notice of Inquiry initiating its five-year review to establish the oil pipeline index level for the July 1, 2021 to June 30, 2026 time period.[1] The NOI requested comment regarding: (a) The proposed index level of Producer Price Index for Finished Goods plus 0.09% (PPI–FG+0.09%); and (b) any alternative methodologies for calculating the index level.

2. For the reasons discussed below, we adopt an index level of PPI–FG+0.78%. The departure from the NOI results from: (a) Trimming the data set to the middle 80% of cost changes; (b) adopting Designated Carriers'[2] proposal to adjust the data set to remove the effects of the Commission's 2018 income tax policy change for Master Limited Partnership (MLP)-owned pipelines; and (c) updated Form No. 6 filings and other corrections to the data set. The Commission's indexing calculations and other data analysis are contained in Attachment A to this order. As discussed below, we decline to adopt other changes to the index calculation proposed by commenters.

I. Background

A. Establishment of the Indexing Methodology

3. The Energy Policy Act of 1992 (EPAct 1992) required the Commission to establish a ''simplified and generally applicable'' ratemaking methodology[3] that was consistent with the just and reasonable standard of the Interstate Commerce Act (ICA).[4] To implement this mandate, the Commission issued Order No. 561[5] establishing an indexing methodology that allows oil pipelines to change their rates subject to certain ceiling levels as opposed to making cost-of-service filings.[6]

4. In Order No. 561, the Commission committed to review the index level every five years to ensure that it adequately reflects changes to industry costs.[7] The Commission conducted five-year index reviews in 2000,[8] 2005,[9] 2010,[10] and 2015.[11] In the 2015 review, the Commission established the index level of PPI–FG+1.23%, to be effective for the five-year period beginning July 1, 2016.[12] The index level established herein results from the Commission's fifth five-year review of the index level.

B. The Kahn Methodology

5. In Order No. 561 and each successive five-year review, the Commission has calculated the index level based upon a methodology developed by Dr. Alfred E. Kahn.[13] The Kahn Methodology uses pipeline data from Form No. 6, page 700 from the prior five-year period to determine an appropriate adjustment to be applied to PPI–FG. The calculation is as follows. Each pipeline's cost change on a per-barrel mile basis over the prior five-year period (*e.g.,* the years 2014–2019 in this proceeding) is calculated. In order to remove statistical outliers and spurious data, under the Kahn Methodology, the resulting data set is trimmed to those oil pipelines in the middle 50% of cost changes (middle 50%). The Kahn Methodology then calculates three measures of the middle 50%'s central tendency: The median, the mean, and a weighted mean.[14] The Kahn Methodology calculates a composite by averaging these measures of central tendency and measures the difference between the composite and the PPI–FG over the prior five-year period. The Commission then sets the index level at PPI–FG plus (or minus) this differential.

C. The 2020 Five-Year Review

6. On June 18, 2020, the Commission issued the NOI initiating its five-year

[1] *Five-Year Review of the Oil Pipeline Index,* 171 FERC ¶ 61,239, at P 1 (2020) (NOI).

[2] Designated Carriers include Buckeye Partners, L.P., Colonial Pipeline Company, Energy Transfer LP, Enterprise Products Partners L.P., and Plains All American Pipeline, L.P.

[3] Public Law 102–486 1801(a), 106 Stat. 3010 (Oct. 24, 1992). This mandate to establish a simplified and generally applicable ratemaking methodology specifically excluded the Trans-Alaska Pipeline System (TAPS), or any pipeline delivering oil, directly or indirectly, into TAPS. *Id.* 1804(2)(B).

[4] 49 U.S.C. app. 1 *et seq.*

[5] *Revisions to Oil Pipeline Regulations Pursuant to Energy Policy Act of 1992,* Order No. 561, 58 FR 58753 (Nov. 4, 1993) FERC Stats. & Regs. ¶ 30,985 (1993) (cross-referenced at 65 FERC ¶ 61,109), *order on reh'g,* Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 (1994) (cross-referenced at 68 FERC ¶ 61,138), *aff'd sub nom. Ass'n of Oil Pipe Lines* v. *FERC,* 83 F.3d 1424 (D.C. Cir. 1996) (*AOPL I*).

[6] Pursuant to the Commission's indexing methodology, oil pipelines change their rate ceiling levels effective every July 1 by ''multiplying the previous index year's ceiling level by the most recent index published by the Commission.'' 18 CFR 342.3(d)(1). Oil pipelines may adjust their rates to the ceiling levels pursuant to Commission's regulations so long as no protest or complaint demonstrates that the index rate change substantially diverges from the pipeline's cost changes. *Id.* 343.2(c)(1).

[7] Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,941.

[8] *Five-Year Review of Oil Pipeline Pricing Index,* 93 FERC ¶ 61,266 (2000), *aff'd in part and remanded in part sub nom. Ass'n of Oil Pipe Lines* v. *FERC,* 281 F.3d 239 (D.C. Cir. 2002) (*AOPL II*), *order on remand,* 102 FERC ¶ 61,195 (2003), *aff'd sub nom. Flying J Inc.* v. *FERC,* 363 F.3d 495 (D.C. Cir. 2004).

[9] *Five-Year Review of Oil Pipeline Pricing Index,* 114 FERC ¶ 61,293 (2006) (2005 Index Review).

[10] *Five-Year Review of Oil Pipeline Pricing Index,* 133 FERC ¶ 61,228 (2010) (2010 Index Review), *reh'g denied,* 135 FERC ¶ 61,172 (2011).

[11] *Five-Year Review of the Oil Pipeline Index,* 153 FERC ¶ 61,312 (2015) (2015 Index Review), *aff'd sub nom. Ass'n of Oil Pipe Lines* v. *FERC,* 876 F.3d 336 (D.C. Cir. 2017) (*AOPL III*).

[12] 2015 Index Review, 153 FERC ¶ 61,312 at P 9.

[13] The United States Court of Appeals for the District of Columbia Circuit has affirmed the Commission's use of the Kahn Methodology. *AOPL I,* 83 F.3d at 1433–37; *Flying J Inc.* v. *FERC,* 363 F.3d at 497–500.

[14] The weighted mean assigns a different weight to each pipeline's cost change based upon the pipeline's total barrel-miles.

review to establish the index level for the July 1, 2021 to June 30, 2026 period. The NOI proposed an index level of PPI–FG+0.09% and requested comment on this proposal and any alternative methodologies for calculating the index level.[15] The Commission explained that commenters could address issues including, but not limited to, different data trimming methodologies and whether, and if so how, the Commission should reflect the effects of cost-of-service policy changes in the index calculation.[16]

II. Comments

7. Initial comments filed in response to the NOI were due on August 17, 2020, and reply comments were due on September 11, 2020. Comments were filed by the Association of Oil Pipe Lines (AOPL) (together with Designated Carriers, Pipelines), Designated Carriers, Kinder Morgan, Inc., Colonial Pipeline Company, Joint Commenters,[17] the Liquids Shippers Group (Liquids Shippers),[18] the Canadian Association of Petroleum Producers (CAPP) (together with Joint Commenters and Liquids Shippers, Shippers), the Energy Infrastructure Council (EIC), the Pipeline Safety Trust, and the Pipeline and Hazardous Materials Safety Administration (PHMSA).

8. The commenters discuss numerous issues related to the proposed index level, including statistical data trimming and whether the index should incorporate the effects of the Commission's 2018 policy change requiring MLP-owned pipelines to eliminate the income tax allowance and previously accrued Accumulated Deferred Income Taxes (ADIT) balances from their page 700 summary costs of service (Income Tax Policy Change).[19] In addition, Liquids Shippers propose to replace the weighted mean in the Kahn Methodology's calculation of central tendency with the weighted median and to replace the returns on equity (ROE) reported on page 700 for 2014 and 2019 with standardized, industry-wide ROEs for both years. The commenters propose varying index levels, including AOPL's proposal to adopt an index level of at least PPI–FG+0.79%, Designated Carriers' proposals of PPI–FG+1.27% (using the middle 80% of cost changes) or PPI–FG+0.82% (using the middle 50%), Joint Commenters' proposal of PPI–FG–0.19%, and Liquids Shippers' proposal of PPI–FG–1.58%.

III. Discussion

9. We adopt an index level of PPI–FG+0.78% for the five-year period beginning July 1, 2021. We adopt Designated Carriers' proposed adjustment to remove the effects of the Income Tax Policy Change from the page 700 data used to derive the index and we adopt Pipelines' proposal to calculate the index level using the middle 80% of cost changes. We also reject Liquids Shippers' proposals to: (a) Calculate the composite measure of the data set's central tendency using the median of the barrel-mile weighted unit cost change; and (b) replace the reported page 700 ROEs for 2014 and 2019 with standardized ROEs. We also address arguments regarding negotiated rate contracts as raised by CAPP, pipeline costs resulting from integrity management regulations, and the treatment of mergers and acquisitions in the data set.

A. 2018 MLP Income Tax Policy Change

1. Comments

10. Commenters disagree about whether the Commission should incorporate the effects of the Income Tax Policy Change in the index calculation.[20] Pipelines argue that the Income Tax Policy Change should not be incorporated and present proposals for adjusting the page 700 data to remove its effects from the calculation. Shippers oppose Pipelines' adjustments and contend that the policy change's effects are appropriately reflected in the index.

11. AOPL argues that its proposed adjustment to eliminate the effects of the Income Tax Policy Change is necessary to calculate an index that accurately measures cost changes incurred during the 2014–2019 period and predicts the likely rate of future cost changes. According to AOPL, eliminating the income tax allowance from page 700 did not affect costs because MLP pipelines' income tax costs were the same before and after the policy change. Thus, AOPL asserts that the Commission should remove the policy change's effects to ensure that the page 700 data reflects consistent policies.

12. To remove the policy change's effects from the data set, AOPL's witness Dr. Shehadeh proposes to adjust the reported page 700 data for pipelines that were MLPs throughout the 2014–2019 period based upon the following steps. First, Dr. Shehadeh eliminates the 2014 income tax allowance for all pipelines that reduced their page 700 income tax allowance for 2016 from a positive number to zero following the Income Tax Policy Change.[21] Second, Dr. Shehadeh adjusts these pipelines' 2014 page 700 return on rate base to reflect the elimination of their previously accumulated ADIT balances.[22] This adjustment involves, for each pipeline: (a) Taking the difference between the 2016 rate base reported in the pipeline's April 18, 2017 page 700 filing (with ADIT balances included) and the higher 2016 rate base reported in its April 18, 2018 filing (with ADIT balances removed); (b) adding this amount to the 2014 rate base; and (c) calculating the return on the higher 2014 rate base by multiplying the higher rate base by the 2014 weighted average cost of capital.[23]

13. Designated Carriers support AOPL's position and propose to extend AOPL's proposed adjustments to all pipelines that were owned by MLPs in 2014 and later converted to C-Corporations, not just those pipelines that were MLPs throughout the 2014–2019 data period. Designated Carriers contend that this approach is necessary to avoid treating one class of MLPs (those that were MLPs in 2014 and remained MLPs in 2019) differently from another class (those that were MLPs in 2014 and converted to C-

[15] NOI, 171 FERC ¶ 61,239 at PP 7–8.

[16] *Id.* P 8.

[17] Joint Commenters include: The Airlines for America; Chevron Products Company; the National Propane Gas Association; and Valero Marketing and Supply Company.

[18] For purposes of this proceeding, Liquids Shippers include: Apache Corporation; Cenovus Energy Marketing Services Ltd.; ConocoPhillips Company; Devon Gas Services, L.P.; Equinor Marketing & Trading US Inc.; Fieldwood Energy LLC; Marathon Oil Company; Murphy Exploration and Production Company—USA; Ovintiv Marketing Inc.; and Pioneer Natural Resources USA, Inc.

[19] *Inquiry Regarding the Commission's Policy for Recovery of Income Tax Costs,* 162 FERC ¶ 61,227, at P 8 (2018 Income Tax Policy Statement), *reh'g denied,* 164 FERC ¶ 61,030, at P 13 (2018).

[20] Commenters either agree or do not dispute that the effects of the Tax Cuts and Jobs Act of 2017 (TCJA) are appropriately reflected in the data set; and no adjustment is necessary to reflect the Commission's May 21, 2020 policy statement revising its ROE policy for natural gas and oil pipelines because that policy change occurred after the conclusion of the 2014–2019 period. *Inquiry Regarding the Commission's Policy for Determining Return on Equity,* 171 FERC ¶ 61,155 (2020) (ROE Policy Statement).

[21] 2016 is the only year for which pipelines filed page 700 data reflecting both the 2018 Income Tax Policy Change and the Commission's prior income tax allowance policy. Oil pipelines filed page 700 data for 2016 on two occasions: As current-year data in the Form No. 6 filings due for submission on April 18, 2017, before the Income Tax Policy Change; and as prior-year data in Form No. 6 filings due for submission on April 18, 2018, after the Income Tax Policy Change. *See* 2018 Income Tax Policy Statement, 162 FERC ¶ 61,227 at P 46 & n.83 (directing MLP pipelines to eliminate the income tax allowance in the 2016 and 2017 data reported in their April 18, 2018 Form No. 6, page 700 filings).

[22] AOPL Initial Comments at 28–29 (citing Shehadeh Initial Decl. at 14–15).

[23] *Id.;* Shehadeh Initial Decl. at 16.

Corporations during the review period).[24]

14. Shippers oppose Pipelines' proposed adjustments and argue that the Commission should incorporate the effects of the Income Tax Policy Change in the index calculation. Shippers contend that the index is meant to reflect changes to recoverable pipeline costs as determined under the Commission's Opinion No. 154–B cost-of-service methodology.[25] Because the Income Tax Policy Change prohibits MLP pipelines from recovering an income tax allowance under that methodology, Shippers assert that the index should reflect this reduction in recoverable costs.[26]

15. Furthermore, Shippers claim that adopting Pipelines' proposals would contravene the Commission's commitment in the 2018 Income Tax Policy Statement to ''incorporate the effects of [the policy change] on industry-wide oil pipeline costs'' and ''ensure that the industry-wide reduced costs are incorporated on an industry-wide basis as part of'' the 2020 five-year review.[27] Shippers argue that the Commission opted to incorporate these effects in the index in lieu of directing pipelines to submit rate filings or initiating rate investigations to eliminate the income tax double recovery from MLP oil pipeline rates, as the Commission did for MLP natural gas pipelines. Thus, Shippers contend that the Commission must reflect the elimination of the income tax allowance and associated ADIT balances from MLP oil pipelines' page 700 costs of service in order to bring those pipelines' rates in line with their recoverable costs.[28]

2. Commission Determination

16. Whether the index should reflect the effects of cost-of-service policy changes is an issue of first impression.[29] For the reasons discussed below, we adopt Designated Carriers' proposal to adjust the page 700 data set to remove the effects of the Income Tax Policy Change from the index calculation. As a result, for all pipelines that were MLPs in 2014, we reduce the 2014 income tax allowance to zero and revise the 2014 return on rate base to reflect the removal of ADIT. We find that this adjustment is necessary to accurately calculate the index.

17. First, the purpose of indexing is to allow the indexed rate to keep pace with industry-wide cost changes,[30] not to reflect alterations to the Commission's Opinion No. 154–B cost-of-service methodology.[31] Although the Commission uses the Opinion No. 154–B methodology cost data on page 700 for purposes of the five-year review, changes to the Opinion No. 154–B methodology itself are distinct from the annual changes to the pipeline costs that are input into the Opinion No. 154–B methodology. Where the Commission modifies an Opinion No. 154–B cost-of-service policy used to measure recoverable costs midway through the five-year review period, the Opinion No. 154–B cost of service reported on page 700 for the first and last years of the period will reflect different sets of policies. Just as a business must account for changes to its accounting policies when comparing its costs over two different periods, we must make a similar adjustment to the reported page 700 data here to derive an ''apples-to-apples'' comparison of pipeline cost changes. By contrast, comparing data reported under different sets of policies will produce a less accurate measure of normal industry-wide cost changes.

18. Second, although we recognize that in the 2018 Income Tax Policy Statement the Commission stated that it would ''incorporate the effects of the post-*United Airlines'* policy changes on industry-wide oil pipeline costs in the 2020 five-year review of the oil pipeline index level,''[32] we conclude that the index is not an appropriate mechanism for incorporating the post-*United Airlines'* policy changes. The index allows for incremental rate adjustments to enable pipelines to recover normal cost changes in future years. It is not a true-up designed to remedy prior over- or under-recoveries in pre-existing rates resulting from cost-of-service policy changes during the prior five-year period. Accordingly, we find that it would be improper to address any double recovery via the index.

19. Third, it is not clear that the double recovery of MLP pipelines' income tax costs was ever incorporated into the index. Before the Commission updated its calculation of the index in the 2015 Index Review to use page 700 data, the Kahn Methodology used net carrier property as a proxy for capital costs and income taxes.[33] This proxy did not reflect changes in the Commission's Opinion No. 154–B methodology, including changes to the Commission's income tax policy.[34] As a result, the Commission's prior policies permitting MLP pipelines to recover a partial[35] or full[36] income tax allowance were never directly incorporated into

[24] Designated Carriers Initial Comments at 21 (citing Webb Initial Affidavit at P 24).

[25] Joint Commenters Reply Comments at 13–14 (quoting 2015 Index Review, 153 FERC ¶ 61,312 at P 13) (citing *AOPL III,* 876 F.3d at 345–46); Liquids Shippers Reply Comments at 6 (quoting *AOPL III,* 876 F.3d at 345; 2015 Index Review, 153 FERC ¶ 61,312 at P 13).

[26] Joint Commenters Initial Comments at 12–15; Joint Commenters Reply Comments at 13–15; Liquids Shippers Initial Comments at 33–42; Liquids Shippers Reply Comments at 6–7.

[27] Joint Commenters Reply Comments at 16–17 (quoting 2018 Income Tax Policy Statement, 162 FERC ¶ 61,227 at P 46); Liquids Shippers Initial Comments at 34–35 (same).

[28] Liquids Shippers Initial Comments at 34–35, 40; *see also* Joint Commenters Reply Comments at 16–17 (citing 2018 Income Tax Policy Statement, 162 FERC ¶ 61,227 at P 46).

[29] This issue did not arise prior to the 2015 Index Review because the Commission measured industry-wide cost changes in the Order No. 561 Rulemaking and the 2000, 2005, and 2010 index reviews using Form No. 6 accounting data, rather than the summary cost-of-service data reported on page 700. Because the Commission did not adopt any significant cost-of-service policy changes during the 2009–2014 review period, the Commission likewise did not have occasion to address this issue in the 2015 Index Review.

[30] Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,948, 30,950. Capital costs such as income taxes are among the industry-wide costs that the index is designed to measure. *E.g.,* 2015 Index Review, 153 FERC ¶ 61,312 at P 17.

[31] In 2015, the Commission adopted page 700 because it included actual total cost-of-service data reflecting the costs recoverable under the Opinion No. 154–B methodology. 2015 Index Review, 153 FERC ¶ 61,312 at P 13. We reaffirm that using page 700 data remains a superior means of measuring those recoverable costs as compared to the prior methodology from which the Commission departed in the 2015 Index Review. *Id.* PP 12–16. For example, the Opinion No. 154–B methodology reflected on page 700 more appropriately addresses capital costs. *Id.* PP 14–15 & nn.29–30. However, the purpose of the index is to address changes to those recoverable costs, not changes to what the Commission deems recoverable, such as the complete elimination of a particular cost category such as the MLP income tax allowance.

[32] 2018 Income Tax Policy Statement, 162 FERC ¶ 61,227 at P 46.

[33] 2015 Index Review, 153 FERC ¶ 61,312 at P 14 (citing Order No. 561–A, FERC Stats & Regs. ¶ 31,000 at 31,096, 31,098).

[34] Net carrier property measures changes to the book value of the pipeline's asset base but does not incorporate changes to the costs of financing the asset base, such as ROE. As the Commission explained in the 2015 Index Review, the relationship between net carrier property and income tax costs is attenuated because income taxes are dependent upon the pipeline's ROE, not merely the size of the pipeline's asset base. 2015 Index Review, 153 FERC ¶ 61,312 at P 14.

[35] Under the Commission's *Lakehead* policy from 1995 to 2005, partnership entities like MLP pipelines could recover an income tax allowance for income attributable to corporate partners, but not for income attributable to individuals or other non-corporate partners. *See Lakehead Pipe Line Co., L.P.,* Opinion No. 397, 71 FERC ¶ 61,338 (1995), *reh'g denied,* Opinion No. 397–A, 75 FERC ¶ 61,181, at 61,594–99 (1996).

[36] In 2005, the Commission departed from the *Lakehead* policy and issued a policy statement announcing that it would permit partnership entities to recover an income tax allowance for income attributable to all partners regardless of the partner's corporate form, to the extent that the partner had an actual or potential income tax liability on that income. *Inquiry Regarding Income Tax Allowances,* 111 FERC ¶ 61,139, at P 32 (2005).

the index.[37] Because no prior index calculation incorporated the policies allowing MLP pipelines to recover an index tax allowance, it is not necessary to reflect the policy change denying those pipelines an income tax allowance in the calculation here.

20. Accordingly, we adopt Designated Carriers' proposal to adjust the historical page 700 data for 2014 to remove the effects of the Income Tax Policy Change for all pipelines that were MLPs in 2014, including those that later converted to a business form (such as a C-Corporation) eligible to recover an income tax allowance. This approach is broader than AOPL's more limited proposal to adjust the data for only those pipelines that were MLPs in 2014 and that continued to be MLPs for the remainder of the 2014–2019 period. Because the Commission's revised income tax allowance policy applies equally to all MLP pipelines,[38] we conclude that it is appropriate to make these adjustments for all pipelines that were MLPs in 2014, regardless of subsequent changes in corporate form. By applying these adjustments to all pipelines subject to the Income Tax Policy Change, we will ensure that the entirety of the page 700 data reflects the same MLP income tax allowance policy for both 2014 and 2019. Furthermore, those pipelines that converted from the MLP form to the corporate form incurred increased tax costs as a result of the change in business form. This cost change, just like any other cost change, should be reflected in the index.[39]

B. Statistical Data Trimming

1. Comments

21. AOPL argues that the Commission should calculate the index level by trimming the data set to the middle 80%.[40] AOPL asserts that absent errors in the data, it is preferable to use more data points because this makes the measurement of industry-wide cost changes more precise.[41] AOPL contends that using the middle 50% in this proceeding would go beyond excluding statistical outliers by removing valuable data from the analysis, resulting in a less accurate measurement of industry cost changes.[42]

22. In addition, AOPL maintains that considerations the Commission has previously found to support trimming the data set to the middle 50% should not control here. It states that whereas the Commission found in Order No. 561 that data reporting errors supported restricting the analysis to the middle 50%, subsequent improvements in reporting accuracy obviated these concerns.[43] Furthermore, AOPL states that contrary to the Commission's finding in the 2015 Index Review, the fact that pipelines in the middle 80% are further removed from the median does not support excluding their cost data unless that data is anomalous or spurious.[44] Designated Carriers, Kinder Morgan, and EIC support AOPL's proposal to rely solely upon the middle 80%.[45]

23. Shippers oppose use of the middle 80% and argue that the record does not provide a sufficient basis for departing from the Commission's practice in the 2015 and 2010 Index Reviews of relying solely upon the middle 50%.[46] Shippers cite the Commission's findings in the 2015 and 2010 Index Reviews that using the middle 50% provides a simple and effective method of excluding outlying data from the sample and minimizes the need to analyze individual pipeline data. Here, Shippers argue that the middle 80% contains outlying data and that AOPL did not undertake a company-by-company review of the incremental data included in the middle 80% to prove otherwise.[47] Joint Commenters also contend that the middle 80% is more dispersed than the middle 50% in this proceeding and the middle 80% in prior index reviews, indicating that it contains cost changes that are not representative of typical experience.[48] Moreover, Shippers assert that it is unnecessary to use the middle 80% in this proceeding to obtain a representative sample of industry cost changes because the middle 50% contains a greater percentage of barrel-miles subject to the index (82%) than in the 2015 Index Review (56%) or the 2010 Index Review (76%).[49]

24. Shippers further argue that AOPL's arguments for using the middle 80% are unavailing and inconsistent with the Commission's findings in the 2015 Index Review.[50] Joint Commenters maintain that the Commission has previously rejected the argument that using the middle 50% will bias the index calculation downwards.[51] Liquids Shippers state that AOPL incorrectly argues that the sole purpose of statistical data trimming is to remove inaccurate data and statistical outliers. According to Liquids Shippers, data trimming also serves to exclude data that, while accurate, fails to represent normal industry cost experience.[52]

2. Commission Determination

25. Based upon our review of the instant record, we calculate the index level by trimming the data set to the middle 80%. We recognize that this is a departure from the Commission's practice in the 2015 and 2010 Index Reviews of trimming the data set to the middle 50%.[53] An agency may change its position in light of experience or further analysis so long as it articulates a satisfactory explanation for its new position.[54] Thus, notwithstanding the

[37] MLP pipelines therefore would not have benefitted from these policies unless they established an initial cost-based rate under 18 CFR 342.2(a) of the Commission's regulations or changed an existing rate pursuant to the cost-of-service methodology under 18 CFR 342.4(a) while these policies were in effect. 18 CFR 342.2(a), 342.4(a).

[38] *See* 2018 Income Tax Policy Statement, 162 FERC ¶ 61,227 at PP 45–46.

[39] As the Commission has explained, investors in MLP pipelines and C-Corporation pipelines incur an investor-level income tax cost that is reflected in the pipeline's rate of return. *SFPP, L.P.,* Opinion No. 511–C, 162 FERC ¶ 61,228, at PP 22–24 (2018), *order on reh'g and compliance,* Opinion No. 511–D, 166 FERC ¶ 61,142, at PP 10–11 (2019), *aff'd, SFPP, L.P.* v. *FERC,* 967 F.3d 788, 795–97 (D.C. Cir. 2020). However, unlike MLPs, corporations incur an additional corporate income tax liability prior to the distributions to investors. *See* Opinion No. 511–C, 162 FERC ¶ 61,228 at PP 22 n.44, 25 n.53.

[40] AOPL Initial Comments at 17–24; AOPL Reply Comments at 7–9.

[41] AOPL Initial Comments at 18 (quoting Shehadeh Initial Decl. at 23); AOPL Reply Comments at 9.

[42] AOPL Initial Comments at 19. Trimming the data set to the middle 50% would exclude 80 of the 160 pipelines in the data set, whereas trimming to the middle 80% would exclude 32 pipelines.

[43] AOPL Initial Comments at 21–22 (citing *AOPL I,* 83 F.3d at 1433).

[44] *Id.* at 23 (citing *AOPL II,* 281 F.3d at 245–46).

[45] Designated Carriers Initial Comments at 7; Kinder Morgan Initial Comments at 3; EIC Comments at 7–8, 17.

[46] Joint Commenters Initial Comments at 15–16; Joint Commenters Reply Comments at 5–7; Liquids Shippers Reply Comments at 17; CAPP Reply Comments at 15–16.

[47] Joint Commenters Reply Comments at 10 (citing Brattle Group Report at 13–20); Brattle Group Report at 22; Liquids Shippers Reply Comments at 19–21 (citing Crowe Reply Aff. at 4–5).

[48] Joint Commenters Reply Comments, Brattle Group Report at 17–20.

[49] Joint Commenters Reply Comments at 7–8; Liquids Shippers Reply Comments at 26.

[50] Joint Commenters Reply Comments at 9–11 (quoting 2015 Index Review, 153 FERC ¶ 61,312 at P 42 n.80) (citing 2015 Index Review, 153 FERC ¶ 61,312 at P 43); Liquids Shippers Reply Comments at 23–25 (citing 2015 Index Review, 153 FERC ¶ 61,312 at PP 40, 43).

[51] Joint Commenters Reply Comments, Brattle Report at PP 46–48 (citing 2015 Index Review, 153 FERC ¶ 61,312 at P 43; Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 at 31,098).

[52] Liquids Shippers Reply Comments at 22–23 (citing Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 at 31,097).

[53] 2015 Index Review, 153 FERC ¶ 61,312 at PP 42–44; 2010 Index Review, 133 FERC ¶ 61,228 at PP 60–63.

[54] *E.g., Encino Motorcars, LLC* v. *Navarro,* 136 S. Ct. 2117, 2125–26 (2016) (''Agencies are free to change their existing policies so long as they provide a reasoned explanation for the change. . . . But the agency must at least display awareness that it is changing position and show that there are good

Continued

Commission's determinations in the 2015 and 2010 Index Reviews, the Commission ''retain[s] a substantial measure of freedom to refine, reformulate, and even reverse [its] precedents in the light of new insights'' [55] if it describes good reasons for the new policy.[56] In the NOI, the Commission requested comments that address whether the Commission should continue to trim the data set to the middle 50% or adopt an alternative approach to data trimming, including using the middle 80%.[57] Based upon our review of the resulting record, we conclude that using the middle 80% is appropriate for this index review.

26. Three primary considerations support using the middle 80% instead of the middle 50% in this proceeding. First, we find it is appropriate to consider more data in measuring industry-wide cost changes rather than less. The Kahn Methodology derives the index level by computing the central tendency of a statistically trimmed data sample. As a general matter, considering a broader sample of data should enhance the Commission's calculation of the central tendency of industry cost experience. In this proceeding, using the middle 50% would exclude 48 pipelines [58] from the Commission's review of industry-wide cost changes over the 2014–2019 period. We are reluctant to discard this additional data.

27. Second, we find in this proceeding that ''normal'' cost changes are best defined by using the inclusive data sample embodied in the middle 80%. Prematurely discarding data prior to determining the central tendency could skew the index such that it does not actually reflect industry-wide trends. By using this inclusive data sample, the Commission is able to accurately identify the central tendency of industry-wide cost changes that reflects the ''normal'' cost changes recoverable by the index.[59] Moreover, even if the middle 80% (or, for that matter, the middle 50%) includes relatively high cost changes at its upper bound, the index average will be significantly below that upper bound and will not allow pipelines to recover such extraordinary costs.[60] Rather, the index will reflect the central tendency of the industry-wide data, which, by definition, represents normal industry-wide costs. Absent a compelling showing that including data from the middle 80% distorts our measurement of the industry-wide central tendency, we are inclined to consider this more comprehensive data set.

28. Third, along similar lines, we emphasize that mere generalized concerns about outlying or unrepresentative data do not justify excluding the experiences of pipelines in the incremental 30% (*i.e.,* those pipelines that are included in the middle 80% but not the middle 50%) from our review of industry cost changes. Unlike in prior index reviews, the record in this proceeding does not contain sufficient evidence that pipelines in the incremental 30% experienced anomalous cost changes that would skew the index. In the 2015 and 2010 Index Reviews, commenters presented detailed analyses demonstrating that the incremental 30% contained anomalous cost changes resulting from factors not broadly shared across the industry that would materially distort the index calculation.[61] The record here does not contain a comparably detailed analysis of the incremental 30%. Although Joint Commenters identify 7 pipelines (out of 48) with anomalous cost changes in the incremental 30%, removing those pipelines from the sample would only marginally affect the central tendency of the middle 80%.[62] Furthermore, the record contains no evidence that the cost experiences of the remaining 41 pipelines similarly diverged from industry norms.[63] Finally, the mere presence of pipelines with anomalous cost experiences in a data sample is not sufficient reason to use an alternative sample. The Commission recognized in the 2015 and 2010 Index Reviews that the middle 50% likely includes pipelines with idiosyncratic cost experiences, such as rate base expansions.[64] Accordingly, this record does not justify discarding the additional data in the incremental 30% via statistical data trimming to the middle 50%.[65]

29. Shippers' arguments for a contrary result are unavailing. Notwithstanding that the middle 80% is more dispersed than in prior reviews, the record contains no evidence addressing

reasons for the new policy.'') (internal quotation mark and citations omitted); *New England Power Generators Ass'n, Inc.* v. *FERC,* 879 F.3d 1192, 1201 (D.C. Cir. 2018) (''So long as any change is reasonably explained, it is not arbitrary and capricious for an agency to change its mind in light of experience . . . or further analysis or other factors indicating that the agency's earlier decision should be altered or abandoned.'' (citing *FCC* v. *Fox Television Studios,* 556 U.S. 502, 514–16 (2009)); *Defenders of Wildlife* v. *Zinke,* 856 F.2d 1248, 1262 (9th Cir. 2017).

[55] *Davila-Bardales* v. *INS,* 27 F.3d 1, 5 (1st Cir. 1994) (citing *Rust* v. *Sullivan,* 500 U.S. 173, 186–87 (1991); *Motor Vehicles Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 42 (1983)).

[56] *FCC* v. *Fox Television Studios, Inc.,* 556 U.S. at 515; *see also id.* (explaining that an agency ''need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better'') (emphasis in original).

[57] NOI, 171 FERC ¶ 61,239 at P 9 (citing 2005 Index Review, 114 FERC ¶ 61,293).

[58] Shehadeh Initial Decl. at 26.

[59] The definition of idiosyncratic data can vary from review to review. In any given five-year review period, an historically high level of cost change (due to, *e.g.,* new regulatory requirements) may be widely experienced by pipelines across the industry and, accordingly, will be reflected in the central tendency of the industry-wide data and thus identified as a ''normal'' cost change. On the other hand, if during a different five-year review period, only a small number of pipelines experience that same level of cost change, then the cost change will be idiosyncratic and will differ significantly from the central tendency of the industry-wide data. Generally, the best method of identifying normal and idiosyncratic costs is to consider an inclusive and broadly representative data set such as the middle 80% and to compare those costs to the central tendency of that data set.

[60] Likewise, if the lower bound of the middle 80% includes pipelines with cost changes that are below industry norms, the index average will significantly exceed this lower bound.

[61] For instance, commenters proposing various manual data trimming methodologies demonstrated that the middle 80% included pipelines whose cost changes resulted from idiosyncratic circumstances such as major rate base expansions or increases in net plant. *See* 2015 Index Review, 153 FERC ¶ 61,312 at PP 20–29; 2010 Index Review, 133 FERC ¶ 61,228 at PP 34–55.

[62] When these pipelines are removed from the data set, the mean of the middle 80% declines from 1.46% to 1.29%, while the median and weighted mean remain nearly unchanged. This reduces the composite central tendency of the middle 80% only marginally, from 0.78% to 0.72%. *Compare* Attachment A, Ex. 1, *with id.,* Ex. 6. Furthermore, even this limited reduction may be exaggerated because it results in part from reducing the overall number of pipelines in the sample, which would tend to lower the mean of the sample. Additionally, because four of the seven removed pipelines are located below the median, it is unsurprising that excluding them from the middle 80% would reduce the mean.

[63] In using the middle 80% in this proceeding, we observe that the index level established herein is nonetheless the lowest index since the 2000 Index Review. This mitigates concerns that using the middle 80% leads to an anomalous index level.

[64] *See* 2015 Index Review, 153 FERC ¶ 61,312 at P 33 n.60 (noting that 26 of the 41 pipelines that commenters proposed to exclude for reporting ''non-comparable'' data were included in the middle 50%); 2010 Index Review, 133 FERC ¶ 61,228 at P 48 n.25 (noting that 7 of the 25 pipelines that a commenter proposed to exclude for experiencing rate base expansions were included in the middle 50%). Just as the presence of those pipelines did not preclude use of the middle 50% in earlier reviews, we find that the pipelines Joint Commenters identified do not preclude use of the middle 80% in this proceeding.

[65] AOPL also argues that the Commission should use the middle 80% because it conforms more closely to a lognormal distribution than the middle 50%. AOPL Initial Comments at 20–21, 24 (citing Shehadeh Initial Decl. at 24); AOPL Reply Comments at 8–9. Shippers contend that this argument is mathematically flawed and unsound. Joint Commenters Reply Comments, Brattle Report at PP 50–54; Liquids Shippers Reply Comments at 24–25 (quoting Crowe Reply Aff. at 5). Given these objections, we do not rely upon this argument in reaching our decision to use the middle 80% here. *See also* 2015 Index Review, 153 FERC ¶ 61,312 at P 43 (rejecting this same argument).

whether the more dispersed cost changes in the incremental 30% resulted from pipeline-specific factors rather than from broadly shared circumstances representative of ordinary pipeline operations. Furthermore, Shippers' own evidence demonstrates the dispersion is primarily just a few pipelines at the top of the middle 80%. Although it may be possible that analyses of the middle 80% in this proceeding similar to those provided in prior index reviews would have raised similar concerns about considering the middle 80%, no commenter presented such a comprehensive analysis. In the absence of a more detailed showing, we prefer to use a larger sample, representing a broader array of cost experience, in determining the data set's central tendency.

30. We are likewise unpersuaded by Shippers' reliance upon the Commission's findings in the 2015 and 2010 Index Reviews that the middle 80% includes pipelines further removed from the median and that using the middle 50% provides a more effective method of excluding outlying data. As discussed above, we have reconsidered our prior findings and now conclude that based upon the record in this proceeding, the benefits of considering the additional data in the middle 80% outweigh concerns about introducing anomalous data that could bias the index calculation.

31. We also find unpersuasive Shippers' argument that it is unnecessary to use the middle 80% to obtain a representative sample of industry cost data. We acknowledge that the middle 50% represents a greater percentage of barrel-miles subject to the index than in 2015 or 2010. However, we find that on this record, it is preferable to consider additional data that more fully reflects the diversity of industry cost experience than the middle 50%.

32. Similarly, we disagree with Shippers' assertion that using the middle 80% here would result in an index that encompasses extraordinary cost changes.[66] As discussed above, the Kahn Methodology determines the index level using the central tendency of the trimmed data sample, and does not set the index at the sample's upper or lower bounds. Thus, using the middle 80% will not allow pipelines at the top or bottom of the sample to recover their particular cost changes, which by definition would diverge from the experience of pipelines closer to the central tendency. Instead, this approach only ensures that those pipelines' cost experiences are reflected in calculating the data set's central tendency. As discussed above, we find that considering a wide spectrum of industry experience will aid the Commission in calculating a central tendency that better represents normal industry-wide cost changes.

C. Liquids Shippers' Proposal To Calculate the Composite Measure of Central Tendency Using the Weighted Median

1. Comments

33. As discussed above, the Kahn Methodology calculates the median, mean, and weighted mean of the data set and averages the results to calculate a composite measure of central tendency. Liquids Shippers argue that the weighted mean of the data set in this proceeding accords undue weight to two pipelines, Colonial and Enbridge Energy, L.P. Liquids Shippers allege that these pipelines are substantial outliers in terms of barrel-miles and cost changes[67] and that both reported inaccurate page 700 data for 2014 and 2019.[68] Because the weighted mean accords significant weight to these pipelines, Liquids Shippers state that using it to calculate the composite measure of central tendency will skew the index level upwards and fail to track normal industry-wide cost changes.[69]

34. To remedy this issue, Liquids Shippers propose to replace the weighted mean in the index calculation with the median of the barrel-mile weighted cost changes in the middle 50% (weighted median),[70] as calculated by their witness Elizabeth H. Crowe. Liquids Shippers contend that the Commission has recognized that the median is the preferred statistical measure of central tendency where the data distribution is highly skewed.[71] Thus, Liquids Shippers argue that using the weighted median is a statistically appropriate method of ameliorating the undue influence that Colonial and Enbridge exert upon the index calculation.[72] Alternatively, if the Commission decides not to replace the weighted mean with the weighted median, Liquids Shippers propose reducing the weighting afforded to the weighted mean in the Kahn Methodology from 33.3% to 20% or 10%.[73]

35. Pipelines oppose this proposal and argue that Liquids Shippers have not justified modifying the Kahn Methodology to exclude the weighted mean. Pipelines disagree with Liquids Shippers' claim that the weighted mean affords excessive weight to Colonial or Enbridge. Rather, Pipelines assert that averaging the weighted mean with the median and unweighted mean ensures that larger pipelines receive appropriate weighting in the index calculation, consistent with indexing's aim to measure cost changes on an industry-wide basis. Pipelines also assert that neither Colonial nor Enbridge is an outlier because both pipelines are included in the middle 50% of the data set. In addition, Pipelines maintain that Liquids Shippers' allegations regarding Colonial's and Enbridge's page 700 inputs are both irrelevant and outside the scope of the five-year review. Finally, Pipelines contend that Liquids Shippers' calculation of the weighted median is methodologically flawed and would distort the index by affording undue weight to smaller pipelines in the data set.[74] Colonial filed separate reply comments echoing these arguments and urging the Commission to disregard Liquids Shippers' claims regarding its page 700.[75]

2. Commission Determination

36. We decline to adopt Liquids Shippers' proposal to replace the weighted mean with the weighted median. First, removing the weighted mean from the index calculation would contravene longstanding Commission practice and Dr. Kahn's testimony in the rulemaking proceeding that established

[66] *See* Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 at 31,097 (rejecting request to adopt index ''sufficiently high and generous to encompass even the most extraordinary costs'' because such an index ''would provide windfalls to many oil pipelines by allowing rate changes substantially above cost changes'').

[67] Liquids Shippers Initial Comments at 13–15. For instance, Liquids Shippers state that Colonial and Enbridge comprise 40% of the total barrel-miles for all of the 160 pipelines in the data set. *Id.* In addition, Liquids Shippers claim that Colonial reported a higher unit cost change over the 2014–2019 period than 69 of the 80 pipelines included in the middle 50% and Enbridge reported a higher cost change than 47 of those pipelines. *Id.* at 15.

[68] Specifically, Liquids Shippers claim that Colonial reported an inaccurate capital structure in both 2014 and 2019 and that Enbridge's reported ROEs are inconsistent with Commission policy. *Id.* at 17–19.

[69] *Id.* at 16–19.

[70] The standard median identifies the cost change for which the same number of pipelines have a smaller cost change and a larger cost change. By contrast, the weighted median identifies the cost change for which the same share of barrel-miles (rather than the number of pipelines) is accounted for by the pipelines below and above the selected median.

[71] Liquids Shippers Initial Comments at 19–20 (quoting Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 at 31,097).

[72] *Id.* at 20.

[73] *Id.* at 20 n.45; Crowe Initial Affidavit at 8–9.

[74] AOPL Reply Comments at 22–27; Designated Carriers Reply Comments at 6–13.

[75] Colonial Reply Comments at 3–11.

the indexing regime. In proposing to average the weighted mean with the median and unweighted mean to derive the composite central tendency, Dr. Kahn explained that each of these measures ''captured a significant aspect of the composite results from an industry perspective.'' [76] The Commission credited Dr. Kahn's testimony and adopted this approach to calculating the composite central tendency in that proceeding and in all subsequent five-year reviews. As discussed below, we find that Liquids Shippers' arguments do not provide an adequate basis for departing from this consistent practice.

37. Second, we reject as unpersuasive Liquids Shippers' claim that the Commission should replace the weighted mean merely because it provides greater weight to larger pipelines like Colonial and Enbridge.[77] The index strives to track cost changes on an industry-wide basis among pipelines of all sizes. To this end, the Kahn Methodology strikes a balance between large and small pipelines by determining the central tendency of the cost data using two measures that do not take pipeline size into account (the median and the mean) together with the weighted mean, which weights each pipeline's cost change by its transported volumes. Including the weighted mean in this analysis ensures that the cost-change calculation takes sufficient account of pipeline size so that ''minor pipelines do not skew'' the result.[78] Thus, the fact that the weighted mean may accord additional weight to larger pipelines in this data set is fully consistent with its role in the index calculation. Removing it from the analysis as Liquids Shippers propose would upset the balance between large and small pipelines that the Kahn Methodology achieves. For this reason, we likewise reject Liquids Shippers' alternative proposal to reduce the weighting of the weighted mean in the calculation from 33.3% to 20% or 10%.

38. Third, Ms. Crowe's calculation of the weighted median is methodologically flawed. AOPL's witness Dr. Shehadeh testifies that the established statistically appropriate method for calculating the weighted median, as applied to pipeline cost changes, is to identify the cost change in the data set for which the same share of barrel-miles (rather than the same number of pipelines) is accounted for by the pipelines below and above the selected median.[79] Shehadeh Reply Decl. at 11 n.17 (citing Thomas H. Cormen, Introduction to Algorithms 194 (2009); 6 F.Y. Edgeworth, On Observations Relating to Several Quantities 279–85 (1887) (The weighted median may be defined as follows:

For n distinct ordered elements $x_1, x_{2,}, \ldots, x_n$ with positive weights

$w_1, w_{2,}, \ldots, w_n$ such that $\sum_{i=1}^{n} w_i = 1$, the weighted median is the element x_k satisfying

$\sum_{i=1}^{k-1} w_i \leq 1/2$ and $\sum_{i=k+1}^{n} w_i \leq 1/2$).

This value is appropriately derived by ordering the pipelines by cost-change percentage, computing each pipeline's share of total barrel-miles, and measuring the cumulative share of total barrel-miles represented as each pipeline is included in the sample.[80] The pipeline whose share of total barrel-miles causes the cumulative share to reach 50% represents the data set's weighted median.[81]

39. Ms. Crowe, however, performed a different calculation by identifying the median weighted barrel-mile cost-change percentage and dividing that figure by the average of those pipelines' 2014 barrel-miles.[82] This calculation departs from the proper method of calculating the weighted median discussed above. Rather than identify the pipeline that causes the cumulative share of total-barrel miles represented in the sample to reach 50%, Ms. Crowe derives the median value of the weighted cost-change percentages for 2019 without regard to the barrel-miles represented below and above that cost change.[83] Unlike the Commission's calculation of the standard median and Dr. Shehadeh's calculation of the weighted median, Ms. Crowe does not order pipelines by cost changes, and instead orders them by cost changes times barrel-miles.[84] Thus, the median of Ms. Crowe's data sample does not capture the central tendency of industry-wide cost changes, as evidenced by the significant and multidirectional fluctuations above and

[76] Testimony of Dr. Alfred E. Kahn, Docket No. RM93–11–000, at 9 (filed Aug. 12, 1993).

[77] The Commission has previously recognized that large pipelines like Colonial can exert significant influence upon the weighted mean. 2015 Index Review, 153 FERC ¶ 61,312 at P 24 n.49 (explaining that ''[b]ecause Colonial is a large pipeline, it heavily influences the weighted average in the Kahn Methodology'').

[78] *AOPL II,* 281 F.3d at 241. Although Order No. 561–A recognized that the median is often the preferred statistical measure of central tendency where the distribution is highly skewed, the Commission made this observation in affirming the use of statistical data trimming to derive a median sample of the overall data set rather than in the context of using the median to determine the data set's central tendency. *See* Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 at 31,096–97. In that proceeding and in each subsequent index review, the Commission has consistently calculated the composite measure of central tendency by averaging the median, mean, and weighted mean.

[79] Shehadeh Reply Decl. at 11.

[80] For example, consider a set of numbers 3, 4, 6, 10, where each number is weighted 1, 2, 3, and 5, respectively. In this scenario, the weighted median of the data set would equal 6, because including 6 in the set increases the cumulative weighting to 50%. (1+2+3)/(1+2+3+5) = 6/11 = 54.55%. By contrast, the standard median would be 5, which equals the average of the second and third numbers of the set.

[81] Dr. Shehadeh correctly performs this calculation using Liquids Shippers' data set and derives a weighted median cost change of 0.68%, as reported by Enbridge. Shehadeh Reply Decl., App. B, Ex. 1.

[82] Shehadeh Reply Decl. at 13; *see also* Crowe Initial Aff., App. 6 at Cost Changes Tab. Although Ms. Crowe's testimony on this issue was unclear, our understanding of her calculation is as follows. First, she identified the pipelines with percentage cost changes in the middle 50%. Second, she multiplied each pipeline's percentage cost change by its barrel-miles. Third, she arranged the pipelines based upon these results from smallest to largest. Fourth, she determined the median of this data sample. Because Ms. Crowe's sample consists of an even number of pipelines, the median lies at the midpoint between two pipelines, Hilcorp Pipeline Company, LLC, and BOE Pipeline, LLC. Finally, she divided the median percentage cost change by those pipelines' 2014 barrel-miles, which produces a final result of −0.57%. *See* Crowe Initial Aff., App. 3, at Cost Changes Tab; Shehadeh Reply Decl. at 10, Figure 1 and App. B, at Figure 1—Chart Backup Tab.

[83] In essence, Ms. Crowe attempts to calculate the weighted median by using a modified version of the formula the Commission uses to compute the weighted mean.

[84] *See* Crowe Initial Aff., App. 3 at Cost Changes Tab. Under this approach, it is unclear whether the median pipeline of a given sample reported (a) relatively high cost changes and low barrel-miles or (b) relatively low cost changes and high barrel-miles.

below the purported median that follow no discernible pattern.[85] Accordingly, we conclude that Ms. Crowe's calculation does not provide a useful measure of central tendency for purposes of calculating the index.[86]

40. Fourth, Liquids Shippers' challenges to Colonial's and Enbridge's page 700 data are both misplaced and unavailing on the merits. Indexing proceedings are not an appropriate forum for challenging specific pipelines' page 700 inputs[87] and the Commission has declined to scrutinize individual pipeline data in prior index reviews.[88] In any event, the record does not support Liquids Shippers' claim that Colonial and Enbridge reported outlying cost changes. Both pipelines are included in the middle 50% of all pipelines in the data set, which indicates that their cost experiences did not diverge significantly from industry norms. In fact, as Dr. Shehadeh demonstrates, Enbridge's reported cost change represents the correctly calculated weighted median of the data sample,[89] refuting Liquids Shippers' contention that it is an outlier in terms of cost changes.

D. Liquids Shippers' Proposal To Adopt Standardized ROEs for 2014 and 2019

1. Comments

41. Liquids Shippers state that the Commission should replace the ROEs that pipelines reported on page 700 for 2014 and 2019 with single, standardized figures for both years.[90] Liquids Shippers contend that the data used to calculate the index level should conform to the Commission's cost-of-service methodology[91] and that the reported ROEs for 2014 and 2019 are inconsistent with this methodology in two respects. First, Liquids Shippers claim that pipelines' reported ROEs are self-selected and do not reflect what investors would demand in the market.[92] Second, Liquids Shippers state that if all oil pipeline rates were litigated at the same time, absent unusual circumstances, the Commission would adopt the same ROE for every pipeline because regulated pipelines typically fall within a broad range of average risk.[93] Liquids Shippers assert that the reported ROEs conflict with this principle because they vary substantially.[94]

42. Liquids Shippers also claim that uncertainty surrounding the Commission's oil pipeline ROE policy undermines the reliability of the reported ROEs for 2019. They state that the Commission initiated a review of its ROE policy in Docket No. PL19–4–000 on March 21, 2019 but did not clarify its ROE methodology for oil pipelines until it issued the ROE Policy Statement on May 21, 2020.[95] Because oil pipelines were required to submit page 700 cost-of-service data for 2019 in April 2020, Liquids Shippers allege that pipelines were not certain of the Commission's prevailing policy when they reported their 2019 ROEs. In support of this claim, Liquids Shippers observe that two pipelines submitted updated Form No. 6 filings in July 2020 indicating that the page 700 ROEs they filed in April 2020 did not comply with the Commission's then-applicable policy relying solely upon the DCF model.[96]

43. In light of these concerns, Liquids Shippers urge the Commission to replace each pipeline's reported page 700 ROE for 2014 and 2019 with standardized ROEs for purposes of calculating the index level. For 2014, Liquids Shippers propose a standardized ROE of 10.29%, which 54 pipelines reported in their 2014 page 700 filings.[97] For 2019, Liquids Shippers propose to use the 10.02% ROE that Trial Staff has proposed in testimony in an ongoing oil pipeline rate proceeding based upon data for the six-month period ending in November 2019.[98]

44. Pipelines oppose Liquids Shippers' proposal and disagree with their assertions. AOPL disputes Liquids Shippers' claim that variation in the reported page 700 ROEs indicates that this data is unreliable or inconsistent with Commission policy.[99] Pipelines contend, moreover, that the Commission found in the 2015 Index Review that statistical data trimming is sufficient to remove pipelines with outlying equity cost changes from the data set and that Liquids Shippers' arguments do not undermine this conclusion.[100] In addition, AOPL argues that Liquids Shippers failed to support their proposed standardized ROEs and that adopting their proposal would complicate the five-year review by introducing complex cost-of-service ratemaking issues.[101]

[85] A small shift in the data sample's median would produce significant and multidirectional changes in the calculation's result. For instance, a median reflecting the pipeline with the next lowest weighted percentage change (Wildcat Liquids Caddo LLC) would reduce Ms. Crowe's result from 0.57 to −1.74% (a decrease of over 200%), whereas a median reflecting the next highest change (reported by Wesco Pipeline, LLC) would reduce the result by an even greater amount, from −0.57% to −2.28% (a decrease of 400%). These haphazard results do not reflect a convergence towards a central tendency of industry-wide cost changes.

[86] In addition to failing to reflect the central tendency of industry-wide cost changes, Ms. Crowe's calculation also improperly reduces the weighting attributed to larger pipelines in the data set. Because Ms. Crowe orders the pipelines by barrel-mile cost change times barrel-miles, a pipeline with high barrel-miles would likely only lie near the median of the data sample if it reported extremely low cost changes. Thus, Ms. Crowe's methodology would nullify the influence of larger pipelines upon the index calculation and thereby defeat the purpose of relying upon a weighted measure of central tendency. *See AOPL II,* 281 F.3d at 241 (explaining that the weighted mean serves to ensure that ''minor firms do not skew the result'').

[87] *See AOPL I,* 83 F.3d at 1437 (holding that the Commission did not err in Order No. 561 by declining to periodically review individual pipeline costs and instead requiring shippers to challenge individual pipeline rates via protests or complaints); *see also Calnev Pipe Line L.L.C.,* 127 FERC ¶ 61,304, at P 5 (2009) (''[T]he Commission has made quite clear that it will not review allegations regarding the appropriateness of a pipeline's cost of service or the accuracy of its accounting in an index proceeding. Such allegations must be included in a complaint once the index-based filing becomes effective.'' (citing *SFPP, L.P.,* 123 FERC ¶ 61,317 (2008); *BP W. Coast Prods. LLC* v. *SFPP, L.P.,* 121 FERC ¶ 61,243 (2007)).

[88] 2015 Index Review, 153 FERC ¶ 61,312 at PP 22–30, 33–39 (declining to adopt manual data trimming proposals that would have required analyzing individual pipeline data); 2010 Index Review, 133 FERC ¶ 61,228 at PP 48–55 (same).

[89] Shehadeh Reply Decl. at 14; *see also supra* n.81.

[90] Liquids Shippers Initial Comments at 21–22.

[91] *Id.* at 21, 25 (citing 2015 Index Review, 153 FERC ¶ 61,312 at PP 13, 15).

[92] *Id.* at 21 (citing *FPC* v. *Hope Nat. Gas Co.,* 320 U.S. 591, 603 (1944); *Bluefield Water Works & Improvement Co.* v. *Pub. Serv. Comm'n of W. Va.,* 262 U.S. 679, 692–93 (1923); *Farmers Union Cent. Exch., Inc.* v. *FERC,* 734 F.2d 1486, 1502 (D.C. Cir. 1984)).

[93] *Id.* at 22–23. Liquids Shippers assert that regulated pipelines typically face comparable risks and that the Commission typically sets oil pipeline ROEs at the median of the proxy group results. *Id.*

[94] *Id.* at 23. For instance, Liquids Shippers state that among the 160 pipelines included in the untrimmed data set, reported page 700 ROEs for 2019 ranged from 0.9% to 22.3%. *Id.* at 24 (citing Crowe Initial Aff. at 9).

[95] *Id.* at 25–26 (citing *Inquiry Regarding the Commission's Policy for Determining Return on Equity,* 166 FERC ¶ 61,207 (2019)). As discussed above, the Commission issued a policy statement revising its ROE methodology for natural gas and oil pipelines on May 21, 2020. ROE Policy Statement, 171 FERC ¶ 61,155.

[96] *Id.* at 27–28 (citing Crowe Initial Aff., App. 4 at 1–2) (referring to updated Form No. 6 filings of Plains Pipeline, LP and Rocky Mountain Pipeline System LLC).

[97] Ms. Crowe states that 45 pipelines reported a 10.29% ROE on their page 700s for 2014. Crowe Initial Aff. at 11–12. However, as shown in Attachment A, Exhibit 7 to this order, the Commission's review of Form No. 6 filings submitted in 2016 indicates that 54 pipelines reported this ROE for 2014 in the column on page 700 for prior-year data.

[98] Liquids Shippers Initial Comments at 30–31; Crowe Initial Aff. at 12 (citing Trial Staff, Direct and Answering Cost-Based Rate Testimony of Commission Trial Staff Witness Robert J. Keyton, Docket Nos. OR18–7–002 *et al.* (filed Jan. 14, 2020)).

[99] AOPL Reply Comments at 30.

[100] *Id.* at 28 (quoting 2015 Index Review, 153 FERC ¶ 61,312 at P 17); Designated Carriers Reply Comments at 13–14 (same).

[101] AOPL Reply Comments at 32.

2. Commission Determination

45. We decline to adopt Liquids Shippers' proposal to replace the reported page 700 ROE data for 2014 and 2019 with standardized ROEs. We conclude that Liquids Shippers have not adequately demonstrated that the reported page 700 ROEs are unreliable or inconsistent with Commission policy.

46. Contrary to Liquids Shippers' contention, the fact that page 700 ROEs are self-reported does not demonstrate that this data is unreliable or fails to capture the returns that investors would demand in the market. Rather, one of the primary reasons the Commission updated the index calculation to use page 700 data is that this data is based upon ''established ratemaking techniques.'' [102] During the 2014–2019 period, these techniques included determining ROE using the DCF model, which is designed to reflect investors' required returns. The instructions on page 700 required pipelines to determine their ROE (as well as other page 700 inputs) consistent with this methodology and pipelines submitted page 700 under oath and subject to sanction if there were purposeful errors in their reported data.[103] In addition, if a pipeline makes any major changes to its application of the Opinion No. 154–B methodology in preparing page 700, it must describe such changes in a footnote on page 700. Given these facts, we find that Liquids Shippers have not adequately demonstrated that the reported page 700 ROE data is unreliable merely because pipelines self-reported.[104]

47. Similarly, variation among page 700 ROEs does not indicate that the reported ROE data is unreliable. To the contrary, multiple factors can cause the DCF model to yield different results for different pipelines. For example, even when analyzing data from the same time period, the appropriate proxy group may vary from pipeline to pipeline depending upon differences in risk. Liquids Shippers themselves acknowledge [105] that although the Commission typically sets the real ROE for oil pipelines at the median of the proxy group results, it may set the ROE above or below the median where the record demonstrates that the pipeline faces anomalously high or low risks.[106] Accordingly, the fact that pipelines reported different ROEs for the same years does not demonstrate that this data is inaccurate or inconsistent with Commission policy. Moreover, the Commission explained in the 2015 Index Review that to the extent a particular pipeline's per barrel-mile equity cost changes departed substantially from industry norms, that pipeline would not be among the middle 50% used to calculate the index level.[107] Similarly, such pipelines would not be among the middle 80% used to calculate the index level in this proceeding. Liquids Shippers provide no basis for altering this conclusion.

49. We conclude, moreover, that Liquids Shippers have not supported their proposed standardized ROEs. For 2014, Liquids Shippers seek to replace all pipelines' reported ROEs with an ROE figure that only 29% of pipelines reported for that year.[108] However, Liquids Shippers do not demonstrate that this figure accurately measures the investor-required cost of equity for all pipelines in the data set. Similarly, Liquids Shippers do not justify why the Commission should adopt, as the 2019 ROE for all pipelines in the data set, a figure that a participant has proposed in an ongoing hearing on which neither the Presiding Judge nor the Commission have opined.[109] Given that oil pipelines have diverse business models and different risk levels, we cannot simply assume that any single ROE could reflect the investor-required return for all pipelines in the data set.

50. Finally, we find that adopting Liquids Shippers' proposal would undermine indexing's purpose as a simplified and streamlined ratemaking regime. Whereas the Kahn Methodology promotes simplification by relying upon reported page 700 data, Liquids Shippers' proposal would require the Commission, in this proceeding and in future five-year reviews, to undertake separate analyses to determine just and reasonable industry-wide ROEs for the first and last years of the five-year review period. Determining a just and reasonable ROE, particularly on an industry-wide basis, would be a complex and fact-intensive inquiry that could require considerable time and resources to resolve. The Commission explained in the NOI that addressing such complex cost-of-service issues would improperly complicate and prolong the five-year review process in violation of EPAct 1992's mandate for simplified and streamlined ratemaking,[110] and Liquids Shippers have not refuted these concerns.

E. CAPP's Argument Regarding Negotiated Rate Contracts

1. Comments

51. CAPP argues that the Commission should quantify the effects of negotiated rate contracts upon oil pipelines' reported costs of equity. CAPP states that these contracts typically contain provisions such as shipper volume commitments that serve to transfer risk from the pipeline to its shippers and that failing to reflect pipelines' reduced risks in the page 700 data could improperly inflate the index calculation.[111] CAPP notes that the Commission found in the 2015 Index Review that the page 700 total cost-of-service would reflect any reduction in the pipeline's risk, but argues that the page 700 data in this proceeding does not indicate whether this occurred over the 2014–2019 period.[112] To provide

[102] 2015 Index Review, 153 FERC ¶ 61,312 at P 15.

[103] *See BP W. Coast Prods. LLC* v. *SFPP, L.P.,* 121 FERC ¶ 61,243, at P 9 (observing that ''pipelines submit their FERC Form No. 6 under oath and exposes the pipeline and its employees to civil and criminal sanctions if there are purposeful errors in'' applying the Commission's existing cost-of-service methodology to develop the underlying cost inputs). Furthermore, the Commission calculates the index level based upon changes in cost over the applicable review period, rather than total costs in a given year. Because the last year of any particular review period (*e.g.,* 2014–2019) is the first year of the next review period (*e.g.,* 2019–2024), any attempt by pipelines to distort the index calculation by reporting inflated cost data in the last year of one period would harm their interests by establishing a higher cost baseline in the first year of the next period.

[104] If a shipper determines that a pipeline has reported inaccurate data on its page 700, the shipper may file a complaint alleging that the pipeline did not properly apply the Opinion No. 154–B methodology in developing its page 700 cost inputs. *See BP W. Coast Prods. LLC* v. *SFPP, L.P.,* 121 FERC ¶ 61,243 at P 9 (explaining that shippers may file ''a complaint that provides reasonable grounds to conclude that the pipeline did not properly apply its existing cost-of-service methodology to develop the underlying cost inputs used to develop the Page 700 in its annual FERC Form No. 6, or the inputs were improperly entered into its accounts or the calculation.'').

[105] *See* Liquids Shippers Initial Comments at 22–23 (quoting *El Paso Nat. Gas Co.,* Opinion No. 528, 145 FERC ¶ 61,040, at P 592 (2013)).

[106] *E.g., BP Pipelines (Alaska) Inc.,* Opinion No. 502, 123 FERC ¶ 61,287, at P 195 (2008) (citing *Transcon. Gas Pipe Line Corp.,* Opinion No. 414–A, 84 FERC ¶ 61,084, at 61,423–24 (1998)), *order on reh'g and compliance,* 125 FERC ¶ 61,215 (2008), *reh'g denied,* 127 FERC ¶ 61,317 (2009), *aff'd sub nom. Flint Hills Res. Alaska, LLC* v. *FERC,* 726 F.3d 881 (D.C. Cir. 2010).

[107] 2015 Index Review, 153 FERC ¶ 61,312 at P 17.

[108] Whereas Liquids Shippers state that 45 of 158 pipelines filing page 700 for 2014 reported an ROE of 10.29%, the Commission's review of Form No. 6 data indicates that 54 of 184 filing pipelines reported that particular ROE for 2014. *Compare* Liquids Shippers Initial Comments at 31 *with* Attachment A, Ex. 7.

[109] According to the most recent procedural schedule adopted in Docket Nos. OR18–7–002 *et al.,* the initial decision in that proceeding is currently scheduled for issuance on May 28, 2021. *Epsilon Trading, LLC* v. *Colonial Pipeline Co.,* Docket No. OR18–7–002, at Attachment A (June 23, 2020).

[110] NOI, 171 FERC ¶ 61,239 at P 11.

[111] CAPP Initial Comments at 2–5.

[112] *Id.* at 4 (quoting 2015 Index Review, 153 FERC ¶ 61,312 at P 28).

increased transparency, CAPP urges the Commission to consider requiring pipelines to provide shippers with the workpapers underlying their page 700 calculations.[113] AOPL contends CAPP's claims are unsupported and that the Commission has previously rejected this precise argument.[114]

2. Commission Determination

52. We find CAPP's arguments unpersuasive. First, as the Commission explained in the 2015 Index Review, ''[t]o the extent that volume commitments in [negotiated rate] agreements have reduced the pipeline's risk, the page 700 total cost of service would reflect this reduction in the embedded costs of equity and costs of debt.'' [115] These effects would tend to reduce pipeline costs and thereby produce a lower index level, rendering CAPP's concerns unfounded. Although CAPP questions whether the effects of reduced pipeline risk are reflected in the page 700 data, it provides no basis for the Commission to conclude that the reported data fails to adequately account for pipelines' risks in measuring changes in cost of equity and costs of debt.

53. Second, to the extent that CAPP requests that the Commission review individual pipeline data to evaluate the effects of contract rates upon the pipeline's risks, this request is both unsupported and misplaced. CAPP has not presented any method for quantifying any disparity in the risks pipelines face when using contract rates versus non-contract rates. Although CAPP states that the Commission should consider requiring pipelines to provide shippers with the workpapers underlying their page 700 cost of service calculations, it has not explained how these workpapers would aid in identifying differences in risk between contract and non-contract rates. Moreover, as CAPP itself acknowledges, the Commission recently declined to require pipelines to provide workpapers [116] and CAPP has not provided a sufficient basis for the Commission to revisit this decision here. More broadly, the Kahn Methodology measures changes in barrel-mile costs on a generic, industry-wide basis. Thus, in calculating the index level, the Commission does not scrutinize the inputs underlying individual pipelines' page 700 data. Accordingly, the review that CAPP appears to seek would exceed the scope of the five-year index review and conflict with streamlined and simplified ratemaking.[117]

F. Pipeline Costs Resulting From Integrity Management Regulations and Other Developments

1. Comments

54. AOPL states that oil pipelines have experienced significant cost increases due to pipeline safety and integrity measures and that these costs are likely to increase in the future.[118] AOPL submits a declaration from William R. Byrd identifying new and continuing regulatory obligations related to pipeline integrity as well as other factors affecting pipeline costs, such as expenditures related to security and cybersecurity, opposition to pipeline infrastructure, and the COVID–19 pandemic.[119] Mr. Byrd also describes anticipated regulatory requirements that he states will increase pipelines' obligations and compliance costs in the future.[120] AOPL maintains that pipelines' ability to undertake future expansions and adopt environmental, safety, and security measures in compliance with applicable regulatory requirements depends upon the Commission adopting an index level that allows pipelines to recover expected future cost increases.[121]

55. Other commenters make similar assertions. PST states that pipeline safety requirements have increased over the last five years and that setting the index level too low could reduce pipelines' incentives to invest in safety measures.[122] EIC echoes AOPL's statements regarding increasing costs and explains that pipelines' ability to invest in building and operating facilities depends upon ready access to capital markets and a predictable regulatory environment that reduces investment risks. Thus, EIC asserts that the Commission should be mindful that an insufficiently high index level could impair pipelines' ability to attract investment.[123]

56. PHMSA filed comments describing safety rules it has enacted since the 2015 Index Review as well as several pending rulemakings that, if adopted, would impose additional costs upon pipeline operators. Although it takes no position on the specific index level the Commission should adopt, PHMSA states that the index should reflect the costs that its existing and future regulations impose upon pipeline operators.[124]

57. Shippers reject these arguments and contend that the Commission has previously found that future costs are speculative and inappropriate for inclusion in the index calculation.[125] Liquids Shippers argue that costs related to safety or integrity measures incurred during the 2014–2019 period should be reflected in the page 700 data.[126] In addition, Joint Commenters and Liquids Shippers contend that if safety or integrity-related costs are not captured in this index calculation, they will be reflected in future index reviews and pipelines may seek to recover those costs in the interim through cost-of-service rate filings, where appropriate.[127]

2. Commission Determination

58. We decline to alter our calculation of the index level based upon the arguments concerning safety or integrity-related costs. To the extent that new or continuing regulatory requirements caused pipelines' barrel-mile costs to increase during the 2014–2019 period, those cost changes would be reflected in the page 700 data.[128] We also decline to adjust the index calculation based upon projections of future costs or other developments occurring after the conclusion of the 2014–2019 period. As the Commission has previously explained, future cost projections related to regulatory changes are speculative and inappropriate for inclusion in the index.[129] Additionally, because the Kahn Methodology only considers cost changes incurred during

[113] *Id.* at 5.

[114] AOPL Reply Comments at 33–37.

[115] 2015 Index Review, 153 FERC ¶ 61,312 at P 28.

[116] *Revisions to Indexing Policies and Page 700 of FERC Form No. 6,* 170 FERC ¶ 61,134, at P 6 (2020).

[117] As discussed above, if a shipper determines that a particular pipeline's page 700 inputs do not accord with the Commission's existing Opinion No. 154–B methodology, it may file a complaint to that effect with the Commission. *BP W. Coast Prods. LLC* v. *SFPP, L.P.,* 121 FERC ¶ 61,243 at P 9.

[118] AOPL Initial Comments at 36–39; Declaration of William R. Byrd, P.E. at 21.

[119] Byrd Declaration at 7–17.

[120] *Id.* at 17–20.

[121] AOPL Initial Comments at 40 (quoting 2005 Index Review, 114 FERC ¶ 61,293 at P 63).

[122] PST Comments at 1–2.

[123] EIC Comments at 7, 11–16.

[124] PHMSA Reply Comments at 1–4.

[125] Joint Commenters Reply Comments at 19–20 (quoting 2010 Index Review, 133 FERC ¶ 61,312 at P 125); Liquids Shippers Reply Comments at 31–32 (same); CAPP Initial Comments at 2.

[126] Liquids Shippers Reply Comments at 33.

[127] Joint Commenters Reply Comments at 20; Liquids Shippers Reply Comments at 33.

[128] If such obligations result in a substantial divergence between a pipeline's actual costs and the rate resulting from application of the index, the pipeline may file to change its rate using the Commission's cost-of-service methodology pursuant to 18 CFR 342.4(a) of the Commission's regulations. 18 CFR 342.4(a); *see also* Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,957 (explaining that ''such circumstances as increased safety or environmental regulations may justify the use of a cost-of-service methodology'').

[129] 2010 Index Review, 133 FERC ¶ 61,228 at P 125.

the prior five years, regulatory changes and other developments occurring after the 2014–2019 period concluded on December 31, 2019, are beyond the scope of this index review.[130] To the extent that such developments affect barrel-mile costs going forward, the Commission will incorporate those cost changes as reflected in page 700 cost-of-service data in future index calculations.

G. Treatment of Mergers in the Data Set

1. Comments

59. To account for mergers that occurred during the study period, the Kahn Methodology adds the separate costs the pipelines reported on Form No. 6 in the first year of the data set (*e.g.,* 2014) and compares this sum to the newly combined company's costs in the last year of the data set (*e.g.,* 2019).[131] The Commission employs a similar process for addressing divestitures, adding the separate costs that the pipelines reported on Form No. 6 in the last year of the data set and comparing this sum to the previously combined company's costs in the first year of the data set. Joint Commenters and AOPL each propose to adjust the data set to account for merger activity that they claim occurred during the 2014–2019 period but was not reflected in the data underlying the Commission's proposal in the NOI.

60. Joint Commenters propose to account for six additional mergers: (1) Plains Southcap Inc. and Plains Pipeline, LP; (2) Red River Crude Pipeline LLC and Enterprise Crude Pipeline LLC; (3) Regency Liquids Pipeline LLC and Lone Start NGL Pipeline LP; (4) Independent Trading & Transportation Company I, L.L.C. and Hiland Crude, LLC; (5) Phillips 66 Pipeline LLC and Phillips 66 Carrier LLC; and (6) Excel Pipeline LLC and Sunoco Pipeline L.P.[132] AOPL proposes to reflect the Excel-Sunoco merger and two additional mergers: (i) Mid-Valley Pipeline Company and Energy Transfer Crude Oil Company LLC (Energy Transfer Crude); and (ii) The Premcor Pipeline Co. and Valero Partners Lucas, LLC (Valero Lucas).[133] Joint Commenters disagree with AOPL's proposals to reflect mergers between Mid-Valley-Energy Transfer Crude and Premcor-Valero Lucas.[134]

2. Commission Determination

61. We will adjust the data set to reflect mergers between: (1) Plains Southcap Inc. and Plains Pipeline, LP; (2) Red River Crude Pipeline LLC and Enterprise Crude Pipeline LLC; (3) Regency Liquids Pipeline LLC and Lone Star NGL Pipeline LP; (4) Independent Trading & Transportation Company I, L.L.C. and Hiland Crude, LLC; (5) Phillips 66 Pipeline LLC and Phillips 66 Carrier LLC; and (6) Excel Pipeline LLC and Sunoco Pipeline L.P.[135] We have verified through a review of Form No. 6 data that these mergers took place during the 2014–2019 period and will therefore revise the data set to combine these pipelines' costs in 2019 as appropriate.

62. We decline, however, to adopt AOPL's proposal to reflect mergers between Mid-Valley-Energy Transfer Crude and Premcor-Valero Lucas. We find that the record does not support adjusting the Form No. 6 data to reflect these mergers. For instance, a review of the total miles owned at year end does not indicate that any transfer of assets took place between these companies during the review period.[136] The Commission's review of other Form No. 6 data likewise did not confirm whether these mergers in fact took place.[137]

IV. 2021–2026 Oil Pipeline Index

63. Based upon the foregoing, we calculate the index level used to determine annual changes to oil pipeline rate ceilings for the five-year period beginning July 1, 2021 as follows. First, as shown in Attachment A (Exhibit 2) we remove those pipelines that did not provide Form No. 6, page 700 data or provided incomplete data. Second, as shown in Attachment A (Exhibit 5), we consider the data on Form No. 6, page 700 to calculate each pipeline's cost change on a per barrel-mile basis over the prior five-year period (*e.g.,* the years 2014–2019 in this proceeding). Third, to remove statistical outliers and spurious or unrepresentative data, we trim the data set to those pipelines in the middle 80% of cost changes. Fourth, as shown in Attachment A (Exhibit 5), we calculate three measures of the middle 80%'s central tendency: The median, the mean, and a weighted mean. Fifth, we calculate a composite by taking a simple average of those three measures of central tendency, as shown in Attachment A (Exhibit 1). Finally, we compare this composite to the value of the PPI–FG index data over the same period (0.52% in this proceeding) and set the index level at PPI–FG plus (or minus) this differential. Using these calculations, we establish an index level of PPI–FG+0.78% for the five-year period beginning July 1, 2021.

The Commission Orders

Consistent with the discussion in this order, the Commission determines that the appropriate oil pipeline index level for the next five years, July 1, 2021 through June 30, 2026, is PPI–FG+0.78%.

By the Commission. Commissioner Glick is dissenting with a separate statement attached. Commissioner Clements is not participating.

Issued: December 17, 2020.

Kimberly D. Bose,

Secretary.

Federal Energy Regulatory Commission

Five-Year Review of Oil Pipeline Index

Glick, Commissioner, Dissenting

1. Today's order is a complete abdication of the Commission's responsibility to protect oil pipeline customers. It overthrows well-established Commission policy and goes back on explicit promises we made to customers just a few years ago. As a result, the Commission is handing oil pipelines a multi-billion-dollar windfall for which customers are left to pick up the tab. I dissent strongly from those unreasoned and indefensible determinations.

* * * * *

2. A little background is necessary to appreciate just how seriously the Commission has fallen down on the job. In the Energy Policy Act of 1992, Congress directed the Commission to promulgate a rule to simplify its ratemaking methodology for oil pipelines.[1] Shortly thereafter, the Commission issued Order No. 561, which adopted an indexing methodology as part of the Commission's approach for regulating

[130] Cost changes incurred during the 2019–2024 period as a result of integrity management and other regulatory obligations will be addressed in the 2025 index review.

[131] 2015 Index Review, 153 FERC ¶ 61,312 at P 38. The Commission has explained that without this step, the absorbed pipeline's cost data would be needlessly discarded. *Id.*

[132] Joint Commenters Reply Comments, Brattle Group Report, Attachment D at 2, 4–7 (Data Merger Analysis).

[133] Shehadeh Initial Decl., Ex. A1 (Companies Consolidated to Adjust for Mergers, Acquisitions, and Changes in Corporate Form 2014–2019).

[134] Joint Commenters Reply Comments, Brattle Group Report at 48–50.

[135] The Commission identified the Excel Pipeline LLC-Sunoco Pipeline L.P. merger in the NOI proposal but did not combine their data for 2019.

[136] Joint Commenters Reply Comments, Brattle Report at 49–50.

[137] For example, despite its alleged merger with Energy Transfer Partners, Mid-Valley continued filing Form No. 6 in its own name for each year of the review period through 2019.

[1] Energy Policy Act of 1992, Public Law 102–486, 1801(a) (Oct. 24, 1992) (codified at 42 U.S.C. 7172 note (2006)).

oil pipeline rates.[2] Under that approach, if an oil pipeline increases its rates by less than the annual ceiling established by the index, the pipeline does not need to justify those rates through a cost-of-service filing.[3] The majority of oil pipelines under the Commission's jurisdiction use this index to demonstrate that their rate increases are just and reasonable.

3. Following Order No. 561, the Commission updates the index every five years to ensure that it represents a reasonable measure of the annual change in a typical oil pipeline's cost of service. To set the annual index, the Commission calculates each jurisdictional pipeline's change in its cost-of-service over the previous five-year period—we call this oil pipelines' ''cost change data.'' The Commission then uses that data to determine an appropriate adjustment to the Producer Price Index for Finished Goods (PPI–FG) established by the U.S. Department of Labor.[4] To avoid outliers or other anomalous, unrepresentative cost data, the Commission has historically relied on only the cost change data for the middle 50% of pipelines when updating the index—that is, it excludes data from the 25% of pipelines with the lowest cost changes and the data from the 25% of pipelines with the highest.[5]

4. In June of this year, the Commission issued a notice of inquiry that commenced its five-year update to the index. In that notice, the Commission proposed an index level of PPI–FG+0.09, based on our historical practice of relying on the middle 50% of cost change data.[6] Today's order tosses that historical practice aside and establishes an index level that is *nearly ten times higher* at PPI–FG+0.78.[7] That order of magnitude increase is largely the result of a pair of unreasoned, illogical and unsupported changes that lack any meaningful support in the record before us. I'll discuss them in turn.

5. The Commission's first major mistake is to abandon its well-established practice of updating the index using the cost change data from the middle 50% of oil pipelines. As noted, in order to weed out potential anomalous, unrepresentative cost data and ensure that the cost change data reflects the experience of a typical pipeline, the Commission's established practice is to ''trim'' the data down to the middle 50% of cost changes. The Commission has explained that relying only on those central values best approximates the operations of a typical pipeline because it prevents the Commission from relying on unrepresentative cost changes, such as a one-time increase in rate base, plant retirement, significant expansions or acquisitions, or localized changes in supply and demand.[8]

6. Today's order abandons that approach and instead uses the data from the middle 80% of pipelines.[9] That change dramatically increases the likelihood that the updated index will reflect anomalous data that does not shed light on the cost changes experienced by a typical pipeline, which, in practice, skews the index upwards. Relying upon those relative outliers is particularly inappropriate here since the middle 50% of pipelines corresponds to a much larger percentage of the total barrel-miles shipped over the last five years than in previous index updates.[10] In other words, the middle 50% already corresponds to a significantly larger percentage of total oil transportation service provided than in previous index updates, which would seem to undermine any need to expand the data set.

7. The Commission's justification for abandoning the 50% approach consists of nothing more than variations on the theme that more data is better.[11] But, as with most things in life, quality is more important than quantity. Including more cost change data is not necessarily an improvement when there is good reason to believe that the incremental data is made up of outliers whose experience is less representative of a typical oil pipeline with a normal cost structure. As noted, the purpose of the index is to approximate a typical oil pipeline's change in cost—an exercise that does not benefit from including cost change data from pipelines that are, by definition, unrepresentative of the average pipeline.[12] And that is exactly why the Commission has consistently rejected replacing the 50% approach with the 80% approach adopted in today's order.[13] In addition, the Commission chastises shippers for not arguing that every pipeline whose cost change data would have been excluded using the middle 50% was an outlier.[14] As an initial matter, the shippers did provide illustrative data explaining why seven of those pipelines' cost change data was not representative, which you might think would suffice to support the Commission continuing its historical practice.[15] In any case, the burden to show that the index is reasonable is on the Commission, and it cannot be carried simply by arguing that the shippers should have done more.

8. The Commission's second major mistake is to break its promise to protect ratepayers following the U.S. Court of Appeals for the District of Columbia Circuit's decision in *United Airlines* v. *FERC,*[16] which struck down the Commission's practice of allowing Master Limited Partnerships (MLPs) to double recover their income tax cost.[17] As a result of that decision, MLPs may no longer recover an income tax

[2] *Revisions to Oil Pipeline Reguls. Pursuant to Energy Pol'y Act of 1992,* Order No. 561, FERC Stats. & Regs. ¶ 30,985, at 30,955 (1993) (cross-referenced at 65 FERC ¶ 61,109), *order on reh'g,* Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 (1994) (cross-referenced at 68 FERC ¶ 61,138), *aff'd sub nom. Ass'n of Oil Pipe Lines* v. *FERC,* 83 F.3d 1424 (D.C. Cir. 1996).

[3] At least absent a protest to the update. *See* Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,947.

[4] *Five-Year Rev. of the Oil Pipeline Index,* 173 FERC ¶ 61,245, at P 5 (2020) (2020 Index Review). The resulting index level is expressed as the PPI–FG plus or minus a value that corresponds to the cost change data adjustment.

[5] This practice of excluding the top and bottom 25% was part of Dr. Alfred Kahn's original proposal that the Commission adopted in 1994. *Ass'n of Oil Pipe Lines* v. *FERC,* 876 F.3d 336, 340 (D.C. Cir. 2017) (noting that in 1994 Dr. Kahn ''omitted from his analysis the pipelines within the upper and lower 25 percent of the cost spectrum in order to exclude statistical outliers and incomplete or questionable data'').

[6] *Five-Year Rev. of the Oil Pipeline Index,* 171 FERC ¶ 61,239, at P 9 (2020).

[7] 2020 Index Review, 173 FERC ¶ 61,245 at P 2.

[8] *Five-Year Rev. of Oil Pricing Index,* 133 FERC ¶ 61,228, at P 61 (2010) (citing Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 at 31,097) (2010 Index Review); *Five-Year Rev. of Oil Pipeline Index,* 153 FERC ¶ 61,312, at P 24 (2015) (2015 Index Review).

[9] 2020 Index Review, 173 FERC ¶ 61,245 at P 25.

[10] The middle 50% of this data set contains 82% of total barrel-miles subject to the index while, in 2015 and 2010, the middle 50% contained only 56% and 76% of total barrel-miles, respectively. *Id.* P 23.

[11] *Id.* PP 26–29.

[12] *See* 2015 Index Review, 153 FERC ¶ 61,312 at P 43 (''[B]y definition, costs at the top (or bottom) of the middle 80 percent deviate significantly from the cost experience of other pipelines. To the extent that the middle 80 percent data conforms to a lognormal distribution, outlying cost increases per barrel-mile will not be offset by similarly outlying cost decreases. Thus, using the middle 80 percent would skew the index upward based upon these outlying cost increases, which is contrary to the objective of the index to reflect normal industry-wide cost changes.''); 2010 Index Review, 133 FERC ¶ 61,228 at P 63 (''[T]he use of the middle 50 minimizes the risk of including pipelines that experienced either large increases or decreases in cost (or errant data) that may be included in an 80 percent sample, while still capturing changes from a broad spectrum of the pipeline industry.'').

[13] *See* 2015 Index Review, 153 FERC ¶ 61,312 at PP 42–44; 2010 Index Review, 133 FERC ¶ 61,228 at PP 60–63.

[14] 2020 Index Review, 173 FERC ¶ 61,245 at P 28.

[15] *Id.*

[16] *United Airlines, Inc.* v. *FERC,* 827 F.3d 122 (D.C. Cir. 2016) (finding that the Commission permitted a double recovery of income tax costs by allowing an MLP to recover both an income tax allowance and a return on equity determined pursuant to the discounted cash flow methodology, which already reflects income tax costs).

[17] *Inquiry Regarding the Commission's Pol. for Recovery of Income Tax Costs,* 162 FERC ¶ 61,227 (2018 Income Tax Policy Statement), *reh'g denied,* 164 FERC ¶ 61,030 (2018).

allowance in their cost of service.[18] Following *United Airlines,* in 2018, the Commission required natural gas pipelines to immediately eliminate that double recovery,[19] but declined to require something similar for oil pipelines, promising, quite explicitly, that it would address the issue when it next updated the index.[20]

9. So much for that. In today's order, the Commission goes back on its word and allows any oil pipeline that was an MLP in 2014 to retroactively remove its income tax allowance from its 2014 cost-of-service data.[21] That change juices the data to make it look like oil pipeline costs increased by more than they actually did between 2014 and 2019, thereby leading to a higher index value. And, as if that weren't bad enough, today's order also allows any pipeline that transitioned from an MLP to a C-Corporation, thereby regaining the right to an income tax allowance, to remove the income tax allowance from their 2014 numbers.[22] The result is, you guessed it, another increase in the cost change data, a higher index level, and more expensive rates for customers.

10. Nothing in today's order justifies that result. The Commission summarily concludes that the index update is not an appropriate vehicle for incorporating the post-*United Airlines'* policy changes.[23] That proposition is hardly self-evident, especially given that all five then-Commissioners felt differently just two years ago.[24] In any case, the fact of the matter is that tax costs are real costs,[25] meaning that oil pipelines' costs in the past five years have changed as a result of the *United Airlines* decision. Finally, reneging on our promise in the 2018 Income Tax Policy Statement perpetuates the effects of the double recovery gravy train that the court invalidated in *United Airlines.* That is simply indefensible.

* * * * *

11. The Commission's actions today hand oil pipelines what will amount to a multi-billion-dollar windfall over the next five years. Calling these decisions arbitrary and capricious or unreasoned would let the Commission off easy. They represent a complete abdication of our statutory responsibility to protect consumers—the companies and individuals who will be stuck paying those additional billions of dollars to the oil pipelines. Although our responsibilities under the Interstate Commerce Act don't always get the same attention from the public as some of our other proceedings, today's order illustrates the tremendous financial consequences that they can have for everyday customers. I hope that proceedings like today's lead interested parties everywhere to more closely scrutinize the Commission's oil orders so that these multi-billion-dollar handouts do not become a matter of course.

For these reasons, I respectfully dissent.

Richard Glick,

Commissioner.

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[18] *Id.* P 2.

[19] *Interstate & Intrastate Nat. Gas Pipelines; Rate Changes Relating to Fed. Income Tax Rate,* 162 FERC ¶ 61,226 (2018).

[20] The Commission's statement is worth reading in whole: ''When oil pipelines file Form No. 6, page 700 on April 18, 2018, they must report an income tax allowance consistent with *United Airlines* and the Commission's subsequent holdings denying an MLP an income tax allowance. Based upon page 700 data, the Commission will incorporate the effects of the post-*United Airlines'* policy changes (as well as the Tax Cuts and Jobs Act of 2017) on industry-wide oil pipeline costs in the 2020 five-year review of the oil pipeline index level. In this way the Commission will ensure that the industry-wide reduced costs are incorporated on an industry-wide basis as part of the index review.'' 2018 Income Tax Policy Statement, 162 FERC ¶ 61,227 at P 46.

[21] 2020 Index Review, 173 FERC ¶ 61,245 at P 16.

[22] *Id.* P 20.

[23] *Id.* P 18.

[24] 2018 Income Tax Policy Statement, 162 FERC ¶ 61,227 at P 46.

[25] Ask anyone who pays their taxes.

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2021–0057]

RIN 1625–AA00

Emergency Safety Zone; Richmond Entrance Channel, Richmond, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters of the Richmond Entrance Channel off of Richmond, CA in support of the safe navigation of vessels and environmental response efforts to address the hydrocarbon release from the Richmond Long Wharf on February 09, 2021. Based on this information, this safety zone is necessary to protect life, vessels, and the maritime environment. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission from the Captain of the Port San Francisco or a Captain of the Port San Francisco designated representative.

DATES: This rule is effective without actual notice on February 16, 2021. For the purposes of enforcement, actual notice will be used from 12:01 a.m. February 10, 2021 until February 16, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0057 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Chief Warrant Officer Mickey Price, Waterways Management, U.S. Coast Guard; telephone (415) 399–7442, email *SFWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port San Francisco
DHS Department of Homeland Security
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking with respect to this rule because it is impracticable. The Coast Guard received notice of the hydrocarbon release into the waterway and the resulting need for this safety zone on February 9, 2021. It is impracticable to go through the full rulemaking process, including providing a reasonable comment period and considering those comments, because the Coast Guard must establish this emergency temporary safety zone by February 10, 2021.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is

needed to protect personnel, vessels, and the maritime environment from potential hazards near the Richmond Long Wharf.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port San Francisco has determined that potential hazards associated with the hydrocarbon release exist near the Richmond Long Wharf. This rule is needed because environmental response operations create a significant hazard to any vessels transiting the safety zone area. The environmental response operations may be complex in nature and involve multiple vessels. These operations, when conducted in close proximity to transiting vessels, create unpredictable hazards, making it necessary to restrict vessel traffic within the impacted area until environmental response operations are completed.

IV. Discussion of the Rule

This rule establishes a temporary safety zone in navigable waters 250 yards around the Richmond Long Wharf, Richmond, CA as announced in a mariner information broadcast from February 10, 2021 at 12:01 a.m. through February 16, 2021 at 11:59 p.m. The effect of the temporary safety zone will be to restrict vessel navigation in this area until the Coast Guard determines that the hazards associated with the hydrocarbon release and response efforts are no longer present. Except for persons or vessels authorized by the Captain of the Port or a designated representative, no vessel may enter or remain in the restricted area. A ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the COTP in the enforcement of the safety zone.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the limited duration and narrowly tailored geographic area of the safety zone. Although this rule restricts access to the water encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users will be notified to ensure the safety zone will result in minimum impact. The vessels desiring to transit through or around the temporary safety zone may do so upon express permission from the COTP or the COTP's designated representative.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the temporary safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human

environment. This rule involves a safety zone established to deal with an emergency situation, lasting less than one week, that will prohibit vessel traffic near the hydrocarbon response efforts in the vicinity of the Richmond Long Wharf. It is categorically excluded from further review under paragraph L60(c) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T11–048 to read as follows:

§ 165.T11–048 Emergency Safety Zone; Richmond Entrance Channel, Richmond, CA.

(a) *Location.* The following area is a safety zone: All navigable waters 250 yards around the Richmond Long Wharf, Richmond, CA.

(b) *Definitions.* As used in this section, ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request permission to enter the safety zone on VHF–23A or through the 24-hour Command Center at telephone (415) 399–3547.

(d) *Enforcement period.* This section will be enforced from February 10, 2021 at 12:01 a.m. until Febuary 16, 2021 at 11:59 p.m. or as announced via marine information broadcast.

(e) *Information broadcasts.* The COTP or the COTP's designated representative will notify the maritime community of periods during which this zone will be enforced in accordance with 33 CFR 165.7.

Dated: February 9, 2021.

Marie B. Byrd,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco.

[FR Doc. 2021–03101 Filed 2–11–21; 11:15 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 303

[Docket No. 20–CRB–0013–RM]

Procedural Regulations of the Copyright Royalty Board Regarding Electronic Filing System (eCRB)

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Final rule.

SUMMARY: The Copyright Royalty Judges are amending regulations governing the electronic filing of documents through the Copyright Royalty Board's electronic filing system (eCRB) to permit attorney designees with approved eCRB user accounts to file on behalf of attorneys.

DATES: Effective February 16, 2021.

ADDRESSES: Docket: For access to the docket to read background documents, go to eCRB at *https://app.crb.gov* and perform a case search for docket 20–CRB–0013–RM.

FOR FURTHER INFORMATION CONTACT: Anita Blaine, CRB Program Specialist, at 202–707–7658 or *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: On December 28, 2020, the Copyright Royalty Judges (Judges) published a document in the **Federal Register** seeking comments on a proposed rule to add to Rule 303.5(c) a fourth category of filer that would be required to obtain an eCRB password: attorney designee. *See* 85 FR 84279 (Dec. 28, 2020). An attorney designee would be defined as ''a person authorized to file documents on behalf of an attorney.'' The proposed rule also included non-substantive changes to Rule 303.5.[1] The Judges received no comments. Therefore, for the reasons indicated in the December 28, 2020 document, the Judges adopt the changes and additions to part 303 proposed in that document, as detailed in this final rule.

List of Subjects in 37 CFR Part 303

Administrative practice and procedure, Copyright, Lawyers.

Final Regulations

For the reasons set forth in the preamble, the Copyright Royalty Judges amend 37 CFR part 303 as follows:

PART 303—GENERAL ADMINISTRATIVE PROVISIONS

■ 1. The authority citation for part 303 continues to read as follows:

Authority: 17 U.S.C. 803.

■ 2. Revise § 303.5 to read as follows:

§ 303.5 Electronic filing system (eCRB).

(a) *Documents to be filed by electronic means.* Except as otherwise provided in this chapter, all attorneys must file documents with the Copyright Royalty Board through eCRB. Pro se parties may file documents with the Copyright Royalty Board through eCRB, subject to § 303.4(c)(2).

(b) *Official record.* The electronic version of a document filed through and stored in eCRB will be the official record of the Copyright Royalty Board.

(c) *Obtaining an electronic filing password*—(1) *Attorneys.* An attorney must register for an eCRB account and create an eCRB password in order to file documents or to receive copies of orders and determinations of the Copyright Royalty Judges. The attorney's eCRB account and password will be activated upon approval by the Copyright Royalty Board of the attorney's completed online application form available on the eCRB website.

(2) *Attorney designees.* A person authorized by an attorney to file documents on behalf of that attorney (an attorney designee) must register for an eCRB account and create an eCRB password in order to file documents on

[1] *See* 85 FR 84279.

the attorney's behalf. The attorney designee's eCRB account and password will be activated upon approval by the Copyright Royalty Board of the attorney designee's completed online registration form available on the eCRB website.

(3) *Pro se parties.* A party not represented by an attorney (a pro se party) may register for an eCRB account and create an eCRB password. The pro se party's eCRB account and password will be activated if the Copyright Royalty Judges, in their discretion, approve the pro se party's completed online application form available on the eCRB website. Once a pro se party's application has been approved, that party must make all subsequent filings by electronic means through eCRB.

(4) *Claimants.* Any person desiring to file a claim with the Copyright Royalty Board for copyright royalties must register for an eCRB account and create an eCRB password for the limited purpose of filing claims by completing the registration form available on the eCRB website.

(d) *Use of an eCRB password.* An eCRB password may be used only by the person to whom it is assigned. The person to whom an eCRB password is assigned is responsible for any document filed using that password, except that designating attorneys are responsible for any document filed on the attorney's behalf by an attorney designee.

(e) *Signature.* The use of an eCRB password to log in and submit documents creates an electronic record. The password operates and serves as the signature of the person to whom the password is assigned for all purposes under this chapter III, except that the password of an attorney designee serves as the signature of the designating attorney on whose behalf the document is filed.

(f) *Originals of sworn documents.* The electronic filing of a document that contains a sworn declaration, verification, certificate, statement, oath, or affidavit certifies that the original signed document is in the possession of the attorney or pro se party responsible for the filing and that it is available for review upon request by a party or by the Copyright Royalty Judges. The filer must file through eCRB a scanned copy of the signature page of the sworn document together with the document itself.

(g) *Consent to delivery by electronic means.* An attorney or pro se party who obtains an eCRB password consents to electronic delivery of all documents, subsequent to the petition to participate, that are filed by electronic means through eCRB. Attorneys and pro se parties are responsible for monitoring their email accounts and, upon receipt of notice of an electronic filing, for retrieving the noticed filing. Parties and their counsel bear the responsibility to keep the contact information in their eCRB profiles current.

(h) *Accuracy of docket entry.* A person filing a document by electronic means, or, if the filer is an attorney designee, the designating attorney, is responsible for ensuring the accuracy of the official docket entry generated by the eCRB system, including proper identification of the proceeding, the filing party, and the description of the document. The Copyright Royalty Board will maintain on its website (*www.loc.gov/crb*) appropriate guidance regarding naming protocols for eCRB filers.

(i) *Documents subject to a protective order.* A person filing a document by electronic means must ensure, at the time of filing, that any documents subject to a protective order are identified to the eCRB system as ''restricted'' documents. This requirement is in addition to any requirements detailed in the applicable protective order. Failure to identify documents as ''restricted'' to the eCRB system may result in inadvertent publication of sensitive, protected material.

(j) *Exceptions to requirement of electronic filing*—(1) *Certain exhibits or attachments.* Parties may file in paper form any exhibits or attachments that are not in a format that readily permits electronic filing, such as oversized documents; or are illegible when scanned into electronic format. Parties filing paper documents or things pursuant to this paragraph must deliver legible or usable copies of the documents or things in accordance with § 303.6(a)(2) and must file electronically a notice of filing that includes a certificate of delivery.

(2) *Pro se parties.* A pro se party may file documents in paper form and must deliver and accept delivery of documents in paper form, unless the pro se party has obtained an eCRB password.

(k) *Privacy requirements.* (1) Unless otherwise instructed by the Copyright Royalty Judges, parties must exclude or redact from all electronically filed documents, whether designated ''restricted'' or not:

(i) *Social Security numbers.* If an individual's Social Security number must be included in a filed document for evidentiary reasons, the filer must use only the last four digits of that number.

(ii) *Names of minor children.* If a minor child must be mentioned in a document for evidentiary reasons, the filer must use only the initials of that child.

(iii) *Dates of birth.* If an individual's date of birth must be included in a pleading for evidentiary reasons, the filer must use only the year of birth.

(iv) *Financial account numbers.* If a financial account number must be included in a pleading for evidentiary reasons, the filer must use only the last four digits of the account identifier.

(2) Protection of personally identifiable information. If any information identified in paragraph (k)(1) of this section must be included in a filed document, the filing party must treat it as confidential information subject to the applicable protective order. In addition, parties may treat as confidential, and subject to the applicable protective order, other personal information that is not material to the proceeding.

(l) *Incorrectly filed documents.* (1) The Copyright Royalty Board may direct an eCRB filer to re-file a document that has been incorrectly filed, or to correct an erroneous or inaccurate docket entry.

(2) If an attorney or a pro se party who has been issued an eCRB password inadvertently presents a document for filing in paper form, the Copyright Royalty Board may direct that person to file the document electronically. The document will be deemed filed on the date it was first presented for filing if, no later than the next business day after being so directed by the Copyright Royalty Board, the attorney or pro se participant files the document electronically. If the filer fails to make the electronic filing on the next business day, the document will be deemed filed on the date of the electronic filing.

(m) *Technical difficulties.* (1) A filer encountering technical problems with an eCRB filing must immediately notify the Copyright Royalty Board of the problem either by email, or by telephone, followed promptly by written confirmation.

(2) If a filer is unable, due to technical problems, to make a filing with eCRB by an applicable deadline, and makes the notification required by paragraph (m)(1) of this section, the filer shall use electronic mail to make the filing with the Copyright Royalty Board and deliver the filing to the other parties to the proceeding. The filing shall be considered to have been made at the time it was filed by electronic mail. The Copyright Royalty Judges may direct the filer to refile the document through eCRB when the technical problem has been resolved, but the document shall retain its original filing date.

(3) The inability to complete an electronic filing because of technical problems arising in the eCRB system may constitute ''good cause'' (as used in § 303.6(b)(4)) for an order enlarging time or excusable neglect for the failure to act within the specified time, provided the filer complies with paragraph (m)(1) of this section. This section does not provide authority to extend statutory time limits.

Dated: February 1, 2021.

Jesse M. Feder,

Chief Copyright Royalty Judge.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2021–02474 Filed 2–12–21; 8:45 am]

BILLING CODE 1410–72–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3040

[Docket No. RM2020–8]

Update to Competitive Product List

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is announcing an update to the competitive product list. This action reflects a publication policy adopted by Commission rules. The referenced policy assumes periodic updates. The updates are identified in the body of this document. The competitive product list, which is re-published in its entirety, includes these updates.

DATES: This rule is effective April 2, 2021, without further action, unless adverse comment is received by March 18, 2021. If adverse comment is received, the Commission will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: For additional information, this document can be accessed electronically through the Commission's website at *https://www.prc.gov.*

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6800.

SUPPLEMENTARY INFORMATION:

I. Introduction
II. Commission Process
III. Authorization
IV. Modifications
V. Ordering Paragraphs

I. Introduction

Pursuant to 39 U.S.C. 3642(d)(2) and 39 CFR 3040.103, the Commission provides a Notice of Update to Competitive Product List by listing all modifications to the competitive product list between October 1, 2020 and December 31, 2020.

II. Commission Process

Pursuant to 39 CFR part 3040, the Commission maintains a Mail Classification Schedule (MCS) that includes rates, fees, and product descriptions for each market dominant and competitive product, as well as product lists that categorize Postal Service products as either market dominant or competitive. *See generally* 39 CFR part 3040. The product lists are published in the Code of Federal Regulations as 39 CFR Appendix A to Subpart A of Part 3040—Market Dominant Product List and Appendix B to Subpart A of Part 3040—Competitive Product List pursuant to 39 U.S.C. 3642(d)(2). *See* 39 U.S.C. 3642(d)(2). Both the MCS and its product lists are updated by the Commission on its website on a quarterly basis.[1] In addition, these quarterly updates to the product lists are also published in the **Federal Register** pursuant to 39 CFR 3040.103. *See* 39 CFR 3040.103.

III. Authorization

Pursuant to 39 CFR 3040.103(d)(1), this Notice of Update to Product Lists identifies any modifications made to the market dominant or competitive product list, including product additions, removals, and transfers.[2] Pursuant to 39 CFR 3040.103(d)(2), the modifications identified in this document result from the Commission's most recent MCS update posted on the Commission's website on January 4, 2021, and supersede all previous product lists.[3]

IV. Modifications

The following list of products is being added to 39 CFR Appendix B to Subpart A of Part 3040—Competitive Product List:

1. First-Class Package Service Contract 113
2. First-Class Package Service Contract 114
3. Parcel Select Contract 38
4. Parcel Select Contract 39
5. Parcel Select Contract 40
6. Parcel Select Contract 41
7. Parcel Select Contract 42
8. Parcel Select Contract 43
9. Parcel Select Contract 44
10. Priority Mail & First-Class Package Service Contract 168
11. Priority Mail & First-Class Package Service Contract 169
12. Priority Mail & First-Class Package Service Contract 170
13. Priority Mail & First-Class Package Service Contract 171
14. Priority Mail & First-Class Package Service Contract 172
15. Priority Mail & First-Class Package Service Contract 173
16. Priority Mail & First-Class Package Service Contract 174
17. Priority Mail & First-Class Package Service Contract 175
18. Priority Mail & First-Class Package Service Contract 176
19. Priority Mail & First-Class Package Service Contract 177
20. Priority Mail & First-Class Package Service Contract 178
21. Priority Mail & First-Class Package Service Contract 179
22. Priority Mail & First-Class Package Service Contract 180
23. Priority Mail & First-Class Package Service Contract 181
24. Priority Mail & First-Class Package Service Contract 182
25. Priority Mail & First-Class Package Service Contract 183
26. Priority Mail Contract 664
27. Priority Mail Contract 665
28. Priority Mail Contract 666
29. Priority Mail Contract 667
30. Priority Mail Contract 668
31. Priority Mail Contract 669
32. Priority Mail Contract 670
33. Priority Mail Contract 671
34. Priority Mail Contract 672
35. Priority Mail Contract 673
36. Priority Mail Contract 674
37. Priority Mail Contract 675
38. Priority Mail Contract 676
39. Priority Mail Contract 677
40. Priority Mail Contract 678
41. Priority Mail Contract 679
42. Priority Mail Contract 680
43. Priority Mail Contract 681
44. Priority Mail Contract 682
45. Priority Mail Contract 683
46. Priority Mail Contract 684
47. Priority Mail Contract 685
48. Priority Mail Express & Priority Mail Contract 118
49. Priority Mail Express & Priority Mail Contract 119
50. Priority Mail Express & Priority Mail Contract 120
51. Priority Mail Express & Priority Mail Contract 121
52. Priority Mail Express Contract 83
53. Priority Mail Express Contract 84
54. Priority Mail Express Contract 85
55. Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket 9
56. Priority Mail, First-Class Package Service & Parcel Select Contract 2

The following list of products is being removed from 39 CFR Appendix B to

[1] *See https://www.prc.gov/mail-classification-schedule* in the Current MCS section.

[2] 39 CFR 3040.103(d)(1). More detailed information (*e.g.,* Docket Nos., Order Nos., effective dates, and extensions) for each market dominant and competitive product can be found in the MCS, including the ''Revision History'' section. *See, e.g.,* file ''MCSRedline03312020.docx,'' available at: *https://www.prc.gov/mail-classification-schedule.*

[3] Previous versions of the MCS and its product lists can be found on the Commission's website, available at: *https://www.prc.gov/mail-classification-schedule* in the MCS Archives section.

Subpart A of Part 3040—Competitive Product List:

1. First-Class Package Service Contract 82
2. First-Class Package Service Contract 89
3. First-Class Package Service Contract 91
4. First-Class Package Service Contract 95
5. First-Class Package Service Contract 96
6. First-Class Package Service Contract 105
7. Parcel Select & Parcel Return Service Contract 3
8. Parcel Select Contract 25
9. Priority Mail & First-Class Package Service Contract 49
10. Priority Mail & First-Class Package Service Contract 54
11. Priority Mail & First-Class Package Service Contract 59
12. Priority Mail & First-Class Package Service Contract 62
13. Priority Mail & First-Class Package Service Contract 64
14. Priority Mail & First-Class Package Service Contract 70
15. Priority Mail Contract 231
16. Priority Mail Contract 334
17. Priority Mail Contract 337
18. Priority Mail Contract 359
19. Priority Mail Contract 361
20. Priority Mail Contract 362
21. Priority Mail Contract 367
22. Priority Mail Contract 368
23. Priority Mail Contract 371
24. Priority Mail Contract 374
25. Priority Mail Contract 378
26. Priority Mail Contract 381
27. Priority Mail Contract 384
28. Priority Mail Contract 386
29. Priority Mail Contract 390
30. Priority Mail Contract 391
31. Priority Mail Contract 394
32. Priority Mail Contract 415
33. Priority Mail Contract 434
34. Priority Mail Contract 466
35. Priority Mail Contract 473
36. Priority Mail Contract 514
37. Priority Mail Contract 515
38. Priority Mail Contract 519
39. Priority Mail Contract 520
40. Priority Mail Contract 546
41. Priority Mail Contract 558
42. Priority Mail Contract 564
43. Priority Mail Contract 568
44. Priority Mail Contract 569
45. Priority Mail Contract 571
46. Priority Mail Contract 575
47. Priority Mail Contract 576
48. Priority Mail Contract 578
49. Priority Mail Contract 581
50. Priority Mail Contract 582
51. Priority Mail Contract 583
52. Priority Mail Contract 586
53. Priority Mail Contract 612
54. Priority Mail Contract 620
55. Priority Mail Contract 634
56. Priority Mail Express & Priority Mail Contract 56
57. Priority Mail Express & Priority Mail Contract 94
58. Priority Mail Express & Priority Mail Contract 106
59. Priority Mail Express Contract 53
60. Priority Mail Express Contract 55
61. Priority Mail Express Contract 75
62. Priority Mail Express, Priority Mail & First-Class Package Service Contract 16
63. Priority Mail Express, Priority Mail & First-Class Package Service Contract 21
64. Priority Mail Express, Priority Mail & First-Class Package Service Contract 24
65. Priority Mail Express, Priority Mail & First-Class Package Service Contract 30
66. Priority Mail Express, Priority Mail & First-Class Package Service Contract 32
67. Priority Mail Express, Priority Mail & First-Class Package Service Contract 56
68. Priority Mail Express, Priority Mail & First-Class Package Service Contract 59
69. Priority Mail Express, Priority Mail & First-Class Package Service Contract 65

The above-referenced changes to the competitive product list are incorporated into 39 CFR Appendix B to Subpart A of Part 3040—Competitive Product List.

V. Ordering Paragraphs

It is ordered:

1. Part 3040 of title 39, Code of Federal Regulations, is amended as set forth below the signature of this Notice, effective 45 days after the date of publication of the Notice in the **Federal Register** without further action, unless adverse comments are received.

2. The Secretary shall arrange for publication of the Notice in the **Federal Register**.

3. Interested persons may submit adverse comments no later than 30 days from the date of the publication of this Notice in the **Federal Register**.

4. If adverse comments are received, the Secretary will publish a timely withdrawal of the Notice in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

Editorial note: This document was received for publication at the Office of the Federal Register on January 15, 2021.

List of Subjects in 39 CFR Part 3040

Administrative practice and procedure, Postal Service.

For the reasons discussed in the preamble, the Postal Regulatory Commission amends chapter III, part 3040, of title 39 of the Code of Federal Regulations as follows:

PART 3040—PRODUCT LISTS

■ 1. The authority citation for part 3040 continues to read as follows:

Authority: 39 U.S.C. 503; 3622; 3631; 3642; 3682.

■ 2. Revise appendix A to subpart A of part 3040 to read as follows:

Appendix A to Subpart A of Part 3040—Market Dominant Product List

(An asterisk (*) indicates an organizational class or group, not a Postal Service product.)

First-Class Mail *
- Single-Piece Letters/Postcards
- Presorted Letters/Postcards
- Flats
- Outbound Single-Piece First-Class Mail International
- Inbound Letter Post

USPS Marketing Mail (Commercial and Nonprofit) *
- High Density and Saturation Letters
- High Density and Saturation Flats/Parcels
- Carrier Route
- Letters
- Flats
- Parcels
- Every Door Direct Mail—Retail

Periodicals *
- In-County Periodicals
- Outside County Periodicals

Package Services *
- Alaska Bypass Service
- Bound Printed Matter Flats
- Bound Printed Matter Parcels
- Media Mail/Library Mail

Special Services *
- Ancillary Services
- International Ancillary Services
- Address Management Services
- Caller Service
- Credit Card Authentication
- International Reply Coupon Service
- International Business Reply Mail Service
- Money Orders
- Post Office Box Service
- Customized Postage
- Stamp Fulfillment Services

Negotiated Service Agreements *
- Domestic *
- International *
- Inbound Market Dominant Multi-Service Agreements with Foreign Postal Operators

Nonpostal Services *
- Alliances with the Private Sector to Defray Cost of Key Postal Functions
- Philatelic Sales

Market Tests *
- Plus One
- Commercial PO Box Redirect Service
- Extended Mail Forwarding

■ 3. Revise appendix B to subpart A of part 3040 to read as follows:

Appendix B to Subpart A of Part 3040—Competitive Product List

(An asterisk (*) indicates an organizational class or group, not a Postal Service product.)

Domestic Products *
- Priority Mail Express
- Priority Mail
- Parcel Select
- Parcel Return Service
- First-Class Package Service
- USPS Retail Ground

International Products *
- Outbound International Expedited Services
- Inbound Parcel Post (at UPU rates)
- Outbound Priority Mail International
- International Priority Airmail (IPA)
- International Surface Air Lift (ISAL)
- International Direct Sacks—M-Bags
- Outbound Single-Piece First-Class Package International Service
- Inbound Letter Post Small Packets and Bulky Letters

Negotiated Service Agreements *
Domestic *
Priority Mail Express Contract 54
Priority Mail Express Contract 56
Priority Mail Express Contract 57
Priority Mail Express Contract 60
Priority Mail Express Contract 61
Priority Mail Express Contract 62
Priority Mail Express Contract 64
Priority Mail Express Contract 65
Priority Mail Express Contract 74
Priority Mail Express Contract 77
Priority Mail Express Contract 81
Priority Mail Express Contract 82
Priority Mail Express Contract 83
Priority Mail Express Contract 84
Priority Mail Express Contract 85
Parcel Return Service Contract 11
Parcel Return Service Contract 14
Parcel Return Service Contract 15
Parcel Return Service Contract 16
Parcel Return Service Contract 17
Parcel Return Service Contract 18
Priority Mail Contract 80
Priority Mail Contract 125
Priority Mail Contract 153
Priority Mail Contract 203
Priority Mail Contract 292
Priority Mail Contract 340
Priority Mail Contract 357
Priority Mail Contract 358
Priority Mail Contract 360
Priority Mail Contract 364
Priority Mail Contract 365
Priority Mail Contract 383
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Priority Mail Contract 685
Priority Mail Express & Priority Mail Contract 13
Priority Mail Express & Priority Mail Contract 48
Priority Mail Express & Priority Mail Contract 55
Priority Mail Express & Priority Mail Contract 57
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Priority Mail Express & Priority Mail Contract 121
Parcel Select & Parcel Return Service Contract 7
Parcel Select & Parcel Return Service Contract 8
Parcel Select & Parcel Return Service Contract 9
Parcel Select & Parcel Return Service Contract 10
Parcel Select & Parcel Return Service Contract 11
Parcel Select & Parcel Return Service Contract 12
Parcel Select Contract 20
Parcel Select Contract 27
Parcel Select Contract 29
Parcel Select Contract 34
Parcel Select Contract 35
Parcel Select Contract 36
Parcel Select Contract 37
Parcel Select Contract 38
Parcel Select Contract 39
Parcel Select Contract 40
Parcel Select Contract 41
Parcel Select Contract 42
Parcel Select Contract 43
Parcel Select Contract 44
Priority Mail—Non-Published Rates 1
Priority Mail—Non-Published Rates 2
First-Class Package Service Contract 75
First-Class Package Service Contract 78
First-Class Package Service Contract 85
First-Class Package Service Contract 87
First-Class Package Service Contract 92
First-Class Package Service Contract 93
First-Class Package Service Contract 94
First-Class Package Service Contract 99
First-Class Package Service Contract 100
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Priority Mail Express, Priority Mail & First-Class Package Service Contract 20
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Priority Mail & First-Class Package Service Contract 26
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Priority Mail & First-Class Package Service Contract 145
Priority Mail & First-Class Package Service Contract 146
Priority Mail & First-Class Package Service Contract 147
Priority Mail & First-Class Package Service Contract 148
Priority Mail & First-Class Package Service Contract 149
Priority Mail & First-Class Package Service Contract 150
Priority Mail & First-Class Package Service Contract 151
Priority Mail & First-Class Package Service Contract 152
Priority Mail & First-Class Package Service Contract 153
Priority Mail & First-Class Package Service Contract 154
Priority Mail & First-Class Package Service Contract 155
Priority Mail & First-Class Package Service Contract 156
Priority Mail & First-Class Package Service Contract 157
Priority Mail & First-Class Package Service Contract 158
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Priority Mail & First-Class Package Service Contract 167
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Priority Mail & First-Class Package Service Contract 176
Priority Mail & First-Class Package Service Contract 177
Priority Mail & First-Class Package Service Contract 178
Priority Mail & First-Class Package Service Contract 179
Priority Mail & First-Class Package Service Contract 180
Priority Mail & First-Class Package Service Contract 181
Priority Mail & First-Class Package Service Contract 182
Priority Mail & First-Class Package Service Contract 183
Priority Mail & Parcel Select Contract 3
Priority Mail & Parcel Select Contract 4
Priority Mail Express & First-Class Package Service Contract 1
Priority Mail Express & First-Class Package Service Contract 3
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 1
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 2
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 3
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 4
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 5
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 6
Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 7
Priority Mail, First-Class Package Service & Parcel Select Contract 1
Priority Mail, First-Class Package Service & Parcel Select Contract 2
Outbound International*
Global Expedited Package Services (GEPS) Contracts
GEPS 3
GEPS 5
GEPS 6
GEPS 7
GEPS 8
GEPS 9
GEPS 10
Global Bulk Economy (GBE) Contracts
Global Plus Contracts
Global Plus 1C
Global Plus 1D
Global Plus 1E
Global Plus 2C
Global Plus 3
Global Plus 4
Global Plus 5
Global Plus 6
Global Reseller Expedited Package Contracts
Global Reseller Expedited Package Services 1
Global Reseller Expedited Package Services 2
Global Reseller Expedited Package Services 3
Global Reseller Expedited Package Services 4
Global Expedited Package Services (GEPS)—Non-Published Rates
Global Expedited Package Services (GEPS)—Non-Published Rates 2
Global Expedited Package Services (GEPS)—Non-Published Rates 3
Global Expedited Package Services (GEPS)—Non-Published Rates 4
Global Expedited Package Services (GEPS)—Non-Published Rates 5

Global Expedited Package Services (GEPS)—Non-Published Rates 6
Global Expedited Package Services (GEPS)—Non-Published Rates 7
Global Expedited Package Services (GEPS)—Non-Published Rates 8
Global Expedited Package Services (GEPS)—Non-Published Rates 9
Global Expedited Package Services (GEPS)—Non-Published Rates 10
Global Expedited Package Services (GEPS)—Non-Published Rates 11
Global Expedited Package Services (GEPS)—Non-Published Rates 12
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Global Expedited Package Services (GEPS)—Non-Published Rates 14
Global Expedited Package Services (GEPS)—Non-Published Rates 15
Priority Mail International Regional Rate Boxes—Non-Published Rates
Outbound Competitive International Merchandise Return Service Agreement with Royal Mail Group, Ltd.
Priority Mail International Regional Rate Boxes Contracts
Priority Mail International Regional Rate Boxes Contracts 1
Competitive International Merchandise Return Service Agreements with Foreign Postal Operators
Competitive International Merchandise Return Service Agreements with Foreign Postal Operators 1
Competitive International Merchandise Return Service Agreements with Foreign Postal Operators 2
Alternative Delivery Provider (ADP) Contracts
ADP 1
Alternative Delivery Provider Reseller (ADPR) Contracts
ADPR 1
Priority Mail Express International, Priority Mail International & First-Class Package International Service Contracts
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket Contracts
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket 2
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket 3
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket 4
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket 5
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket 6
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket 7
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket 8
Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial ePacket 9
Priority Mail Express International, Priority Mail International & Commercial ePacket Contracts
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contracts
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 1
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 2
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 3
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 4
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 5
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 6
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 7
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 8
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 9
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contracts
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contract 1
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contract 2
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contract 3
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contract 4
International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contract 5
International Priority Airmail Contracts
International Priority Airmail Contract 1
International Priority Airmail, International Surface Air Lift, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contracts
International Priority Airmail, International Surface Air Lift, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contract 1
International Priority Airmail, International Surface Air Lift, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contract 2
Inbound International*
International Business Reply Service (IBRS) Competitive Contracts
International Business Reply Service Competitive Contract 1
International Business Reply Service Competitive Contract 3
Inbound Direct Entry Contracts with Customers
Inbound Direct Entry Contracts with Foreign Postal Administrations
Inbound Direct Entry Contracts with Foreign Postal Administrations
Inbound Direct Entry Contracts with Foreign Postal Administrations 1
Inbound EMS
Inbound EMS 2
Inbound Air Parcel Post (at non-UPU rates)
Inbound Competitive Multi-Service Agreements with Foreign Postal Operators
Inbound Competitive Multi-Service Agreements with Foreign Postal Operators 1
Special Services *
Address Enhancement Services
Greeting Cards, Gift Cards, and Stationery
International Ancillary Services
International Money Transfer Service—Outbound
International Money Transfer Service—Inbound
Premium Forwarding Service
Shipping and Mailing Supplies
Post Office Box Service
Competitive Ancillary Services
Nonpostal Services *
Advertising
Licensing of Intellectual Property other than Officially Licensed Retail Products (OLRP)

Mail Service Promotion
Officially Licensed Retail Products (OLRP)
Passport Photo Service
Photocopying Service
Rental, Leasing, Licensing or other Non-Sale Disposition of Tangible Property
Training Facilities and Related Services
USPS Electronic Postmark (EPM) Program
Market Tests *

[FR Doc. 2021–01363 Filed 2–12–21; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51, 60, 61, and 63

[EPA–HQ–OAR–2018–0815; FRL–10012–11–OAR]

RIN 2060–AU39

Test Methods and Performance Specifications for Air Emission Sources

Correction

In Rule Document 2020–18824, appearing on pages 63393–63422, in the issue of Wednesday, October 7, 2020, make the following correction:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES [Corrected]

Appendix A–3 to Part 60—Test Methods 4 Through 5I

■ On pages 63413–63414, the ancillary text and table are republished as set forth below.

* * * * *

18.0 * * *

Plant _____
Date _____
Run No. _____
Filter No. _____

Amount liquid lost during transport, mg _____
Acetone blank volume, ml _____
Acetone blank concentration, mg/mg (Equation 5-4) _____
Acetone wash blank, mg (Equation 5-5) _____

Container number	Weight of particulate collected, mg		
	Final weight	Tare weight	Weight gain
1.			
2.			
Total collected particulate			
Less acetone wash blank			
Weight of particulate matter			
	Weight of liquid collected, g		
	Impinger weight	Silica gel weight	
Final			
Initial			
Liquid collected			
Total weight collected			

Figure 5-6. Analytical Data Sheet

* * * * *

[FR Doc. C1–2020–18824 Filed 2–12–21; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 410, 414, 415, 423, 424, and 425

[CMS–1734–F2]

RIN 0938–AU10, 0938–AU31, 0938–AU32, and 0938–AU33

Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-In Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions From the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19; Correcting Amendment

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

ACTION: Final rule and interim final rule; correcting amendment.

SUMMARY: This document corrects a typographical error in the final rule that appeared in the December 28, 2020 **Federal Register** (hereinafter referred to as the CY 2021 PFS final rule). The effective date was January 1, 2021.

DATES: *Effective date:* This correcting amendment is effective February 16, 2021.

Applicability date: The correction indicated in this document is applicable beginning January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Cynthia Lambert Lawson, (410) 786–1366, Gaysha Brooks, (410) 786–9649, or Annette Brewer, (410) 786–6580.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2020–26815 of December 28, 2020, the CY 2021 PFS final rule (85 FR 84472), there was a typographical error that is identified and corrected in the regulation text of this correcting amendment. The correction is applicable as of January 1, 2021.

II. Summary of Error in the Regulations Text

On page 85033 of the CY 2021 PFS final rule, we made a typographical error in amendatory instruction 24b for the regulation text of § 414.1400(b)(2) introductory text. In this amendatory instruction, we inadvertently noted that we were revising paragraph (b)(2) introductory text instead of adding it. Accordingly, we are revising amendatory instruction 24b to accurately reflect the addition of paragraph (b)(2) introductory text.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (the APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the APA notice and comment, and delay in effective date requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal notice and comment rulemaking procedures for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and includes a statement of the finding and the reasons for it in the rule. In addition, section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and the agency includes in the rule a statement of the finding and the reasons for it.

In our view, this correcting amendment does not constitute a rulemaking that would be subject to these requirements. This document merely corrects a typographical error in the CY 2021 PFS final rule. The correction contained in this document is consistent with, and does not make substantive changes to, the policies and payment methodologies that were proposed, subject to notice and comment procedures, and adopted in the CY 2021 PFS final rule. As a result, the correction made through this correcting amendment is intended to resolve a typographical error so that the CY 2021 PFS final rule accurately reflects the policies adopted in the final rule. Even if this were a rulemaking to which the notice and comment and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the CY 2021 PFS final rule or delaying the effective date of the corrections would be contrary to the public interest because it is in the public interest to ensure that the rule accurately reflects our policies as of the date they take effect. Further, such procedures would be unnecessary because we are not making any substantive revisions to the final rule, but rather, we are simply correcting the **Federal Register** document to reflect the policies that we previously proposed, received public comment on, and subsequently finalized in the CY 2021 PFS final rule. For these reasons, we believe there is good cause to waive the requirements for notice and comment and delay in effective date.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

Accordingly, 42 CFR chapter IV is corrected by making the following correcting amendments to part 414:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 2. Amend § 414.1400 by revising the heading of paragraph (b)(2) and adding paragraph (b)(2) introductory text to read as follows:

§ 414.1400 Third party intermediaries.

* * * * *

(b) * * *

(2) QCDR conditions for approval. In addition to the other requirements in this section, the criteria for an entity to be approved as a QCDR include the following:

* * * * *

Dated: February 9, 2021.

Wilma M. Robinson,

Deputy Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2021–02985 Filed 2–12–21; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 20–1489; FRS 17355]

Radio Broadcasting Services; Various Locations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document amends the FM Table of Allotments, of the Commission's rules, by reinstating certain vacant FM allotments. These FM allotments are considered vacant because of the cancellation of the associated authorizations and licenses, or the dismissal of long-form auction applications. Theses vacant FM allotments have previously undergone notice and comment rule making. Reinstatement of the vacant allotments is merely a ministerial action to effectuate licensing procedures. Therefore, we find for good cause that further notice and comment are unnecessary.

DATES: Effective February 16, 2021.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Order,* adopted December 17, 2020 and released December 18, 2020. The full text of this Commission decision is available online at *http://apps.fcc.gov/ecfs/.* This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. The Commission will not send a copy of the *Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A) because the *Order* is a ministerial action.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

Editorial note: This document was received for publication at the Office of the Federal Register on January 4, 2021.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.202, the table in paragraph (b) is amended under Missouri by adding entries for Cuba and Wheatland in alphabetical order to read as follows:

§ 73.202 Table of Allotments.

* * * * *

(b) * * *

TABLE 1 TO PARAGRAPH (b)

[U.S. States]

	Channel No.
* * * * *	
MISSOURI	
* * * * *	
Cuba	269A
* * * * *	
Wheatland	272A
* * * * *	

[FR Doc. 2021–00084 Filed 2–12–21; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 86, No. 29
Tuesday, February 16, 2021

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 COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 210205–0013]

RIN 0648–BK25

Magnuson-Stevens Act Provisions; Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; 2021 Harvest Specifications for Pacific Whiting, and 2021 Pacific Whiting Tribal Allocation

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS issues the proposed rule for the 2021 Pacific whiting fishery under the authority of the Pacific Coast Groundfish Fishery Management Plan, the Magnuson-Stevens Fishery Conservation and Management Act, the Pacific Whiting Act of 2006, and other applicable laws. This proposed rule would allocate 17.5 percent of the U.S. total allowable catch of Pacific whiting for 2021 to Pacific Coast Indian tribes that have a treaty right to harvest groundfish, and implement set-asides for Pacific whiting research and incidental mortality in other fisheries. The proposed measures are intended to help prevent overfishing, achieve optimum yield, and ensure that management measures are based on the best scientific information available.

DATES: Comments on this proposed rule must be received no later than March 18, 2021.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2021–0002 by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2021-0002,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Barry Thom, c/o Stacey Miller, Sustainable Fisheries Division, West Coast Region, NMFS, 1201 NE Lloyd Blvd. Suite 1100, Portland, OR 97232.

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 part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic Access

This proposed rule is accessible via the internet at the Office of the Federal Register website at *https://www.federalregister.gov.* Background information and documents are available at the NMFS website at *https://www.fisheries.noaa.gov* and at the Pacific Fishery Management Council's website at *http://www.pcouncil.org/.*

FOR FURTHER INFORMATION CONTACT: Stacey Miller, phone: 503–231–6290, and email: *Stacey.Miller@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

This rule proposes establishing the 2021 set-asides for research and incidental mortality of Pacific whiting as recommended by the Pacific Fishery Management Council (Council) and the 2021 tribal allocation for the Pacific whiting fishery. The allocations for Pacific whiting would be effective until December 31, 2021.

The transboundary stock of Pacific whiting is managed through the Agreement Between the Government of the United States of America and the Government of Canada on Pacific Hake/Whiting of 2003 (Agreement). The Agreement establishes bilateral bodies to implement the terms of the Agreement. The bilateral bodies include: The Joint Management Committee (JMC), which recommends the annual catch level for Pacific whiting; the Joint Technical Committee (JTC), which conducts the Pacific whiting stock assessment; the Scientific Review Group (SRG), which reviews the stock assessment; and the Advisory Panel (AP), which provides stakeholder input to the JMC.

The Agreement establishes a default harvest policy of F–40 percent, which means a fishing mortality rate that would reduce the spawning biomass to 40 percent of the estimated unfished level. The Agreement also allocates 73.88 percent of the Pacific whiting total allowable catch (TAC) to the United States and 26.12 percent of the TAC to Canada. Based on recommendations from the Treaty's JTC, SRG, and AP, the JMC determines the overall Pacific whiting TAC by March 25th of each year, which is subsequently approved by NMFS, under the delegation of authority from the Secretary of Commerce.

The final rule will announce the total 2021 U.S. TAC and establish the 2021 tribal allocation and non-tribal fishery harvest guideline (HG), also called the non-tribal allocation. To determine the HG, the 2021 tribal allocation and set-aside for research and incidental mortality are deducted from the total U.S. TAC. The HG is then allocated among the three non-tribal sectors of the Pacific whiting fishery: The catcher/processor (C/P) Coop Program, the Mothership (MS) Coop Program and the Shorebased Individual Fishing Quota (IFQ) Program. The HG is not included in this proposed rule due to the timing of the SRG and JMC meetings when the 2021 overall TAC will be determined by the JMC, and subsequently approved by the Secretary of Commerce, with the concurrence of the Department of State.

Tribal Allocations

The regulations at 50 CFR 660.50(d) identify the procedures for implementing the treaty rights that Pacific Coast treaty Indian tribes have to harvest groundfish in their usual and accustomed fishing areas in U.S. waters. Tribes with treaty fishing rights in the area covered by the Pacific Coast Groundfish FMP request allocations, set-asides, or regulations specific to the tribes during the Council's biennial harvest specifications and management

measures process. The regulations state that the Secretary will develop tribal allocations and regulations in consultation with the affected tribe(s) and, insofar as possible, with tribal consensus.

NMFS allocates a portion of the U.S. TAC of Pacific whiting to the tribal fishery, following the process established in 50 CFR 660.50(d). The tribal allocation is subtracted from the U.S. Pacific whiting TAC before allocation to the non-tribal sectors.

Four Washington coastal treaty Indian tribes including the Makah Indian Tribe, Quileute Indian Tribe, Quinault Indian Nation, and the Hoh Indian Tribe (collectively, the ''Treaty Tribes''), can participate in the tribal Pacific whiting fishery. Tribal allocations of Pacific whiting have been based on discussions with the Treaty Tribes regarding their intent for those fishing years. The Hoh Tribe has not expressed an interest in participating in the Pacific whiting fishery to date. The Quileute Tribe and Quinault Indian Nation have expressed interest in beginning to participate in the Pacific whiting fishery at a future date. To date, only the Makah Tribe has prosecuted a tribal fishery for Pacific whiting, and has harvested Pacific whiting since 1996 using midwater trawl gear.

Table 1 below provides a recent history of U.S. TACs and annual tribal allocation in metric tons (mt).

TABLE 1—U.S. TOTAL ALLOWABLE CATCH AND ANNUAL TRIBAL ALLOCATION IN METRIC TONS

[mt]

Year	U.S. TAC [1]	Tribal allocation
2010	193,935 mt	49,939 mt.
2011	290,903 mt	66,908 mt.
2012	186,037 mt	48,556 mt.
2013	269,745 mt	63,205 mt.
2014	316,206 mt	55,336 mt.
2015	325,072 mt	56,888 mt.
2016	367,553 mt	64,322 mt.
2017	441,433 mt	77,251 mt.
2018	441,433 mt	77,251 mt.
2019	441,433 mt	77,251 mt.
2020	424,810 mt	74,342 mt.

[1] Beginning in 2012, the United States started using the term Total Allowable Catch, or TAC, based on the Agreement between the Government of the United States of America and the Government of Canada on Pacific Hake/Whiting. Prior to 2012, the terms Optimal Yield (OY) and Annual Catch Limit (ACL) were used.

In 2009, NMFS, the states of Washington and Oregon, and the Treaty Tribes started a process to determine the long-term tribal allocation for Pacific whiting. However, these groups have not yet determined a long-term allocation. In order to ensure Treaty Tribes continue to receive allocations, this rule proposes the 2021 tribal allocation of Pacific whiting. This allocation is not intended to set precedent for future allocations.

In exchanges between NMFS and the Treaty Tribes during November and December 2020, the Makah Tribe indicated their intent to participate in the tribal Pacific whiting fishery in 2021 and requested 17.5 percent of the U.S. TAC. The Quinault Indian Nation, Quileute Indian Tribe and Hoh Indian Tribe informed NMFS in December 2020 that they will not participate in the 2021 fishery. NMFS will contact the Tribes during the proposed rule comment period to refine the 2021 allocation before allocating the final U.S. TAC between the tribal and non-tribal whiting fisheries. NMFS proposes a tribal allocation that accommodates the tribal request, specifically 17.5 percent of the U.S. TAC. NMFS has determined that the current scientific information regarding the distribution and abundance of the coastal Pacific whiting stock indicates the 17.5 percent is within the range of the tribal treaty right to Pacific whiting.

The JMC is anticipated to recommend the overall and corresponding U.S./Canada TACs no later than March 25, 2021. The U.S. TAC is 73.88 percent of the overall TAC. Until this TAC is set, NMFS cannot propose a specific amount for the tribal allocation. The Pacific whiting fishery begins on May 15, and we expect to publish the final rule to set Pacific whiting specifications for 2021 by early May. Therefore, to allow for public input on the tribal allocation, NMFS is issuing this proposed rule without the final 2021 TAC. However, to provide a basis for public input, NMFS is describing a range of potential tribal allocations in this proposed rule by applying the proposed tribal allocation to a range of potential TACs derived from past harvest levels.

In order to project a range of potential tribal allocations for 2021, we applied the proposed tribal allocation of 17.5 percent to the range of U.S. TACs over the last 10 years, 2011 through 2020 (plus or minus 25 percent to capture variability in stock abundance). The range of U.S. TACs in that time period was 186,037 mt (2012) to 441,433 mt (2017, 2018 and 2019). Applying the 25 percent variability results in a range of potential TACs of 139,527 mt to 551,791 mt for 2021. Using the proposed tribal allocation of 17.5 percent, the potential range of the tribal allocations for 2021 would be between 24,417 mt; and 96,563 mt.

Non-Tribal Research and Bycatch Set-Asides

The U.S. non-tribal whiting fishery is managed under the Council's Pacific Coast Groundfish FMP. Each year, the Council recommends the amount of Pacific whiting to accommodate incidental mortality of Pacific whiting in research activities and non-groundfish fisheries based on estimates of scientific research catch and estimated bycatch mortality in non-groundfish fisheries. At its November 2020 meeting, the Council recommended an incidental mortality set-aside of 750 mt for 2021. This is a reduction of the amount set-aside for research and incidental mortality from 1,500 mt in 2020. The 750 mt recommendation, however, reflects the recent 3 year average mortality that has declined from 942 mt in 2014–2016 to 216 mt in 2017–2019. This rule proposes the Council's recommendations.

This proposed rule would be implemented under the statutory and regulatory authority of section 304(b) and 305(d) of the Magnuson-Stevens Act, and the Pacific Whiting Act of 2006. With this proposed rule, NMFS, acting on behalf of the Secretary, would ensure that the FMP is implemented in a manner consistent with treaty rights of four Treaty Tribes to fish in their ''usual and accustomed grounds and stations'' in common with non-tribal citizens. *United States* v. *Washington,* 384 F. Supp. 313 (W.D. 1974).

Classification

Pursuant to section 304(b)(1)(A) and 305(d) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Pacific Coast Groundfish FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment. In making its final determination, NMFS will take into account the complete record, including the data, views, and comments received during the comment period.

Pursuant to Executive Order 13175, this proposed rule was developed after meaningful consultation and collaboration with tribal officials from the area covered by the Pacific Coast Groundfish FMP. Under the Magnuson-Stevens Act at 16 U.S.C. 1852(b)(5), one of the voting members of the Pacific Council must be a representative of an Indian tribe with federally recognized fishing rights from the area of the Council's jurisdiction. In addition, regulations implementing the Pacific

Coast Groundfish FMP establish a procedure by which the tribes with treaty fishing rights in the area covered by the Pacific Coast Groundfish FMP request new allocations or regulations specific to the tribes, in writing, before the first of the two meetings at which the Council considers groundfish management measures. The regulations at 50 CFR 660.324(d) further state, ''the Secretary will develop tribal allocations and regulations under this paragraph in consultation with the affected tribe(s) and, insofar as possible, with tribal consensus.'' The tribal management measures in this proposed rule have been developed following these procedures.

The Office of Management and Budget has determined that this proposed rule is not significant for purposes of Executive Order 12866.

An Initial Regulatory Flexibility Analyses (IRFA) were prepared for this action, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action is contained in the **SUMMARY** section and at the beginning of the **SUPPLEMENTARY INFORMATION** section of the preamble. A summary of the IRFA follow. Copies of the IRFAs are available from NMFS (See **ADDRESSES**).

Under the RFA, the term ''small entities'' includes small businesses, small organizations, and small governmental jurisdictions. The Small Business Administration has established size criteria for entities involved in the fishing industry that qualify as small businesses. A business involved in fish harvesting is a small business if it is independently owned and operated and not dominant in its field of operation (including its affiliates) and if it has combined annual receipts, not in excess of $11 million for all its affiliated operations worldwide (see 80 FR 81194, December 29, 2015). A wholesale business servicing the fishing industry is a small business if it employs 100 or fewer persons on a full time, part time, temporary, or other basis, at all its affiliated operations worldwide. For marinas and charter/party boats, a small business now defined as one with annual receipts, not in excess of $7.5 million. A wholesale business servicing the fishing industry is a small business if it employs 100 or fewer persons on a full time, part time, temporary, or other basis, at all its affiliated operations worldwide. A small organization is any nonprofit enterprise that is independently owned and operated and is not dominant in its field. Small governmental jurisdictions such as governments of cities, counties, towns, townships, villages, school districts, or special districts are considered small jurisdictions if their populations are less than 50,000. Effective February 26, 2016, a seafood processor is a small business if it is independently owned and operated, not dominant in its field of operation, and employs 750 or fewer persons on a full time, part time, temporary, or other basis, at all its affiliated operations worldwide (See NAICS 311710 at 81 FR 4469; January 26, 2016). For purposes of rulemaking, NMFS is also applying the seafood processor standard to catcher processors because whiting C/Ps earn the majority of the revenue from processed seafood product.

Description and Estimate of the Number of Small Entities to Which the Rule Applies, and Estimate of Economic Impacts by Entity Size and Industry

This proposed rule would affect how Pacific whiting is allocated to the following sectors/programs: Tribal, Shorebased IFQ Program Trawl Fishery, MS Coop Program Whiting At-sea Trawl Fishery, and C/P Coop Program Whiting At-sea Trawl Fishery. The amount of Pacific whiting allocated to these sectors is based on the U.S. TAC.

We expect one tribal entity to fish for Pacific whiting in 2021. Tribes are not considered small entities for the purposes of RFA. Impacts to tribes are nevertheless considered in this analysis. As of January 2021, the Shorebased IFQ Program is composed of 166 Quota Share permits/accounts (134 of which were allocated whiting quota pounds), and 35 first receivers, one of which is designated as whiting-only receivers and 11 that may receive both whiting and non-whiting. These regulations also directly affect participants in the MS Co-op Program, a general term to describe the limited access program that applies to eligible harvesters and processors in the MS sector of the Pacific whiting at-sea trawl fishery. This program consists of six MS processor permits, and a catcher vessel fleet currently composed of a single co-op, with 34 Mothership/Catcher Vessel (MS/CV) endorsed permits (with three permits each having two catch history assignments). These regulations also directly affect the C/P Co-op Program, composed of 10 C/P endorsed permits owned by three companies that have formed a single co-op. These co-ops are considered large entities from several perspectives; they have participants that are large entities, and have in total more than 750 employees worldwide including affiliates. Although there are three non-tribal sectors, many companies participate in two sectors and some participate in all three sectors. As part of the permit application processes for the non-tribal fisheries, based on a review of the Small Business Administration size criteria, permit applicants are asked if they considered themselves a ''small'' business, and they are asked to provide detailed ownership information. Data on employment worldwide, including affiliates, are not available for these companies, which generally operate in Alaska as well as the West Coast and may have operations in other countries as well. NMFS has limited entry permit holders self-report size status. For 2021, all 10 CP permits reported they are not small businesses, as did 8 mothership catcher vessels. There is substantial, but not complete overlap between permit ownership and vessel ownership so there may be a small number of additional small entity vessel owners who will be impacted by this rule. After accounting for cross participation, multiple Quota Share account holders, and affiliation through ownership, NMFS estimates that there are 103 non-tribal entities directly affected by these proposed regulations, 89 of which are considered ''small'' businesses.

This rule will allocate Pacific whiting between tribal and non-tribal harvesters (a mixture of small and large businesses). Tribal fisheries consist of a mixture of fishing activities that are similar to the activities that non-tribal fisheries undertake. Tribal harvests may be delivered to both shoreside plants and motherships for processing. These processing facilities also process fish harvested by non-tribal fisheries. The effect of the tribal allocation on non-tribal fisheries will depend on the level of tribal harvests relative to their allocation and the reapportionment process. If the tribes do not harvest their entire allocation, there are opportunities during the year to reapportion unharvested tribal amounts to the non-tribal fleets. For example, in 2020 NMFS reapportioned 40,000 mt of the original 74,342 mt tribal allocation. This reapportionment was based on conversations with the tribes and the best information available at the time, which indicated that this amount would not limit tribal harvest opportunities for the remainder of the year. The reapportioning process allows unharvested tribal allocations of Pacific whiting to be fished by the non-tribal fleets, benefitting both large and small entities. The revised Pacific whiting allocations for 2020 following the

reapportionment were: Tribal 34,342 mt, C/P Co-op 132,249 mt; MS Co-op 93,352 mt; and Shorebased IFQ Program 163,367 mt.

The prices for Pacific whiting are largely determined by the world market because most of the Pacific whiting harvested in the U.S. is exported. The U.S. Pacific whiting TAC is highly variable, as have subsequent harvests and ex-vessel revenues. For the years 2016 to 2020, the total Pacific whiting fishery (tribal and non-tribal) averaged harvests of approximately 303,782 mt annually. The 2020 U.S. non-tribal fishery had a Pacific whiting catch of approximately 287,400 mt, and the tribal fishery landed less than 200 mt.

Impacts to tribal catcher vessels who elect to participate in the tribal fishery are measured with an estimate of ex-vessel revenue. In lieu of more complete information on tribal deliveries, total ex-vessel revenue is estimated with the 2020 average shoreside ex-vessel price of Pacific whiting, which was $154 per mt. At that price, the proposed 2020 tribal allocation (potentially 24,417 mt—96,563 mt) would have an ex-vessel value between $3.8 million and $14.9 million.

A Description of Any Significant Alternatives to the Proposed Rule That Accomplish the Stated Objectives of Applicable Statutes and That Minimize Any Significant Economic Impact of the Proposed Rule on Small Entities

NMFS considered two alternatives for the Pacific whiting action: The ''No Action'' and the ''Proposed Action.'' NMFS did not consider a broader range of alternatives to the proposed allocation. The tribal allocation is based primarily on the requests of the tribes. These requests reflect the level of participation in the fishery that will allow them to exercise their treaty right to fish for Pacific whiting. Under the Proposed Action alternative, NMFS proposes to set the tribal allocation percentage at 17.5 percent, as requested by the Tribes. This would yield a tribal allocation of between 24,417 mt and 96,563 mt for 2021. Consideration of a percentage lower than the tribal request of 17.5 percent is not appropriate in this instance. As a matter of policy, NMFS has historically supported the harvest levels requested by the Tribes. Based on the information available to NMFS, the tribal request is within their tribal treaty rights. A higher percentage would arguably also be within the scope of the treaty right. However, a higher percentage would unnecessarily limit the non-tribal fishery.

Under the no action alternative, NMFS would not make an allocation to the tribal sector. This alternative was considered, but the regulatory framework provides for a tribal allocation on an annual basis only. Therefore, the no action alternative would result in no allocation of Pacific whiting to the tribal sector in 2021, which would be inconsistent with NMFS' responsibility to manage the fishery consistent with the Tribes' treaty rights. Given that there is a tribal request for allocation in 2021, this alternative received no further consideration.

Regulatory Flexibility Act Determination of No Significant Impact

NMFS determined this proposed rule would not adversely affect small entities. The reapportioning process allows unharvested tribal allocations of Pacific whiting, fished by small entities, to be fished by the non-tribal fleets, benefitting both large and small entities.

NMFS has prepared an IRFA and is requesting comments on this conclusion. See **ADDRESSES**.

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

No Federal rules have been identified that duplicate, overlap, or conflict with this action.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Indian Fisheries.

Dated: February 8, 2021.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 660 is proposed to be amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 773 *et seq.,* and 16 U.S.C. 7001 *et seq.*

■ 2. In § 660.50, revise paragraph (f)(4) to read as follows:

§ 660.50 Pacific Coast treaty Indian fisheries.

* * * * *

(f) * * *

(4) *Pacific whiting.* The tribal allocation for 2021 will be 17.5 percent of the U.S. TAC.

* * * * *

[FR Doc. 2021–02814 Filed 2–12–21; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 86, No. 29

Tuesday, February 16, 2021

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

Agency Information Collection Activities: Proposed Collection Comment Request—Supplemental Nutritional Assistance Program Education (SNAP Ed) Connection Resource Sharing Form

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 this notice announces the Food and Nutrition Service's intent to request approval to collect information via an online form. This is a revision of a currently approved collection for the Supplemental Nutrition Assistance Program (SNAP) Forms: FNS–0625 Resource Sharing Form. This form update will help improve the submission process by clarifying the information requested for certain fields, thus providing data that is accurate and beneficial to stakeholders using the resource. These updates will also align with changes to the SNAP-Ed Program in the areas of evaluation and impact.

This voluntary form is used by SNAP Education (SNAP-Ed) personnel and nutrition education material developers to submit materials for review and possible inclusion in the SNAP-Ed Library (formerly known as the SNAP-Ed Connection Resource Finder). The following materials may be submitted: obesity prevention education materials targeting Supplemental Nutrition Assistance Program (SNAP)-eligible persons; materials related to the development, implementation, administration and evaluation of SNAP Education (SNAP-Ed) programs; reports or other materials that demonstrate the effectiveness of SNAP-Ed funded programs; other materials developed by SNAP-Ed funded programs. The SNAP-Ed Library may be used by SNAP-Ed personnel and others to easily search for resources and to learn about the work of other SNAP-Ed programs.

Revisions to this form will not add additional burden to users.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of agency functions, 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 the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who respond, including the use of appropriate automated, electronic, mechanical, or other technology. Comments should be sent to the address in the preamble. All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

DATES: Comments on this notice must be received by April 19, 2021 to be assured of consideration.

ADDRESSES: Comments may be sent to Usha Kalro, Food and Nutrition Service, Supplemental Nutrition Assistance Program, Program Administration and Accountability Division, SNAP-Ed Connection, 1320 Braddock Place, 5th Floor, Alexandria, VA 22314, telephone (703) 305–2397. Submit electronic comments to *snap-edconnection@usda.gov;* comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Usha Kalro at *usha.kalro@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: SNAP-Ed Connection Resource Sharing Form.

Form Number: FNS–889.

OMB Number: 0584–0625.

Expiration Date: 4/30/2021.

Type of Request: Revision of currently approved data collection.

Abstract: In 2001, the United States Department of Agriculture's (USDA) Food and Nutrition Service (FNS) established the Food Stamp Nutrition Connection to improve access to Food Stamp Program Education resources. In 2008, the website was renamed the SNAP-Ed Connection. The website is developed and maintained at the FNS. The SNAP-Ed Connection is a resource website for SNAP-Ed administrators and educators. SNAP-Ed personnel use the SNAP-Ed Connection website to locate curricula, participant materials, nutrition research, administrative documents, and information regarding SNAP-Ed program development, implementation and evaluation. This resource website helps SNAP-Ed personnel find the tools and information they need to implement high-quality evidence-based obesity prevention programs.

The SNAP-Ed Library is an online database of SNAP-Ed-related materials. The SNAP-Ed Connection Resource Sharing Form gives SNAP-Ed personnel, as well as those who develop nutrition education materials, the opportunity to voluntarily share information about resources that can be used to administer, develop, implement, evaluate or showcase SNAP-Ed programs. Information collected via this form enables the SNAP-Ed Connection staff to review materials for possible inclusion in the SNAP-Ed Library. SNAP-Ed personnel and other interested parties then search this database via the SNAP-Ed Connection website *https://snaped.fns.usda.gov* to locate materials of interest. By using this database, SNAP-Ed-funded programs can share resources with each other, reduce duplication of efforts, and improve program quality. SNAP-Ed-funded programs can also learn about useful nutrition education materials created by other organizations.

Users may complete the form online. Respondents will provide contact information, ordering information, and information about the resource they are submitting.

Revisions to the FNS–889 are not yet finalized, however, the following updates are projected:

Removal of the question on Race and Ethnicity

Addition of Data element: Addition of the terms ''Required Field'' to the *Year the material was developed* section.

Addition of Data element: Adding the term ''website'' to clarify instructions for multiple links in the *website* section.

Addition of Data element: Addition of language ''please add any additional information about cost'' to the *Cost* section.

Addition of Data element: Addition of a Yes/No question: Is this resource part of the SNAP-Ed Toolkit? to the *Toolkit* section.

Addition of Data element: Addition of two fields—''Emerging'' and ''N/A'' to the *Evidence* section.

Addition of Data element: Addition of language '' summarize evaluation efforts and results here'' to the *Evaluation text box* section.

Addition of Data element: Addition of the word ''Related'' to the *Research Article field* section.

Addition of Data element: Addition of the word ''Article'' to the ''*Add Another*'' *button* section.

Addition of Data element: Addition of ''Select all that apply'' to the *Audience, Settings and Format* Sections.

Addition of Data element: Addition of a field ''Remote/at-home/virtual'' to the *Setting* section.

Addition of Data element: Addition of a field ''Remote/Virtual Leraning'' to the *Format* section.

Addition of Data element: Addition of ''Adding option for ''other'' with write in box'' in the *Language* section.

Affected Public: 14 State Agencies, 10 Business, and 1 Federal Government (Respondents are SNAP-Ed instructors and others educators who develop nutrition education materials).

Estimated Number of Respondents: 25.

Estimated Number of Responses per Respondent: 4.44.

Estimated Total Annual Response: 111.

Estimated Time per Response: 0.167 (10 minutes).

Estimated Total Annual Burden on Respondents: 18.54 (rounded up to 19 burden hours).

Respondent category	Instruments	Number of respondents	Frequency of response	Total annual responses	Hours per response	Annual burden (hours)
State, Local or Tribal Agencies.	SNAP-Ed Connection Resource Sharing Form.	14	5	70	0.167	11.7
Business-for-not-for-profit ...	SNAP-Ed Connection Resource Sharing Form.	10	4	40	0.167	6.68
Federal Government (such as CDC).	SNAP-Ed Connection Resource Sharing Form.	1	1	1	0.167	0.167
Total	.....	25	4.440	111	0.167	18.54

Cindy Long,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2021–03067 Filed 2–12–21; 8:45 am]

BILLING CODE 3410–30–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Kansas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Kansas Advisory Committee (Committee) will hold a meeting via the web platform Webex on, February 25, 2021 at 12:00 p.m. Central Time. The purpose of the meeting is for the committee to discuss civil rights concerns in the state in a search of a new topic of study.

DATES: The meetings will be held on:

• Thursday, February 25, 2021, at 12:00 p.m. Central Time, *https://civilrights.webex.com/civilrights/j.php?MTID=m1afdb6c01136c7c1b0bdecb806db4fe5*, or Join by phone, 800–360–9505 USA Toll Free, Access code: 1991 655 811.

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Officer, at *dbarreras@usccr.gov* or (202) 499–4066.

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. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to David Barreras at *dbarreras@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Kansas Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Chair's Comments
III. Committee Discussion
IV. Next Steps
V. Public Comment
VI. Adjournment

Dated: February 9, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–03004 Filed 2–12–21; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Alabama Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Alabama Advisory Committee (Committee) will hold a meeting via the web platform Webex on Thursday,

February 18, 2021 at 10:00 a.m. Central Time. The purpose of the meeting is for the committee to discuss civil rights concerns in the state, and to work on logistics for their upcoming briefings.

DATES: The meetings will be held on:

• Thursday, February 18, 2021, at 10:00 a.m. Central Time, *https://civilrights.webex.com/civilrights/j.php?MTID=madd740b602a57f45fe85eec1114633eb* or Join by phone, 800–360–9505 USA Toll Free, Access code: 1990 598 676.

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Officer, at *dbarreras@usccr.gov* or (202) 499–4066.

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. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to David Barreras at *dbarreras@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Alabama Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Chair's Comments
III. Committee Discussion
IV. Next Steps
V. Public Comment
VI. Adjournment

Dated: February 9, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–03005 Filed 2–12–21; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Tennessee Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Tennessee Advisory Committee (Committee) will hold a meeting via the web platform Webex on Thursday, February 18, 2021 at 12:00 p.m. Central Time. The purpose of the meeting is for the committee to discuss civil rights concerns in the state.

DATES: The meetings will be held on:

• Thursday, February 18, 2021, at 12:00 p.m. Central Time, *https://civilrights.webex.com/civilrights/j.php?MTID=m992749f83df222cdaaa858ecac88662f* or Join by phone: 800–360–9505 USA Toll Free, Access code: 1992 414 037.

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Officer, at *dbarreras@usccr.gov* or (202) 499–4066.

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. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to David Barreras at *dbarreras@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Tennessee Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Chair's Comments
III. Committee Discussion
IV. Next Steps
V. Public Comment
VI. Adjournment

Dated: February 9, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–03006 Filed 2–12–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–821–825]

Phosphate Fertilizers From the Russian Federation: Final Affirmative Countervailing Duty Determination

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

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of phosphate fertilizers from the Russian Federation (Russia).

DATES: Applicable February 16, 2021.

FOR FURTHER INFORMATION CONTACT: George Ayache or William Horn, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2623 or (202) 482–4868, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 30, 2020, Commerce published its *Preliminary Determination.*[1] On December 21, 2020, Commerce released its Post-Preliminary Analysis.[2] For a complete description of

[1] *See Phosphate Fertilizers from the Russian Federation: Preliminary Affirmative Countervailing Duty Determination,* 85 FR 76524 (November 30, 2020) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Decision Memorandum for the Post-Preliminary Analysis of the Countervailing

Continued

the events that followed the *Preliminary Determination, see* the Issues and Decision Memorandum.[3] The Issues and Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Period of Investigation

The period of investigation is January 1, 2019, through December 31, 2019.

Scope of the Investigation

The products covered by this investigation are phosphate fertilizers from Russia. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

No interested party commented on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, no changes were made to the scope of the investigation.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, *see* Appendix II to this notice.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, Commerce determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[4] For a full description of the methodology underlying our final determination, *see* the Issues and Decision Memorandum.

In making this final determination, Commerce relied, in part, on facts available pursuant to section 776(a) of the Act. Additionally, as discussed in the Issues and Decision Memorandum, because one or more respondents did not act to the best of their ability in responding to our requests for information, we drew adverse inferences, where appropriate, in selecting from among the facts otherwise available, pursuant to section 776(b) of the Act. For further information, see the section ''Use of Facts Otherwise Available and Adverse Inferences'' in the accompanying Issues and Decision Memorandum.

Verification

Commerce was unable to conduct on-site verification of the information relied upon in making its final determination in this investigation. However, we took additional steps in lieu of an on-site verification to verify the information relied upon in making this final determination, in accordance with section 782(i) of the Act.[5]

Changes Since the Preliminary Determination

Based on our review and analysis of the comments received from parties, we made certain changes to Industrial Group Phosphorite LLC (Phosphorite) and Joint Stock Company Apatit (JSC Apatit)'s subsidy rate calculations. For a discussion of these changes, *see* the Issues and Decision Memorandum.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate *ad valorem* (percent)
Industrial Group Phosphorite LLC[6]	47.05
Joint Stock Company Apatit[7]	9.19
All Others	17.20

All-Others Rate

We continue to calculate the all-others rate using a weighted average of the individual estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged data for the value of their exports to the United States of subject merchandise, in accordance with section 705(c)(5)(A)(i) of the Act.[8]

Disclosure

Commerce intends to disclose to interested parties the calculations and analysis performed in this final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of the publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination* and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, we instructed U.S. Customs and Border Protection to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after November 30, 2020, the date of publication of the *Preliminary Determination* in the **Federal Register**.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order and require a cash deposit of estimated countervailing duties for entries of subject merchandise in the amounts indicated above, in accordance with section 706(a) of the Act. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result

Duty Investigation of Phosphate Fertilizers from the Russian Federation,'' dated December 21, 2020 (Post-Preliminary Analysis).

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination of the Countervailing Duty Investigation of Phosphate Fertilizers from the Russian Federation,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[5] *See* Commerce's Letters, ''Countervailing Duty Investigation of Phosphate Fertilizers from the Russian Federation: Supplemental Questionnaire in Lieu of On-Site Verification,'' dated December 18, 2020; *see also* EuroChem Group's Letter, ''Phosphate Fertilizers from Russia,'' dated December 28, 2020; and PhosAgro PJSC's Letter, ''Countervailing Duty Investigation of Phosphate Fertilizers from Russia: PhosAgro PJSC In Lieu-of Verification Questionnaire Response,'' dated December 29, 2020.

[6] Commerce has found the following companies to be cross-owned with Phosphorite: Mineral and Chemical Company EuroChem, JSC; NAK Azot, JSC; EuroChem Northwest, JSC; Joint Stock Company Kovdorksy GOK; EuroChem-Energo, LLC; EuroChem-Usolsky Potash Complex, LLC; EuroChem-BMU, LLC; JSC Nevinnomyssky Azot; and EuroChem Trading Rus, LLC.

[7] Commerce has found the following companies to be cross-owned with JSC Apatit: PhosAgro PJSC; PhosAgro-Belgorod LLC; PhosAgro-Don LLC; PhosAgro-Kuban LLC; PhosAgro-Kursk LLC; PhosAgro-Lipetsk LLC; PhosAgro-Orel LLC; PhosAgro-Stavropol LLC; PhosAgro-Volga LLC; PhosAgro-SeveroZapad LLC; PhosAgro-Tambov LLC; and Martynovsk AgrokhimSnab LLC.

[8] For discussion of the calculation of this rate, *see* Memorandum, ''Countervailing Duty Investigation of Phosphate Fertilizers from the Russian Federation: Final Determination Calculation of the All-Others Rate,'' dated February 8, 2021.

of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final affirmative determination that countervailable subsidies are being provided to producers and exporters of phosphate fertilizers from Russia. As Commerce's final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured or threatened with material injury. In addition, we are making available to the ITC all non-privileged and nonproprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Notification Regarding APO

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: February 8, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is phosphate fertilizers in all physical forms (*i.e.,* solid or liquid form), with or without coating or additives such as anti-caking agents. Phosphate fertilizers in solid form are covered whether granular, prilled (*i.e.,* pelletized), or in other solid form (*e.g.,* powdered).

The covered merchandise includes phosphate fertilizers in the following forms: Ammonium dihydrogenorthophosphate or monoammonium phosphate (MAP), chemical formula NH4H2PO4; diammonium hydrogenorthophosphate or diammonium phosphate (DAP), chemical formula (NH4)2HPO4; normal superphosphate (NSP), also known as ordinary superphosphate or single superphosphate, chemical formula Ca(H2PO4)2·CaSO4; concentrated superphosphate, also known as double, treble, or triple superphosphate (TSP), chemical formula Ca(H2PO4)2·H2O; and proprietary formulations of MAP, DAP, NSP, and TSP.

The covered merchandise also includes other fertilizer formulations incorporating phosphorous and non-phosphorous plant nutrient components, whether chemically-bonded, granulated (*e.g.,* when multiple components are incorporated into granules through, *e.g.,* a slurry process), or compounded (*e.g.,* when multiple components are compacted together under high pressure), including nitrogen, phosphate, sulfur (NPS) fertilizers, nitrogen, phosphorous, potassium (NPK) fertilizers, nitric phosphate (also known as nitrophosphate) fertilizers, ammoniated superphosphate fertilizers, and proprietary formulations thereof that may or may not include other nonphosphorous plant nutrient components. For phosphate fertilizers that contain non-phosphorous plant nutrient components, such as nitrogen, potassium, sulfur, zinc, or other non-phosphorous components, the entire article is covered, including the non-phosphorous content, provided that the phosphorous content (measured by available diphosphorous pentaoxide, chemical formula P2O5) is at least 5% by actual weight.

Phosphate fertilizers that are otherwise subject to this investigation are included when commingled (*i.e.,* mixed or blended) with phosphate fertilizers from sources not subject to this investigation. Phosphate fertilizers that are otherwise subject to this investigation are included when commingled with substances other than phosphate fertilizers subject to this investigation (*e.g.,* granules containing only non-phosphate fertilizers such as potash or urea). Only the subject component of such commingled products is covered by the scope of this investigation. The following products are specifically excluded from the scope of this investigation:

(1) ABC dry chemical powder preparations for fire extinguishers containing MAP or DAP in powdered form;

(2) industrial or technical grade MAP in white crystalline form with available P2O5 content of at least 60% by actual weight;

(3) industrial or technical grade diammonium phosphate in white crystalline form with available P2O5 content of at least 50% by actual weight;

(4) liquid ammonium polyphosphate fertilizers;

(5) dicalcium phosphate, chemical formula CaHPO4;

(6) monocalcium phosphate, chemical formula CaH4P2O8;

(7) trisodium phosphate, chemical formula Na3PO4;

(8) sodium tripolyphosphate, chemical formula Na5P3O10;

(9) prepared baking powders containing sodium bicarbonate and any form of phosphate;

(10) animal or vegetable fertilizers not containing phosphate fertilizers otherwise covered by the scope of this investigation;

(11) phosphoric acid, chemical formula H3PO4.

The Chemical Abstracts Service (CAS) numbers for covered phosphate fertilizers include, but are not limited to: 7722–76–1 (MAP); 7783–28–0 (DAP); and 65996–95–4 (TSP). The covered products may also be identified by Nitrogen-Phosphate- Potash composition, including but not limited to: NP 11–52–0 (MAP); NP 18–46–0 (DAP); and NP 0–46–0 (TSP).

The covered merchandise is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings 3103.11.0000; 3103.19.0000; 3105.20.0000; 3105.30.0000; 3105.40.0010; 3105.40.0050; 3105.51.0000; and 3105.59.0000. Phosphate fertilizers subject to this investigation may also enter under subheadings 3103.90.0010, 3105.10.0000, 3105.60.0000, 3105.90.0010, and 3105.90.0050. Although the HTSUS subheadings and CAS registry numbers are provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Use of Facts Otherwise Available and Adverse Inferences
IV. Subsidies Valuation
V. Benchmarks and Interest Rates
VI. Analysis of Programs
VII. Analysis of Comments
Comment 1: Whether Commerce's Rejection of PhosAgro's Extension Request to Submit Case and Rebuttal Briefs Was Unreasonable
Comment 2: Whether the Mining Rights for Less than Adequate Remuneration (LTAR) Program Is Countervailable
Comment 2a: Whether the Mining Rights for LTAR Program Constitutes a Financial Contribution
Comment 2b: Whether the Mining Rights for LTAR Program Is Specific
Comment 2c: Whether the Mining Rights for LTAR Program Confers a Benefit
Comment 2d: Whether Mining Rights Provided Prior to the Non-Market Economy ''Cut-off'' Date Should Be Included in the Mining Rights for LTAR Calculation
Comment 2e: Whether Commerce Should Include Freight, Value Added Taxes (VAT), and Import Duties in the Mining Rights Benchmark
Comment 2f: Whether the Calculation Methodology of the Mining Rights for LTAR Program Was Appropriate
Comment 3: Whether the Natural Gas for LTAR Program Is Countervailable
Comment 3a: Whether PJSC Gazprom (Gazprom) Is a Government Authority that Provides a Financial Contribution
Comment 3b: Whether Oil Company Rosneft, Public Joint Stock Company

(Rosneft) Is a Government Authority that Provides a Financial Contribution
Comment 3c: Whether the Saint Petersburg International Commodity Exchange (SPIMEX) Is a Government Authority that Provides a Financial Contribution
Comment 3d: Whether the Provision of Natural Gas by Gazprom Is Specific
Comment 3e: Whether the Provision of Natural Gas by SPIMEX Is Specific
Comment 3f: Whether the Provision of Natural Gas for LTAR Confers a Benefit
Comment 3g: Whether Commerce Should Adjust the Natural Gas Benchmark to ''Tier One''
Comment 3h: Whether Commerce Should Adjust the Natural Gas Benchmark to ''Tier Two''
Comment 3i: Whether Commerce Should Change the Data Relied Upon in its Natural Gas Benchmark ''Tier Three'' Analysis
Comment 3j: Whether Commerce Should Adjust the Natural Gas Benchmark Data in its ''Tier Three'' Analysis.
Comment 3k: Whether Commerce Should Use a VAT Inclusive Sales Denominator
Comment 3l: Whether 19 CFR 351.525(b)(6) Applies to EuroChem's Natural Gas for LTAR
Comment 3m: Whether Commerce Should Consider the Relative Consumption of Natural Gas in the Production of Subject Merchandise for Purposes of Attribution
Comment 3n: Whether Commerce Should Use EuroChem's 2019 Audited Financials for Its Sales Denominators
Comment 3o: Whether the Delivery Cost of SPIMEX Natural Gas from EuroChem-Energo LLC (Energo) to JSC Nevinnomyssky Azot (Nevinka) and EuroChem Northwest JSC (EuroChem NW) Should Be Considered in Any Natural Gas Subsidy Calculation
Comment 4: Whether the Tax Incentives for Mining Operations—Income Tax Deduction for Exploration Expenses Program Is Specific
Comment 5: Whether the Income Tax Deduction for Research and Development (R&D) Expenses Is Specific
Comment 6: Whether the Regional Support of Industrial Development Programs, the Special Investment Contract (SPIC) with Perm Krai, and the Preferential Debt Financing of Projects Aimed at Introducing the Best Available Technologies Program Are Specific
Comment 7: Whether Commerce Used the Appropriate Denominator to Calculate PhosAgro's Subsidy Rates
VIII. Recommendation

[FR Doc. 2021–03010 Filed 2–12–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–714–001]

Phosphate Fertilizers From the Kingdom of Morocco: Final Affirmative Countervailing Duty Determination

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

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of phosphate fertilizers from the Kingdom of Morocco (Morocco).

DATES: Applicable February 16, 2021.

FOR FURTHER INFORMATION CONTACT: Robert Palmer or Janae Martin, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9068 or (202) 482–0238, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 30, 2020, Commerce published its *Preliminary Determination.*[1] On December 29, 2020, Commerce published its *Amended Preliminary Determination.*[2] On January 6, 2021, Commerce released its Post-Preliminary Determination.[3] For a complete description of the events that followed the *Preliminary Determination, see* the Issues and Decision Memorandum.[4] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Period of Investigation

The period of investigation is January 1, 2019, through December 31, 2019.

Scope of the Investigation

The products covered by this investigation are phosphate fertilizers from Morocco. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

No interested party commented on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, no changes were made to the scope of the investigation.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, *see* Appendix II to this notice.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, Commerce determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[5] For a full description of the methodology underlying our final determination, *see* the Issues and Decision Memorandum.

Verification

Commerce was unable to conduct on-site verification of the information relied upon in making its final determination in this investigation. However, we took additional steps in lieu of an on-site verification to verify

[1] *See Phosphate Fertilizers from the Kingdom of Morocco: Preliminary Affirmative Countervailing Duty Determination,* 85 FR 76522 (November 30, 2020) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See Phosphate Fertilizers from the Kingdom of Morocco: Amended Preliminary Determination of Countervailing Duty Investigation,* 85 FR 85585 (December 29, 2020) (*Amended Preliminary Determination*), and accompanying PDM.

[3] *See* Memorandum, ''Post-Preliminary Determination of Countervailing Duty Investigation: Phosphate Fertilizers from the Kingdom of Morocco,'' dated January 6, 2020 (Post-Preliminary Determination).

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination of the Countervailing Duty Investigation of Phosphate Fertilizers from the Kingdom of Morocco,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[5] *See* Commerce's Letters, ''Supplemental Questionnaire in Lieu of On-Site Verification,'' dated December 17, 2020; *see also* OCP's Letter, ''Response to Questionnaire in Lieu of On-Site Verification,'' dated December 30, 2020; and the GOM's Letter, ''In Lieu of On-Site Verification Questionnaire Response of the Government of the Kingdom of Morocco,'' dated December 29, 2020.

the information relied upon in making this final determination, in accordance with section 782(i) of the Act.[6]

Changes Since the Preliminary Determination

Based on our review and analysis of the comments received from parties, we made certain changes to OCP S.A.'s subsidy rate calculations. For a discussion of these changes, *see* the Issues and Decision Memorandum.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate *ad valorem* (percent)
OCP S.A.[6]	19.97
All Others	19.97

All-Others Rate

We continue to calculate the all-others rate using the estimated weighted-average subsidy rate calculated for OCP S.A., the only individually examined exporter/producer in this investigation, pursuant to section 705(c)(5)(A)(i) of the Act.

Disclosure

Commerce intends to disclose to interested parties the calculations and analysis performed in this final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of the publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination,* and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after November 30, 2020, the date of publication of the *Preliminary Determination* in the **Federal Register**.

As a result of the *Amended Preliminary Determination*, the amended rates for OCP and all others resulted in decreased cash deposits, which were applied retroactively to November 30, 2020, the date of publication of the *Preliminary Determination.*

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order and require a cash deposit of estimated countervailing duties for entries of subject merchandise in the amounts indicated above, in accordance with section 706(a) of the Act. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final affirmative determination that countervailable subsidies are being provided to producers and exporters of phosphate fertilizers from Morocco. As Commerce's final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured or threatened with material injury. In addition, we are making available to the ITC all non-privileged and nonproprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Notification Regarding APO

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: February 8, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is phosphate fertilizers in all physical forms (*i.e.,* solid or liquid form), with or without coating or additives such as anti-caking agents. Phosphate fertilizers in solid form are covered whether granular, prilled (*i.e.,* pelletized), or in other solid form (*e.g.,* powdered).

The covered merchandise includes phosphate fertilizers in the following forms: Ammonium dihydrogenorthophosphate or monoammonium phosphate (MAP), chemical formula NH4H2PO4; diammonium hydrogenorthophosphate or diammonium phosphate (DAP), chemical formula (NH4)2HPO4; normal superphosphate (NSP), also known as ordinary superphosphate or single superphosphate, chemical formula Ca(H2PO4)2CaSO4; concentrated superphosphate, also known as double, treble, or triple superphosphate (TSP), chemical formula Ca(H2PO4)2H2O; and proprietary formulations of MAP, DAP, NSP, and TSP.

The covered merchandise also includes other fertilizer formulations incorporating phosphorous and non-phosphorous plant nutrient components, whether chemically-bonded, granulated (*e.g.,* when multiple components are incorporated into granules through, *e.g.,* a slurry process), or compounded (*e.g.,* when multiple components are compacted together under high pressure), including nitrogen, phosphate, sulfur (NPS) fertilizers, nitrogen, phosphorous, potassium (NPK) fertilizers, nitric phosphate (also known as nitrophosphate) fertilizers, ammoniated superphosphate fertilizers, and proprietary formulations thereof that may or may not include other nonphosphorous plant nutrient components. For phosphate fertilizers that contain non-phosphorous plant nutrient components, such as nitrogen, potassium, sulfur, zinc, or other non-phosphorous components, the entire article is covered, including the non-phosphorous content, provided that the phosphorous content (measured by available diphosphorous pentaoxide, chemical formula P2O5) is at least 5% by actual weight.

Phosphate fertilizers that are otherwise subject to this investigation are included when commingled (*i.e.,* mixed or blended) with phosphate fertilizers from sources not subject to this investigation. Phosphate fertilizers that are otherwise subject to this investigation are included when commingled with substances other than phosphate fertilizers subject to this investigation (*e.g.,* granules containing only non-phosphate fertilizers such as potash or urea). Only the subject component of such commingled products is covered by the scope of this investigation. The following products are specifically excluded from the scope of this investigation:

[6] Commerce has found the following companies to be cross-owned with OCP S.A.: Jorf Fertilizers Company I, Jorf Fertilizers Company II, Jorf Fertilizers Company III, Jorf Fertilizers Company IV, Jorf Fertilizers Company V, and Maroc Phosphore.

(1) ABC dry chemical powder preparations for fire extinguishers containing MAP or DAP in powdered form;

(2) industrial or technical grade MAP in white crystalline form with available P2O5 content of at least 60% by actual weight;

(3) industrial or technical grade diammonium phosphate in white crystalline form with available P2O5 content of at least 50% by actual weight;

(4) liquid ammonium polyphosphate fertilizers;

(5) dicalcium phosphate, chemical formula CaHPO4;

(6) monocalcium phosphate, chemical formula CaH4P2O8;

(7) trisodium phosphate, chemical formula Na3PO4;

(8) sodium tripolyphosphate, chemical formula Na5P3O10;

(9) prepared baking powders containing sodium bicarbonate and any form of phosphate;

(10) animal or vegetable fertilizers not containing phosphate fertilizers otherwise covered by the scope of this investigation;

(11) phosphoric acid, chemical formula H3PO4.

The Chemical Abstracts Service (CAS) numbers for covered phosphate fertilizers include, but are not limited to: 7722–76–1 (MAP); 7783–28–0 (DAP); and 65996–95–4 (TSP). The covered products may also be identified by Nitrogen-Phosphate- Potash composition, including but not limited to: NP 11–52–0 (MAP); NP 18–46–0 (DAP); and NP 0–46–0 (TSP).

The covered merchandise is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings 3103.11.0000; 3103.19.0000; 3105.20.0000; 3105.30.0000; 3105.40.0010; 3105.40.0050; 3105.51.0000; and 3105.59.0000. Phosphate fertilizers subject to this investigation may also enter under subheadings 3103.90.0010, 3105.10.0000, 3105.60.0000, 3105.90.0010, and 3105.90.0050. Although the HTSUS subheadings and CAS registry numbers are provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Subsidies Valuation
IV. Benchmarks and Interest Rates
V. Analysis of Programs
VI. Analysis of Comments
General Issues
Comment 1: Whether the Petition Demonstrated Sufficient Industry Support
Comment 2: Whether Commerce's ''Other Assistance'' Question Is Contrary to Law
Mining Rights for Less Than Adequate Remuneration (LTAR)
Comment 3: Whether Commerce Should Revise the Phosphate Rock Benchmark
Comment 4: Whether to Include or Exclude HQ, Support, Debt, and Other Costs as Costs of Producing Phosphate Rock
Comment 5: Whether to Include a Profit Component
Comment 6: Whether Freight Costs Are Double Counted in the Mining Costs
Comment 7: The Appropriate Quantity for the Mining Rights for LTAR Benefit Calculation
Comment 8: The Appropriate Analysis for the Provision of Mining Rights for LTAR
Creditworthiness
Comment 9: Whether Commerce Correctly Analyzed OCP S.A. (OCP)'s Financial Ratios
Comment 10: Whether OCP Is Uncreditworthy in 2018
Comment 11: Whether Commerce Should Consider OCP's Long-Term Loans in the Creditworthiness Analysis
Comment 12: Whether Commerce Misinterpreted OCP's Credit Ratings
Authority Determinations
Comment 13: Whether BCP [7] Is an Authority and Provides a Financial Contribution
Comment 14: Whether Al Mada and AWB [8] Are Authorities and Provide a Financial Contribution
OCP 2016 and 2018 Bond Issuance
Comment 15: Whether OCP's 2016 Bond Issue Conferred a Benefit
Comment 16: Whether OCP's Bond Issuance Is Specific
Comment 17: Whether Commerce Should Revise the Uncreditworthy Benchmark Interest Rate
Loans
Comment 18: Whether Direct Loans From AWB, BCP, and CAM [9] Are Countervailable
Comment 19: Whether the Provision of Loan Guarantees Is Countervailable
Tax Programs
Comment 20: Whether Commerce Overstated Taxable Income for the Tax Incentives for Export Operations Program
Comment 21: Whether Commerce Should Adjust OCP's Cash Deposit Rate
Comment 22: Whether the Reductions in Tax Fines and Penalties Is Specific
Value-Added Tax (VAT)
Comment 23: Whether the MAD [10] 20.5 Billion VAT Refund Is Countervailable
Comment 24: Whether VAT Exemptions for Capital Goods, Machinery and Equipment Are Countervailable
Other Subsidies
Comment 25: Whether the Provision of Phosphogypsum Waste Disposal Is Countervailable
Comment 26: Whether the Provision of Phosphogypsum Waste Disposal Was Properly Initiated
Comment 27: Whether the Provision of Rail Service for LTAR Is Specific
VII. Recommendation

[FR Doc. 2021–03011 Filed 2–12–21; 8:45 am]

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[7] Banque Centrale Populaire (BCP).
[8] Attijariwafa Bank Group (AWB).
[9] Credit Agricole du Maroc (CAM).
[10] Morocco dirhams (MAD).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–118]

Wood Mouldings and Millwork Products From the People's Republic of China: Countervailing Duty Order

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

SUMMARY: Based on the affirmative final determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC), Commerce is issuing its countervailing duty order on wood mouldings and millwork products (millwork products) from the People's Republic of China (China).

DATES: Applicable February 16, 2021.

FOR FURTHER INFORMATION CONTACT: Irene Gorelik or Faris Montgomery, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6905 or (202) 482–1537, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 4, 2021, Commerce published its *Final Determination* in the countervailing duty investigation of millwork products from China.[1] On February 10, 2021, the ITC notified Commerce of its final determination, pursuant to sections 705(b)(1)(A)(i) and 705(d) of the Tariff Act of 1930, as amended (the Act), that an industry in the United States is materially injured by reason of subsidized imports of millwork products from China.[2]

Scope of the Order

The products covered by this order are millwork products from China. For a full description of the scope of this order, *see* the appendix to this notice.

Countervailing Duty Order

On February 10, 2021, in accordance with sections 705(b)(1)(A)(i) and 705(d) of the Act, the ITC notified Commerce of its final determination in this investigation, in which it found that an industry in the United States is materially injured by reason of

[1] *See Wood Mouldings and Millwork Products from the People's Republic of China: Final Affirmative Countervailing Duty Determination,* 86 FR 67 (January 4, 2021) (*Final Determination*).

[2] *See* ITC Notification Letter, Investigations, Inv. Nos. 701–TA–636 and 731–TA–1470 (Final) (February 10, 2021).

subsidized imports of millwork products from China.[3] In accordance with section 705(c)(2) of the Act, Commerce is issuing this countervailing duty order.

Therefore, in accordance with section 706(a) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, countervailing duties on unliquidated entries of millwork products from China entered, or withdrawn from warehouse, for consumption on or after June 12, 2020, the date on which Commerce published its preliminary countervailing duty determination in the **Federal Register**,[4] and before October 10, 2020, the effective date on which Commerce instructed CBP to discontinue the suspension of liquidation, in accordance with section 703(d) of the Act. Section 703(d) of the Act states that the suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months. Therefore, entries of millwork products from China made on or after October 10, 2020, and prior to the date of publication of the ITC's final determination in the **Federal Register**, are not subject to the assessment of countervailing duties due to Commerce's discontinuation of the suspension of liquidation.

Suspension of Liquidation

In accordance with section 706 of the Act, Commerce will direct CBP to reinstitute the suspension of liquidation of millwork products from China, effective the date of publication of the ITC's notice of final determination in the **Federal Register**, and to assess, upon further instruction by Commerce pursuant to section 706(a)(1) of the Act, countervailing duties for each entry of the subject merchandise in an amount based on the net countervailable subsidy rates for the subject merchandise. On or after the date of publication of the ITC's final injury determination in the **Federal Register**, CBP must require, at the same time as importers would deposit estimated normal customs duties on this merchandise, a cash deposit equal to the subsidy rates noted below. These instructions suspending liquidation will remain in effect until further notice. The all-others rate applies to all producers or exporters not specifically listed below.

Company	Subsidy rate (percent)
Fujian Yinfeng Imp & Exp Trading Co., Ltd[5]	20.56
Fujian Nanping Yuanqiao Wood Industry Co., Ltd	252.29
All Others	20.56

Provisional Measures

Section 703(d) of the Act states that the suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months. In the underlying investigation, Commerce published the *Preliminary Determination* on June 12, 2020.[6] Therefore, entries of millwork products from China made on or after October 10, 2020, and prior to the date of publication of the ITC's final determination in the **Federal Register**, are not subject to the assessment of countervailing duties due to Commerce's discontinuation of the suspension of liquidation.

In accordance with section 703(d) of the Act, Commerce instructed CBP to terminate the suspension of liquidation and to liquidate, without regard to countervailing duties, unliquidated entries of millwork products from China entered, or withdrawn from warehouse, for consumption on or after October 10, 2020, the date on which the provisional countervailing duty measures expired, through the day preceding the date of publication of the ITC final injury determination in the **Federal Register**. Suspension of liquidation will resume on the date of publication of the ITC final injury determination in the **Federal Register**.

Notifications to Interested Parties

This notice constitutes the countervailing duty order with respect to millwork products from China pursuant to section 706(a) of the Act. Interested parties can find a list of countervailing duty orders currently in effect at *http://enforcement.trade.gov/stats/iastats1.html.*

This order is issued and published in accordance with section 706(a) of the Act and 19 CFR 351.211(b).

Dated: February 10, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Order

The merchandise subject to this order consists of wood mouldings and millwork products that are made of wood (regardless of wood species), bamboo, laminated veneer lumber (LVL), or of wood and composite materials (where the composite materials make up less than 50 percent of the total merchandise), and which are continuously shaped wood or finger-jointed or edge-glued moulding or millwork blanks (whether or not resawn). The merchandise subject to this order can be continuously shaped along any of its edges, ends, or faces.

The percentage of composite materials contained in a wood moulding or millwork product is measured by length, except when the composite material is a coating or cladding. Wood mouldings and millwork products that are coated or clad, even along their entire length, with a composite material, but that are otherwise comprised of wood, LVL, or wood and composite materials (where the non-coating composite materials make up 50 percent or less of the total merchandise) are covered by the scope.

The merchandise subject to this order consists of wood, LVL, bamboo, or a combination of wood and composite materials that is continuously shaped throughout its length (with the exception of any endwork/dados), profiled wood having a repetitive design in relief, similar milled wood architectural accessories, such as rosettes and plinth blocks, and finger-jointed or edge-glued moulding or millwork blanks (whether or not resawn). The scope includes continuously shaped wood in the forms of dowels, building components such as interior paneling and jamb parts, and door components such as rails, stiles, interior and exterior door frames or jambs (including split, flat, stop applied, single- or double-rabbeted), frame or jamb kits, and packaged door frame trim or casing sets, whether or not the door components are imported as part of a door kit or set.

The covered products may be solid wood, laminated, finger-jointed, edge-glued, face-glued, or otherwise joined in the production or remanufacturing process and are covered by the scope whether imported raw, coated (*e.g.,* gesso, polymer, or plastic), primed, painted, stained, wrapped (paper or vinyl overlay), any combination of the aforementioned surface coatings, treated, or which incorporate rot-resistant elements (whether wood or composite). The covered products are covered by the scope whether or not any surface coating(s) or covers obscure the grain, textures, or markings of the wood, whether or not they are ready for use or require final machining (*e.g.,* endwork/dado, hinge/strike machining, weatherstrip or application thereof, mitre) or packaging.

[3] *Id.*

[4] *See Wood Mouldings and Millwork Products from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination,* 85 FR 35900 (June 12, 2020) (*Preliminary Determination*).

[5] As discussed in the *Preliminary Determination,* Commerce found that Fujian Province Youxi City Mangrove Wood Machining Co., Ltd.; Fujian Province Youxi City Mangrove Wood Machining Co., Ltd.; and Xicheng Branch are cross-owned affiliates of mandatory respondent Fujian Yinfeng Imp & Exp Trading Co., Ltd. *See Preliminary Determination,* 85 FR at 35901, unchanged in the *Final Determination.*

[6] *See Preliminary Determination.*

All wood mouldings and millwork products are included within the scope even if they are trimmed; cut-to-size; notched; punched; drilled; or have undergone other forms of minor processing.

Subject merchandise also includes wood mouldings and millwork products that have been further processed in a third country, including but not limited to trimming, cutting, notching, punching, drilling, coating, or any other processing that would not otherwise remove the merchandise from the scope of this order if performed in the country of manufacture of the in-scope product.

Excluded from the scope of this order are countertop/butcherblocks imported as a full countertop/butcherblock panel, exterior fencing, exterior decking and exterior siding products (including solid wood siding, non-wood siding (*e.g.,* composite or cement), and shingles) that are not LVL or finger jointed; finished and unfinished doors; flooring; parts of stair steps (including newel posts, balusters, easing, gooseneck, risers, treads, rail fittings and stair stringers); picture frame components three feet and under in individual lengths; and lumber whether solid, finger-jointed, or edge-glued. To be excluded from the scope, finger-jointed or edge-glued lumber must have a nominal thickness of 1.5 inches or greater and a certification stamp from an American Lumber Standard Committee-certified grading agency. The exclusion for lumber whether solid, finger-jointed, or edge-glued does not apply to screen/''surfaced on 4 sides'' (S4S) and/or ''surface 1 side, 2 edges'' (SlS2E) stock (also called boards) that are finger-jointed and/or edge-glued, or to finger-jointed and/or edge-glued moulding or millwork blanks (whether or not resawn). Accordingly, S4S and S1S2E stock/boards that are not finger-jointed or edge-glued are excluded from the scope of this order.

Excluded from the scope of this order are all products covered by the scope of the countervailing duty order on *Hardwood Plywood from the People's Republic of China. See Certain Hardwood Plywood Products from the People's Republic of China: Countervailing Duty Order,* 83 FR 513 (January 4, 2018).

Excluded from the scope of this order are all products covered by the scope of the countervailing duty order on *Multilayered Wood Flooring from the People's Republic of China. See Multilayered Wood Flooring from the People's Republic of China: Countervailing Duty Order,* 76 FR 76693 (December 8, 2011).

Excluded from the scope of this order are all products covered by the scope of the countervailing duty order on *Wooden Cabinets and Vanities from the People's Republic of China. See Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Countervailing Duty Order,* 85 FR 22134 (April 21, 2020).

Imports of wood mouldings and millwork products are primarily entered under the following Harmonized Tariff Schedule of the United States (HTSUS) numbers: 4409.10.4010, 4409.10.4090, 4409.10.4500, 4409.10.5000, 4409.22.4000, 4409.22.5000,4409.29.4100, and 4409.29.5100. Imports of wood mouldings and millwork products may also enter under HTSUS numbers: 4409.10.6000,4409.10.6500, 4409.22.6000, 4409.22.6500, 4409.29.6100, 4409.29.6600, 4418.20.4000, 4418.20.8030, 4418.20.8060, 4418.99.9095 and 4421.99.9780. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–117]

Wood Mouldings and Millwork Products From the People's Republic of China: Amended Final Antidumping Duty Determination and Antidumping Duty Order

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

SUMMARY: Based on affirmative final determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC), Commerce is issuing an antidumping duty order on wood mouldings and millwork products (millwork products) from the People's Republic of China (China). In addition, Commerce is amending its final affirmative determination.

DATES: Applicable February 16, 2021.

FOR FURTHER INFORMATION CONTACT: Brian Smith or Samuel Glickstein, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1766 or (202) 482–5307, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 4, 2021, Commerce published its affirmative *Final Determination* in the less-than-fair-value (LTFV) investigation of millwork products from China.[1] On January 5, 2021, Commerce received a ministerial error allegation with respect to its *Final Determination.*[2] *See* the ''Amendment to Final Determination'' section of this notice for further discussion. On February 10, 2021, the ITC notified Commerce of its final determination, pursuant to section 735(d) of the Tariff Act of 1930, as amended (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 millwork products from China.[3]

Scope of the Order

The products covered by this order are millwork products from China. For a complete description of the scope of this order, *see* the appendix to this notice.

Amendment to Final Determination

A ministerial error is defined as an error in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any other similar type of unintentional error which the Secretary considers ministerial.[4] Pursuant to section 735(e) of the Act and 19 CFR 351.224(e) and (f), Commerce is amending the *Final Determination* to reflect the correction of a ministerial error in the final estimated weighted-average dumping margin calculated for Fujian Yinfeng Imp & Exp Trading Co., Ltd./Fujian Province Youxi City Mangrove Wood Machining Co., Ltd. (Yinfeng/Mangrove).[5] In addition, because Yinfeng/Mangrove's estimated weighted-average dumping margin is the basis for the estimated weighted-average dumping margins for 42 non-selected separate rate companies, and its highest transaction margin is the basis for the estimated weighted-average dumping margin determined for the China-wide entity, we are also revising the estimated weighted-average dumping margins for the separate rate companies and the China-wide entity rate in the *Final Determination.*[6]

Antidumping Duty Order

On February 10, 2021, in accordance with section 735(d) of the Act, the ITC notified Commerce of its final determination in this investigation, in

[1] *See Wood Mouldings and Millwork Products from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 86 FR 63 (January 4, 2021) (*Final Determination*).

[2] *See* Coalition of American Millwork Producers' Letter, ''Wood Mouldings and Millwork Products from the People's Republic of China: Ministerial Error Comments,'' dated January 5, 2021.

[3] *See* ITC Notification Letter, Investigations, Inv. Nos. 701–TA–636 and 731–TA–1470 (Final) (February 10, 2021) (ITC Notification Letter).

[4] *See* section 735(e) of the Act; *see also* 19 CFR 351.224(f).

[5] *See* Memorandum, ''Final Determination of Sales at Less-Than-Fair-Value: Wood Mouldings and Millwork Products from the People's Republic of China: Ministerial Error Allegations,'' dated January 11, 2021 (Ministerial Error Memorandum).

[6] *See infra,* section on ''Estimated Weighted-Average Dumping Margins''; *see also* Ministerial Error Memorandum.

which it found that an industry in the United States is materially injured by reason of imports of millwork products from China.[7] In accordance with section 735(c)(2) of the Act, Commerce is issuing this antidumping duty order. Because the ITC determined that imports of millwork products from China are materially injuring a U.S. industry, unliquidated entries of such merchandise from China, 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 millwork products from China. With the exception of entries occurring after the expiration of the provisional measures period and before publication of the ITC's final affirmative injury determinations, as further described below, antidumping duties will be assessed on unliquidated entries of millwork products from China entered, or withdrawn from warehouse, for consumption, on or after August 12, 2020, the date of publication of the *Preliminary Determination*.[8]

Continuation of Suspension of Liquidation

Except as noted in the ''Provisional Measures'' section of this notice, in accordance with section 735(c)(1)(B) of the Act, Commerce will instruct CBP to continue to suspend liquidation on all relevant entries of millwork products from China. These instructions suspending liquidation will remain in effect until further notice.

Commerce will also instruct CBP to require cash deposits equal to the estimated weighted-average dumping margins indicated in the table below, adjusted by the export subsidy offset. Given that the provisional measures period has expired, as explained below, effective on the date of publication in the **Federal Register** of the notice of the ITC's final affirmative injury determination, CBP must require, at the same time as importers would deposit estimated normal customs duties on this merchandise, a cash deposit equal to the rates noted below.[9]

The China-wide entity rate applies to all exporter-producer combinations not specifically listed.

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. At the request of exporters that account for a significant proportion of millwork products from China, Commerce extended the four-month period to six months in this investigation. Commerce published the *Preliminary Determination* in this investigation on August 12, 2020.[10]

The extended provisional measures period, beginning on the date of publication of the *Preliminary Determination,* ended on February 8, 2021. Therefore, in accordance with section 733(d) of the Act and our practice,[11] Commerce will instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, unliquidated entries of millwork products from China entered, or withdrawn from warehouse, for consumption after February 8, 2021, the final day on which the provisional measures were in effect, until and 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 determination in the **Federal Register**.

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margins are as follows:

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Fujian Yinfeng Imp & Exp Trading Co., Ltd./Fujian Province Youxi City Mangrove Wood Machining Co., Ltd.	Fujian Yinfeng Imp & Exp Trading Co., Ltd./Fujian Province Youxi City Mangrove Wood Machining Co., Ltd.	45.49	34.76
Anji Golden Elephant Bamboo Wooden Industry Co., Ltd.	Anji Golden Elephant Bamboo Wooden Industry Co., Ltd.	45.49	34.76
Anji Huaxin Bamboo & Wood Products Co., Ltd	Anji Huaxin Bamboo & Wood Products Co., Ltd	45.49	34.76
Cao County Hengda Wood Products Co., Ltd	Cao County Hengda Wood Products Co., Ltd	45.49	34.76
Evermark (Yantai) Co., Ltd	Evermark (Yantai) Co., Ltd	45.49	34.76
Fujian Hongjia Craft Products Co., Ltd	Fujian Hongjia Craft Products Co., Ltd	45.49	34.76
Fujian Jinquan Trade Co., Ltd	Fujian Province Youxi County Baiyuan Wood Machining Co., Ltd.	45.49	34.76
Fujian Nanping Yuanqiao Wood Industry Co., Ltd	Fujian Nanping Yuanqiao Wood Industry Co., Ltd	45.49	34.76
Fujian Province Youxi County Chang Sheng Wood Machining Co., Ltd.	Fujian Province Youxi County Chang Sheng Wood Machining Co., Ltd.	45.49	34.76
Fujian Sanming City Donglai Wood Co., Ltd	Fujian Sanming City Donglai Wood Co., Ltd	45.49	34.76
Fujian Shunchang Shengsheng Wood Industry Limited Company.	Fujian Shunchang Shengsheng Wood Industry Limited Company.	45.49	34.76
Fujian Wangbin Decorative Material Co., Ltd	Fujian Wangbin Decorative Material Co., Ltd	45.49	34.76

[7] *See* ITC Notification Letter.

[8] *See Wood Mouldings and Millwork Products from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures,* 85 FR 48669 (August 12, 2020) (*Preliminary Determination*).

[9] *See* section 736(a)(3) of the Act.

[10] *See Preliminary Determination.*

[11] *See, e.g., Certain Corrosion-Resistant Steel Products from India, Italy, the People's Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders,* 81 FR 48390, 48392 (July 25, 2016).

Exporter	Producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Fujian Youxi Best Arts & Crafts Co., Ltd	Fujian Ruisen International Industrial Co., Ltd	45.49	34.76
Fujian Zhangping Kimura Forestry Products Co., Ltd	Fujian Zhangping Kimura Forestry Products Co., Ltd	45.49	34.76
Heze Huasheng Wooden Co., Ltd	Heze Huasheng Wooden Co., Ltd	45.49	34.76
Huaan Longda Wood Industry Co., Ltd	Huaan Longda Wood Industry Co., Ltd	45.49	34.76
Jiangsu Chen Sheng Forestry Development Co., Ltd	Jiangsu Chen Sheng Forestry Development Co., Ltd	45.49	34.76
Jiangsu Wenfeng Wood Co., Ltd	Jiangsu Wenfeng Wood Co., Ltd	45.49	34.76
Lanzhou Xinyoulian Industrial Co., Ltd	Lanzhou Xinyoulian Industrial Co., Ltd	45.49	34.76
Lianyungang Tianke New Energy Technology Co., Ltd	Lianyungang Tianke New Energy Technology Co., Ltd	45.49	34.76
Longquan Jiefeng Trade Co., Ltd	Zhejiang Senya Board Industry Co., Ltd	45.49	34.76
Nanping Huatai Wood & Bamboo Co., Ltd	Nanping Huatai Wood & Bamboo Co., Ltd	45.49	34.76
Nanping Qiangmei Import & Export Co., Ltd	Pucheng County Qiangmei Wood Company, Ltd	45.49	34.76
Oppein Home Group Inc	Oppein Home Group Inc	45.49	34.76
Putian Yihong Wood Industry Co., Ltd	Putian Yihong Wood Industry Co., Ltd	45.49	34.76
Qimen Jianxing Bamboo and Wood Goods Co., Ltd	Qimen Jianxing Bamboo and Wood Goods Co., Ltd	45.49	34.76
Qingdao Sanhe Dacheng International Trade Co., Ltd	Yongan Tenlong Bamboo & Wood Products Co., Ltd	45.49	34.76
Rizhao Duli Trade Co., Ltd	Rizhao Jiayue Industry & Trading Co., Ltd	45.49	34.76
Rizhao Guantong Woodworking Co., Ltd	Shouguang Luli Wood Industry Co., Ltd./Rizhao Forest International Trading Co., Ltd./Xiamen Oubai Industry & Trade Co., Ltd.	45.49	34.76
Sanming Lingtong Trading Co., Ltd	Sanming Shitong Wood Industry Co., Ltd	45.49	34.76
Shandong Miting Household Co., Ltd	Shandong Jicheng Decorative Material Co., Ltd	45.49	34.76
Shaxian Hengtong Wood Industry Co., Ltd	Shaxian Hengtong Wood Industry Co., Ltd	45.49	34.76
Shaxian Shiyiwood, Ltd	Shaxian Shiyiwood, Ltd	45.49	34.76
Shuyang Kevin International Co., Ltd	Shuyang Zhongding Decoration Materials Co., Ltd	45.49	34.76
Suqian Sulu Import & Export Trading Co., Ltd	Suqian Sulu Import & Export Trading Co., Ltd	45.49	34.76
The Ancientree Cabinet Co., Ltd	The Ancientree Cabinet Co., Ltd	45.49	34.76
Xiamen Jinxi Building Material Co., Ltd	Zhangzhou City Jinxi Building Material Co., Ltd	45.49	34.76
Xuzhou Goodwill Resource Co., Ltd	Pucheng County Qiangmei Wood Company, Ltd./Lianyungang Tianke New Energy Technology Co., Ltd./Fujian Sanming City Donglai Wood Co., Ltd./Zhangzhou Fukangyuan Industry and Trade Co., Ltd.	45.49	34.76
Xuzhou Hexi Wood Co., Ltd	Xuzhou Hexi Wood Co., Ltd	45.49	34.76
Zhangping San Chuan Industrial & Trade Co., Ltd	Zhangping San Chuan Industrial & Trade Co., Ltd	45.49	34.76
Zhangzhou Green Wood Industry and Trade Co., Ltd	Zhangzhou Green Wood Industry and Trade Co., Ltd	45.49	34.76
Zhangzhou Wangjiamei Industry and Trade Co., Ltd	Zhangzhou Wangjiamei Industry and Trade Co., Ltd	45.49	34.76
Zhangzhou Yihong Industrial Co., Ltd	Zhangzhou Yihong Industrial Co., Ltd	45.49	34.76
China-Wide Entity		231.60	220.87

Notification to Interested Parties

This notice constitutes the antidumping duty order with respect to millwork products from China pursuant to section 736(a) of the Act. Interested parties can find a list of antidumping duty orders currently in effect at *http://enforcement.trade.gov/stats/iastats1.html.*

This amended final determination and antidumping duty order are published in accordance with sections 735(e) and 736(a) of the Act and 19 CFR 351.224(e) and 19 CFR 351.211(b).

Dated: February 10, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix—Scope of the Order

The merchandise subject to this order consists of wood mouldings and millwork products that are made of wood (regardless of wood species), bamboo, laminated veneer lumber (LVL), or of wood and composite materials (where the composite materials make up less than 50 percent of the total merchandise), and which are continuously shaped wood or finger-jointed or edge-glued moulding or millwork blanks (whether or not resawn). The merchandise subject to this order can be continuously shaped along any of its edges, ends, or faces.

The percentage of composite materials contained in a wood moulding or millwork product is measured by length, except when the composite material is a coating or cladding. Wood mouldings and millwork products that are coated or clad, even along their entire length, with a composite material, but that are otherwise comprised of wood, LVL, or wood and composite materials (where the non-coating composite materials make up 50 percent or less of the total merchandise) are covered by the scope.

The merchandise subject to this order consists of wood, LVL, bamboo, or a combination of wood and composite materials that is continuously shaped throughout its length (with the exception of any endwork/dados), profiled wood having a repetitive design in relief, similar milled wood architectural accessories, such as rosettes and plinth blocks, and finger-jointed or edge-glued moulding or millwork blanks (whether or not resawn). The scope includes continuously shaped wood in the forms of dowels, building components such as interior paneling and jamb parts, and door components such as rails, stiles, interior and exterior door frames or jambs (including split, flat, stop applied, single- or double-rabbeted), frame or jamb kits, and packaged door frame trim or casing sets, whether or not the door components are imported as part of a door kit or set.

The covered products may be solid wood, laminated, finger-jointed, edge-glued, face-glued, or otherwise joined in the production or remanufacturing process and are covered by the scope whether imported raw, coated (*e.g.,* gesso, polymer, or plastic), primed, painted, stained, wrapped (paper or vinyl overlay), any combination of the aforementioned surface coatings, treated, or which incorporate rot-resistant elements (whether wood or composite). The covered products are covered by the scope whether or not any surface coating(s) or covers obscure the grain, textures, or markings of the wood, whether or not they are ready for use or require final machining (*e.g.,* endwork/dado,

hinge/strike machining, weatherstrip or application thereof, mitre) or packaging.

All wood mouldings and millwork products are included within the scope even if they are trimmed; cut-to-size; notched; punched; drilled; or have undergone other forms of minor processing.

Subject merchandise also includes wood mouldings and millwork products that have been further processed in a third country, including but not limited to trimming, cutting, notching, punching, drilling, coating, or any other processing that would not otherwise remove the merchandise from the scope of this order if performed in the country of manufacture of the in-scope product.

Excluded from the scope of this order are countertop/butcherblocks imported as a full countertop/butcherblock panel, exterior fencing, exterior decking and exterior siding products (including solid wood siding, non-wood siding (*e.g.,* composite or cement), and shingles) that are not LVL or finger jointed; finished and unfinished doors; flooring; parts of stair steps (including newel posts, balusters, easing, gooseneck, risers, treads, rail fittings and stair stringers); picture frame components three feet and under in individual lengths; and lumber whether solid, finger-jointed, or edge-glued. To be excluded from the scope, finger-jointed or edge-glued lumber must have a nominal thickness of 1.5 inches or greater and a certification stamp from an American Lumber Standard Committee-certified grading agency. The exclusion for lumber whether solid, finger-jointed, or edge-glued does not apply to screen/''surfaced on 4 sides'' (S4S) and/or ''surface 1 side, 2 edges'' (SlS2E) stock (also called boards) that are finger-jointed and/or edge-glued, or to finger-jointed and/or edge-glued moulding or millwork blanks (whether or not resawn). Accordingly, S4S and S1S2E stock/boards that are not finger-jointed or edge glued are excluded from the scope of this order.

Excluded from the scope of this order are all products covered by the scope of the antidumping duty order on *Hardwood Plywood from the People's Republic of China. See Certain Hardwood Plywood Products from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 83 FR 504 (January 4, 2018).

Excluded from the scope of this order are all products covered by the scope of the antidumping duty order on *Multilayered Wood Flooring from the People's Republic of China. See Multilayered Wood Flooring from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 76 FR 76690 (December 8, 2011).

Excluded from the scope of this order are all products covered by the scope of the antidumping duty order on *Wooden Cabinets and Vanities from the People's Republic of China. See Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Antidumping Duty Order,* 85 FR 22126 (April 21, 2020).

Excluded from the scope of this order are all products covered by the scope of the antidumping duty order on *Wooden Bedroom Furniture from the People's Republic of China. See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture from the People's Republic of China,* 70 FR 329 (January 4, 2005).

Imports of wood mouldings and millwork products are primarily entered under the following Harmonized Tariff Schedule of the United States (HTSUS) numbers: 4409.10.4010, 4409.10.4090, 4409.10.4500, 4409.10.5000, 4409.22.4000, 4409.22.5000,4409.29.4100, and 4409.29.5100. Imports of wood mouldings and millwork products may also enter under HTSUS numbers: 4409.10.6000,4409.10.6500, 4409.22.6000, 4409.22.6500, 4409.29.6100, 4409.29.6600, 4418.20.4000, 4418.20.8030, 4418.20.8060, 4418.99.9095 and 4421.99.9780. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

[FR Doc. 2021–03151 Filed 2–12–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA872]

Endangered and Threatened Species; Take of Abalone

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

ACTION: Notice; receipt of application to renew one scientific research permit.

SUMMARY: Notice is hereby given that NMFS has received a request to renew an existing scientific research permit relating to black abalone. The proposed work is intended to increase knowledge of species listed under the Endangered Species Act (ESA) and to help guide management, conservation, and recovery efforts. The application may be viewed online at: *https://apps.nmfs.noaa.gov/preview/preview_open_for_comment.cfm.*

DATES: Comments or requests for a public hearing on the application must be received at the provided email address (see **ADDRESSES**) no later than 5 p.m. Pacific standard time on March 18, 2021.

ADDRESSES: Because all West Coast NMFS offices are currently closed, all written comments on the application should be submitted by email to *nmfs.wcr-apps@noaa.gov.* Please include the permit number (19571–2R) in the subject line of the email.

FOR FURTHER INFORMATION CONTACT: Susan Wang, Long Beach, CA (email: *Susan.Wang@noaa.gov*). Permit application instructions are available from the address above, or online at *https://apps.nmfs.noaa.gov.*

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

The following listed species are covered in this notice:

Endangered black abalone (*Haliotis cracherodii*).

Background

Permit 19571–2R

The NMFS Southwest Fisheries Science Center in La Jolla, California, has requested to renew for five years a research permit that currently allows them to hold, breed, and conduct lab studies on captive black abalone. Under the permit, researchers would continue to maintain healthy populations of black abalone in captive facilities throughout California and test broodstock conditioning and spawning methods at the NMFS Southwest Fisheries Science Center.

The main purpose of the proposed research is to support recovery efforts by developing reliable spawning techniques to consistently produce high quality juvenile black abalone. The proposed research would examine:

(1) Broodstock conditioning under different temperatures, diets, and photoperiod regimes;

(2) Broodstock conditioning using hormones and simulated seasonal tidal cycles;

(3) Spawning induction using dessication, thermal shock, hydrogen peroxide treatments, hormones, and seasonal tidal cycles; and

(4) Growth and survival of captively-produced juveniles under different temperatures and diets.

Activities would include captive holding, breeding, rearing, grow-out, lab experiments, epipodial tissue sampling, observation, and transport of black abalone. Black abalone are currently held at the Southwest Fisheries Science Center (SWFSC), the California Department of Fish and Wildlife Shellfish Health Laboratory, and the Monterey Bay Aquarium. The captive animals include pre-listed abalone that have been in captivity since before black abalone were listed as endangered under the ESA. Some of these were confiscated in law enforcement cases and some were collected as part of emergency response activities. Additional wild origin black abalone may be obtained through future confiscations and emergency response

activities that involve live black abalone.

This notice is provided pursuant to section 10(c) of the ESA. NMFS will evaluate the application, associated documents, and comments submitted to determine whether the application meets the requirements of section 10(a) of the ESA and Federal regulations. The final permit decision will not be made until after the end of the 30-day comment period. NMFS will publish notice of its final action in the **Federal Register**.

Authority

Scientific research 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 parts 222–226). NMFS issues permits based on findings that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

Anyone requesting a hearing on the application listed in this notice should set out the specific reasons why a hearing on the application would be appropriate (see **ADDRESSES**). Such hearings are held at the discretion of the Assistant Administrator for Fisheries, NMFS.

Dated: February 9, 2021.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–02987 Filed 2–12–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA873]

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice, receipt of 17 application permit renewals, 2 permit modifications, and 6 new permits.

SUMMARY: Notice is hereby given that NMFS has received 25 scientific research permit application requests relating to Pacific salmon, steelhead, green sturgeon, rockfish, and eulachon. The proposed research is intended to increase knowledge of species listed under the Endangered Species Act (ESA) and to help guide management and conservation efforts. The applications may be viewed online at: *https://apps.nmfs.noaa.gov/preview/preview_open_for_comment.cfm.*

DATES: Comments or requests for a public hearing on the applications must be received at the appropriate address or fax number (see **ADDRESSES**) no later than 5 p.m. Pacific standard time on March 18, 2021.

ADDRESSES: Because all West Coast NMFS offices are currently closed, all written comments on the applications should be sent to by email to *nmfs.wcr-apps@noaa.gov* (please include the permit number in the subject line of the email).

FOR FURTHER INFORMATION CONTACT: Rob Clapp, Portland, OR (ph.: 503–231–2314, fax: 503–230–5441, email: *Robert.Clapp@noaa.gov*). Permit application instructions are available from the address above, or online at *https://apps.nmfs.noaa.gov.*

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

Chinook salmon (*Oncorhynchus tshawytscha*): Threatened Lower Columbia River (LCR); threatened Puget Sound (PS); threatened Snake River (SnkR) spring/summer-run; threatened SnkR fall-run; endangered Upper Columbia River (UCR) spring-run; threatened Upper Willamette River (UWR), threatened Central Valley spring-run (CVS); endangered Sacramento River (SacR) winter-run; threatened California Coastal (CC).

Steelhead (*O. mykiss*): Threatened LCR; threatened Middle Columbia River (MCR); threatened PS; threatened SnkR; threatened UCR; threatened UWR; threatened Northern California (NC); threatened Central California Coast (CCC); threatened California Central Valley (CCV); threatened South-Central California Coast (S–CCC); endangered Southern California (SC).

Chum salmon (*O. keta*): Threatened Hood Canal Summer-run (HCS), threatened Columbia River (CR).

Coho salmon (*O. kisutch*): Threatened LCR; threatened Oregon Coast (OC) coho; threatened Southern Oregon/Northern California Coast (SONCC), endangered Central California Coast (CCC).

Sockeye salmon (*O. nerka*): Endangered SnkR.

Eulachon (*Thaleichthys pacificus*): Threatened southern (S).

Green sturgeon (*Acipenser medirostris*): Threatened southern Distinct Population Segment (SDPS).

Rockfish (*Sebastes spp.*): Endangered Puget Sound/Georgia Basin (PS/GB) bocaccio (*Sebastes paucispinis*); threatened PS/GB yelloweye rockfish (*S. ruberrimus*).

Background

1415–5R

The U.S. Fish and Wildlife Service's Red Bluff Office is seeking to renew a permit that allows them to annually take juvenile and adult SacR winter-run and CVS Chinook salmon, adult and juvenile CCV steelhead, and egg, larval, and juvenile SDPS green sturgeon in the Sacramento River and in Clear and Battle Creeks in the Central Valley, California. This permit renewal would cover nine research projects carried out by the U.S. Fish and Wildlife Service Red Bluff office. The names and purposes of the nine studies are: (1) Battle Creek Fish Community Structure Evaluation (Pre/Post-Restoration)—the primary goal of this study is to assess how fish community distribution changes in response to the restoration project. (2) Battle Creek Juvenile Salmonid Monitoring Project—the goal is to monitor annual juvenile production and develop production indices, assess restoration efforts, and gather information on the history and migration of juvenile salmonids. (3) Battle Creek Adult Salmonid Monitoring Project—the purpose is to monitor escapement, migration timing, and population distribution of adult spring run and steelhead. (4) Battle Creek emergence trapping—the purpose is to monitor fry emergence in conjunction with the Battle Creek winter-run Jumpstart Project and Reintroduction Program efforts. (5) Clear Creek Juvenile Salmonid Monitoring Project—the purpose is to monitor juvenile Chinook and steelhead production, size, condition, and environmental data with the goal of information restoration actions in Clear Creek. (6) Clear Creek Fish Restoration Program Monitoring—the purpose is to monitor restored stream channel form and function (*i.e.,* improved water quality and quantity, reduced sedimentation, etc.). (7) Sacramento River Juvenile Fish Monitoring at Red Bluff Diversion Dam (RBDD)—the primary objectives of this project are to (a) obtain juvenile winter Chinook production indices and to correlate these indices with estimated escapement from adult estimates provided by the winter Chinook carcass survey, (b) define seasonal and temporal patterns of abundance of winter, spring,

fall and late-fall run Chinook salmon and steelhead trout passing the RBDD, and (c) obtain relative abundance information for green sturgeon and lamprey to monitor trends in abundance. (8) Life History Studies on the Sacramento River SDPS green sturgeon—the goal is to identify spawning habitat and larval and monitor juvenile rearing and migration movements in the Sacramento River. (9) Sacramento River Winter Chinook Salmon Carcass Survey—the carcass survey would help managers estimate the annual abundance of winter Chinook salmon spawners. Estimates of abundance would be made for both hatchery- and natural-origin fish. The research, a whole, would benefit listed fish by adding greatly to a large number of datasets that managers use to help them survive and recover.

Under the various studies, juvenile salmon would be observed via snorkel surveys and captured using backpack electrofishing, rotary screw traps, emergence traps, trammel nets, and beach seines. In addition, juvenile salmon would be handled (anesthetized, weighed, measured, and checked for marks or tags), and released. A subsample of captured those fish may be anesthetized, tissue sampled and passive integrated transponder (PIT)-tagged prior to release. A small number of juvenile CVS Chinook and CCV steelhead (100 of each) would be sacrificed for otolith sampling and analysis. Adult salmon would be observed via snorkel surveys or spawning surveys and captured using beach seines and fish weirs. Tissues would be collected from any carcasses encountered during snorkel surveys. Juvenile green sturgeon would be captured (benthic trawls, trammel or gill nets), anesthetized, tissue sampled and tagged (PIT or acoustic). Larval green sturgeon would be captured using fyke nets. The same procedures described above would be performed on larvae captured with fyke nets (tagging would be dependent on size). Egg Mats would be used to sample green sturgeon larvae and eggs (eggs and larvae would be sacrificed). With the exception of the juvenile salmon otolith research (above), the researchers are not proposing to kill any of the fish being captured, but a small number of fish may be killed as an inadvertent result of these activities.

1440–3R

The Interagency Ecological Program (IEP) is a consortium of nine state and Federal agencies that work in partnership with non-governmental organizations to provide ecological information and scientific leadership in managing the San Francisco Bay-Delta estuary. The IEP is seeking to renew a permit that allows them to annually take adult and juvenile SacR winter-run and CVS Chinook salmon, CV and CCC steelhead, and SDPS green sturgeon in the San Francisco Bay-Delta Region, California. This permit renewal includes eleven projects.

The names and purposes of the 11 studies are: (1) The Adult Striped Bass Tagging Study—it is designed to quantify the population dynamics of Striped Bass (*Morone saxatilis*) in the San Francisco Estuary and thereby provide metrics to inform science-based resource management decisions. These metrics include relative and absolute abundance, harvest rate, mortality rate, individual growth rates, and large-scale movement/migration patterns. (2) The Fall Midwater Trawl Survey—the study is a fish monitoring survey that provides trends in abundance and distribution of pelagic fish in the upper San Francisco Estuary. (3) The adult Sturgeon Population Tagging Study is designed to quantify the population dynamics of white and green Sturgeon in the San Francisco Estuary and provide metrics to inform science-based resource management decisions. These metrics include relative and absolute abundance, harvest rates, mortality rates, and individual growth rates. (4) The Summer Tow-net Survey is a fish monitoring survey that provides trends in abundance and distribution of young pelagic fish in the upper San Francisco estuary. (5) The San Francisco Bay Study—its purpose is to determine the effects of freshwater outflow on the abundance and distribution of fish and mobile crustaceans in the San Francisco Estuary, primarily downstream of the Sacramento-San Joaquin Delta. (6) The 20-mm Survey is designed to monitor post-larval and juvenile Delta Smelt distribution and relative abundance throughout their historical spring range in the upper San Francisco estuary. (7) The Yolo Bypass Fish Monitoring Program is a monitoring effort designed to help mangers understand fish and invertebrate use in the Yolo Bypass seasonal floodplain/tidal slough habitat. (8) The Zooplankton Study—its purpose is to estimate the abundance of zooplankton taxa and thereby help managers assess trends in fish food resources from the eastern San Pablo Bay area through the eastern Sacramento-San Joaquin Delta and Suisun Marsh. The study is also intended to detect and monitor zooplankton recently introduced to the estuary and determine their effects on native species. (9) The Spring Kodiak Trawl Survey—its purpose is to determine the relative abundance and distribution of adult Delta Smelt in the San Francisco Bay area and identify the onset of spawning. (10) The Suisun Marsh Survey is designed to determine effects of the Suisun Marsh Salinity Control Gates operation (as well as other anthropogenic habitat changes) and monitor presence and abundance for juvenile striped bass, Chinook salmon, and other species of concern. (11) The Smelt Larva Survey is intended to provide near real-time distribution data for Longfin Smelt larvae in the upper San Francisco Estuary. The data generated from this study would be used to help improve the effectiveness of water operations, aquatic habitat restoration, and fish management practices. The research, as a whole, would benefit fish by adding greatly to the knowledge base that state, private, and Federal managers depend on to help them make decisions about the best ways in which resources can be allocated to help listed species recover.

Under the various projects juvenile salmon would be captured (via fyke nets, gill nets, midwater trawls, trammel nets, hoop nets, otter trawls, larval fish nets, zooplankton nets, Kodiak trawl nets, rotatory screw traps, and beach seine), handled, and released. A small subset of the juvenile fish would be captured, anesthetized, measured, weighed, tagged, tissue sampled, and released. Adult salmon would be captured (via fyke nets, midwater trawls, trammel nets, hoop nets, otter trawls, Kodiak trawl nets, and beach seines), handled, and released. A small subset of adult salmon would be captured, anesthetized, measured, weighed, tagged, tissue sampled and released. Under three of the projects (Studies 5, 7, and 9) some adipose-clipped, artificially propagated juvenile spring- and winter-run Chinook salmon would intentionally be sacrificed to collect coded wire tags (the data from which would be used for management purposes). In addition, adult green sturgeon would be captured (fyke net, trammel net, midwater trawl, otter trawl), handled, and released. A subset of juvenile and adult greens sturgeon would be captured, anesthetized, measured, weighed, tagged, tissue sampled, and released. With the exception of the directed mortality of adipose-clipped juvenile salmon (above), the researchers are not proposing to kill any of the fish being captured, but a small number of juveniles may be killed as an inadvertent result of these activities.

13675–3R

The Fishery Foundation of California is seeking to renew a permit that currently allows them to annually take juvenile SacR winter-run and CVS Chinook salmon, juvenile CV steelhead, and juvenile SDPS green sturgeon in the Sacramento River, CA. Juvenile salmon and green sturgeon would be captured (via beach seines and fyke nets), handled, and released. The purpose of this research is to evaluate salmon presence and habitat in flood plain areas. The data generated from this research would benefit listed fish by helping managers design, implement, and manage riparian habitat sites along the Sacramento River for the purpose of helping anadromous salmonids recover. The researchers are not proposing to kill any of the fish being captured, but a small number of juveniles may be killed as an inadvertent result of these activities.

15486–3R

West Fork Environmental is seeking to renew a previously held permit that in its new iteration would allow them to capture and handle juvenile UCR Chinook salmon, LCR Chinook salmon, UWR Chinook salmon, SnkR spr/sum Chinook, SnkR fall Chinook, PS Chinook salmon, LCR coho salmon, OC coho salmon, UCR steelhead, SnkR steelhead, MCR steelhead, LCR steelhead, UWR steelhead, and PS steelhead during the course of headwater stream surveys over wide parts of Oregon and Washington. The purpose of the research is to provide owners of industrial forest lands and state lands managers with accurate maps of where threatened and endangered salmonids are found. The work would benefit the salmon and steelhead by helping land managers plan and carry out their activities in ways that would have the smallest effect possible on the listed fish. The researchers would use backpack electrofishing equipment to capture the fish. After capture, the fish would be swiftly released without tagging or even handling more than is necessary to ensure that they have recovered from the effects of being captured. The West Fork Environmental researchers do not intend to kill any listed salmonids, but a small number may die as an unintended result of the activities.

15549–3R

The Columbia River Inter-Tribal Fish Commission (CRITFC) is seeking a 5-year permit to expand on and extend work previously conducted under other research permits (Permits 1532 and 15549–2R). The research would take place in Satus, Ahtanum, Naches, and Toppenish Creeks in Washington State. The researchers wish to take juvenile MCR steelhead during the course of research designed to determine the fishes' freshwater movements and examine how those movements are affected by the area's substantially altered hydrograph. They would also collect baseline information on stock status and yearly abundance and seek to determine whether repeat spawners from a kelt reconditioning program run by the Confederated Bands and Tribes of the Yakama Nation are successfully reproducing.

The fish would be captured (via screw traps and backpack electrofishing equipment) and then be anesthetized and measured. Some would be tissue-sampled for DNA and aging purposes and some would receive PIT tags. The information gathered would be used to determine the fishes' movements and abundance and monitor the ongoing status of the various MCR steelhead populations in the Yakima River subbasin. The research would benefit the fish by helping managers determine the effectiveness of current recovery measures and design new ones where needed. The researchers do not plan to kill any of the fish being captured, but a few may die as an unintentional result of the research.

15611–3R

The Washington Department of Fish and Wildlife is seeking to renew a permit that allows it to take adult LCR Chinook salmon, LCR steelhead, LCR coho salmon, and CR chum salmon while operating a fish collection facility on the North Fork Toutle River in Washington State. The fish collection facility is located at river mile 47.5, approximately 1.3 miles (about 2.1 km) downstream from the Mount St. Helens Sediment Retention Structure. The purpose of the project is to trap and haul salmon and steelhead around the sediment retention structure. The Washington Department of Fish and Wildlife would also collect scientific information and tag a portion of the fish to monitor migration patterns and spawning success. The activities' primary benefit would be to allow listed salmon and steelhead to spawn in historically accessible habitat upstream of the sediment retention structure. Also, researchers would collect information that would increase our understanding of the various species' spawning habits. The Washington Department of Fish and Wildlife proposes to operate the trap several days a week during the species' upstream migration. Captured fish would be transported in a tanker truck and released upstream of the sediment retention structure. The Washington Department of Fish and Wildlife does not intend to kill any fish being captured but some may die as an unintentional result of the activities.

16274–2R

The Mendocino Redwood Company (MRC) is seeking to renew a permit that currently allows them to annually take adult and juvenile CCC Chinook, CCC steelhead, SONCC coho, and CCC coho salmon in Mendocino and Northern Sonoma Counties on Mendocino Redwood Company lands. Adult fish would be observed and tissue samples would be collected from carcasses found during spawning surveys. Juvenile salmon would be observed via snorkel surveys and captured (via backpack electrofishing and screw traps), anesthetized, weighed, measured, and released. A small subset of juvenile fish would be captured, marked (dye, elastomer, or fin clip), PIT-tagged, tissue sampled, and released. The purpose of the research is to assess juvenile and adult distribution and population structure in streams on MRC's property. The data gathered in these studies would benefit listed fish by helping MRC better understand salmonid distribution, abundance, and habitat use in these areas—and thereby design and carry out their management activities in the most fish-friendly way possible. The researchers are not proposing to kill any of the fish being captured, but a small number of juveniles may be killed as an inadvertent result of these activities.

16290–4R

The Oregon Department of Fish and Wildlife (ODFW) is seeking to renew permit that allows it to take juvenile UWR Chinook salmon, UWR steelhead, LCR Chinook salmon, LCR steelhead, LCR coho salmon, and CR chum salmon while conducting research on the Oregon chub. The purpose of the research is to study the distribution, abundance, and factors limiting the recovery of Oregon chub. The Oregon chub is endemic to the Willamette Valley of Oregon and the habitats it depends on are important to salmonids. Research on the Oregon chub would benefit listed salmonids by helping managers recover habitats that the species share. The ODFW researchers would use boat electrofishing equipment, minnow traps, beach seines, dip nets, hoop nets, and fyke nets to capture juvenile fish. Once the fish are captured, they would swiftly be counted, allowed to recover, and then

released back to the sites of their capture. Researchers would avoid contact with adult fish at all times. If listed salmonids are captured during the research they would be released before processing any other fish. The researchers do not expect to kill any listed salmonids but a small number may die as an unintended result of the research activities.

17077–3R

The Center for Watershed Sciences at the University of California at Davis, is seeking to renew a permit that currently allows them to annually take adult and juvenile SacR winter-run and CVS Chinook salmon, CCV steelhead and SDPS green sturgeon in the Sacramento-San Joaquin Delta and Suisun Marsh in the Central Valley, CA. The project specifically targets splittail and other native minnow populations, however ESA-listed species may be taken as well. Juvenile fish would be captured (via otter trawling, beach seining, and electrofishing), handled and released. Adult fish would also be captured (via otter trawling, beach seining), handled, and released. The purpose of this project is to better understand how physical habitats, flow, and other factors interact to maintain assemblages of native and non-native aquatic species in the upper San Francisco estuary. This study would benefit listed fish by providing knowledge about food webs and the habitats that support them. It would improve our ability to create and restore additional habitat and help managers anticipate the effects of drought, climate change, sea level rise, increased temperatures, and changing hydrologic conditions. The researchers are not proposing to kill any of the fish being captured, but a small number of juveniles may be killed as an inadvertent result of these activities.

17219–3R

NMFS's Southwest Fisheries Science Center, Fisheries Ecology Division, is seeking to renew a permit that currently allows them to annually take juvenile and adult CCC, NC and S–CCC steelhead, and CCC and SONCC coho salmon in coastal streams throughout California. Juvenile fish would be captured (via screw trap, backpack electrofishing, beach seines, hook and line fishing, and hand- or dip nets), handled, and released. A subset of the captured fish would be anesthetized, sampled (collection of scales, fin clips, or stomach contents), marked or tagged (using fin clips, PIT tags, pop-off satellite tags, acoustic tags, or radio tags), and released. In limited cases, some juvenile steelhead would be captured and euthanized for otolith ad contaminant analysis. Adult steelhead and coho would be observed via spawning surveys, and tissue samples would be collected from carcasses found during those surveys. Adult steelhead would be captured (at fish ladders and by hook-and-line angling), tagged, tissue sampled, and released.

The purpose of this research is to support conservation and management of ESA-listed anadromous salmonids in California by directly addressing information needs that NMFS and other agencies identify for the benefit of the listed fish. This data collected would be used to elucidate population abundance and dynamics; evaluate factors affecting growth, survival, and life-histories; assess life-stage specific habitat use and movement; inform various types of models (*e.g.,* population, life-cycle, bioenergetics, and habitat-use models); determine genetic structure within populations; evaluate the effects how activities such as water management and habitat restoration affect populations; and develop improved sampling and monitoring methods. With the exception of a small number of juvenile steelhead that would be sacrificed for otolith and contaminant research (above), the researchers are not proposing to kill any of the fish being captured, but a small number of juveniles may be killed as an inadvertent result of these activities.

17351–2R

The Green Diamond Resource Company is seeking to renew a permit that currently allows them to annually take juvenile and adult CC Chinook, SONCC coho, and NC steelhead on Green Diamond lands in the Chetco, Smith, Lower Klamath, Mad-Redwood, and Lower Eel watersheds in Northern California. Adult salmon would be observed during spawning surveys and tissue samples would be collected from carcasses found during those surveys. A small number of adult steelhead may also be captured during screw trapping. Juvenile salmon would be captured (via backpack electrofishing, snorkel surveys, and screw trapping), handled and released. A small subset of juvenile fish would be captured, anesthetized, marked, tagged, tissue sampled and released.

The purpose of this research is to determine fish presence and distribution, monitor timing and abundance of out-migrating salmon, determine population estimates of summer rearing juveniles, and determine habitat use and relative number of spawning adults. The data from this research would be used to benefit listed fish by helping Green Diamond Resource Company minimize the effects that timber harvest activities on their land may have. The researchers are not proposing to kill any of the fish being captured, but a small number of juveniles may be killed as an inadvertent result of these activities.

18696–5M

The Idaho Power company is seeking to modify a 5-year permit that currently allows them to annually capture juvenile and adult SnkR fall Chinook salmon, SnkR spr/sum Chinook salmon, SnkR steelhead, and SnkR sockeye salmon while studying juvenile white sturgeon in and near Lower Granite Reservoir on the Snake River. The permit would be modified by combining it with a similar permit that Idaho Power holds (19846) that currently allows it to take those same species while studying bull trout in much the same area. The total action area of the two permits combined would extend from the confluence of the Snake and Grande Ronde Rivers up to the first of the Hells Canyon Complex of dams. The researchers would use small-mesh gill nets, benthic otter trawls, and hook-and-line angling to capture the fish. The gill net fishing would take place at times (October and November) and in areas (the bottom of the reservoir) that have purposefully been chosen to have the least possible impact on listed fish. When the nets are pulled to the surface, listed species would immediately be released (including by cutting the net, if necessary) and allowed to return to the reservoir. The d-ring fishing would take place in June and July, but the same restrictions (immediately releasing listed fish, etc.) would still apply. The same is true for the otter trawls that would take place solely in July and the angling that would be performed from December-March.

The research targets species that are not listed, but the research would benefit listed salmonids by generating information about the habitat conditions in the Snake River and by helping managers develop conservation plans for the species that inhabit it. The researchers are not proposing to kill any of the fish they capture, but a small number of individuals may be killed as an inadvertent result of the activities.

18908–2R

The Skagit Fisheries Enhancement Group (SFEG) is seeking to renew a permit that allows them to annually take juvenile PS Chinook salmon and PS steelhead while conducting research to monitor how fish use side-channel habitat in floodplain and tributaries of

the Skagit River in Washington. Fish would be captured by beach seine, handled (weighed, measured, and checked for marks or tags), and released. The purpose of the research is to assess juvenile salmonid habitat use and relative abundance in off-channel areas and thereby help improve efforts to increase access to off-channel areas and enhance rearing habitat quality in those areas. The SFEG would use the data to identify sites in need of restoration, target enhancement efforts, confirm post-project effectiveness, and guide future projects so that ongoing work can focus on appropriate areas and help create conditions that provide high quality rearing habitat. The project also aims to educate the public on the importance of floodplain habitat restoration for juvenile salmonids, and would contribute data to other regional research projects currently evaluating the role of off-channel habitats in salmonid growth and development. The researchers are not proposing to kill any fish they capture, but a small number of juvenile salmon and steelhead may be killed as an inadvertent result of these activities.

19320–2R

NMFS's Southwest Fisheries Science Center is seeking to renew a permit that currently allows them to annually take listed salmonids while conducting research designed to: (1) Determine the inter-annual and seasonal variability in growth, feeding, and energy status among juvenile salmonids in the coastal ocean off northern and central California; (2) determine migration paths and spatial distribution among genetically distinct salmonid stocks during their early ocean residence; (3) characterize the biological and physical oceanographic features associated with juvenile salmon ocean habitat from the shore to the continental shelf break; (4) identify potential links between coastal geography, oceanographic features, and salmon distribution patterns; and (5) identify and test ecological indices for salmon survival. The renewed permit would allow the researchers to take juvenile and subadult CC Chinook, CVS Chinook, LCR Chinook, SacR winter-run Chinook, SnkR spr/sum Chinook, CCC coho, SONCC coho, CCV steelhead, CCC steelhead, and NC steelhead.

This research would benefit listed fish by informing comprehensive lifecycle models that incorporate both freshwater and marine conditions and seek to account for the relationship between the two habitats. The data would also be used to identify and predict sources of salmon mortality at sea and thereby help managers develop indices of salmonid survival in the marine environment. Listed fish would be captured primarily via surface trawling, however beach seining would be used occasionally as would hook-and-line microtrolling. Subadult salmonids (*i.e.,* fish larger than 250 mm) that survive capture would have fin tissue and scale samples taken, and then be released. During the trawling operations, any subadult salmonids that do not survive capture, and all juvenile salmonids (*i.e.,* fish larger than 80 mm but less than 250 mm) would be lethally sampled (sacrificed) in order to collect (1) otoliths for age and growth studies; (2) coded wire tags for origin and age of hatchery fish; (3) muscle tissue for stable isotopes and/or lipid assays; (4) stomachs and contents for diet studies; and (5) other tissues including the heart, liver, intestines, pyloric caeca, and kidney for special studies upon request. For the other types of capture, some of the fish may be tissue sampled, tagged, and released (particularly adults), though some juveniles would still be lethally sampled for the reasons just described. In all cases, whenever a fish dies simply as a result of being captured, that fish would be used in place of an intentional mortality (that is, instead of a fish that would otherwise be sacrificed).

19738–2R

The Washington Department of Natural Resources (DNR) is seeking to renew a permit that allows them to annually take juvenile PS Chinook salmon and PS steelhead while conducting research in headwater streams on DNR-managed lands that drain into Puget Sound. Juvenile fish would be detected via backpack electrofishing encounters (considered a capture event for this method) and, if stunned, would be netted (dip net) and released in a low gradient stream segment or pool and allowed to recover. The purpose of this research is to determine fish presence in small streams on state-managed lands to ensure that those streams are appropriately typed, adequately protected with riparian management zones (RMZs), and adequately restored (*e.g.,* via removal of man-made structures that limit or restrict fish passage to upstream habitat). Data generated by this proposal would benefit listed fish by informing land management decision-making (*e.g.,* RMZ width, culvert replacement/sizing), and it would also be submitted to DNR Forest Practices division to improve the existing stream type geographic information systems database. The researchers are not proposing to kill any fish captured, but a small number of juveniles may be killed as an inadvertent result of these activities.

19741–2R

The Yakama Nation is seeking a 5-year permit to annually take juvenile, natural MCR steelhead during the course of a research project designed to assess their current abundance in the Rock Creek watershed in south central Washington. Under the permit, the researchers would employ backpack electrofishing to capture a number of juvenile MCR steelhead. Some of those fish would be tagged with PIT-tags, and some would be tissue-sampled, but most would simply be handled and released. The researchers would work primarily in five reference areas (reaches) and they would use mark/recapture techniques to study juvenile development and movement in Rock Creek. They would also conduct some boat electrofishing in the inundated pool downstream from the research area in Rock Creek—primarily to look at predator abundance. In addition, the researchers would take tissue samples from dead adults during spawning ground surveys. The purpose of the research is to assess the current distribution and relative abundance of MCR steelhead in selected portions of Rock Creek. That information would be integrated with information being collected on other ecological parameters and the researches would use that information as a whole to determine species status in the system and evaluate the effectiveness of several habitat restoration actions that have been going on there for a number of years. This research would benefit listed steelhead in that it would be used by fish managers such as the Rock Creek Subbasin Recovery Planning Group to prioritize to plan restoration, protection, and recovery actions for Rock Creek steelhead.

22482–2R

NMFS's Northwest Fisheries Science Center (NWFSC) is seeking to renew for 5 years a permit that currently allows them to take juvenile LCR, SnkR fall-run, UCR spring-run, and UWR Chinook salmon; CR chum salmon; LCR coho salmon; SnkR sockeye salmon; and LCR, MCR, SnkR basin, UCR, and UWR steelhead. The purpose of the study is to measure contaminant levels in resident sculpin in the lower Willamette River (Oregon) near a Superfund site with high levels of pollutants. The target species for sampling, prickly sculpin, is benthic-feeding and has a small home range, thus contaminant analysis of its tissues reflects environmental

conditions at a localized area. Listed salmonids could be unintentionally captured during sampling activities. The study results would support an ongoing Natural Resource Damage Assessment, the purpose of which is to document and quantify injuries to natural resources resulting from exposure to hazardous substances. The proposed research study would benefit listed species by improving managers' understanding of the extent of contamination in the studied habitats and informing habitat restoration activities.

The researchers propose to collect fish between river miles 2 and 11 of the Willamette River, and at appropriate reference sites nearby in the Lower Willamette River. The researchers would conduct sampling from August through October. The researchers would use vinyl-coated wire shrimp traps with 1.0 cm x 0.5 cm openings and baited with canned meat and bait scent. Any listed salmonids that are unintentionally captured would be transferred to buckets of aerated water, identified, counted, checked for fin clips, passive integrated transponder, and coded wire tags, and then swiftly released near the site of capture.

23029–2R

The NWFSC is seeking to renew a permit that allows them to annually take juvenile PS/GB bocaccio rockfish and yelloweye rockfish, juvenile PS steelhead, and juvenile and adult PS Chinook salmon and SDPS eulachon in several river estuaries and bays of South Puget Sound, Washington. Fish would be captured via beach seine or otter trawl, handled (identified, measured, checked for marks or tags), and released. The goal of this research is to sample juvenile English sole and juvenile starry flounder and use the study results to support an ongoing Natural Resource Damage Assessment—the purpose of which is to document and quantify injuries to natural resources resulting from exposure to hazardous substances. The proposed research study would benefit listed species by improving managers' understanding of the extent of contamination in the studied habitats and helping inform habitat restoration activities.

The researchers are not targeting any ESA-listed fish for capture as part of this research, but juveniles and adults may be unintentionally captured. The work would benefit listed species by helping guide habitat restoration activities in the Puget Sound. The researchers are also not proposing to kill any ESA-listed fish, but a small number may be killed as an inadvertent result of these activities.

23649–2M

Mount Hood Environmental is seeking to modify a 5-year permit that currently allows them to annually take juvenile MCR steelhead from a non-essential experimental population (NEP) in the Crooked River (Deschutes River watershed) in central Oregon. They are seeking to modify the permit by slightly increasing the take they are allotted, and the reason for this request is that new information has come to light indicating that there may be more steelhead present in the action area than previously believed. The researchers would use backpack electrofishing units and screw traps to capture the fish, which would then be measured, weighed, checked for marks and tags, allowed to recover, and released back to the river. A subsample of the captured fish may also be tissue-sampled for genetic assays. The purpose of the research is to establish baseline population information (presence, abundance, density, etc.) on MCR steelhead and native redband trout in the vicinity of Bowman Dam, on the Crooked River.

As noted above, the MCR steelhead that currently occupy the action area are technically part of an NEP. Taking members of this population for scientific purposes is permitted by regulation at 50 CFR 223.301 but, for the sake of analysis, they are considered part of the listed MCR steelhead DPS. The reason for that is that the NEP will expire on January 15, 2025—at which point the population will simply be considered part of the MCR steelhead DPS (although it should be noted the NEP abundance is not currently counted along with the rest of the DPS). The proposed work would benefit the species by helping managers maintain and operate Bowman Dam (and a possible new hydroelectric turbine proposed for construction there) in the most fish-friendly manner possible. The researchers do not intend to kill any of the fish being captured, but a small number may die as an unintended result of the activities

Permit 24151

The U.S. Forest Service is seeking a 5-year permit that would allow them to take juvenile OC coho salmon during the course of research intended to help managers understand how juvenile coho salmon continue to thrive in a coastal lake currently containing resident populations of trophy predatory fishes (Tahkenitch Lake, Oregon). The researchers would use beach seines, minnow traps, and backpack electrofishing to capture fish in the tributaries to the lake and boat seines, beach seines, and hook-and-line fishing with barbless hooks in the lake and along the lake margins. The purpose of the research is to document coho salmon habitat shifts (seasonal and otherwise) and determine when and where predation by bass is occurring. The captured fish would be sedated and then weighed and measured. The fish would then be allowed to recover and be released back to the sites of their capture. The proposed work would benefit the species by helping managers better understand species interaction in critical coastal lake habitat and thereby help them take measures to promote coho salmon recovery. The researchers do not intend to kill any of the fish being captured, but a small number may die as an inadvertent result of the proposed activities.

24255

The California Department of Fish and Wildlife, Fish Restoration Program, is seeking a new 5-year permit that would allow them to annually take juvenile and adult SacR winter-run and CVS Chinook salmon, CCV steelhead, and SDPS green sturgeon in the Sacramento-San Joaquin Delta including Suisun Marsh and Grizzly Bay. Adult fish would be captured (via otter trawl, lampara seine), handled, and released. Juvenile fish could be captured (via beach seine, otter trawl, lampara seine, zooplankton net, backpack electrofishing) handled, and released. The purpose of this research is to monitor food web dynamics and fish populations before and after restoration and among reference, restored, and pre-restoration sites. This data would be used to assess the effectiveness of habitat restoration with regard to native fish populations and would therefore benefit listed fish by helping improve such restoration activities. The researchers are not proposing to kill any of the fish being captured, but a small number of juveniles may be killed as an inadvertent result of these activities.

24367

NMFS's Northwest Fisheries Science Center is seeking a permit that would allow them to annually take juvenile PS Chinook salmon, PS steelhead, and HC summer-run chum salmon in nearshore areas of the San Juan Islands, Whidbey Island, and in the Central and Southern Puget Sound, Washington. Fish would be captured by lampara seines, handled (weighed, measured, and checked for marks or tags), and released. A subset of juvenile PS Chinook salmon and HC

chum would be intentionally lethally taken (sacrificed) for stable isotope analysis. The purposes of the research are (1) to evaluate how shoreline restoration affects subtidal use of nearshore habitats by fishes—namely salmonids and forage fish, in Puget Sound; and (2) assess the role landscape context (particularly shoreline armoring) plays in influencing these relationships. Data would be used to establish relationships between nearshore subtidal fish abundance and the degree of shoreline development, and fish habitat use data would be incorporated into the existing Beach Strategies database to further inform restoration decisions (and thereby benefit the listed fish). The researchers are proposing to kill a small subset of juvenile ESA-listed PS Chinook salmon and Hood Canal chum salmon captured, and a small number of juveniles of all species may be killed as an inadvertent result of sampling activities.

25409

Researchers from Oregon State University are seeking a 5-year permit that would allow them to document changes in fish community composition, macroinvertebrate community composition, and water quality that result from maintenance activities in agricultural channels. The project comes in response to Oregon State legislation (HB 2437 section 10), and is designed to help managers understand how cleaning and maintenance activities in agricultural ditches affect the ecosystems in those ditches. The researchers would capture fish by electrofishing, minnow traps, and seine nets in 50-meter, closed-off (with mesh block nets) channel sections. Minnow traps would be deployed the afternoon before the sampling day and be checked the following morning before the next capture method is deployed. Seine netting would be used when the site is safely accessible to capture animals that are not easily caught (too large) in minnow traps. Electrofishing would be used after both other methods are completed and would be conducted in a one-pass collecting event. Once collected, the fish would be housed in aerated containers, weighed, measured, and then released back to the sites of their capture. The research would benefit the listed species by helping mangers understand how a common agricultural practices—ditch cleaning and maintenance—affects them and the habitats upon which they depend. The researchers do not intend to kill any of the fish being captured, but some may die as an inadvertent result of the activities.

25463

The Moss Landing Marine Lab is seeing a new 5-year permit that would allow them to annually take adult and juvenile SacR winter-run, CVS, and CC Chinook salmon; SONCC and CCC coho salmon; CCV, CCC, NC, S–CCC and SC steelhead; and SDPS steelhead throughout California. Fish would be captured (via electrofishing, hook-and-line angling, otter trawls, cast nets, beach seines, gill nets, and minnow traps), handled, and released. The Moss Landing Marine Laboratories' Marine Pollution Studies Lab is a primary contributor to the California State Water Board's Surface Water Ambient Monitoring Program's Bioaccumulation Oversight Group. Results from these efforts in streams, rivers, lakes, reservoirs, bays, harbors, and coastal water bodies in California would be used to (1) measure contaminant levels in fish and shellfish over time to track temporal trends and evaluate the effectiveness of management efforts; (2) help managers evaluate contaminant spatial patterns; (3) perform Clean Water Act assessments; and (4) create and update human health advisories and assessments. Fish sampling would occur in California's anadromous and non-anadromous water bodies (streams, rivers, lakes, reservoirs, bays, harbors, and coastal) using various methods of take that would be variably employed to minimize risk to (non-targeted) listed species. Tissue samples would be analyzed for contaminants such as (but not limited to) mercury, metals, selenium, PCBs, legacy pesticides, and contaminants of emerging concern. The research would benefit listed fish by helping managers keep track of contaminants throughout the state and develop response plans accordingly. The researchers are not proposing to kill any of the listed fish being captured, but a small number of juveniles may be killed as an inadvertent result of these activities.

25466

Tim Salamunovich, Senior Fish Biologist for TRPA Fish Biologists, is seeing a new 5-year permit that would allow him to annually take juvenile and adult steelhead in Ulatis Project Flood Control channels in (mainly) channelized portions of Ulatis, New Alamo, Sweeney, Gibson, Canyon, Horse, and McCune creeks in the Lower Sacramento River, CA. Fish would be captured via backpack electrofishing, anesthetized, measured, weighed, tissue sampled, and released. The purpose of this research is to assess fish population responses to managed flows by collecting biological data (lengths, weights, and counts) on the fish populations in order to monitor their distribution and diversity as well as their overall condition and health. The data from this research would be used to update information on the distribution, relative abundance, diversity, and health of fish in Ulatis Project stream channels and would therefore benefit the fish by helping managers operate the channels in as fish-friendly a manner as possible. The researchers are not proposing to kill any of the fish being captured, but a small number of juveniles may be killed as an inadvertent result of these activities.

Authority

Scientific research 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 parts 222–226). NMFS issues permits based on findings that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

Anyone requesting a hearing on an application listed in this notice should set out the specific reasons why a hearing on that application would be appropriate (see **ADDRESSES**). Such hearings are held at the discretion of the Assistant Administrator for Fisheries, NMFS.

Applications Received

This notice is provided pursuant to section 10(c) of the ESA. NMFS will evaluate the applications, associated documents, and comments submitted to determine whether the applications meet 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. NMFS will publish notice of its final action in the **Federal Register**.

Dated: February 9, 2021.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2021–02989 Filed 2–12–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2021–SCC–0020]

Agency Information Collection Activities; Comment Request; Randolph-Sheppard Financial Relief and Restoration Payments Appropriation

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is requesting the Office of Management and Budget (OMB) to conduct an emergency review of a new information collection.

DATES: The Department has requested emergency processing from OMB for this information collection request by February 10, 2021; and therefore, the regular clearance process is hereby being initiated to provide the public with the opportunity to comment under the full comment period. Interested persons are invited to submit comments on or before April 19, 2021.

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–2021–SCC–0020. 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* site is not available to the public for any reason, ED 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 by fax or email and those 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 Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Jesse Hartle, (202) 245–6415.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Randolph-Sheppard Financial Relief and Restoration Payments Appropriation.

OMB Control Number: 1820–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Federal Government.

Total Estimated Number of Annual Responses: 51.

Total Estimated Number of Annual Burden Hours: 51.

Abstract: This is an emergency clearance of a new information collection resulting from enactment of the Consolidated Appropriations Act of 2021, Division H, Title III, Section 318. This provision authorized the Secretary of Education to allot $20,000,000 for one-time financial relief and restoration grants consistent with the purposes of the Randolph-Sheppard Act as authorized under section 10 of such Act (20 U.S.C. 107f). Prior to this legislation, Congress has not appropriated such funds concerning the Randolph-Sheppard Vending Facility Program, as such the Department is seeking this data collection in order to meet its obligation to ensure that Federal funds are being used for their prescribed purposes.

Additional Information: An emergency clearance approval for the use of the system is described below due to the following conditions: If this emergency collection is not approved, ED will be unable to provide the timely awards to SLAs who, in turn, will not be able to provide the financial relief and restoration payments to blind vendors for their losses incurred in 2020 that was mandated by section 318 in a timely manner.

Dated: February 9, 2021.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2021–02990 Filed 2–12–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Nevada

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open virtual meeting.

SUMMARY: This notice announces an online virtual meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Nevada. The Federal Advisory Committee Act requires that public notice of this online virtual meeting be announced in the **Federal Register**.

DATES: Wednesday, March 17, 2021; 4:00 p.m.–6:00 p.m.

ADDRESSES: Online Virtual Meeting. To attend, please send an email to: *nssab@emcbc.doe.gov* by no later than 4:00 p.m. PST on Monday, March 15, 2021.

To Submit Public Comments: Public comments will be accepted via email prior to and after the meeting. Comments received by no later than 4:00 p.m. PST on Monday, March 15, 2021 will be read aloud during the virtual meeting. Comments will also be accepted after the meeting, by no later than 4:00 p.m. PST on Friday, April 2, 2021. Please submit comments to *nssab@emcbc.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Barbara Ulmer, Nevada Site Specific Advisory Board (NSSAB) Administrator, by Phone: (702) 523–0894 or Email: *nssab@emcbc.doe.gov.*

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. Follow-up to Communication Plan for Pahute Mesa Groundwater Sampling Results Briefing and Path Forward—Work Plan Item #6

2. Development of EM SSAB Round Robin

Public Participation: The online virtual meeting is open to the public. Written statements may be filed with the Board either before or after the meeting as there will not be opportunities for live public comment during this online virtual meeting. 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 submit public comments should email them as directed above.

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_FY21.html.*

Signed in Washington, DC, on February 9, 2021.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2021–03025 Filed 2–12–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open virtual meeting.

SUMMARY: This notice announces an online virtual meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act requires that public notice of this online virtual meeting be announced in the **Federal Register**.

DATES: Wednesday, March 17, 2021; 1:00 p.m.–5:00 p.m.

ADDRESSES: This meeting will be held virtually via Webex. To attend, please contact Menice Santistevan by email, *Menice.Santistevan@em.doe.gov*, no later than 5:00 p.m. MST on Monday, March 15, 2021.

To Sign Up For Public Comment: Please contact Menice Santistevan by email, *Menice.Santistevan@em.doe.gov*, no later than 5:00 p.m. MST on Monday, March 15, 2021.

FOR FURTHER INFORMATION CONTACT: Menice Santistevan, Northern New Mexico Citizens' Advisory Board (NNMCAB), 94 Cities of Gold Road, Santa Fe, NM 87506. Phone (505) 995–0393 or Email: *Menice.Santistevan@em.doe.gov.*

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

- Call to Order
- Welcome and Introductions
- Roll Call
- Overview and Approval of Agenda
- Approval of January 13, 2021 Minutes
- Old Business
  - Report from NNMCAB Chair and Vice Chair
  - Report from NNMCAB Committee Chairs
  - Discussion on Charges from Acting Assistant Secretary for EM
- New Business
  - Discussion on Draft Recommendation(s)
  - Other Items
- Update on the Waste Isolation Pilot Plant
- Budget Update from EM Los Alamos Field Office
- Update from EM Los Alamos Field Office
- Update from NNMCAB Deputy Designated Federal Officer
- Update from N3B
- Update from New Mexico Environment Department
- Public Comment Period
- Future Presentation Requests
- Wrap-Up and Comments from NNMCAB Members
- Adjourn

Public Participation: The online virtual meeting is open to the public. Written statements may be filed with the Board either before or within five days after the meeting by sending them to Menice Santistevan at the aforementioned email address. 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 Menice Santistevan at the address or telephone number listed above. Minutes and other Board documents are on the internet at: *https://www.energy.gov/em/nnmcab/meeting-materials.*

Signed in Washington, DC, on February 9, 2021.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2021–03022 Filed 2–12–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open virtual meeting.

SUMMARY: This notice announces an online virtual meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge. The Federal Advisory Committee Act requires that public notice of this online meeting be announced in the **Federal Register**.

DATES: Wednesday, March 10, 2021; 6:00 p.m.–7:30 p.m.

ADDRESSES: Online Virtual Meeting. To attend, please send an email to: *orssab@orem.doe.gov* by no later than 5:00 p.m. EST on Wednesday, March 3, 2021.

To Submit Public Comments: Public comments will be accepted via email prior to and after the meeting. Comments received by no later than 5:00 p.m. EST on Wednesday, March 3, 2021 will be read aloud during the virtual meeting. Comments will also be accepted after the meeting, by no later than 5:00 p.m. EST on Monday, March 15, 2021. Please submit comments to *orssab@orem.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Melyssa P. Noe, Alternate Deputy Designated Federal Officer, U.S. Department of Energy (DOE), Oak Ridge Office of Environmental Management (OREM), P.O. Box 2001, EM–942, Oak Ridge, TN 37831; Phone (865) 241–3315; or Email: *Melyssa.Noe@orem.doe.gov.* Or visit the website at *https://www.energy.gov/orem/services/community-engagement/oak-ridge-site-specific-advisory-board.*

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

- Welcome and Announcements
- Comments from the Deputy Designated Federal Officer (DDFO)
- Comments from the DOE, Tennessee Department of Environment and

Conservation, and Environmental Protection Agency Liaisons
- Presentation: Budget Update
- Public Comment Period
- Motions/Approval of February 12, 2020 and March 11, 2020 Meeting Minutes
- Status of Outstanding Recommendations
- Alternate DDFO Report
- Committee Reports
- Adjourn

Public Participation: The online meeting is open to the public. Written statements may be filed with the Board either before or after the meeting as there will not be opportunities for live public comment during this online virtual meeting. 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 submit public comments should email them as directed above.

Minutes: Minutes will be available by writing or calling Melyssa P. Noe at the address and telephone number listed above. Minutes will also be available at the following website: *https://www.energy.gov/orem/listings/oak-ridge-site-specific-advisory-board-meetings.*

Signed in Washington, DC, on February 9, 2021.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2021–03021 Filed 2–12–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL21–24–000]

System Energy Resources, Inc.; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On February 5, 2021, the Commission issued an order in Docket No. EL21–24–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, instituting an investigation into whether System Energy Resources, Inc.'s proposed rate decrease is unjust, unreasonable, unduly discriminatory, or preferential, or otherwise unlawful and further decreases may be warranted. *System Energy Resources, Inc.,* 174 FERC ¶ 61,082 (2021).

The refund effective date in Docket No. EL21–24–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL21–24–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2020), within 21 days of the date of issuance of the order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* 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.

Dated: February 9, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–03030 Filed 2–12–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC21–10–000]

Commission Information Collection Activities (FERC–725F); 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 725F (Mandatory Reliability Standard for Nuclear Plant Interface Coordination).

DATES: Comments on the collection of information are due April 19, 2021.

ADDRESSES: You may submit comments (identified by Docket No. IC21–10–000) by either of the following methods:

- *eFiling at Commission's Website: http://www.ferc.gov.*
- *U.S. Postal Service Mail:* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, Office of the Secretary, 888 First Street NE, Washington, DC 20426
- Delivery of filings other than by eFiling or the U.S. Postal Service should be delivered to Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://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 *http://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 725F, Mandatory Reliability Standard for Nuclear Plant Interface Coordination.

OMB Control No.: 1902–0249.

Type of Request: Three-year extension of the FERC–725F information collection requirements with no changes to the current reporting requirements.

Abstract: The Commission requires the information collected by the FERC–725F to implement the statutory provisions of section 215 of the Federal Power Act (FPA) (16 U.S.C. 824o). On August 8, 2005, the Electricity Modernization Act of 2005, which is Title XII, Subtitle A, of the Energy Policy Act of 2005 (EPAct 2005), was

enacted into law.[1] EPAct 2005 added a new section 215 to the FPA, which required a Commission-certified Electric Reliability Organization (ERO) to develop mandatory and enforceable Reliability Standards, which are subject to Commission review and approval. Once approved, the Reliability Standards may be enforced by the ERO subject to Commission oversight, or the Commission can independently enforce Reliability Standards.[2]

On February 3, 2006, the Commission issued Order No. 672, implementing section 215 of the FPA.[3] Pursuant to Order No. 672, the Commission certified one organization, North American Electric Reliability Corporation (NERC), as the ERO. The Reliability Standards developed by the ERO and approved by the Commission apply to users, owners and operators of the Bulk-Power System as set forth in each Reliability Standard.

On November 19, 2007, NERC filed its petition for Commission approval of the Nuclear Plant Interface Coordination Reliability Standard, designated NUC–001–1. In Order No. 716, issued October 16, 2008, the Commission approved the standard while also directing certain revisions.[4] Revised Reliability Standard, NUC–001–2, was filed with the Commission by NERC in August 2009 and subsequently approved by the Commission January 21, 2010.[5] On November 4, 2014, in Docket No. RD14–13, the Commission approved revised Reliability Standard NUC–001–3.[6] On February 21, 2020 NERC filed a petition in Docket No. RD20–4 to revise Reliability Standard NUC–001–3 to NUC–0001–4.

The purpose of Reliability Standard NUC–001–4 is to require ''coordination between nuclear plant generator operators and transmission entities for the purpose of ensuring nuclear plant safe operation and shutdown.'' [7] The Nuclear Reliability Standard applies to nuclear plant generator operators (generally nuclear power plant owners and operators, including licensees) and ''transmission entities,'' defined in the Reliability Standard as including a nuclear plant's suppliers of off-site power and related transmission and distribution services. To account for the variations in nuclear plant design and grid interconnection characteristics, the Reliability Standard defines transmission entities as ''all entities that are responsible for providing services related to Nuclear Plant Interface Requirements (NPIRs),'' and lists eleven types of functional entities (heretofore described as ''transmission entities'') that could provide services related to NPIRs.[8]

FERC–725F information collection requirements include establishing and maintaining interface agreements, including record retention requirements. These agreements are not filed with FERC, but with the appropriate entities as established by the Reliability Standard.

Type of Respondent: Nuclear operators, nuclear plants, transmission entities

Estimate of Annual Burden: [9] The Commission estimates the average annual burden and cost [10] for this information collection as follows:

FERC–725F	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden hrs. & cost per response ($) (rounded)	Total annual burden hrs. & total annual cost ($) (rounded)	Cost per respondent ($) (rounded)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
New or Modifications to Existing Agreements (Reporting).	57 nuclear plants + 114 transmission entities [11].	2	342	66.67 hrs.; $5,694	22,801 hrs.; $1,947,433	$11,388
New or Modifications to Existing Agreements (Record Keeping).	57 nuclear plants + 114 transmission entities.	2	342	6.67 hrs.; $232	2,281 hrs.; $79,356	464.07
Total			[12] 342		25,082 hrs.; [13] $2,026,789.	

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

[1] Energy Policy Act of 2005, Public Law 109–58, Title XII, Subtitle A, 119 Stat. 594, 941 (2005), 16 U.S.C. 824o.

[2] 16 U.S.C. 824o(e)(3).

[3] *Rules Concerning Certification of the Electric Reliability Organization; and Procedures for the Establishment, Approval, and Enforcement of Electric Reliability Standards,* Order No. 672, FERC Stats. & Regs. 31,204, *order on reh'g,* Order No. 672–A, FERC Stats. & Regs. 31,212 (2006).

[4] *Mandatory Reliability Standard for Nuclear Plant Interface Coordination,* Order No. 716, 125 FERC 61,065, at P 189 & n.90 (2008), *order on reh'g,* Order No. 716–A, 126 FERC 61,122 (2009).

[5] *North American Electric Reliability Corporation,* 130 FERC 61,051 (2010). When the revised Reliability Standard was approved, the Commission did not go to OMB for approval. It is assumed that the changes made did not substantively affect the information collection and therefore a formal submission to OMB was not needed.

[6] The Letter Order is posted at *https://elibrary.ferc.gov/idmws/common/OpenNat.asp?fileID=13675845.*

[7] See Reliability Standard NUC–001–4 at *http://www.nerc.com/files/NUC-001-4.pdf.*

[8] The list of functional entities consists of transmission operators, transmission owners, transmission planners, transmission service providers, balancing authorities, reliability coordinators, planning authorities, distribution providers, load-serving entities, generator owners, and generator operators.

[9] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. Refer to 5 CFR 1320.3 for additional information.

[10] The wage and benefit figures are based on the Bureau of Labor Statistics (BLS) data (at *https://www.bls.gov/oes/current/naics2_22.htm*) for May 2019 for Sector 22, Utilities. (The benefits figure is based on BLS data as of May 2020 *http://www.bls.gov/news.release/ecec.nr0.htm*.) The estimated hourly cost (for wages plus benefits) for reporting requirements is $85.41/hour, based on the average for an electrical engineer (occupation code 17–2071, $70.19/hour), legal (occupation code 23–0000, $142.65/hour), and office and administrative staff (occupation code 43–0000, $43.38/hour). The estimated hourly cost (wages plus benefits) for record keeping is $34.79/hour for a file clerk (occupation code 43–4071).

[11] This figure of 120 transmission entities is based on the assumption that each agreement will be between 1 nuclear plant and 2 transmission entities (57 × 2 = 114). However, there is some double counting in this figure because some transmission entities may be party to multiple agreements with multiple nuclear plants. The double counting does not affect the burden estimate, and the correct number of unique respondents will be reported to OMB.

[12] The 171 respondents affected by the reporting requirements are also affected by the recordkeeping requirements.

[13] The reporting requirements have not changed. The decrease in the number of respondents is due to: (a) Normal fluctuations in industry (*e.g.,* companies merging and splitting, and coming into and going out of business), and (b) no new agreements being issued due to the lack of new nuclear plants being developed.

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: February 9, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–03040 Filed 2–12–21; 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: ER10–2881–037; ER10–2882–038; ER10–2883–036; ER10–2884–036; ER16–2509–007; ER17–2400–008; ER17–2401–008; ER17–2403–008; ER17–2404–008.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company, Southern Power Company, Rutherford Farm, LLC, SP Butler Solar, LLC, SP Decatur Parkway Solar, LLC, SP Pawpaw Solar, LLC, SP Sandhills Solar, LLC.

Description: Notice of Non-Material Change in Status of Alabama Power Company, et al.

Filed Date: 2/8/21.

Accession Number: 20210208–5170.

Comments Due: 5 p.m. ET 3/1/21.

Docket Numbers: ER20–1683–004.

Applicants: Wabash Valley Power Association, Inc.

Description: Compliance filing: Compliance Filing of Amended Distributed Generation Policy D–11 to be effective 9/11/2020.

Filed Date: 2/9/21.

Accession Number: 20210209–5020.

Comments Due: 5 p.m. ET 3/2/21.

Docket Numbers: ER21–653–000; ER21–654–000.

Applicants: Centerfield Cooper Solar, LLC.

Description: Second Supplement to December 15, 2020 Centerfield Cooper Solar, LLC, et al.

Filed Date: 2/5/21.

Accession Number: 20210205–5196.

Comments Due: 5 p.m. ET 2/26/21.

Docket Numbers: ER21–1023–000.

Applicants: Thunderhead Wind Energy LLC.

Description: Request for Prospective Tariff Waiver of Thunderhead Wind Energy LLC.

Filed Date: 2/2/21.

Accession Number: 20210202–5138.

Comments Due: 5 p.m. ET 2/23/21.

Docket Numbers: ER21–1070–000.

Applicants: Upper Missouri G. & T. Electric Cooperation.

Description: § 205(d) Rate Filing: Revised Rate Schedules FERC to be effective 2/9/2021.

Filed Date: 2/8/21.

Accession Number: 20210208–5143.

Comments Due: 5 p.m. ET 3/1/21.

Docket Numbers: ER21–1071–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: Wholesale Contract Revisions to Rate Schedule Nos. 330, 337, and 338 to be effective 1/1/2021.

Filed Date: 2/8/21.

Accession Number: 20210208–5161.

Comments Due: 5 p.m. ET 3/1/21.

Docket Numbers: ER21–1072–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA, SA No. 5100; Queue No. AC1–212 to be effective 2/14/2021.

Filed Date: 2/9/21.

Accession Number: 20210209–5034.

Comments Due: 5 p.m. ET 3/2/21.

Docket Numbers: ER21–1073–000.

Applicants: DATC SLTP, LLC.

Description: Tariff Cancellation: Cancellation to be effective 3/11/2021.

Filed Date: 2/9/21.

Accession Number: 20210209–5108.

Comments Due: 5 p.m. ET 3/2/21.

Docket Numbers: ER21–1074–000.

Applicants: New York Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 205: enhancements to economic planning process to be effective 4/11/2021.

Filed Date: 2/9/21.

Accession Number: 20210209–5122.

Comments Due: 5 p.m. ET 3/2/21.

Docket Numbers: ER21–1075–000.

Applicants: DATC Midwest Holdings, LLC.

Description: Tariff Cancellation: Cancellation to be effective 3/11/2021.

Filed Date: 2/9/21.

Accession Number: 20210209–5131.

Comments Due: 5 p.m. ET 3/2/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 9, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–03039 Filed 2–12–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1417–277]

Central Nebraska Public Power and Irrigation District; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Amendment of Project Boundary.

b. *Project No:* 1417–277.

c. *Date Filed:* December 31, 2020.

d. *Applicant:* Central Nebraska Public Power and Irrigation District.

e. *Name of Project:* Kingsley Dam Hydroelectric Project.

f. *Location:* The project is located on the North Platte and Platte Rivers in Garden, Keith, Lincoln, Dawson, and Gosper counties, in south-central Nebraska.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mike Drain, Central Nebraska Public Power and Irrigation District, P.O. Box 740, Holdrege, Nebraska 68949, (308) 995–8601 or *mdrain@cnppid.com.*

i. *FERC Contact:* Jon Cofrancesco, (202) 502–8951 or *Jon.Cofrancesco@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* March 11, 2021.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters,

without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. 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, please send 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. The first page of any filing should include docket numbers P–1417–277.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* Central Nebraska Public Power and Irrigation District (CNPPID) filed a non-capacity amendment of license application requesting Commission approval to modify the project boundary for the Kingsley Dam Project based on the findings of its final project boundary review report. CNPPID's request is based on its analysis of the existing lands and shorelines around project reservoirs to determine their need for project operation and other project purposes, including public access for recreation. The proposed boundary modification would add approximately 3,400 acres and remove approximately 900 acres, resulting in a net increase of 2,500 acres of additional lands to be included within the project boundary.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE, Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also 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. 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, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', ''MOTION TO INTERVENE'', ''RECOMMENDATIONS'', or ''TERMS AND CONDITIONS'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: February 9, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–03037 Filed 2–12–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP21–311–001.
Applicants: Northwest Pipeline LLC.
Description: Compliance filing Request to Make Customer Specific Entitlements Tariff Records Effective to be effective 3/15/2021.
Filed Date: 2/5/21.
Accession Number: 20210205–5071.
Comments Due: 5 p.m. ET 2/17/21.

Docket Numbers: RP21–462–000.
Applicants: Guardian Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Pre-Granted Abandonment of Services—Rate Schedules OSS and LBS to be effective 3/7/2021.
Filed Date: 2/5/21.
Accession Number: 20210205–5052.
Comments Due: 5 p.m. ET 2/17/21.

Docket Numbers: RP21–463–000.
Applicants: Dauphin Island Gathering Partners.
Description: Storm Surcharge Adjustment Filing for 2021 of Dauphin Island Gathering Partners under RP21–463.
Filed Date: 2/5/21.
Accession Number: 20210205–5064.
Comments Due: 5 p.m. ET 2/17/21.

Docket Numbers: RP21–464–000.
Applicants: Guardian Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate PAL Agreements—Morgan Stanley to be effective 2/6/2021.
Filed Date: 2/5/21.
Accession Number: 20210205–5156.
Comments Due: 5 p.m. ET 2/17/21.

Docket Numbers: RP21–465–000.
Applicants: Viking Gas Transmission Company.
Description: § 4(d) Rate Filing: Negotiated Rate PAL Agreement—World Fuel Services, Inc. to be effective 2/6/2021.
Filed Date: 2/5/21.
Accession Number: 20210205–5169.
Comments Due: 5 p.m. ET 2/17/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date.

Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 9, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–03038 Filed 2–12–21; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL COMMUNICATIONS COMMISSION

[GN Docket No. 19–329; FR ID 17462]

Federal Advisory Committee Act; Task Force for Reviewing the Connectivity and Technology Needs of Precision Agriculture in the United States

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC or Commission) Task Force for Reviewing the Connectivity and Technology Needs of Precision Agriculture in the United States (Task Force) will hold its next meeting via live internet link.

DATES: March 12, 2021. The meeting will come to order at 12:00 p.m. (noon) EST.

ADDRESSES: The meeting will be held via conference call and be available to the public via live feed from the FCC's web page at *www.fcc.gov/live.*

FOR FURTHER INFORMATION CONTACT: Jesse Jachman, Designated Federal Officer, Federal Communications Commission, Wireline Competition Bureau, (202) 418–2668, or email: *Jesse.Jachman@fcc.gov;* Celia Lewis, Deputy Designated Federal Officer, Federal Communications Commission, Wireline Competition Bureau, (202) 418–7456, or email *Celia.Lewis@fcc.gov;* or Stacy Ferraro, Deputy Designated Federal Officer, Wireless Telecommunications Bureau, (202) 418–0795 or email *Stacy.Ferarro@fcc.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be held on March 12, 2021, at 12:00 p.m. (noon) EST and may be viewed live, by the public, at *http://www.fcc.gov/live.* Any questions that arise during the meeting should be sent to *PrecisionAgTF@fcc.gov* and will be answered at a later date. Members of the public may submit comments to the Task Force in the FCC's Electronic Comment Filing System, ECFS, at *www.fcc.gov/ecfs.* Comments to the Task Force should be filed in GN Docket No. 19–329.

Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530. Such requests should include a detailed description of the accommodation needed. In addition, please include a way the FCC can contact you if it needs more information. Please allow at least five days' advance notice; last-minute requests will be accepted but may be impossible to fill.

Proposed Agenda: At this meeting, the Task Force will consider and vote on a report from its Accelerating Broadband Deployment on Unserved Agricultural Lands Working Group. The Task Force will also discuss any updates and matters from its other working groups. This agenda may be modified at the discretion of the Task Force Chair and the Designated Federal Officer.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2021–02976 Filed 2–12–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[FRS 17465]

Federal Advisory Committee Act; Communications Security, Reliability, and Interoperability Council

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC or Commission) Communications Security, Reliability, and Interoperability Council (CSRIC) VII will hold its eighth and final meeting via live internet link.

DATES: March 10, 2021.

ADDRESSES: The Meeting will be held via conference call and available to the public via WebEx at *http://www.fcc.gov/live.*

FOR FURTHER INFORMATION CONTACT: Suzon Cameron, Designated Federal Officer, (202) 418–1916 (voice) or *CSRIC@fcc.gov* (email); or, Kurian Jacob, Deputy Designated Federal Officer, (202) 418–2040 (voice) or *CSRIC@fcc.gov* (email).

SUPPLEMENTARY INFORMATION:

The meeting on March 10, 2021, from 1:00 p.m. EDT to 5:00 p.m. EST will be held electronically only and may be viewed live, by the public, at *http://www.fcc.gov/live.* Any questions that arise during the meeting should be sent to *CSRIC@fcc.gov* and will be answered at a later date. The meeting is being held in a wholly electronic format in light of travel and gathering restrictions related to COVID–19 in place in Washington, DC, and the larger U.S., which affect members of CSRIC and the FCC.

The CSRIC is a Federal Advisory Committee that will provide recommendations to the FCC to improve the security, reliability, and interoperability of communications systems. On March 15, 2019, the FCC, pursuant to the Federal Advisory Committee Act, renewed the charter for CSRIC VII for a period of two years through March 14, 2021. The meeting on March 10, 2021, will be the eighth and final meeting of CSRIC VII under the current charter.

The Commission will provide audio and/or video coverage of the meeting over the internet from the FCC's web page at *http://www.fcc.gov/live.* The public may submit written comments before the meeting to Suzon Cameron, CSRIC VII Designated Federal Officer, by email to *CSRIC@fcc.gov.*

Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (tty). Such requests should include a detailed description of the accommodation needed. In addition, please include a way the FCC can contact you if it needs more information. Please allow at least five days' advance notice; last-minute requests will be accepted but may be impossible to fill.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2021–02977 Filed 2–12–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than March 18, 2021.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street, NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Community Bancshares of Mississippi, Inc. Employee Stock Ownership Plan, Brandon, Mississippi;* to acquire additional voting shares, for a total of 19.34 percent of the voting shares of Community Bancshares of Mississippi, Inc., Brandon, Mississippi, and thereby indirectly acquire voting shares of Community Bank of Mississippi, Forest, Mississippi.

Board of Governors of the Federal Reserve System, February 10, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–03049 Filed 2–12–21; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

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

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

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

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than March 3, 2021.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Scott A. Schoenmann, Mazomanie, Wisconsin;* to retain voting shares of The Peoples Community Bancshares, Inc., and thereby indirectly retain voting shares of The Peoples Community Bank, both of Mazomanie, Wisconsin.

Board of Governors of the Federal Reserve System, February 10, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–03050 Filed 2–12–21; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the Recordkeeping and Disclosure Provisions Associated with Real Estate Appraisal Standards (FR Y–30; OMB No. 7100–0250). The revisions are effective immediately.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With Revision, of the Following Information Collection

Report title: Recordkeeping and Disclosure Provisions Associated with Real Estate Appraisal Standards.[1]

[1] This information collection was previously titled *Recordkeeping Requirements Associated with Real Estate Appraisal Standards for Federally Related Transactions Pursuant to Regulations H and Y (FR H–4; OMB No. 7100–0250).* Under the proposal, this information collection would no longer include references to section 208.51 of the Board's Regulation H (12 CFR 208.51), which is cleared by the Board as part of the FR H–5 clearance (OMB No. 7100–0261). This change would not affect the burden estimate for this collection of information, as prior burden calculations for the FR H–4 have not included any burden associated with section 208.51 of Regulation H. Additionally, as described in this Supporting Statement, the proposal would replace references to section 208.50 of Regulation H with references to subpart G of Regulation Y as the source for certain appraisal standards for state member banks. Therefore, the Board has modified the title and agency tracking

Agency form number: FR Y–30.

OMB control number: 7100–0250.

Effective Date: The revisions are effective immediately.

Frequency: Event-generated.

Respondents: State member banks (SMBs) and nonbank subsidiaries of bank holding companies (BHCs).

Estimated number of respondents: SMBs, 740; nonbank subsidiaries of BHCs, 1,126.

Estimated average hours per response: SMBs, 5 minutes; nonbank subsidiaries of BHCs, 5 minutes.

Estimated annual burden hours: Recordkeeping, SMBs, 25,837; nonbank subsidiaries of BHCs, 2,346. Disclosure, SMBs, 62; nonbank subsidiaries of BHCs, 94.

General description of report: Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA) (12 U.S.C. 3331 *et seq.*) requires that, for federally related transactions,[2] regulated institutions obtain real estate appraisals performed by certified or licensed appraisers in conformance with uniform appraisal standards.[3] The Board's regulations implementing Title XI of FIRREA, contained in the Board's Regulation Y, include certain recordkeeping requirements that apply to SMBs, BHCs, and nonbank subsidiaries of BHCs that extend mortgage credit (together, institutions). The Board and other supervisory agencies also have issued Interagency Appraisal and Evaluation Guidelines (the Guidelines) that convey supervisory expectations relating to real estate appraisals and evaluations used to support real estate-related financial transactions.[4] These Guidelines recommend that institutions adopt certain policies and procedures to ensure compliance with Title XI of FIRREA and Regulation Y.

Legal authorization and confidentiality: The FR Y–30 is authorized pursuant to Title XI of FIRREA.[3] The obligation to respond is mandatory. The recordkeeping provisions contained in the Guidelines, which is nonbinding, are voluntary.[4]

Because FR Y–30 records would be maintained at each banking organization, the Freedom of Information Act (''FOIA'') would only be implicated if the Board obtained such records as part of the examination or supervision of a banking organization. In the event the records are obtained by the Board as part of an examination or supervision of a financial institution, this information may be considered confidential pursuant to exemption 8 of the FOIA, which protects information contained in ''examination, operating, or condition reports'' obtained in the bank supervisory process.[5] In addition, the information may also be kept confidential under exemption 4 for the FOIA, which protects commercial or financial information obtained from a person that is privileged or confidential.[6]

Current actions: On October 14, 2020, the Board published a notice in the **Federal Register** (85 FR 65050) requesting public comment for 60 days on the extension, with revision, of the FR Y–30. The Board proposes to revise the FR Y–30 to account for the collections of information contained in the Guidelines. Although previous OMB Supporting Statements for the FR H–4, the former agency tracking number for this clearance, referred to the Guidelines, the Board did not formally clear these collections of information or account for their corresponding burden. The comment period for this notice expired on December 14, 2020. The Board did not receive any comments. The revisions will be implemented as proposed.

Board of Governors of the Federal Reserve System, February 10, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–03073 Filed 2–12–21; 8:45 am]

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number of the FR H–4 information collection to reflect that it will no longer account for provisions of Regulation H.

[2] A ''federally related transaction'' means any real estate-related financial transaction which (A) a federal financial institutions regulatory agency or the Resolution Trust Corporation engages in, contracts for, or regulates; and (B) requires the services of an appraiser (12 U.S.C. 3350(4)). The term ''real estate-related financial transaction'' means any transaction involving (A) the sale, lease, purchase, investment in or exchange of real property, including interests in property, or the financing thereof; (B) the refinancing of real property or interests in real property; and (C) the use of real property or interests in property as security for a loan or investment, including mortgage-backed securities (12 U.S.C. 3350(5)).

[3] 12 U.S.C. 3339. The Board also has the authority to require reports from bank holding companies (12 U.S.C. 1844(c)) and state member banks (12 U.S.C. 248(a) and 324).

[4] *See* SR 18–5/CA 18–7: Interagency Statement Clarifying the Role of Supervisory Guidance (Sept. 12, 2018).

[5] 5 U.S.C. 552(b)(8).

[6] 5 U.S.C. 552(b)(4).

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in or to Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than March 3, 2021.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org:*

1. *Hyperion Bancshares, Inc., Philadelphia, Pennsylvania;* as published in 85 FR 82477 (December 18, 2020), to indirectly acquire Hyperion Mortgage, LLC, Atlanta, Georgia, and engage in extending credit and servicing loans and activities related to extending credit pursuant to sections 225.28(b)(1) and (2) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, February 10, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–03048 Filed 2–12–21; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision the Reporting, Recordkeeping, and Disclosure Provisions Associated with the Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice (FR 4100; OMB No. 7100–0309).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829. Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Report title: Reporting, Recordkeeping, and Disclosure Provisions Associated with the Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice.

Agency form number: FR 4100.

OMB control number: 7100–0309.

Frequency: On occasion.

Respondents: State member banks, bank holding companies (BHCs), affiliates and certain non-banking subsidiaries of BHCs, uninsured state agencies and branches of foreign banks, commercial lending companies owned or controlled by foreign banks, savings and loan holding companies, and Edge and agreement corporations.

Estimated number of respondents: Recordkeeping, 1; Reporting, 831; Disclosure, 831.

Estimated average hours per response: Recordkeeping, 24 hours; Reporting, 9 hours; Disclosure, 27 hours.

Estimated annual burden hours: Recordkeeping, 24 hours; Reporting, 7,479 hours; Disclosure, 22,437 hours.

General description of report: The FR 4100 is the Board's information collection associated with the Interagency Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice (''ID-Theft Guidance'' or ''Guidance''). The ID-Theft Guidance was published in the **Federal Register** in March 2005.[1] The ID-Theft Guidance, which applies to financial institutions, was issued in response to developing trends in the theft and accompanying misuse of customer information. The Guidance includes certain voluntary reporting, recordkeeping, and disclosure provisions.

Legal authorization and confidentiality: The FR 4100 is authorized by section 501(b) of the Gramm-Leach-Bliley Act,[2] which requires the Board, the Federal Deposit Insurance Corporation, and the Office of the Comptroller of the Currency to establish appropriate standards for financial institutions to develop and implement an information security program designed to protect their customers' information and a response program that specifies actions to be taken when the institution suspects or detects that unauthorized individuals have gained access to customer information systems.

Because the provisions under the FR 4100 are contained in guidance, which is nonbinding, the provisions are voluntary.[3]

The disclosure provisions of FR 4100 are not confidential. The records maintained under recordkeeping provisions of FR 4100 would be maintained at each banking organization, and the Freedom of Information Act (''FOIA'') would only be implicated if the Board obtained such records as part of the examination or supervision of a banking organization. In the event the records are obtained by the Board as part of an examination or supervision of a financial institution, this information may be considered confidential pursuant to exemption 8 of the FOIA, which protects information contained in ''examination, operating, or condition reports'' obtained in the bank supervisory process. In addition, the information obtained by the Board under the FR 4100 may also be kept confidential under exemption 4 for the FOIA, which protects commercial or financial information obtained from a person that is privileged or confidential.[4]

Current actions: On October 14, 2020, the Board published a notice in the **Federal Register** (85 FR 65046) requesting public comment for 60 days on the extension, without revision, of the Reporting, Recordkeeping, and Disclosure Provisions Associated with the Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice. The comment period for this notice expired on December 14, 2020. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, February 10, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–03072 Filed 2–12–21; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0089]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

[1] *See* 70 FR 15736 (March 29, 2005).

[2] 15 U.S.C. 6801(b).

[3] *See* SR 18–5/CA 18–7: Interagency Statement Clarifying the Role of Supervisory Guidance (Sept. 11, 2018).

[4] 5 U.S.C. 552(b)(4).

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on March 5, 2021, from 9 a.m. Eastern Time to 3:30 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: *https://youtu.be/dG_NjxSYBkA.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0089. The docket will close on March 4, 2021. Submit either electronic or written comments on this public meeting by March 4, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 24, 2021, to be provided to the committee. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 4, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before February 24, 2021, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0089 for ''Vaccines and Related Biological Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.'' FDA 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 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 the 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: Kathleen Hayes or Monique Hill, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6306, Silver Spring, MD 20993–0002, 301–796–7864 or 301–796–4620, respectively; *CBERVRBPAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/advisory-committees* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The Committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2021 to 2022 influenza season.

FDA intends to make background material available to the public no later

than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/advisory-committees/advisory-committee-calendar.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions made to the Docket (see **ADDRESSES**) on or before February 24, 2021, will be provided to the committee. Comments received after February 24, 2021, and by March 4, 2021, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 1:30 p.m. Eastern Time and 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 18, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 19, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Kathleen Hayes, *CBERVRBPAC@fda.hhs.gov,* at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03014 Filed 2–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5364]

Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised); Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised guidance for industry entitled ''Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised).'' This is a revision to the second edition of this final guidance, which issued in May 2020, and is intended to assist those required to submit cigarette plans for cigarette packages and cigarette advertisements by providing content, timing, and other recommendations related to those submissions. FDA is revising this guidance to reflect the December 2, 2020, court order that postponed the effective date of the final rule entitled ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements'' to January 14, 2022. Pursuant to the court order, this revised guidance strongly encourages entities to submit cigarette plans to FDA as soon as possible after publication of the final rule, and in any event, by March 16, 2021.

DATES: The announcement of the revised guidance is published in the **Federal Register** on February 16, 2021.

ADDRESSES: You may submit electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–5364 for ''Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the

claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Lauren Belcher or Courtney Smith, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *AskCTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised guidance for industry entitled ''Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised).'' The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was enacted on June 22, 2009, and granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products. The Tobacco Control Act also amended section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) to direct FDA to issue regulations requiring each cigarette package and advertisement to bear a new textual warning label statement accompanied by color graphics depicting the negative health consequences of smoking (section 201 of the Tobacco Control Act). In enacting this legislation, Congress also provided that FDA may adjust the required warnings if FDA found that such a change would promote greater public understanding of the risks associated with the use of tobacco products (section 202 of the Tobacco Control Act). The Tobacco Control Act also modified the requirements of the FCLAA regarding the submission of cigarette plans for the random and equal display and distribution of required warnings on cigarette packages and quarterly rotation of required warnings in cigarette advertisements. It also requires that such cigarette plans be submitted to FDA for review and approval, rather than to the Federal Trade Commission.

In the **Federal Register** of March 18, 2020, FDA issued a final rule entitled ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements'' (85 FR 15638). The rule specifies the color graphics that must accompany the new textual warning label statements and establishes marketing requirements for cigarette packages and advertisements. The marketing requirements include, among other things, submission of a cigarette plan that provides for the random and equal display and distribution of the required warnings on cigarette packages and quarterly rotation of the required warnings in cigarette advertisements, as described under section 4 of FCLAA.

On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.[1] On May 8, 2020, the Court granted a joint motion to govern proceedings in that case and postpone the effective date of the final rule by 120 days.[2] On December 2, 2020, the same Court granted a new motion by Plaintiffs in the same case to postpone the effective date of the final rule by an additional 90 days.[3] The new effective date of the final rule is January 14, 2022. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date of the final rule is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date. As such, this revised guidance strongly encourages entities to submit cigarette plans to FDA as soon as possible after publication of the final rule, and in any event, by March 16, 2021.

FDA is issuing this guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA regarding the submission of plans for cigarette packages and cigarette advertisements. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 1141.10 have been approved under 0910–0877.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either *https://www.regulations.gov* or *https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance.*

Dated: February 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03020 Filed 2–12–21; 8:45 am]

BILLING CODE 4164–01–P

[1] *R.J. Reynolds Tobacco Co. et al.* v. *United States Food and Drug Administration et al.,* No. 6:20–cv–00176 (E.D. Tex. filed April 3, 2020).

[2] *R.J. Reynolds Tobacco Co. et al.,* No. 6:20–cv–00176 (E.D. Tex. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.

[3] *R.J. Reynolds Tobacco Co. et al.,* No. 6:20–cv–00176 (E.D. Tex. May 8, 2020) (order granting Plaintiffs' motion and postponing effective date), Doc. No. 80.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Food and Drug Administration Approval To Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by March 18, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0001. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Application for FDA Approval To Market a New Drug; OMB Control No. 0910–0001—Revision

This information collection supports FDA regulations. Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States unless an approval of an application filed with FDA under section 505(b) or (j) of the FD&C Act is effective with respect to such drug. We have issued regulations in part 314 (21 CFR part 314) to govern procedures and requirements for applications submitted in accordance with section 505. The regulations in subpart A (§§ 314.1 through 314.3) set forth general provisions, while regulations in subparts B and C (§§ 314.50 through 314.99) set forth content and format requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) respectively. The regulations include requirements for the submission of specific data elements along with patent information, pediatric use information, supplements and amendments, proposed labeling, and specific postmarketing reports. Respondents to the information collection are sponsors of these applications.

To assist respondents to the information collection we have developed the following forms:

- Form FDA 0356h (and instructions): Application to Market a New or Abbreviated New Drug or Biologic for Human Use;
- Form FDA 2252 (and instructions): Transmittal of Annual Reports for Drugs and Biologics For Human Use (§ 314.81);
- Form FDA 2253 (and instructions): Transmittal of Advertisements and Promotional Labeling For Drugs and Biologics For Human Use; and
- Forms FDA 3331/3331a: Field Alert Report and Instruction
- Forms FDA 3542 and 3542a and Instructions: Patent Information Submitted *Upon and After Approval* of an NDA Supplement; Patent Information Submitted *With the Filing* of an NDA, Amendment, or Supplement
- New Draft Form FDA 3898 and Instruction: Drug Master File

Individuals requesting printed forms are instructed to contact the FDA Forms Manager by email at *formsmanager@OC.FDA.GOV.* Certain fees may be applicable.

Regulations in subpart D (§§ 314.100 through 314.170) explain Agency actions on applications and set forth timeframes for FDA review. We are revising the information collection to include provisions established through our Agency user fee programs, most recently authorized under the FDA Reauthorization Act of 2017. These provisions pertain to review transparency, communications with FDA, dispute resolution, drug safety enhancements, and the allocation of Agency resources to align with these program objectives as agreed to with our stakeholders and set forth in our ''Performance Goals for Fiscal Years 2018–2022'' Commitment Letters, which are available from our website at *https://www.fda.gov* along with more information about FDA user fee programs.

Information collection pertaining to hearing and other administrative proceedings covered in 21 CFR subpart E are approved under OMB control no. 0910–0191. Unless otherwise noted, information collection pertaining to postmarket safety reporting and associated recordkeeping is approved under OMB control nos. 0910–0230, 0910–0291, and 0910–0645.

Included among the miscellaneous provisions in subpart G (§§ 314.410 to 314.445), § 314.420 covers information to include in drug master files (DMFs). To assist respondents to this information collection we have prepared templates and resources available from our website at *www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs.* As noted above, we have developed new Form FDA 3898 and accompanying instructions on submitting DMFs in accordance with the applicable regulations. In accordance with § 314.445, we also develop Agency guidance documents to assist respondents in complying with provisions in part 314. These guidance documents are issued consistent with our good guidance practice regulations at § 10.115. To search available FDA guidance documents, visit our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Finally, applications submitted in accordance with subpart H (§§ 314.500 through 314.560) pertain to accelerated approval of new drugs for serious or life-threatening illness, and submissions in subpart I (§§ 314.600 through 314.650) pertain to approval of new drugs when human efficacy studies are not ethical or feasible. The regulations provide for the submission of specific data elements along with promotional material.

We use the information collection to approve drugs shown to be safe and effective and to implement effective public health monitoring systems. We also use product approval and related patent and exclusivity information to publish the ''Approved Drug Products with Therapeutic Equivalence Evaluations'' list (the Orange Book). More information regarding the Orange Book is available from our website at *https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.*

In the **Federal Register** of November 16, 2020 (85 FR 73057), we published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received and we have therefore made no adjustments to our estimate, which is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Subpart B					
314.50(a)–(l)—Content and format of a 505(b)(1) or 505(b)(2) application	121	1.15	139	1,921	267,019
314.50(i)(1)—patent certifications:					
Form FDA 3542	281	2.875	808	10	8,080
Form FDA 3542a	310	2.084	646	15	9,690
314.50(i)(6) amended patent certifications	17	1	17	2	34
314.52(a), (b), and (e)—NDAs—notice of noninfringement of patent certification	15	3	45	15	675
314.52(c)—Noninfringement of patent certification notice content	22	3	66	0.33 (20 minutes)	22
314.53(f)(1)—Correction of patent information errors by persons other than the NDA holder	24	1	24	10	240
314.53(f)(2)—Correction of patent information errors by the NDA holder	28	1.4	39	1	39
314.60—Amendments to unapproved NDA, supplement or resubmission	256	8.23	2,106	80	168,480
314.60(f)—patent certifications for unapproved applications	6	1	6	2	12
314.65—Withdrawal of unapproved applications	14	1.21	17	2	34
314.70 and 314.71—Supplements and other changes to approved application	492	6.57	3,232	150	484,800
314.72—Changes of ownership of NDAs	67	1.45	97	2	194
314.81—Other postmarketing reports 314.81(b)(1) [3331 and 3331a field alert reports and followups]	484	20.3	9,834	8	78,672
314.81(b)(2)[2252]—Annual reports	626	4.9	3,066	40	122,640
314.81(b)(2)[2253]—Promotional labeling	331	141.3	46,782	2	93,564
Subpart C					
314.94(a)and(d)—ANDA content	229	4.3	987	480	473,760
314.94(a)(12)(viii) amended patent certifications before approval of ANDA	153	1	153	2	306
314.95(c)—Non-infringement of patents (ANDAs)	400	3	1,200	0.33 (20 minutes)	400
314.96(a)(1)—Amendments to unapproved ANDAs	451	36.2	16,311	80	1,304,880
314.96(c) amendment for pharmaceutical equivalent to a listed drug other than RLD	1	1	1	300	300
314.96(d)—patent certification requirements	100	1	100	2	200
314.97—Supplements and other changes to ANDAs	361	22.8	8,237	80	658,960
314.97(b) Supplements to ANDA for pharmaceutical equivalent to a listed drug other than RLD	1	1	1	300	300
314.99(a)—ANDA Applicants: Withdrawal of unapproved ANDAs	77	2.3	177	2	354
314.99(a)—ANDA Transfer of ownership	135	1.24	167	2	334
Subpart D					
314.101(a)—NDA or ANDA filing over protest	1	1	1	0.5 (30 minutes)	0.5
314.107(e)—notification of court actions or written consent to approval	247	2	494	0.5 (30 minutes)	247
Subparts G, H, and I					
314.420—drug master files [FDA 3938]—original amendments	36	27.2	981	61	59,841
DMFs—technical, administrative, REMS)	2,946	11.4	33,590	8	268,720
DMFs—annual reports	2,946	3.33	9,834	4	39,336
314.550—Promotional material and subpart H applications	55	11.6	640	120	76,800
Total					4,118,933.5

Our estimated burden for the information collection reflects a decrease. We attribute this adjustment to improved operational efficiencies with regard to Agency data systems and digital submission processes.

Dated: February 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03023 Filed 2–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0134]

Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on March 24, 2021, from 9 a.m. to 4:30 p.m. Eastern Time and March 25, 2021, from 10 a.m. to 1 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0134. The docket will close on March 23, 2021. Submit either electronic or written comments on this public meeting by March 23, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 23, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 23, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before March 10, 2021, will be provided to the committees. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0134 for ''Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.'' FDA 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 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 the 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: Moon Hee V. Choi, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, email: *AAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committees will discuss biologics license application (BLA) 761130, tanezumab subcutaneous injection, submitted by Pfizer Inc., for the proposed indication of relief of signs and symptoms of moderate to severe osteoarthritis in adult patients for whom use of other analgesics is ineffective or not appropriate.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before March 10, 2021, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 3:30 p.m. and 4:30 p.m. Eastern Time on March 24, 2021. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 2, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 3, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Moon Hee V. Choi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 10, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03068 Filed 2–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee, Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on March 23, 2021, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993–0002, *Patricio.Garcia@fda.hhs.gov,* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at: *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On March 23, 2021, the committee will discuss and make recommendations regarding the benefits and risks of dermal fillers concerning the following topics: (1) Risks associated with intravascular injection of dermal fillers and (2) patient preference and informed decision making. FDA is convening this meeting to seek expert opinion on the clinical evaluation and regulation of dermal filler products.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background

material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at: *https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/general-and-plastic-surgery-devices-panel.* Select the link for the 2021 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing on issues pending before the committee. Written submissions may be made to the contact person on or before March 9, 2021. Oral presentations from the public and organizations will be scheduled on March 23, 2021, between approximately 12:40 p.m. Eastern Time to 1:40 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 11, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing sessions. The contact person will notify interested persons regarding their request to speak by March 12, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallet at *artair.mallett@fda.hhs.gov* or 301–796–9638 at least 7 days in advance of the meeting. FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03066 Filed 2–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that OXLUMO (lumasiran) injection, manufactured by Alnylam Pharmaceuticals Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, email: *althea.cuff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that OXLUMO (lumasiran) injection, manufactured by Alnylam Pharmaceuticals Inc., meets the criteria for a priority review voucher. OXLUMO (lumasiran) injection is indicated for the treatment of primary hyperoxaluria type 1 to lower urinary oxalate levels in pediatric and adult patients.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about OXLUMO (lumasiran) injection, go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: February 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03012 Filed 2–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5569]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by March 18, 2021.

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 0910–0442. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Device Tracking—21 CFR Part 821

OMB Control Number 0910–0442—Extension

Section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)(1)), as amended by Food and Drug Administration Modernization Act (Pub. L. 105–115), provides that FDA may require by order that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) The failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a ''tracked implant''), or (3) the device is life-sustaining or life-supporting (referred to as a ''tracked l/s-l/s device'') and is used outside a device user facility.

Tracked device information is collected to facilitate identifying the current location of medical devices and patients possessing those devices, to the extent that patients permit the collection of identifying information. Manufacturers and FDA (where necessary) use the data to: (1) Expedite the recall of distributed medical devices that are dangerous or defective and (2) facilitate the timely notification of patients or licensed practitioners of the risks associated with the medical device.

In addition, the regulations include provisions for: (1) Exemptions and variances; (2) system and content requirements for tracking; (3) obligations of persons other than device manufacturers, *e.g.,* distributors; (4) records and inspection requirements; (5) confidentiality; and (6) record retention requirements.

Respondents for this collection of information are medical device manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals.

The annual hourly burden for respondents involved with medical device tracking is estimated to be 615,380 hours per year. The burden estimates cited in tables 1 through 3 are based on the approximate number of device tracking orders, 12 annually. FDA estimates that approximately 22,000 respondents may be subject to tracking reporting requirements.

Under § 821.25(a) (21 CFR 821.25(a)), device manufacturers subject to FDA tracking orders must adopt a tracking method that can provide certain device, patient, and distributor information to FDA within 3 to 10 working days. Assuming one occurrence per year, FDA estimates it would take a firm 20 hours to provide FDA with location data for all tracked devices and 56 hours to identify all patients and/or multiple distributors possessing tracked devices.

Under § 821.25(d) manufacturers must notify FDA of distributor noncompliance with reporting requirements. Based on the number of audits manufacturers conduct annually, FDA estimates it would receive no more than one notice in any year, and that it would take 1 hour per incident.

Under § 821.30(c)(2) (21 CFR 821.30(c)(2)), multiple distributors must provide data on current users of tracked devices, current device locations, and other information, upon request from a manufacturer or FDA. FDA has not made such a request and is not aware of any manufacturer making a request. Assuming one multiple distributor receives one request in a year from either a manufacturer or FDA, and that lists may be generated electronically, the Agency estimates a burden of 1 hour to comply.

Under § 821.30(d) distributors must verify data or make required records available for auditing, if a manufacturer provides a written request. FDA's estimate of the burden for distributor audit responses assumes that manufacturers audit database entries for 5 percent of tracked devices distributed. Each audited database entry prompts one distributor audit response. Because lists may be generated electronically, FDA estimates a burden of 1 hour to comply.

In the **Federal Register** of November 5, 2020 (85 FR 70634), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Discontinuation of business—821.1(d)	1	1	1	1	1
Exemption or variance—821.2 and 821.30(e)	1	1	1	1	1
Notification of failure to comply—821.25(d)	1	1	1	1	1
Multiple distributor data—821.30(c)(2)	1	1	1	1	1
Total					4

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Tracking information—821.25(a)	12	1	12	76	912
Record of tracking data—821.25(b)	12	46,260	555,120	1	555,120
Standard operating procedures—821.25(c) [2]	12	1	12	63	756
Manufacturer data audit—821.25(c)(3)	12	1,124	13,488	1	13,488

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity; 21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	22,000	1	22,000	1	22,000
Total					592,276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Acquisition of tracked devices and final distributor data—821.30(a) and (b)	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	1,100	1	1,100	1	1,100
Total					23,100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this information collection has not changed since the last OMB approval.

Dated: February 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03017 Filed 2–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of amendment.

SUMMARY: The Acting Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer covered countermeasures under section VI of this Declaration.

DATES: This amendment to the Declaration is effective as of February 16, 2021.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health andHuman Services, 200 Independence Avenue SW, Washington, DC 20201; 202–260–0365, *paige.ezernack@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013 and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Countermeasures under the PREP Act.

On January 31, 2020, former Secretary, Alex M. Azar II, declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation's health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that declaration effective on April 26, 2020, July 25, 2020, October 23, 2020, and January 21, 2021.

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the former Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID–19 might otherwise cause. (85 FR 35100, June 8, 2020). On August 19, the former Secretary amended the declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the administration or use of the Covered Countermeasures. (85 FR 52136, August 24, 2020). On December 3, 2020, the former Secretary amended the declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the Secretary's Declaration and

authorizations issued by the Department's Office of the Assistant Secretary for Health as an Authority Having Jurisdiction to respond; added an additional category of qualified persons under Section V of the Declaration; made explicit that the Declaration covers all qualified pandemic and epidemic products as defined under the PREP Act; added a third method of distribution to provide liability protections for, among other things, private distribution channels; made explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration's liability protections; made explicit that there are substantive federal legal and policy issues and interests in having a unified whole-of-nation response to the COVID–19 pandemic among federal, state, local, and private-sector entities; revised the effective time period of the Declaration; and republished the declaration in full. (85 FR 79190 December 9, 2020). On January 28, 2021, the Acting Secretary amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 7872, February 2, 2021).

The Acting Secretary now amends section V of the Declaration to add a new subsection (h) to add an additional category of qualified persons covered under the PREP Act, and thus authorizes:

(h) Any Federal government employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such Federal government employees, contractors, or volunteers are qualified persons if the following requirement is met: The executive department or agency by or for which the Federal employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that employee, contractor, or volunteer, even if those authorized duties or responsibilities ordinarily would not extend to members of the public or otherwise would be more limited in scope than the activities such employees, contractors, or volunteers are authorized to carry out under this declaration.

Description of This Amendment by Section

Section V. Covered Persons

Under the PREP Act and the Declaration, a ''qualified person'' is a ''covered person.'' Subject to certain limitations, a covered person is immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure. ''Qualified person'' includes (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) ''a person within a category of persons so identified in a declaration by the Secretary'' under subsection (b) of the PREP Act. 42 U.S.C. 247d–6d(i)(8)

By this amendment to the Declaration, the Acting Secretary identifies an additional category of persons who are qualified persons under section 247d–6d(i)(8)(B): Federal employees, contractors and volunteers authorized by their Department or agency to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of their duties or responsibilities.

The Acting Secretary has determined that there is an urgent need to expand the pool of available COVID–19 vaccinators in order to respond effectively to the pandemic. As vaccine supply is made more widely available over the coming months, health care system capacity and the vaccination workforce are likely to become increasingly strained throughout the Nation. The United States is deploying federal personnel, contractors and volunteers to assist in the national COVID–19 vaccination program. While the United States is a covered person under the PREP Act and the Declaration, this amendment clarifies that federal employees, contractors and volunteers are also qualified persons authorized by the Secretary to prescribe, dispense, or administer covered countermeasures, consistent with the terms and conditions of the Declaration.

As qualified persons, these employees, contractors and volunteers will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration in addition to the protection that is afforded to the United States as a covered person. Second, to the extent that any State law that would otherwise prohibit the employees, contractors, or volunteers who are a ''qualified person'' from prescribing, dispensing, or administering COVID–19 vaccines or other Covered Countermeasures, such law is preempted. On May 19, 2020, the Office of the General Counsel issued an advisory opinion concluding that, because licensed pharmacists are ''qualified persons'' under this declaration, the PREP Act preempts state law that would otherwise prohibit such pharmacists from ordering and administering authorized COVID–19 diagnostic tests.[1] The opinion relied in part on the fact that the Congressional delegation of authority to the Secretary under the PREP Act to specify a class of persons, beyond those who are authorized to administer a covered countermeasure under State law, as ''qualified persons'' would be rendered a nullity in the absence of such preemption. This opinion is incorporated by reference into this declaration. Based on the reasoning set forth in the May 19, 2020 advisory opinion, any State law that would otherwise prohibit a member of any of the classes of ''qualified persons'' specified in this declaration from administering a covered countermeasure is likewise preempted. In accordance with section 319F–3(i)(8)(A) of the Public Health Service Act, a State remains free to expand the universe of individuals authorized to administer covered countermeasures within its jurisdiction under State law.

The plain language of the PREP Act makes clear that there is preemption of state law as described above. Furthermore, preemption of State law is justified to respond to the nation-wide public health emergency caused by COVID–19 as it will enable States to quickly expand the vaccination workforce with additional qualified healthcare professionals where State or local requirements might otherwise inhibit or delay allowing these healthcare professionals to participate in the COVID–19 vaccination program.

[1] Department of Health and Human Services General Counsel Advisory Opinion on the Public Readiness and Emergency Preparedness Act, May 19, 2020, available at: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf/* (last visited Jan. 24, 2021). *See also,* Department of Justice Office of Legal Counsel Advisory Opinion for Robert P. Charrow, General Counsel of the Department of Health and Human Services, January 12, 2020, available at: *https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf* (last visited Jan. 24, 2021).

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

Section V of the March 10, 2020 Declaration under the PREP Act for medical countermeasures against COVID–19, as amended April 10, 2020, June 4, 2020, August 19, 2020, as amended and republished on December 3, 2020, and as amended on February 2, 2021, is further amended pursuant to section 319F–3(b)(4) of the PHS Act as described below. All other sections of the Declaration remain in effect as republished at 85 FR 79190 (December 9, 2020).

1. Covered Persons, section V, delete in full and replace with:

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States. ''Order'' as used herein and in guidance issued by the Office of the Assistant Secretary for Health [2] means a provider medication order, which includes prescribing of vaccines, or a laboratory order, which includes prescribing laboratory orders, if required. In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an Emergency, as that term is defined in Section VII of this Declaration; [3]

(b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;

(c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act;

(d) A State-licensed pharmacist who orders and administers, and pharmacy interns who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy),[4] (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule or (2) FDA authorized or FDA licensed COVID –19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. In the case of a COVID–19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID–19 vaccine recommendation(s).

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;

iv. The licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

v. The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

vi. The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation; [5]

[2] *See* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021).

[3] *See, e.g.,* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for COVID–19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf* (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf* (last visited Jan. 24, 2021) (collectively, OASH PREP Act Authorizations). Nothing herein shall suggest that, for purposes of the Declaration, the foregoing are the only persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction.

[4] Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, ''State-licensed or registered intern'' (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. *See* Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020 at 2, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

[5] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase ''current certificate in basic cardiopulmonary resuscitation,'' when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://*

vii. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;

viii. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine;

ix. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate; and

x. The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

(e) Healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are licensed or otherwise permitted to practice. When ordering and administering Covered Countermeasures by means of telehealth to patients in a state where the healthcare personnel are not already permitted to practice, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures by means of telehealth is preempted.[6] Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services.

(f) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or as authorized under the section V(d) of this Declaration, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a COVID–19 vaccination effort by a federal, State, local Tribal or territorial authority or by an institution in the State in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to: (i) Documentation of completion of the Centers for Disease Control and Prevention COVID–19 (CDC) Vaccine Training Modules[7] and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID–19 vaccine(s) to be administered; and

(g) Any physician, advanced practice registered nurse, registered nurse, or practical nurse who has held an active license or certification to prescribe, dispense, or administer vaccines under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a federal, State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to (i) documentation of completion of the Centers for Disease Control and Prevention COVID–19 Vaccine Training Modules and (ii) documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID–19 vaccine(s) to be administered.

(h) Any Federal government employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such Federal government employees, contractors, or volunteers are qualified persons if the following requirement is met: The executive department or agency by or for which the Federal employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that employee, contractor, or volunteer, even if those authorized duties or responsibilities ordinarily would not extend to members of the public or otherwise would be more limited ien scope than the activities such employees, contractors, or volunteers are authorized to carry out under this declaration.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures.

www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf (last visited Jan. 24, 2021).

[6] *See, e.g.,*Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Jan. 24, 2021).

[7] *See* COVID–19 Vaccine Training Modules, available at *https://www.cdc.gov/vaccines/covid-19/training.html.*

2. Effective Time Period, Section XII, Add to the End of the Section:

Liability protections for Qualified Persons under sections V(f) and V(d) of the declaration begin on February 8, 2021 and last through October 1, 2024.

Authority: 42 U.S.C. 247d–6d.

Norris Cochran,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2021–03106 Filed 2–11–21; 4:15 pm]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Peter Soukas, J.D., 301–594–8730; *peter.soukas@nih.gov.* Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Epstein-Barr Virus Antibody That Blocks Fusion And Neutralizes Virus Infection of B Cells

Description of Technology

Epstein-Barr virus (EBV) is the most common cause of infectious mononucleosis and is associated with nearly 200,000 cancers and 140,000 deaths each year. EBV-associated cancers include Hodgkin's lymphoma, non-Hodgkin's lymphoma, Burkitt B cell lymphoma, and EBV post-transplant lymphoproliferative disease. The latent reservoir for EBV in the body is the B lymphocyte. Thus, blocking B cell infection is important for reducing EBV-related disease.

EBV can infect both B cells and epithelial cells; however, the method of entry differs between these two cell types. To initiate B cell infection, EBV glycoprotein 350 (gp350) binds to compliment receptor 2 (CR2; also known as CD21), followed by binding of glycoprotein 42 (gp42) to HLA class II molecules, which triggers fusion of EBV with the B cell, allowing virus entry into the cell. Fusion also requires the EBV proteins gH/gL, which are found complexed with gp42 as a heterotrimer, and gB. Infection of epithelial cells is initiated by the binding of the EBV protein BMRF2 to cellular integrins, followed by binding of gH/gL to ephrin receptor A2 and integrins, which triggers fusion by EBV gB.

Monoclonal antibodies that specifically bind EBV gp42 are described by this invention. The gp42-specific antibodies are capable of neutralizing EBV infection and inhibiting fusion of EBV with B cells. The monoclonal antibodies can be used for the treatment or prophylaxis of EBV infection, prevention of EBV-associated disease or infection in immunocompromised subjects, diagnosis of EBV infection, and detection of EBV in a biological sample.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- Viral diagnostics
- Viral therapeutics
- Viral prophylaxis
- Vaccine research

Competitive Advantages

- Ease of manufacture
- Strongly neutralizing antibodies
- Alternative to EBV vaccines

Development Stage

- In vivo data assessment (animal)

Inventors: Jeffrey Cohen (NIAID), Wei Bu (NIAID), Nathan Board (NIAID), Kennichi Dowdell (NIAID).

Intellectual Property: HHS Reference No. E–020–2020–0—U.S. Provisional Application No. 62/979,070, filed February 20, 2020.

Licensing Contact: Peter Soukas, J.D., 301–594–8730; *peter.soukas@nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301–594–8730; *peter.soukas@nih.gov.*

Dated: January 28, 2021.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021–03045 Filed 2–12–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Renal RC2 Applications.

Date: March 19, 2021.

Time: 3:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, 6707 Democracy Boulevard, Room 7015, Bethesda, MD 20892–2542, 301–594–4721, *ryan.morris@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 9, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–03015 Filed 2–12–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed 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 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2021–1 Phase I: Pediatric Formulations of Select Second Line Drugs for Treating Tuberculosis (Topic 97).

Date: February 22, 2021.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Mario Cerritelli, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892, 240–669–5199, *cerritem@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2021–1 Phase I: Pediatric Formulations of Select Second Line Drugs for Treating Tuberculosis (Topic 96).

Date: February 24, 2021.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Mario Cerritelli, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892, 240–669–5199, *cerritem@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2021–1 Phase II: Pediatric Formulations of Select Second Line Drugs for Treating Tuberculosis (Topic 97).

Date: February 24, 2021.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Mario Cerritelli, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892, 240–669–5199, *cerritem@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: February 9, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–03016 Filed 2–12–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov.* Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Replication-Competent Adenovirus Type 4 SARS–CoV–2 Vaccines and Their Use

Description of Technology

NIAID has produced recombinant adenovirus type 4 (Ad4), SARS–CoV–2 spike, vectors for administration to humans. These recombinant vaccines permit rapid development of high levels of neutralizing antibodies to SARS–CoV–2 in experimental animals. This vaccine is designed to improve the durability of the immune response by inducing mucosal and systemic immunity. Further, this system should be incredibly simple and efficient when producing vaccine at scale. This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- Vaccine composition(s)

Competitive Advantages

- Stimulates a durable immune response;
- Induction of mucosal and systemic immunity;
- Potential for transmission interruption;
- Intranasal administration minimizes the impact of pre-existing immunity;
- Notable improvement for manufacturing yield and cost, ease of administration, and distribution as compared to current candidates.

Inventor: Mark Connors, M.D. (NIAID)

Publications: Matsuda et al. Journal of Clinical Investigation, 2021. (*https://doi.org/10.1172/JCI140794*). Matsuda et al., Science Immunology 2019 (*https://doi.org/10.1126/sciimmunol.aau2710*).

Intellectual Property: HHS Reference E–055–2021; Application No. 63/138,221.

Licensing Contact: To license this technology, please contact Chris Kornak at *chris.kornak@nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this invention. Interested parties should have the ability to manufacture viruses under cGMP, suitable for Phase 1–2 testing by NIAID. Capabilities for further clinical development, and experience with Phase 3 testing, licensure, and rollout are preferred. For collaboration opportunities, please contact Chris Kornak at *chris.kornak@nih.gov.*

Dated: January 29, 2021.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021–03044 Filed 2–12–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Notice is hereby given of a meeting of the HEAL (Helping to End Addiction Long-term) Multi-Disciplinary Working Group

The meeting will be open to the public as indicated below via NIH Videocast. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 program documents and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the program documents, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: HEAL Multi-Disciplinary Working Group Meeting.

Date: March 2–3, 2021.

Open: March 02, 2021, 11:00 a.m. to 12:20 p.m.

Closed: March 02, 2021, 12:20 p.m. to 4:30 p.m.

Open: March 03, 2021, 10:30 a.m. to 11:05 a.m.

Closed: March 03, 2021, 11:05 a.m. to 2:45 p.m.

Agenda: Provide an update on Helping to End Addiction Long-Term (HEAL) Initiative projects and obtain expertise from MDWG relevant to the NIH HEAL Initiative and to specific HEAL projects.

Videocast: The open portion of the meeting will be live webcast at: *https://videocast.nih.gov/.*

Place: National Institutes of Health Building 1, Wilson Hall, 1 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rebecca G Baker, Ph.D., Office of the Director, National Institutes of Health, 1 Center Drive, Room 103A, Bethesda, MD 20892, (301) 402–1994, *Rebecca.baker@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Office of the Director for the NIH HEAL Initiative home page: *https://heal.nih.gov/news* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: February 9, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–03018 Filed 2–12–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Diabetes Mellitus Interagency Coordinating Committee Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Diabetes Mellitus Interagency Coordinating Committee (DMICC) will hold a meeting on March 3, 2021. The topic for this meeting will be ''COVID–19 and Diabetes.'' The meeting is open to the public.

DATES: The meeting will be held on March 3, 2021 from 12 noon to 4:00 p.m. EST.

ADDRESSES: The meeting will be held via the online video conferencing—Zoom. For details, and to register, please contact *dmicc@mail.nih.gov.*

FOR FURTHER INFORMATION CONTACT: For further information concerning this meeting, including a draft agenda, see the DMICC website, *www.diabetescommittee.gov,* or contact Dr. B. Tibor Roberts, Executive Secretary of the Diabetes Mellitus Interagency Coordinating Committee, National Institute of Diabetes and Digestive and Kidney Diseases, 31 Center Drive, Building 31A, Room 9A19, MSC 2560, Bethesda, MD 20892–2560, telephone: 301–496–6623; FAX: 301–480–6741; email: *dmicc@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: In accordance with 42 U.S. Code 285c–3, the DMICC, chaired by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) comprising members of the Department of Health and Human Services and other federal agencies that support diabetes-related activities, facilitates cooperation, communication, and collaboration on diabetes among government entities. DMICC meetings, held several times a year, provide an opportunity for Committee members to learn about and discuss current and future diabetes programs in DMICC member organizations and to identify opportunities for collaboration. The March 3, 2021 DMICC meeting will focus on ''COVID–19 and Diabetes.''

Any member of the public interested in presenting oral comments to the Committee should notify the contact person listed on this notice at least 5 days in advance of the meeting. Interested individuals and representatives or organizations should submit a letter of intent, a brief description of the organization represented, and a written copy of their oral presentation in advance of the meeting. Only one representative of an organization will be allowed to present; oral comments and presentations will be limited to a maximum of 5 minutes. Printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the Committee by forwarding their statement to the contact person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Because of time constraints for the meeting, oral comments will be allowed on a first-come, first-serve basis.

Members of the public who would like to receive email notification about future DMICC meetings should register for the listserv available on the DMICC website, *www.diabetescommittee.gov.*

Dated: February 4, 2021.

Bruce Tibor Roberts,

Executive Secretary, DMICC, Office of Scientific Program and Policy Analysis, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

[FR Doc. 2021–03047 Filed 2–12–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR18–877: Alzheimer's Disease Clinical Trials.

Date: March 10, 2021.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sara Louise Hargrave, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, (301) 443–7193, *hargravesl@mail.nih.gov*.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Biostatistical Methods and Research Design Study Section.

Date: March 10–12, 2021.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Victoriya Volkova, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3140, Bethesda, MD 20892, (301) 594–7781, *victoriya.volkova@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biostatistical Methods and Research Design.

Date: March 12, 2021.

Time: 9:30 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237–9838, *bhagavas@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Diagnostics and Treatments (CDT).

Date: March 15–16, 2021.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maria Elena Cardenas-Corona, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, (301) 867–5309, *maria.cardenas-corona@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR Panel: Community Interventions to Address the Consequences of the COVID–19 Pandemic Among Health Disparity and Vulnerable Populations.

Date: March 15–16, 2021.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pia Kristina Peltola, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1266, *pia.peltola@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Disease Prevention and Management, Risk Reduction and Health Behavior Change.

Date: March 15–16, 2021.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michael J. McQuestion, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7808, Bethesda, MD 20892, (301) 480–1276, *mike.mcquestion@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Diseases and Immunology Research Enhancement Review.

Date: March 15, 2021.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, (301) 996–5819, *zhengli@csr.nih.gov*.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; HIV/AIDS Intra- and Inter-personal Determinants and Behavioral Interventions Study Section.

Date: March 15–16, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mark P. Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, (301) 806–6596, *rubertm@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Electronic Nicotine Delivery Systems (ENDS): Population, Clinical and Applied Prevention Research.

Date: March 15, 2021.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Miriam Mintzer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, MSC 7808, Bethesda, MD 20892, (301) 523–0646, *mintzermz@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; SBIR/STTR Applications in Drug Discovery and Development.

Date: March 15–16, 2021.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, (301) 435–1180, *ruvinser@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Electronic Nicotine Delivery Systems (ENDS): Population, Clinical and Applied Prevention Research.

Date: March 15, 2021.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mark A. Vosvick, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110,

Bethesda, MD 20892, (301) 402–4128, *mark.vosvick@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 9, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–03019 Filed 2–12–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; CTEP Branch and Support Contracts Forms and Surveys (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

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

FOR FURTHER INFORMATION CONTACT: Michael Montello, Pharm. D., Cancer Therapy Evaluation Program (CTEP), 9609 Medical Center Drive, MSC 9742, Rockville, MD 20850 or call non-toll-free number 240–276–6080 or Email your request, including your address to: *montellom@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on October 8, 2020, page 63565 (Vol. 85, No. 196, FR 63565) and allowed 60 days for public comment. No public comments were received. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection Title: CTEP Support Contract Forms and Surveys (NCI), OMB #0925–0753 Expiration Date 07/31/2021, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) and the Division of Cancer Prevention (DCP) fund an extensive national program of cancer research, sponsoring clinical trials in cancer prevention, symptom management and treatment for qualified clinical investigators. As part of this effort, CTEP implements programs to register clinical site investigators and clinical site staff, and to oversee the conduct of research at the clinical sites. CTEP and DCP also oversee two support programs, the NCI Central Institutional Review Board (CIRB) and the Cancer Trial Support Unit (CTSU). The combined systems and processes for initiating and managing clinical trials is termed the Clinical Oncology Research Enterprise (CORE) and represents an integrated set of information systems and processes which support investigator registration, trial oversight, patient enrollment, and clinical data collection. The information collected is required to ensure compliance with applicable federal regulations governing the conduct of human subjects research (45 CFR 46 and 21 CRF 50), and when CTEP acts as the Investigational New Drug (IND) holder, FDA regulations pertaining to the sponsor of clinical trials and the selection of qualified investigators under 21 CRF 312.53). Survey collections assess satisfaction and provide feedback to guide improvements with processes and technology.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 151,792.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
CTSU IRB/Regulatory Approval Transmittal Form (Attachment A01).	Health Care Practitioner	2,444	12	2/60	978
CTSU IRB Certification Form (Attachment A02) ..	Health Care Practitioner	2,444	12	10/60	4,888
Withdrawal from Protocol Participation Form (Attachment A03).	Health Care Practitioner	279	1	10/60	47
Site Addition Form (Attachment A04)	Health Care Practitioner	80	12	10/60	160
CTSU Request for Clinical Brochure (Attachment A06).	Health Care Practitioner	360	1	10/60	60
CTSU Supply Request Form (Attachment A07) ..	Health Care Practitioner	90	12	10/60	180
RTOG 0834 CTSU Data Transmittal Form (Attachment A10).	Health Care Practitioner	12	76	10/60	152
CTSU Patient Enrollment Transmittal Form (Attachment A15).	Health Care Practitioner	12	12	10/60	24
CTSU Transfer Form (Attachment A16)	Health Care Practitioner	360	2	10/60	120
CTSU System Access Request Form (Attachment A17).	Health Care Practitioner	180	1	10/60	30
CTSU OPEN Rave Request Form (Attachment A18).	Health Care Practitioner	30	21	10/60	105

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
CTSU LPO Form Creation (Attachment A19)	Health Care Practitioner	5	2	120/60	20
CTSU Site Form Creation (Attachment A20)	Health Care Practitioner	400	10	30/60	2,000
CTSU Electronic Signature Form (Attachment A21).	Health Care Practitioner	400	10	10/60	667
NCI CIRB AA & DOR between the NCI CIRB and Signatory Institution (Attachment B01).	Participants	50	1	15/60	13
NCI CIRB Signatory Enrollment Form (Attachment B02).	Participants	50	1	15/60	13
CIRB Board Member Application (Attachment B03).	Board Member	100	1	30/60	50
CIRB Member COI Screening Worksheet (Attachment B08).	Board Members	100	1	15/60	25
CIRB COI Screening for CIRB meetings (Attachment B09).	Board Members	72	1	15/60	18
CIRB IR Application (Attachment B10)	Health Care Practitioner	80	1	60/60	80
CIRB IR Application for Exempt Studies (Attachment B11).	Health Care Practitioner	4	1	30/60	2
CIRB Amendment Review Application (Attachment B12).	Health Care Practitioner	400	1	15/60	100
CIRB Ancillary Studies Application (Attachment B13).	Health Care Practitioner	1	1	60/60	1
CIRB Continuing Review Application (Attachment B14).	Health Care Practitioner	400	1	15/60	100
Adult IR of Cooperative Group Protocol (Attachment B15).	Board Members	65	1	180/60	195
Pediatric IR of Cooperative Group Protocol (Attachment B16).	Board Members	15	1	180/60	45
Adult Continuing Review of Cooperative Group Protocol (Attachment B17).	Board Members	275	1	60/60	275
Adult Amendment of Cooperative Group Protocol (Attachment B19).	Board Members	40	1	120/60	80
Pediatric Amendment of Cooperative Group Protocol (Attachment B20).	Board Members	25	1	120/60	50
Pharmacist's Review of a Cooperative Group Study (Attachment B21).	Board Members	50	1	120/60	100
Adult Expedited Amendment Review (Attachment B23).	Board Members	348	1	30/60	174
Pediatric Expedited Amendment Review (Attachment B24).	Board Members	140	1	30/60	70
Adult Expedited Continuing Review (Attachment B25).	Board Members	140	1	30/60	70
Pediatric Expedited Continuing Review (Attachment B26).	Board Members	36	1	30/60	18
Adult Cooperative Group Response to CIRB Review (Attachment B27).	Health Care Practitioner	30	1	60/60	30
Pediatric Cooperative Group Response to CIRB Review (Attachment B28).	Health Care Practitioner	5	1	60/60	5
Adult Expedited Study Chair Response to Required Modifications (Attachment B29).	Board Members	40	1	30/60	20
Reviewer Worksheet—Determination of UP or SCN (Attachment B31).	Board Members	400	1	10/60	67
Reviewer Worksheet—CIRB Statistical Reviewer Form (Attachment B32).	Board Members	100	1	15/60	25
CIRB Application for Translated Documents (Attachment B33).	Health Care Practitioner	100	1	30/60	50
Reviewer Worksheet of Translated Documents (Attachment B34).	Board Members	100	1	15/60	25
Reviewer Worksheet of Recruitment Material (Attachment B35).	Board Members	20	1	15/60	5
Reviewer Worksheet Expedited Study Closure Review (Attachment B36).	Board Members	20	1	15/60	5
Reviewer Worksheet of Expedited IR (Attachment B38).	Board Members	5	1	30/60	3
Annual Signatory Institution Worksheet About Local Context (Attachment B40).	Health Care Practitioner	400	1	40/60	267
Annual Principal Investigator Worksheet About Local Context (Attachment B41).	Health Care Practitioner	1,800	1	20/60	600
Study-Specific Worksheet About Local Context (Attachment B42).	Health Care Practitioner	4,800	1	15/60	1,200

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Study Closure or Transfer of Study Review Responsibility (Attachment B43).	Health Care Practitioner	1,680	1	15/60	420
Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form (Attachment B44).	Health Care Practitioner	360	1	20/60	120
Change of Signatory Institution PI Form (Attachment B45).	Health Care Practitioner	120	1	20/60	40
Request Waiver of Assent Form (Attachment B46).	Health Care Practitioner	35	1	20/60	12
CIRB Waiver of Consent Request Supplemental Form (Attachment B47).	Health Care Practitioner	20	1	15/60	5
Review Worksheet CIRB Review for Inclusion of Incarcerated Participants (Attachment B48).	Board Members	20	1	60/60	20
Notification of Incarcerated Participant Form (B49).	Health Care Practitioner	20	1	20/60	7
CTSU OPEN Survey (Attachment C03)	Health Care Practitioner	10	1	15/60	3
CIRB Customer Satisfaction Survey (Attachment C04).	Participants	600	1	15/60	150
Follow-up Survey (Communication Audit) (Attachment C05).	Participants/Board Members.	300	1	15/60	75
CIRB Board Member Annual Assessment Survey (Attachment C07).	Board Members	60	1	15/60	15
PIO Customer Satisfaction Survey (Attachment C08).	Health Care Practitioner	60	1	5/60	5
Audit Scheduling Form (Attachment D01)	Health Care Practitioner	152	5	21/60	266
Preliminary Audit Finding Form (Attachment D02)	Health Care Practitioner	152	5	10/60	127
Audit Maintenance Form (Attachment D03)	Health Care Practitioner	152	5	9/60	114
Final Audit finding Report Form (Attachment D04).	Health Care Practitioner	75	11	1,098/60	15,098
Follow-up Form (Attachment D05)	Health Care Practitioner	75	7	27/60	236
Roster Maintenance Form (Attachment D06)	Health Care Practitioner	5	1	18/60	2
Final Report and CAPA Request Form (Attachment D07).	Health Care Practitioner	12	9	1,800/60	3,240
NCI/DCTD/CTEP FDA Form 1572 for Annual Submission (Attachment E01).	Physician	26,500	1	15/60	6,625
NCI/DCTD/CTE Biosketch (Attachment E02)	Physician; Health Care Practitioner.	48,000	1	120/60	96,000
NCI/DCTD/CTEP Financial Disclosure Form (Attachment E03).	Physician; Health Care Practitioner.	48,000	1	15/60	12,000
NCI/DCTD/CTEP Agent Shipment Form (ASF) (Attachment E04).	Physician	24,000	1	10/60	4,000
Totals		167,715	235,670		151,792

Dated: February 1, 2021.

Diane Kreinbrink,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2021–03046 Filed 2–12–21; 8:45 am]

BILLING CODE 4140–01–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 2nd, 2021, from 10:00 a.m. EST to 4:30 p.m. EST, and March 3rd, 2021, from 10:00 a.m. EST to 4:30 p.m. EST.

The board will meet in open-session March 2nd, 2021, from 10:00 a.m. EST to 2:00 p.m. EST to discuss the Mandatory Guidelines for Federal Workplace Drug Testing Programs with updates from the Department of Transportation, the Nuclear Regulatory Commission, and the Department of Defense. Other discussion topics include an update on marijuana studies and efforts as well as the Employee Assistance Program (EAP) Toolkit. The board will meet in closed-session on March 2nd, 2021, from 2:15 p.m. EST to 4:30 p.m. EST, and March 3rd, 2021, from 10:00 a.m. EST to 4:30 p.m. EST, to discuss confidential issues surrounding the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs (hair), the Federal Drug-Free Workplace Programs and emerging issues, updates on the revisions of the Urine and Oral Fluid Mandatory Guidelines and the Biomarker Table, preliminary and unpublished studies from the Johns Hopkins University Behavioral Pharmacology Research Unit (BPRU), and cannabidiol (CBD) information from FDA. Therefore, the March 2nd, 2021, from 2:15 p.m. EST to 4:30 p.m. EST, and the March 3rd, 2021, from 10:00 a.m. EST to 4:30 p.m. EST, meetings are 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)(4) and

(9)(B), and 5 U.S.C. App. 2, Section 10(d).

Meeting registration can be completed at *http://snacregister.samhsa.gov/MeetingList.aspx.* 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, Jennifer Fan.

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention, Drug Testing Advisory Board.

Dates/Time/Type: March 2, 2021, from 10:00 a.m. to 2:00 p.m. EST: OPEN, March 2, 2021, from 2:15 p.m. to 4:30 p.m. EST: CLOSED, March 3, 2021, from 10:00 a.m. to 4:30 p.m. EST: CLOSED.

Place: Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857.

Contact: Jennifer Fan, Senior Pharmacist, Center for Substance Abuse Prevention, 5600 Fishers Lane, Room 16N06D, Rockville, Maryland 20857, Telephone: (240) 276–1759, Email: *jennifer.fan@samhsa.hhs.gov.*

Note: For technical reasons, SAMHSA was unable to provide the normal 15-day advance noticification of the meeting.

Anastasia Marie Donovan,

Policy Anayst.

[FR Doc. 2021–03065 Filed 2–12–21; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0136]

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than March 18, 2021 to be assured of consideration.

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

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (85 FR 75347) on November 25, 2020, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Number: 1651–0136.

Current Actions: This submission is being made to extend the expiration date with no change to the burden hours.

Type of Review: Extension (without change).

Affected Public: Individuals and businesses.

Abstract: Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to work continuously to ensure that our programs are effective and meet our customers' needs, U.S. Customs and Border Protection (CBP) (hereafter ''the Agency'') seeks to obtain OMB approval of a generic clearance to collect qualitative feedback on our service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study.

This collection of information is necessary to enable CBP to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with CBP's programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between CBP and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Type of Information Collection: Comment Cards.

Estimated Number of Respondents: 10,000.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 10,000.

Estimated Time per Response: 3 minutes.

Estimated Total Annual Burden Hours: 500 hours.

Type of Information Collection: Customer Surveys.

Estimated Number of Respondents: 290,000.

Estimated Numbers of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 290,000.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 24,490.

Dated: February 9, 2021.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2021–02998 Filed 2–12–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2007–0008]

National Advisory Council

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Committee management; request for applicants for appointment to the National Advisory Council.

SUMMARY: The Federal Emergency Management Agency (FEMA) requests that qualified individuals interested in serving on the FEMA National Advisory Council (NAC) apply for appointment as identified in this notice. Pursuant to the *Post-Katrina Emergency Management Reform Act of 2006* (PKEMRA), the NAC advises the FEMA Administrator on all aspects of emergency management to incorporate input from and ensure coordination with State, local, Tribal, and territorial governments, and the non-governmental and private sectors on developing and revising national plans and strategies, the administration of and assessment of FEMA's grant programs, and the development and evaluation of risk assessment methodologies. The NAC consists of up to thirty-five (35) members, all of whom are experts and leaders in their respective fields. FEMA seeks to appoint individuals to seven (7) discipline-specific positions on the NAC and up to four (4) members as Administrator Selections. If other positions open during the application and selection period, FEMA may select qualified candidates from the pool of applications.

DATES: FEMA will accept applications until 11:59 p.m. Eastern Time on March 12, 2021.

ADDRESSES: Please submit application packages via email to *FEMA-NAC@fema.dhs.gov.* Save materials in one file using the naming convention, ''Last Name_First Name_NAC Application'' and attach to the email. The Office of the National Advisory Council will send you an email that confirms receipt of your application and will notify you of the final status of your application once FEMA selects new members.

FOR FURTHER INFORMATION CONTACT: Rob Long, Designated Federal Officer, Office of the National Advisory Council, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472–3184; telephone (202) 646–2700; email *FEMA-NAC@fema.dhs.gov.* For more information on the NAC, including membership application instructions, visit *https://www.fema.gov/national-advisory-council.*

SUPPLEMENTARY INFORMATION: The NAC is an advisory committee established in accordance with the provisions of the *Federal Advisory Committee Act* (FACA), 5 U.S.C. Appendix. As required by PKEMRA, the Secretary of Homeland Security established the NAC to ensure effective and ongoing coordination of Federal preparedness, protection, response, recovery, and mitigation for natural disasters, acts of terrorism, and other man-made disasters. FEMA is requesting that individuals who are interested in and qualified to serve on the NAC apply for appointment to an open position in one of the following discipline areas: Cybersecurity (Special Government Employee (SGE)); Communications (SGE); In-Patient Medical Providers (SGE); Elected Local Officials (Representative); Emergency Management (Representative); and two open positions for Emergency Response Providers (Representatives). The Administrator may appoint up to four (4) additional candidates to serve as FEMA Administrator Selections (as SGE appointments). Please visit *https://www.fema.gov/membership-applications* for further information on expertise required to fill these positions. Appointments will be for three-year terms commencing December 2021.

The NAC Charter contains more information and can be found at: *https://www.fema.gov/media-library/assets/documents/35316.*

If you are interested, qualified, and would like to be considered for appointment to the NAC, please submit an application package to the Office of the NAC as listed in the **ADDRESSES** section of this notice. The NAC does not provide a formal application form; however, each electronic application package MUST include the following information:

- Cover letter, addressed to the Office of the NAC, that includes or indicates: Current position title and employer or organization you represent, home and work addresses, and preferred telephone number and email address; the discipline area position(s) for which you are qualified; why you are interested in serving on the NAC; and how you heard about the solicitation for NAC members;
- A summary of the most important accomplishments that qualify you to serve on the NAC, in the form of three to five (3–5) bullets in less than 75 words total;
- Resume or Curriculum Vitae (CV); and
- One Letter of Recommendation addressed to the Office of the NAC.

Your application package must be less than eight (8) pages to be considered by FEMA. Information contained in your application package should indicate clearly your qualifications to serve on the NAC and fill one of the current open positions. FEMA will not consider incomplete applications. FEMA will review the information contained in application packages and make selections based on: (1) Leadership attributes; (2) emergency management experience; (3) expert knowledge in discipline area; and (4) ability to meet NAC member expectations. FEMA will also consider overall NAC composition, including geographic diversity and mix of officials, emergency managers, and emergency response providers from state, local, and tribal governments, when selecting members.

Appointees may be designated as an SGE as defined in section 202(a) of title 18, U.S.C., as a Representative member, or as an RGE. SGEs speak in a personal capacity as experts in their field and Representative members speak for the stakeholder group they represent. Candidates selected for appointment as SGEs are required to complete a new entrant Confidential Financial Disclosure Form (Office of Government Ethics (OGE) Form 450) each year. You can find this form at the Office of

Government Ethics website (*http://www.oge.gov*). However, please do not submit this form with your application.

The NAC generally meets in person twice per year. FEMA does not pay NAC members for their time, but may reimburse travel expenses such as airfare, per diem to include hotel stays, and other transportation costs within federal travel guidelines when pre-approved by the Designated Federal Officer. NAC members must serve on one of the three NAC Subcommittees, which meet regularly by teleconference. FEMA estimates the total time commitment for subcommittee participation to be two (2) hours per week (more for NAC leadership).

DHS does not discriminate on the basis of race, color, religion, sex, national origin, sexual orientation, gender identity, marital status, political affiliation, disability and genetic information, age, membership in an employee organization, or other non-merit factor. DHS strives to achieve a widely diverse candidate pool for all of its recruitment actions. Current DHS and FEMA employees, including FEMA Reservists, are not eligible for membership. Federally registered lobbyists may apply for positions designated as Representative appointments but are not eligible for positions that are designated as SGE appointments.

MaryAnn Tierney,

Acting Deputy Administrator, Federal Emergency Management Agency.

[FR Doc. 2021–03060 Filed 2–12–21; 8:45 am]

BILLING CODE 9111–48–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2021–0001]

Notice of the President's National Infrastructure Advisory Council Meeting

AGENCY: Department of Homeland Security (DHS).

ACTION: Notice of Federal Advisory Committee Act (FACA) meeting; request for comments.

SUMMARY: CISA announces a public meeting of the President's National Infrastructure Advisory Council (NIAC). To facilitate public participation, CISA invites public comments on the agenda items and any associated briefing materials to be considered by the council at the meeting.

DATES: *Meeting Registration:* Individual registration to attend the meeting by phone is required and must be received no later than 5:00 p.m. EST on Monday, March 1, 2021. For more information on how to participate, please contact *NIAC@cisa.dhs.gov.*

Speaker Registration: Individuals may register to speak during the meeting's public comment period. The registration must be received no later than 5:00 p.m. EST on Monday, March 1, 2021.

Written Comments: Written comments must be received no later than 5:00 p.m. EST on Monday, February 22, 2021.

Meeting Date: The meeting will be held on Thursday, March 4, 2021 from 1:00 p.m.–3:00 p.m. EST. The meeting may close early if the council has completed its business.

ADDRESSES: The meeting will be held remotely via conference call. For access to the conference call bridge, information on services for individuals with disabilities, or to request special assistance to participate, please email *NIAC@cisa.dhs.gov* by 5:00 p.m. EST on Monday, March 1, 2021.

Comments: Written comments may be submitted on the issues to be considered by the NIAC as described in the **SUPPLEMENTARY INFORMATION** section below and any briefing materials for the meeting. Any briefing materials that will be presented at the meeting will be made publicly available *before the meeting* at the following website: *www.cisa.gov/niac.*

Comments identified by docket number CISA–2020–0017 may be submitted by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting written comments.
- *Email: NIAC@cisa.dhs.gov.* Include docket number CISA–2020–0017 in the subject line of the message.

Instructions: All submissions received must include the agency name and docket number for this notice. All written comments received will be posted without alteration at *www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments and additional information on participating in the upcoming NIAC meeting, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket and comments received by the NIAC, go to *www.regulations.gov* and enter docket number CISA–2020–0017.

A public comment period is scheduled to be held during the meeting from 2:35 p.m.–2:45 p.m. EST. Speakers who wish to participate in the public comment period must register by emailing *NIAC@cisa.dhs.gov.* Speakers are requested to limit their comments to three minutes and will speak in order of registration. Please note that the public comment period may end before the time indicated, following the last request for comments.

FOR FURTHER INFORMATION CONTACT: Rachel Liang, *Rachel.Liang@cisa.dhs.gov*; 202–936–8300.

SUPPLEMENTARY INFORMATION: The NIAC is established under Section 10 of E.O. 13231 issued on October 16, 2001. Notice of this meeting is given under the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix (Pub. L. 92–463). The NIAC shall provide the President, through the Secretary of Homeland Security, with advice on the security and resilience of the Nation's critical infrastructure sectors.

Agenda: The NIAC will meet in an open meeting on Thursday, March 4, 2021, to discuss the following agenda items:

I. Opening of Meeting
II. Roll Call of Members
III. Opening Remarks
IV. Supply Chain Panel Discussion
V. Workforce and Talent Management Study Update
VI. NIAC Member Roundtable Discussion
VII. Public Comment
VIII. Closing Remarks
IX. Adjournment

Public Participation

Meeting Registration Information

Requests to attend via conference call will be accepted and processed in the order in which they are received. Individuals may register to attend the NIAC meeting by phone by sending an email to *NIAC@cisa.dhs.gov.*

Public Comment

While this meeting is open to the public, participation in FACA deliberations are limited to council members. A public comment period will be held during the meeting from approximately 2:35 p.m.–2:45 p.m. EST. Speakers who wish to comment must register in advance and can do so by emailing *NIAC@cisa.dhs.gov* no later than Monday, March 1, 2021, at 5:00 p.m. EST. Speakers are requested to limit their comments to three minutes. Please note that the public comment period may end before the time indicated, following the last call for comments.

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities

or to request special assistance at the meeting, please contact *NIAC@cisa.dhs.gov* by 5:00 p.m. EST on Monday, March 1, 2021.

Rachel Liang,

Designated Federal Officer, President's National Infrastructure Advisory Council, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security.

[FR Doc. 2021–02981 Filed 2–12–21; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Reinstating Deferred Enforced Departure for Liberians

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS).

ACTION: Notice.

A ''Memorandum on Reinstating Deferred Enforced Departure for Liberians'' was issued by President Biden on January 20, 2021. The President determined that it is in the foreign policy interests of the United States to reinstate Deferred Enforced Departure (DED) for Liberians through June 30, 2022. The President directed the Secretary of Homeland Security to extend DED for eligible Liberians currently covered under DED and to provide for continued work authorization through June 30, 2022. The President further authorized and directed the Secretary of Homeland Security to publish this memorandum in the **Federal Register**. The text of the memorandum (published January 25, 2021, at 86 FR 7055) is set out below.

Tracy L. Renaud,

Senior Official Performing the Duties of the Director, U.S. Citizenship and Immigration Services.

Memorandum on Reinstating Deferred Enforced Departure for Liberians

Since 1991, the United States has provided safe haven for Liberians who were forced to flee their country as a result of armed conflict and widespread civil strife, in part through the grant of Temporary Protected Status (TPS). The armed conflict ended in 2003, and TPS for affected Liberian nationals ended effective October 1, 2007. President Bush then deferred the enforced departure of those Liberians originally granted TPS. President Obama, in successive memoranda, extended that grant of Deferred Enforced Departure (DED) to March 31, 2018. President Trump then determined that conditions in Liberia did not warrant a further extension of DED, but that the foreign policy interests of the United States warranted affording an orderly transition period for Liberian DED beneficiaries. President Trump later extended that DED transition period through March 30, 2020.

In December 2019, the Congress enacted the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116–92) (NDAA), which included, as section 7611, the Liberian Refugee Immigration Fairness (LRIF) provision. The LRIF provision, with limited exceptions, makes Liberians who have been continuously present in the United States since November 20, 2014, as well as their spouses and children, eligible for adjustment of status to that of United States lawful permanent resident (LPR). The NDAA gave eligible Liberian nationals until December 20, 2020, to apply for this adjustment of status. After the enactment of the LRIF provision, President Trump further extended the DED transition period through January 10, 2021, to ensure that DED beneficiaries would continue to be eligible for employment authorization during the LRIF application period.

The LRIF application process was hampered by a slow launch, cumbersome procedures, and delays in adjudication. Recognizing these difficulties, the Congress enacted a 1-year extension to the application period in section 901 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260). That legislation, however, did not provide for continued employment authorization past January 10, 2021, the expiration of the most recent DED transition period.

There are compelling foreign policy reasons to reinstate DED for an additional period for those Liberians presently residing in the United States who were under a grant of DED as of January 10, 2021. Providing work authorization to these Liberians, for whom we have long authorized TPS or DED in the United States, while they initiate and complete the LRIF status-adjustment process, honors the historic close relationship between the United States and Liberia and is in the foreign policy interests of the United States. I urge all Liberian DED beneficiaries to apply promptly for adjustment of status, and I direct the Secretary of Homeland Security to review the LRIF application procedures administered by United States Citizenship and Immigration Services to ensure that they facilitate ease of application and timely adjudication.

Pursuant to my constitutional authority to conduct the foreign relations of the United States, I have determined that it is in the foreign policy interests of the United States to defer through June 30, 2022, the removal of any Liberian national, or person without nationality who last habitually resided in Liberia, who is present in the United States and who was under a grant of DED as of January 10, 2021. I have also determined that any Liberian national, or person without nationality who last habitually resided in Liberia, who is present in the United States and who was under a grant of DED as of January 10, 2021, should have continued employment authorization through June 30, 2022.

The Secretary of Homeland Security shall promptly direct the appropriate officials to make provision, by means of a notice published in the **Federal Register**, for immediate allowance of employment authorization for those Liberians who held appropriate DED-related employment authorization documents as of January 10, 2021. The Secretary shall also provide for the prompt issuance of new or replacement documents in appropriate cases.

This grant of DED and continued employment authorization shall apply to any Liberian DED beneficiary as of January 10, 2021, but shall not apply to such persons in the following categories:

(1) Individuals who would be ineligible for TPS for the reasons provided in section 244(c)(2)(B) of the Immigration and Nationality Act, 8 U.S.C. 1254a(c)(2)(B);

(2) Individuals who sought or seek LPR status under the LRIF provision but whose applications have been or are denied by the Secretary of Homeland Security;

(3) Individuals whose removal the Secretary of Homeland Security determines is in the interest of the United States, subject to the LRIF provision;

(4) Individuals whose presence or activities in the United States the Secretary of State has reasonable grounds to believe would have potentially serious adverse foreign policy consequences for the United States;

(5) Individuals who have voluntarily returned to Liberia or their country of last habitual residence outside the United States for an aggregate period of 180 days or more, as specified in subsection (c)(2) of the LRIF provision;

(6) Individuals who were deported, excluded, or removed prior to the date of this memorandum; or

(7) Individuals who are subject to extradition.

Accordingly, I hereby direct the Secretary of Homeland Security to take the necessary steps to implement for eligible Liberians:

(1) A deferral of enforced departure from the United States through June 30, 2022, effective immediately; and

(2) authorization for employment valid through June 30, 2022.

The Secretary of Homeland Security is authorized and directed to publish this memorandum in the **Federal Register**.

JOSEPH R. BIDEN JR.

[FR Doc. 2021–03153 Filed 2–12–21; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Reinstatement of Deferred Enforced Departure and Continuation of Employment Authorization and Automatic Extension of Existing Employment Authorization Documents for Eligible Liberians

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security.

ACTION: Notice.

SUMMARY: On January 20, 2021, President Biden issued a memorandum to the Secretary of Homeland Security (Secretary) directing the Secretary to reinstate Deferred Enforced Departure (DED) for eligible Liberians, and to provide for continued work authorization through June 30, 2022. Eligible Liberian nationals (and persons without nationality who last habitually resided in Liberia) covered under DED as of January 10, 2021 may remain in the United States through June 30, 2022. This notice extends through June 30, 2022 employment authorization for Liberians covered under DED and also automatically extends DED-related Employment Authorization Documents (EADs) for those who already have an EAD with a printed expiration date of March 30, 2020 or January 10, 2021. The reinstatement of DED for Liberians is intended to allow additional time for eligible Liberians to apply for adjustment of status on or before December 20, 2021 under the extension of the Liberian Refugee Immigration Fairness (LRIF) provision in section 901 of the Consolidated Appropriations Act, 2021. Liberians who apply for adjustment of status under LRIF may immediately apply for employment authorization consistent with that provision.

DATES: DED and employment authorization for individuals covered under DED for Liberians is extended through June 30, 2022. Automatically extended DED-related EADs, as specified in this notice, expire after June 30, 2022.

FOR FURTHER INFORMATION CONTACT:

- You may contact Maureen Dunn, Chief, Humanitarian Affairs Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, by mail at 5900 Capital Gateway Drive, Camp Springs, MD 20746.
- For further information on DED, including additional information on eligibility, please visit the USCIS DED web page at *www.uscis.gov/humanitarian/temporary-protected-status/deferred-enforced-departure.* You can find specific information about DED for Liberians by selecting ''DED Granted Country: Liberia'' from the menu on the left of the DED web page. For further information on Liberian Refugee Immigration Fairness (LRIF), including additional information on eligibility, please visit the USCIS LRIF web page *www.uscis.gov/green-card/other-ways-get-green-card/liberian-refugee-immigration-fairness.*
- If you have additional questions about DED or LRIF, please visit *uscis.gov/tools.* Our online virtual assistant, Emma, can answer many of your questions and point you to additional information on our website. If you are unable to find your answers there, you may also call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).
- Applicants seeking information about the status of their individual cases may check Case Status Online, available on the USCIS website at *www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).
- Further information will also be available at local USCIS offices upon publication of this notice.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

CFR—Code of Federal Regulations
DED—Deferred Enforced Departure
DHS—U.S. Department of Homeland Security
EAD—Employment Authorization Document
FNC—Final Nonconfirmation
Form I–485—Application to Register Permanent Residence or Adjust Status
Form I–765—Application for Employment Authorization
Form I–797—Notice of Action (Approval Notice)
Form I–9—Employment Eligibility Verification
Form I–912—Request for Fee Waiver
FR—Federal Register
Government—U.S. Government
IER—U.S. Department of Justice Civil Rights Division, Immigrant and Employee Rights Section
LRIF—Liberian Refugee Immigration Fairness
SAVE—USCIS Systematic Alien Verification for Entitlements Program
Secretary—Secretary of Homeland Security
TNC—Tentative Nonconfirmation
TPS—Temporary Protected Status
TTY—Text Telephone
USCIS—U.S. Citizenship and Immigration Services
U.S.C.—United States Code

Purpose of This Action

Pursuant to the President's constitutional authority to conduct the foreign relations of the United States, President Biden has concluded that foreign policy considerations warrant a reinstatement of DED for Liberians through June 30, 2022.[1] Through this notice, as directed by the President, DHS is extending DED and employment authorization for covered Liberians through June 30, 2022 and automatically extending the validity of DED-related EADs bearing a printed expiration date of March 30, 2020 or January 10, 2021 through June 30, 2022.[2] The President authorized the reinstatement of DED to allow for continued employment authorization for individuals covered under DED. Liberians who apply for adjustment of status on or before December 20, 2021 under the extension of the LRIF provision in section 901 of the Consolidated Appropriations Act, 2021 may immediately apply for employment authorization consistent with that provision. *See* Consolidated Appropriations Act for Fiscal Year 2021,

[1] *See* Presidential Memorandum for the Secretary of State and the Secretary of Homeland Security on Reinstating Deferred Enforced Departure for Liberians January 20, 2021, *available at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/reinstating-deferred-enforced-departure-for-liberians/* Note: Individuals covered by the presidential DED memorandum include certain Liberians as well as persons without nationality who last habitually resided in Liberia who held Temporary Protected Status on September 30, 2007 and who meet all other criteria in the memorandum for DED. Hereinafter, ''DED for Liberians'' also includes such persons without nationality.

[2] USCIS had previously auto-extended to January 10, 2021 those EADs for individuals covered under DED for Liberians with a March 30, 2020 facial expiration date. *See* Continuation of Employment Authorization and Automatic Extension of Existing Employment Authorization Documents for Eligible Liberians During the Period of Extended Wind-Down of Deferred Enforced Departure, 84 FR 19496 (April 7, 2020).

Public Law 116–260 (Dec. 27, 2020) Section 901, *available at https://www.congress.gov/bill/116th-congress/house-bill/133/text;* National Defense Authorization Act for Fiscal Year 2020, Public Law 116–92 (Dec. 20, 2019) Section 7611, *available at https://www.govinfo.gov/content/pkg/PLAW-116publ92/html/PLAW-116publ92.htm.* The extension of the LRIF provision in section 901 of the Consolidated Appropriations Act, 2021 did not provide for continued employment authorization for DED-covered individuals who have not yet applied for adjustment of status. Therefore, the President directed that DED be reinstated for eligible Liberians and certain other persons without nationality who were covered by DED for Liberians to provide for their continued employment authorization through June 20, 2022 while they apply for adjustment of status under LRIF. *See* Presidential Memorandum for the Secretary of State and the Secretary of Homeland Security on Reinstating Deferred Enforced Departure for Liberians January 20, 2021, available at: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/reinstating-deferred-enforced-departure-for-liberians/.* This notice also explains how Liberians covered under DED and their employers may determine which EADs are automatically extended and how this impacts the Employment Eligibility Verification (Form I–9), E-Verify, and USCIS Systematic Alien Verification for Entitlements Program (SAVE) processes. Note that DED only applies to individuals who have continuously resided in the United States since October 1, 2002, and who held Temporary Protected Status (TPS) on September 30, 2007, under the TPS designation for Liberia, which terminated on that date. *Id.; see also* 71 FR 55000 (Sept. 20, 2006) (termination of TPS Liberia notice).

Employment Authorization and Eligibility

How will I know if I am eligible for employment authorization under the Presidential Memorandum that reinstated DED for eligible Liberians?

The procedures for employment authorization in this notice apply only to individuals who are Liberian nationals (and persons without nationality who last habitually resided in Liberia) who:

- Have continuously resided in the United States since October 1, 2002;
- Held TPS on September 30, 2007, the termination date of a former TPS designation for Liberia; and
- Were covered under DED for Liberians as of January 10, 2021.

This DED reinstatement does not include any individual:

- Who would be ineligible for TPS for the reasons set forth in section 244(c)(2)(B) of the Immigration and Nationality Act, 8 U.S.C. 1254a(c)(2)(B);
- Who sought or seeks LPR status under the LRIF provision but whose applications have been or are denied by the Secretary;
- Whose removal the Secretary determines is in the interest of the United States, subject to the LRIF provision and other applicable law;
- Whose presence or activities in the United States the Secretary of State has reasonable grounds to believe would have potentially serious adverse foreign policy consequences for the United States;
- Who has voluntarily returned to Liberia or his or her country of last habitual residence outside the United States for an aggregate period of 180 days or more, as specified in subsection (c) of the LRIF provision;
- Who was deported, excluded, or removed prior to January 20, 2021; or
- Who is subject to extradition.

*Does this **Federal Register** notice automatically extend my current EAD through June 30, 2022?*

Regardless of your country of birth, if you are a national of Liberia (or a person having no nationality who last habitually resided in Liberia), you were covered under DED for Liberians as of January 10, 2021, and you are an individual approved for DED by the President, this notice automatically extends your DED-based EAD with a marked expiration date of March 30, 2020, or January 10, 2021 bearing the notation A–11 on the front of the card under ''Category,'' though June 30, 2022. This means that your EAD is valid through June 30, 2022, even though its marked expiration date has passed.

When hired, what documentation may I show to my employer as evidence of identity and employment authorization when completing Form I–9?

You can find the Lists of Acceptable Documents on the third page of Form I–9 as well as the Acceptable Documents web page at *www.uscis.gov/i-9-central/acceptable-documents.* Employers must complete Form I–9 to verify the identity and employment authorization of all new employees. Within 3 days of hire, employees must present acceptable documents to their employers as evidence of identity and employment authorization to satisfy Form I–9 requirements.

You may present any document from List A (which provides evidence of both identity and employment authorization) or one document from List B (which provides evidence of your identity) together with one document from List C (which provides evidence of employment authorization), or you may present an acceptable receipt as described in the Form I–9 Instructions. Employers may not reject a document based on a future expiration date. You can find additional information about Form I–9 on the I–9 Central web page at *www.uscis.gov/I-9Central.*

An EAD is an acceptable document under List A. See the section ''How do my employer and I complete Form I–9 using my automatically extended EAD for a new job?'' of this **Federal Register** notice for further information. If your EAD has an expiration date of March 30, 2020 or January 10, 2021 on its face, and states A–11 under ''Category,'' it has been extended automatically consistent with the President's directive and by this **Federal Register** notice, and you may choose to present this EAD to your employer as proof of identity and employment eligibility for Form I–9 through June 30, 2022. To minimize confusion over this extension at the time of hire, you may also show your employer a copy of this **Federal Register** notice confirming the extension of your employment authorization through June 30, 2022. *See* the section ''How do my employer and I complete Form I–9 using my automatically extended EAD for a new job?'' for further information. As an alternative to presenting your automatically extended EAD, you may choose to present any other acceptable document from List A, a combination of one selection from List B and one selection from List C, or an acceptable receipt.

What documentation may I present to my employer for Form I–9 if I am already employed but the expiration date listed on my current DED-related EAD has passed?

Even though your EAD has been automatically extended, your employer is required by law to ask you about your continued employment authorization. If your employer did not keep a copy of your EAD when you initially presented it, your employer may need to re-inspect your automatically extended EAD to check the ''Card Expires'' date and ''Category'' code. In this situation presented, your employer should update the EAD expiration date in Section 2 of Form I–9. See the section ''What corrections should my current employer make to Form I–9 if my employment authorization has been automatically

extended?'' of this **Federal Register** notice for further information. You may show this **Federal Register** notice to your employer to explain what to do for Form I–9 and to show that your EAD has been automatically extended through June 30, 2022.

The last day of the automatic extension for your EAD is June 30, 2022. Before you start work on July 1, 2022, your employer is required by law to reverify your employment authorization in Section 3 of Form I–9. At that time, you must present any document from List A or any document from List C on Form I–9, Lists of Acceptable Documents, or an acceptable List A or List C receipt described in the Form I–9 Instructions, to reverify your employment authorization.

If your original Form I–9 was a previous version, your employer must complete Section 3 of the current version of Form I–9, and attach it to your previously completed Form I–9. Your employer can check the I–9 Central web page at *www.uscis.gov/I-9Central* for the most current version of Form I–9.

Your employer may not specify which List A or List C document you must present and cannot reject an acceptable receipt.

Can I obtain a new EAD?

Yes, if you remain eligible for DED, you can obtain a new EAD, regardless of whether you have had an EAD previously; however, you do not need to apply for a new EAD to benefit from this automatic extension. If you are currently covered under DED and want to obtain a new DED-based EAD valid through June 30, 2022, then you must file Form I–765, Application for Employment Authorization, and pay the associated fee. If you are currently covered under DED and are eligible for permanent resident status under LRIF, you may file Form I–765 concurrently with or after you file Form I–485, Application to Register Permanent Residence or Adjust Status. You may be eligible for a fee waiver, if you meet the eligibility criteria. *See* Form I–912, Request for Fee Waiver.

Can my employer require that I provide any other documentation to prove my status, such as proof of my Liberian citizenship?

No. When completing Form I–9, including reverifying employment authorization, employers must accept any documentation that appears on the Form I–9 Lists of Acceptable Documents that reasonably appears to be genuine and that relates to you, or an acceptable List A, List B, or List C receipt. Employers do not need to reverify List B identity documents. Employers may not request documentation that does not appear on the Lists of Acceptable Documents. Therefore, employers may not request proof of Liberian citizenship when completing Form I–9 for new hires or reverifying the employment authorization of current employees. If presented with an EAD that has been automatically extended, employers should accept such document as a valid List A document, as long as the EAD reasonably appears to be genuine and relates to the employee. Refer to the ''Note to Employees'' section of this **Federal Register** notice for important information about your rights if your employer rejects lawful documentation, requires additional documentation, or otherwise discriminates against you based on your citizenship or immigration status, or your national origin.

What happens after June 30, 2022, for purposes of employment authorization?

After June 30, 2022, employers may no longer accept EADs that are automatically extended under this **Federal Register** notice and employees will need to present other evidence of continued work authorization.

What can I do to adjust status based on LRIF?

Individuals who are eligible for permanent resident status under LRIF and who wish to prevent a gap in employment authorization should submit their completed Form I–485 and associated Form I–765 as early as possible. Liberian nationals applying to adjust status under LRIF must properly file Form I–485, and USCIS must receive Form I–485, by December 20, 2021.[3] For more information on applying for adjustment of status under LRIF, see *https://www.uscis.gov/green-card/green-card-eligibility/liberian-refugee-immigration-fairness.*

How do my employer and I complete Form I–9 using an automatically extended EAD for a new job?

When using an automatically extended EAD to complete Form I–9 for a new job on or before June 30, 2022, for Section 1, you should:

a. Check ''An alien authorized to work until'' and enter June 30, 2022 as the expiration date; and

b. Enter your USCIS Number or A-Number where indicated (your EAD or other document from DHS will have your USCIS number or A-Number printed on it; the USCIS Number is the same as your A-Number without the A prefix).

For Section 2, your employer should:

a. Determine if the EAD is auto-extended by ensuring it is in Category A–11 and has a ''Card Expires'' date of March 30, 2020 or January 10, 2021;

b. Write in the document title;

c. Enter the issuing authority;

d. Enter the document number; and

e. Write June 30, 2022 as the expiration date.

Before the start of work on July 1, 2022, employers must reverify the employee's employment authorization in Section 3 of Form I–9.

What corrections should my current employer make to Form I–9 if my EAD has been automatically extended?

If you presented an unexpired DED-related EAD when you first started your job and your EAD has now been automatically extended, your employer may need to reinspect your current EAD if your employer does not have a copy of the EAD on file. Your employer should determine if your EAD is automatically extended by ensuring that it contains Category A–11 and has a Card Expires date of March 30, 2020 or January 10, 2021. If your employer determines that your EAD has been automatically extended, your employer should update Section 2 of your previously completed Form I–9 as follows:

a. Write EAD Ext. and June 30, 2022 as the expiration date in the Additional Information field; and

b. Initial and date the correction.

Note: This is not considered a reverification. Employers do not need to complete Section 3 until either this notice's automatic extension of EADs has ended or the employee presents a new document to show continued employment authorization, whichever is sooner. By July 1, 2022, when the employee's automatically extended EAD has expired, employers are required by law to reverify the employee's employment authorization in Section 3. If your original Form I–9 was a previous version, your employer must complete Section 3 of the current version of Form I–9 and attach it to your previously completed Form I–9. Your employer can check the I–9 Central web page at *www.uscis.gov/I-9Central* for the most current version of Form I–9.

If I am an employer enrolled in E-Verify, how do I verify a new employee whose EAD has been automatically extended?

Employers may create a case in E-Verify for a new employee by providing

[3] **Note:** Persons without nationality who last resided in Liberia are not eligible for adjustment under LRIF.

the Document number from Form I–9 in the Document Number field in E-Verify.

If I am an employer enrolled in E-Verify, what do I do when I receive a ''Work Authorization Documents Expiration'' alert for an automatically extended EAD?

E-Verify automated the verification process for DED-related EADs that are automatically extended. If you have employees who provided a DED-related EAD when they first started working for you, you will receive a ''Work Authorization Documents Expiring'' case alert when the auto-extension period for this EAD is about the expire. Before this employee starts work on July 1, 2022, you must reverify his or her employment authorization in Section 3 of Form I–9. Employers should not use E-Verify for reverification.

Note to All Employers

Employers are reminded that the laws requiring proper employment eligibility verification and prohibiting unfair immigration-related employment practices remain in full force. This **Federal Register** notice does not supersede or in any way limit applicable employment verification rules and policy guidance, including those rules setting forth reverification requirements. For general questions about the employment eligibility verification process, employers may call USCIS at 888–464–4218 (TTY 877–875–6028) or email USCIS at *I-9Central@dhs.gov.* USCIS accepts calls and emails in English and many other languages. For questions about avoiding discrimination during the employment eligibility verification process (Form I–9 and E-Verify), employers may call the U.S. Department of Justice's Civil Rights Division, Immigrant and Employee Rights Section (IER) Employer Hotline at 800–255–8155 (TTY 800–237–2515). IER offers language interpretation in numerous languages. Employers may also email IER at *IER@usdoj.gov.*

Note to Employees

For general questions about the employment eligibility verification process, employees may call USCIS at 888–897–7781 (TTY 877–875–6028) or email USCIS at *I-9Central@dhs.gov.* USCIS accepts calls in English, Spanish and many other languages. Employees or applicants may also call the IER Worker Hotline at 800–255–7688 (TTY 800–237–2515) for information regarding employment discrimination based upon citizenship, immigration status, or national origin, including discrimination related to Form I–9 and E-Verify. The IER Worker Hotline provides language interpretation in numerous languages.

To comply with the law, employers must accept any document or combination of documents from the Lists of Acceptable Documents if the documentation reasonably appears to be genuine and to relate to the employee, or an acceptable List A, List B, or List C receipt as described in the Form I–9 Instructions. Employers may not require extra or additional documentation beyond what is required for Form I–9 completion. Further, employers participating in E-Verify who receive an E-Verify case result of ''Tentative Nonconfirmation'' (TNC) must promptly inform employees of the TNC and give such employees an opportunity to contest the TNC. A TNC case result means that the information entered into E-Verify from Form I–9 differs from records available to DHS.

Employers may not terminate, suspend, delay training, withhold pay, lower pay, or take any adverse action against an employee because of the TNC while the case is still pending with E-Verify. A ''Final Nonconfirmation'' (FNC) case result is received when E-Verify cannot confirm an employee's employment eligibility. An employer may terminate employment based on a case result of FNC. Work-authorized employees who receive an FNC may call USCIS for assistance at 888–897–7781 (TTY 877–875–6028). For more information about E-Verify-related discrimination or to report an employer for discrimination in the E-Verify process based on citizenship, immigration status, or national origin, contact IER's Worker Hotline at 800–255–7688 (TTY 800–237–2515). Additional information about proper nondiscriminatory Form I–9 and E-Verify procedures is available on the IER website at *www.justice.gov/ier* and the USCIS and E-verify websites at *www.uscis.gov/i-9-central* and *www.e-verify.gov.*

Note Regarding Federal, State, and Local Government Agencies (Such as Departments of Motor Vehicles)

For Federal purposes, individuals covered under DED for Liberians presenting an EAD referenced in this **Federal Register** notice do not need to show any other document, such as an I–797, Notice of Action, to prove that they qualify for this extension. However, while Federal Government agencies must follow the guidelines laid out by the Federal Government, state and local government agencies establish their own rules and guidelines when granting certain benefits. Each state may have different laws, requirements, and determinations about what documents you need to provide to prove eligibility for certain benefits. Whether you are applying for a Federal, state, or local government benefit, you may need to provide the government agency with documents that show you are covered under DED and/or show you are authorized to work based on DED. Examples of such documents are:

- Your current EAD;
- Your automatically extended EAD with a copy of this **Federal Register** notice, providing an automatic extension of your EAD; and/or
- A copy of the notice of approval of your past Application for Temporary Protected Status Form I–797, Notice of Action, if you received one from USCIS, coupled with a copy of the January 20, 2021, Presidential Memorandum reinstating DED for Liberians.

Check with the government agency regarding which document(s) the agency will accept. Some benefit-granting agencies use the SAVE program to confirm the current immigration status of applicants for public benefits. While SAVE can verify when an individual has DED, each agency's procedures govern whether they will accept a particular document, such as an EAD or an I–94. If an agency accepts the type of DED-related document you are presenting, such as an EAD, the agency should accept your automatically extended DED-related EAD. You should:

a. Present the agency with a copy of this **Federal Register** notice showing the extension of DED and of your DED-related EAD with your alien number;

b. Explain that SAVE will be able to verify the continuation of your DED using this information; and

c. Ask the agency to initiate a SAVE query with your information and follow through with additional verification steps, if necessary, to get a final SAVE response confirming your DED.

You can also ask the agency to look for SAVE notices or contact SAVE if they have any questions about your immigration status or automatic extension of your DED-related EAD. In most cases, SAVE provides an automated electronic response to benefit-granting agencies within seconds, but, occasionally, verification can be delayed. You can check the status of your SAVE verification by using CaseCheck at *save.uscis.gov/casecheck/,* then by clicking the ''Check Your Case'' button. CaseCheck is a free service that lets you follow the progress of your SAVE verification using your date of birth and one immigration identifier number. If an agency has denied your application based solely or in part on a SAVE response, the agency

must offer you the opportunity to appeal the decision in accordance with the agency's procedures. If the agency has received and acted upon or will act upon a SAVE verification and you do not believe the response is correct, you may make an appointment for an in-person interview at a local USCIS office. Detailed information on how to make corrections or update your immigration record, make an appointment, or submit a written request to correct records under the Freedom of Information Act can be found on the SAVE website at *www.uscis.gov/save.*

Tracy L. Renaud,

Senior Official Performing the Duties of the Director, U.S. Citizenship and Immigration Services.

[FR Doc. 2021–03149 Filed 2–12–21; 8:45 am]

BILLING CODE P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1226]

Certain Artificial Eyelash Extension Systems, Products, and Components Thereof; Commission Determination Not To Review an Initial Determination Granting Complainant's Motion for Leave To Amend the Complaint and Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 10) of the presiding administrative law judge (''ALJ'') granting the complainant's motion for leave to amend the complaint and notice of investigation.

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 October 28, 2020, 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 Lashify, Inc. of Glendale, California (''Complainant''). *See* 85 FR 68366–67. The complaint, as supplemented, alleges a violation of section 337 based upon the importation into the United States, sale for importation, or sale after importation into the United States of certain artificial eyelash extension systems, products, and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 10,660,388 and 10,721,984 and U.S. Design Patent Nos. D877,416 and D867,664. The complaint also alleges the existence of a domestic industry. The notice of investigation names nine respondents, including CVS Health Corporation of Woonsocket, Rhode Island and Ulta Beauty, Inc. of Bolingbrook, Illinois. *See id.* The Office of Unfair Import Investigations is also a party to the investigation. *See id.*

On January 8, 2021, Complainant filed a motion seeking leave to amend the complaint and notice of investigation to substitute: (1) CVS Pharmacy, Inc. in place of CVS Health Corporation and (2) Ulta Salon, Cosmetics & Fragrance, Inc. in place of Ulta Beauty, Inc. No responses to the motion were filed.

On January 22, 2021, the ALJ issued the subject ID (Order No. 10) granting Complainant's motion for leave to amend the complaint and notice of investigation to reflect the substitutions. Order No. 10 (Jan. 22, 2021). The subject ID finds that Complainant's motion is supported by good cause pursuant to Commission Rule 210.14(b) (19 CFR 210.14(b)) and that there is no prejudice if the motion is granted. No party petitioned for review of the subject ID.

The Commission has determined not to review the subject ID. CVS Pharmacy, Inc. and Ulta Salon, Cosmetics & Fragrance, Inc. are named as respondents in this investigation; and CVS Health Corporation and Ulta Beauty, Inc. are terminated from the investigation.

The Commission vote for this determination took place on February 10, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: February 10, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–03059 Filed 2–12–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1059 (Third Review)]

Hand Trucks and Certain Parts Thereof From China

Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty order on hand trucks and certain parts thereof from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted this review on July 1, 2020 (85 FR 39584) and determined on October 5, 2020 that it would conduct an expedited review (86 FR 2001, January 11, 2021).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on February 9, 2021. The views of the Commission are contained in USITC Publication 5159 (February 2021), entitled *Hand Trucks and Certain Parts Thereof from China: Investigation No. 731–TA–1059 (Third Review).*

By order of the Commission.

Issued: February 9, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–02975 Filed 2–12–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–784]

Importer of Controlled Substances Application: S and B Pharma, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

SUMMARY: S&B Pharma, Inc. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before March 18, 2021. Such persons may also file a written request for a hearing on the application on or before March 18, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on December 18, 2020, S&B Pharma, Inc., 405 S Motor Avenue, Azusa, California 91702–3232, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
4-Anilino-N-Phenethyl-4-Piperdine (ANPP).	8333	II
Tapentadol	9780	II

The company plans to import intermediate forms of Tapentadol (9780) for further manufacturing prior to distribution to its customers. The company plans to import ANPP (8333) to bulk manufacture other controlled substances for distribution to its customers. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–02979 Filed 2–12–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–780]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: North Star Holdings California, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections to the issuance of the proposed registration on or before April 19, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. To ensure proper handling of comments, please reference Docket No. DEA–780 in all correspondence, including attachments.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on January 15, 2021, North Star Holdings California, LLC, 69375 Ramon Road, Cathedral City, California 92234, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–02980 Filed 2–12–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–778]

Importer of Controlled Substances Application: Noramco Coventry, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Noramco Coventry, LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before March 18, 2021. Such persons may also file a written request for a hearing on the application on or before March 18, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on January 14, 2021, Noramco Coventry LLC, 498 Washington Street, Coventry, Rhode Island 02816, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I
Methylphenidate	1724	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Morphine	9300	II
Opium, raw	9600	II
Oxymorphone	9652	II
Poppy Straw Concentrate	9670	II

The company (formerly known as Rhodes Technologies) plans to import Opium, raw (9600), and Poppy Straw Concentrate (9670) in order to bulk manufacture controlled substances in Active Pharmaceutical Ingredient (API) form. The company distributes the manufactured APIs in bulk to its customers. The company plans to import the other listed controlled substances for internal reference standards use only. The comparisons of foreign reference standards to the company's domestically manufactured API will allow the company to export domestically manufactured API to foreign markets. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–02971 Filed 2–12–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–774]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Mountain Trading LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections to the issuance of the proposed registration on or before April 19, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. To ensure proper handling of comments, please reference Docket No. DEA–774 in all correspondence, including attachments.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA-registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on November 30, 2018, Mountain Trading LLC, 6 South 89 Street West, Billings, Montana 59106, applied to be registered as a manufacturer, and on January 14, 2021, the application was changed from a manufacturer to a bulk manufacturer, of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–02970 Filed 2–12–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–787]

Importer of Controlled Substances Application: Sigma Aldrich Co., LLC.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Sigma Aldrich Co. LLC. has applied to be registered as an importer

of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before March 18, 2021. Such persons may also file a written request for a hearing on the application on or before March 18, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on January 15, 2021, Sigma Aldrich Co., LLC, 3500 Dekalb Street, Saint Louis, Missouri 63118–4103, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Cathinone	1235	I
Methcathinone	1237	I
Mephedrone (4-Methyl-N-methylcathinone)	1248	I
Gamma Hydroxybutyric Acid	2010	I
Tetrahydrocannabinols	7370	I
4-Bromo-2,5-dimethoxyamphetamine	7391	I
4-Bromo-2,5-dimethoxyphenethylamine	7392	I
2,5-Dimethoxyamphetamine	7396	I
3,4-Methylenedioxyamphetamine	7400	I
3,4-Methylenedioxy-N-ethylamphetamine	7404	I
3,4-Methylenedioxymethamphetamine	7405	I
4-Methoxyamphetamine	7411	I
Dimethyltryptamine	7435	I
N-Benzylpiperazine	7493	I
Heroin	9200	I
Normorphine	9313	I
Amobarbital	2125	II
Secobarbital	2315	II
Nabilone	7379	II
Phencyclidine	7471	II
Ecgonine	9180	II
Ethylmorphine	9190	II
Levorphanol	9220	II
Meperidine	9230	II
Thebaine	9333	II
Opium, powdered	9639	II
Levo-alphacetylmethadol	9648	II

The company plans to import the listed controlled substances for sale to research facilities for drug testing and analysis. In reference to drug code 7370 (Tetrahydrocannabinols) the company plans to import synthetic Tetrahydrocannabinols. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–02978 Filed 2–12–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–775]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: JW Colorado, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections to the issuance of the proposed registration on or before April 19, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. To ensure proper handling of comments, please reference Docket No. DEA–775 in all correspondence, including attachments.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk

manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA-registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on January 13, 2021, JW Colorado, LLC, 3601 Freedom Road, Trinidad, Colorado 81082, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–02972 Filed 2–12–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–779]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Titan Health LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections to the issuance of the proposed registration on or before April 19, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW 8701 Morrissette Drive, Springfield, Virginia 22152. To ensure proper handling of comments, please reference Docket No. DEA–779 in all correspondence, including attachments.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marihuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on January 18, 2021, Titan Health LLC, 5959 East 39th Avenue, Suite 102, Denver, Colorado 80207 applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–02968 Filed 2–12–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–776]

Bulk Manufacturer of Controlled Substances Application: PCI Synthesis

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: PCI Synthesis, has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 19, 2021. Such persons may also file a written request for a hearing on the application on or before April 19, 2021.

ADDRESS: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 24, 2020, PCI Synthesis, 9 Opportunity Way, Newburyport, Massachusetts 01950–0195, applied to be registered as a bulk

manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Amphetamine	1100	II
Methamphetamine	1105	II

The company plans to use the listed controlled substances to develop manufacturing processes, and conduct analytical and stability testing. The company has demonstrated and received patent numbers U.S. 9,278,904 and U.S. 9,321,794 from the U.S. Patent Office for the synthesis process for amphetamines.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–02973 Filed 2–12–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–783]

Importer of Controlled Substances Application: Siegfried USA, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Siegfried USA, LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before March 18, 2021. Such persons may also file a written request for a hearing on the application on or before March 18, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on January 6, 2021, Siegfried USA, LLC, 33 Industrial Park Road, Pennsville, New Jersey 08070, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Phenylacetone	8501	II
Opium, Raw	9600	II
Poppy Straw Concentrate.	9670	II

The company plans to import the listed controlled substances to manufacture bulk active pharmaceutical ingredients (API) for distribution to its customers. Phenylacetone will be used to manufacture Amphetamine. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–02974 Filed 2–12–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Advisory Board; Notice of Meeting

This notice announces a forthcoming meeting of the National Institute of Corrections (NIC) Advisory Board. At least one portion of the meeting will be closed to the public.

Name of the Committee: NIC Advisory Board.

General Function of the Committee: To aid the National Institute of Corrections in developing long-range plans, advise on program development, and recommend guidance to assist NIC's efforts in the areas of training, technical assistance, information services, and policy/program development assistance to Federal, state, and local corrections agencies.

Date and Time: 1:00–4:00 p.m. EDT on Wednesday, March 10, 2021 (approximate time).

Location: Virtual Platform.

Contact Person: Leslie LeMaster, Executive Assistant, National Institute of Corrections, 320 First Street NW, Room 901–3, Washington, DC 20534. To contact Ms. LeMaster, please call (303) 338–6620.

Agenda: On March 10, 2021, the Advisory Board will: (1) Receive a brief Agency Report from the NIC Acting Director, (2) provide input and counsel into an agency decision regarding access to online training courses hosted by NIC, and (3) receive a Subcommittee Report related to the identification of potential NIC Director candidates. Time for questions and counsel is built in to the agenda.

Procedure: On March 10, 2021, from 1:00 p.m. until 3:00 p.m., the meeting is open to the public. Interested persons may request to attend virtually, present data, information, or views, orally or in writing, on issues pending before the committee. Such requests must be made to the contact person on or before February 26, 2021. Oral presentations from the public will be scheduled between approximately 2:45 p.m. to 3:00 p.m. on March 10, 2021. Time allotted for each presentation may be limited. Those who wish to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 26, 2021.

Closed Committee Deliberations: On March 10, 2021, between 3:00 p.m. and 4:00 p.m., the meeting will be closed to permit discussion of information that (1) relates solely to the internal personnel rules and practices of an agency (5 U.S.C. 552b(c)(2)), and (2) is of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The Advisory Board will discuss the outcomes of the subcommittee's review of potential candidates for the position of Director of the National Institute of Corrections and make determinations as to the Advisory Board's recommendations to the U.S. Attorney General.

General Information: NIC welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Leslie LeMaster at least 7 days in advance of the meeting. Notice of this meeting is given under the

Federal Advisory Committee Act (5 U.S.C. app. 2).

Shaina Vanek,

Acting Director, National Institute of Corrections.

[FR Doc. 2021–03003 Filed 2–12–21; 8:45 am]

BILLING CODE 4410–36–P

NATIONAL SECURITY COMMISSION ON ARTIFICIAL INTELLIGENCE

[Docket No.: 2–2021–01]

National Security Commission on Artificial Intelligence; Notice of Federal Advisory Committee Meeting

AGENCY: National Security Commission on Artificial Intelligence.

ACTION: Notice of Federal Advisory Committee virtual public meeting.

SUMMARY: The National Security Commission on Artificial Intelligence (the ''Commission'') is publishing this notice to announce that the following Federal Advisory Committee virtual public meeting will take place.

DATES: Monday, March 1, 2021, 12:00 p.m. to 1:00 p.m. Eastern Standard Time (EST).

ADDRESSES: *Mailing address:* Designated Federal Officer, National Security Commission on Artificial Intelligence, 2530 Crystal Drive, Box 45, Arlington, VA 22202. *website: https://www.nscai.gov.* The most up-to-date information about the meeting and the Commission can be found on the website.

FOR FURTHER INFORMATION CONTACT: Ms. Angela Ponmakha, 571–329–5519 (Voice), *nscai-dfo@nscai.gov.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C., Appendix), the Government in the Sunshine Act (5 U.S.C. 552b), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: The John S. McCain National Defense Authorization Act for Fiscal Year 2019 (FY19 NDAA), Sec. 1051, Public Law 115–232, 132 Stat. 1636, 1962–65 (2018), created the Commission to ''consider the methods and means necessary to advance the development of artificial intelligence, machine learning, and associated technologies by the United States to comprehensively address the national security and defense needs of the United States.'' After a series of meetings in January and February 2021 in which the Commission deliberated on draft recommendations and reached consensus regarding their inclusion in the Commission's Final Report to Congress and the Executive Branch, the Commissioners will meet to formally approve and release the Final Report.

Agenda: The meeting will begin on March 1, 2021 at 12:00 p.m. EST with opening remarks by the Designated Federal Officer, Ms. Angela Ponmakha; the Executive Director, Mr. Yll Bajraktari; the Commission Chair, Dr. Eric Schmidt; and the Commission Vice Chair, Hon. Robert Work. After the opening remarks, other Commission members may provide final remarks. The Commission will consider and vote on the Commission's Final Report and associated materials for submission to Congress and the Administration. The meeting will adjourn at 1:00 p.m. EST.

Meeting Accessibility: Pursuant to Federal statutes and regulations (the FACA, the Sunshine Act, and 41 CFR 102–3.140 through 102–3.165) and the availability of space, the virtual meeting is open to the public March 1, 2021 from 12:00 p.m. to 1:00 p.m. EST. Members of the public wishing to receive a link to the live stream webcast for viewing and audio access to the virtual meeting should register on the Commission's website, *https://www.nscai.gov.* Registration will be available from February 22, 2021 through February 26, 2021. Members of the media should RSVP to the Commission's press office at *press@nscai.gov.*

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact the DFO, see the **FOR FURTHER INFORMATION CONTACT** section for contact information, no later than February 26, 2021, so that appropriate arrangements can be made.

Access to Records of the Meeting: Pursuant to FACA requirements, the meeting materials for the virtual meetings will be available for public inspection on the Commission's website at *https://www.nscai.gov* on March 1, 2021.

Written Statements: Written comments may be submitted to the DFO via email to: *nscai-dfo@nscai.gov* in either Adobe Acrobat or Microsoft Word format. The DFO will compile all written submissions and provide them to the Commissioners for consideration. Please note that all submitted comments will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the Commission's website.

Dated: February 9, 2021.

Michael Gable,

Chief of Staff.

[FR Doc. 2021–02983 Filed 2–12–21; 8:45 am]

BILLING CODE 3610–Y8–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2021–015]

Freedom of Information Act (FOIA) Advisory Committee Meeting

AGENCY: Office of Government Information Services (OGIS), National Archives and Records Administration (NARA).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: We are announcing an upcoming Freedom of Information Act (FOIA) Advisory Committee meeting in accordance with the Federal Advisory Committee Act and the second United States Open Government National Action Plan.

DATES: The meeting will be on March 3, 2021, from 10:00 a.m. to 1:00 p.m. EST. You must register by 11:59 p.m. EST February 28, 2021, to attend the meeting.

ADDRESSES: This meeting will be held virtually. We will send instructions on how to access it to those who register according to the instructions below.

FOR FURTHER INFORMATION CONTACT: Kirsten Mitchell, Designated Federal Officer for this committee, by email at *foia-advisory-committee@nara.gov* or by telephone at 202.741.5770.

SUPPLEMENTARY INFORMATION:

Agenda and meeting materials: We will post all meeting materials at *https://www.archives.gov/ogis/foia-advisory-committee/2020-2022-term.* This will be the third meeting of the 2020–2022 committee term. The purpose of this meeting will be to hear a presentation about access to records in the legislative and judicial branches, and updates from the four subcommittees: Classification, Legislation, Process, and Technology.

Procedures: This virtual meeting is open to the public. You must register in advance through this Eventbrite link, *https://foiaac-mtg-mar-03-2021.eventbrite.com,* if you wish to attend. You must provide an email address so that we can provide you information to access the meeting online. To request additional accommodations (*e.g.,* a transcript), email *foia-advisory-committee@nara.gov* or call 202.741.5770. Members

of the media who wish to register, those who are unable to register online, and those who require special accommodations, should contact Kirsten Mitchell (contact information listed above).

Brian P. McLaughlin,

Acting Committee Management Officer.

[FR Doc. 2021–03001 Filed 2–12–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–21–0003; NARA–2021–014]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on *regulations.gov* for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: NARA must receive comments by April 2, 2021.

ADDRESSES: You may submit comments by either of the following methods. You must cite the control number, which appears on the records schedule in parentheses after the name of the agency that submitted the schedule.

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Mail:* Records Appraisal and Agency Assistance (ACR); National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001.

FOR FURTHER INFORMATION CONTACT: Kimberly Keravuori, Regulatory and External Policy Program Manager, by email at *regulation_comments@nara.gov.* For information about records schedules, contact Records Management Operations by email at *request.schedule@nara.gov,* by mail at the address above, or by phone at 301–837–1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule.

We have uploaded the records schedules and accompanying appraisal memoranda to the *regulations.gov* docket for this notice as ''other'' documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the *regulations.gov* portal, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we will post on *regulations.gov* a ''Consolidated Reply'' summarizing the comments, responding to them, and noting any changes we have made to the proposed records schedule. We will then send the schedule for final approval by the Archivist of the United States. You may elect at *regulations.gov* to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. If you have a question, you can submit it as a comment, and can also submit any concerns or comments you would have to a possible response to the question. We will address these items in consolidated replies along with any other comments submitted on that schedule.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of Homeland Security, U.S. Citizenship and Immigration Services, Waiver Requests in Support of Applications, Petitions, or Requests (DAA–0566–2019–0027).

2. Department of Homeland Security, U.S. Citizenship and Immigration Services, Notice of Appeal or Motion (DAA–0566–2020–0013).

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2021–03070 Filed 2–12–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2021–016]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: We have submitted a request to the Office of Management and Budget (OMB) for approval to reinstate this previously-approved information collection that expired in 2020. Due to disruption in operations from COVID, we were not able to issue the second notice in time last year to renew before the expiration date. We collect this information from private foundations or other entities involved in designing, constructing, and equipping Presidential libraries and use it in a report to Congress. We invite you to comment on the proposed information collection pursuant to the Paperwork Reduction Act of 1995.

DATES: OMB must receive written comments at the address below on or before March 18, 2021.

ADDRESSES: Send any comments and recommendations on the proposed information collection in writing to *www.reginfo.gov/public/do/PRAMain.* You can 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: Tamee Fechhelm, Paperwork Reduction Act Officer, by email at *tamee.fechhelm@nara.gob* or by telephone at 301.837.1694 with any requests for additional information.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we invite the public and other Federal agencies to comment on proposed information collections. We published a notice of proposed collection for this information collection on June 2, 2020 (85 FR 23840), and we received no comments. We are therefore submitting the described information collection to OMB for approval.

If you have comments or suggestions, they should address one or more of the following points: (a) Whether the proposed information collection is necessary for NARA to properly perform its functions; (b) our estimate of the burden of the proposed information collection and its accuracy; (c) ways we could enhance the quality, utility, and clarity of the information we collect; (d) ways we could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether this collection affects small businesses.

In this notice, we solicit comments concerning the following information collection:

Title: Presidential Library Facilities.

OMB number: 3095–0036.

Agency form number: None.

Type of review: Regular.

Affected public: Presidential library foundations or other entities proposing to transfer a Presidential library facility to NARA.

Estimated number of respondents: 1.

Estimated time per response: 40 hours.

Frequency of response: On occasion.

Estimated total annual burden hours: 40 hours.

Abstract: The information collection is required for NARA to meet its obligations under 44 U.S.C. 2112(a)(3) to submit a report to Congress before accepting a new Presidential library facility. The report contains information that can be furnished only by the foundation or other entity responsible for building the facility and establishing the library endowment.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2021–03000 Filed 2–12–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2021–017]

National Industrial Security Program Policy Advisory Committee (NISPPAC) Meeting

AGENCY: Information Security Oversight Office (ISOO), National Archives and Records Administration (NARA).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: We are announcing an upcoming meeting of the National Industrial Security Program Policy Advisory Committee (NISPPAC).

DATES: The meeting will be on April 14, 2021, from 10:00 a.m. to 1:00 p.m. EST.

ADDRESSES: The April 14, 2021, meeting will be a virtual meeting. See supplementary procedures below.

FOR FURTHER INFORMATION CONTACT: Heather Harris Pagán, ISOO Program Analyst, by telephone at 202.357.5351, or by email at *NISPPAC@nara.gov.*

SUPPLEMENTARY INFORMATION: This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. app 2) and implementing regulations at 41 CFR 101–6. The Committee will discuss National Industrial Security Program policy matters.

Procedures: You must register in advance through the Event Services link *https://ems8.intellor.com?do=register&t=1&p=836856* if you wish to attend. NISPPAC members, ISOO employees, and speakers should send an email to *NISPPAC@nara.gov* for the appropriate registration information instead of registering with the above link. Contact us via email at *NISPPAC@nara.gov with any questions.*

Brian P. McLaughlin,

Acting Committee Management Officer.

[FR Doc. 2021–03002 Filed 2–12–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Subject 60-Day Notice for the ''CARES Act Funding State Arts Agency Survey''

AGENCY: National Endowment for the Arts.

ACTION: Notice.

SUMMARY: The National Endowment for the Arts (NEA), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the NEA is soliciting comments concerning the proposed information collection for the survey of state arts agencies in regards to the impact of CARES Act funding awards on grantees. A copy of the current information collection request can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the address section below within April 19, 2021.

ADDRESSES: Send comments to: Sunil Iyengar, National Endowment for the Arts, 400 7th Street SW, Washington, DC 20506–0001, telephone (202) 682–5424 (this is not a toll-free number), fax (202) 682–5677, or send via email to *research@arts.gov.*

SUPPLEMENTARY INFORMATION: The NEA is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Dated: February 1, 2021.

Anthony M. Bennett,

Director of Administrative Services and Contracts, National Endowment for the Arts.

[FR Doc. 2021–02999 Filed 2–12–21; 8:45 am]

BILLING CODE 7537–01–P

NEIGHBORHOOD REINVESTMENT CORPORATION

Sunshine Act Meetings

TIME AND DATE: 2 p.m., Thursday, February 18, 2021.

PLACE: Via Conference Call.

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

MATTERS TO BE CONSIDERED: Regular Board of Directors meeting.

The General Counsel of the Corporation has certified that in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552(b)(2) and (4) permit closure of the following portion(s) of this meeting:

Executive Session

Agenda

I. Call to Order
II. Executive Session: Report from CEO
III. Executive Session: Report of CFO
IV. Executive Session: NeighborWorks Compass Update
V. Action Item Approval of Minutes
VI. Action Item Recognition of Service for Deputy Secretary Brian Montgomery
VII. Action Item FY2021 All-Sources Budget
VIII. Discussion item Capital Corporations
IX. Management Program Background and Updates
X. Adjournment

Portions Open to the Public: Everything except the Executive Session.

Portions Closed to the Public: Executive Session.

CONTACT PERSON FOR MORE INFORMATION: Lakeyia Thompson, Special Assistant, (202) 524–9940; *Lthompson@nw.org.*

Lakeyia Thompson,

Special Assistant.

[FR Doc. 2021–03158 Filed 2–11–21; 4:15 pm]

BILLING CODE 7570–02–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of February 15, 22, March 1, 8, 15, 22, 2021.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

Week of February 15, 2021

Thursday, February 18, 2021

9:55 a.m. Affirmation Session (Public Meeting) (Tentative)
a. Holtec International (HI–STORE Consolidated Interim Storage Facility), Sierra Club Appeal of LBP–20–6 (Tentative)
b. DTE Electric Co. (Fermi 2), Appeal of LBP–20–7 (Denial of Hearing Request Related to Spent Fuel Pool License Amendment) (Tentative)
(Contact: Wesley Held: 301–287–3591)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public Meeting)
(Contact: Nadim Khan: 301–415–1119)

Additional Information: Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Week of February 22, 2021—Tentative

There are no meetings scheduled for the week of February 22, 2021.

Week of March 1, 2021—Tentative

There are no meetings scheduled for the week of March 1, 2021.

Week of March 8, 2021—Tentative

There are no meetings scheduled for the week of March 8, 2021.

Week of March 15, 2021—Tentative

There are no meetings scheduled for the week of March 15, 2021.

Week of March 22, 2021—Tentative

There are no meetings scheduled for the week of March 22, 2021.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Tyesha.Bush@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: February 10, 2021.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2021–03108 Filed 2–11–21; 11:15 am]

BILLING CODE 7590–01–P

PEACE CORPS

Information Collection Request Submission for OMB Review; Reopening of Comment Period

AGENCY: Peace Corps.

ACTION: Notice; reopening of comment period.

SUMMARY: The Peace Corps published a document in the **Federal Register** of December 7, 2020, concerning request for comments on an information collection request submission for OMB Review. The purpose of this notice is to reopen the document comment period.

DATES: The comment period for the notice published December 7, 2020, at 85 FR 78885, is reopened. Submit comments on or before March 18, 2021.

ADDRESSES: Address written comments and recommendations for the proposed information collection to Virginia Burke, FOIA/Privacy Act Officer, by email at *pcfr@peacecorps.gov.* Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: Virginia Burke, 202–692–1887.

SUPPLEMENTARY INFORMATION: In FR Doc. 2020–26806, published at 85 FR 78885 on December 7, 2020, the notice gave a 30-day comment period that closed on January 6, 2021, but the comment period should have been 60 days. The Peace Corps is reopening the comment period to provide an additional 30 days of comments.

This notice is issued in Washington, DC on February 9, 2021.

Virginia Burke,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2021–03062 Filed 2–12–21; 8:45 am]

BILLING CODE 6051–01–P

PEACE CORPS

Information Collection Request Submission for OMB Review; Reopening of Comment Period

AGENCY: Peace Corps.

ACTION: Notice; reopening of comment period.

SUMMARY: The Peace Corps published a document in the **Federal Register** of December 7, 2020, concerning request for comments on an information collection request submission for OMB Review. The purpose of this notice is to reopen the document comment period.

DATES: The comment period for the notice published December 7, 2020, at 85 FR 78885, is reopened. Submit comments on or before March 18, 2021.

ADDRESSES: Address written comments and recommendations for the proposed information collection to Virginia Burke, FOIA/Privacy Act Officer, by email at *pcfr@peacecorps.gov.* Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: Virginia Burke, 202–692–1887.

SUPPLEMENTARY INFORMATION: In FR Doc. 2020–26863, published at 85 FR 78885 on December 7, 2020, the notice gave a 30-day comment period that closed on January 6, 2021, but the comment period should have been 60 days. The Peace Corps is reopening the comment period to provide an additional 30 days of comments.

This notice is issued in Washington, DC, on February 10, 2021.

Virginia Burke,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2021–03071 Filed 2–12–21; 8:45 am]

BILLING CODE 6051–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91084; File No. SR–NYSE–2020–105]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of Longer Period for Commission Action on Proposed Rule Change To Revise Rules 46 and 46A and Other Related Rules To Permit the Appointment of Trading Officials

February 9, 2021.

On December 15, 2020, New York Stock Exchange LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend to revise NYSE Rules 46 and 46A, and other related rules, to permit the appointment of Trading Officials. The proposed rule change was published for comment in the **Federal Register** on December 30, 2020.[3] The Commission has received no comments on the proposal.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is February 13, 2021.

The Commission is extending the 45-day period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, pursuant to Section 19(b)(2) of the Act,[5] the Commission designates March 30, 2021, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change (File No. SR–NYSE–2020–105).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–02992 Filed 2–12–21; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90776 (Dec. 22, 2020), 85 FR 86625 (Dec. 30, 2020).

[4] 15 U.S.C. 78s(b)(2).

[5] 15 U.S.C. 78s(b)(2).

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2 p.m. on Thursday, February 18, 2021.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or

more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Dated: February 11, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–03161 Filed 2–11–21; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91082; File No. SR–NYSE–2021–10]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend its Price List To Extend the Waiver of Equipment and Related Service Charges and Trading License Fees

February 9, 2021.

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 29, 2021, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List to extend the waiver of equipment and related service charges and trading license fees for NYSE Trading Floor-based member organizations commencing January 1, 2021 through the earlier of the first full month of a full reopening of the Trading Floor facilities to Floor personnel or March 2021. The Exchange proposes to implement the fee changes effective February 1, 2021. The proposed rule change is available on the Exchange's website at *www.nys e.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Price List to extend the waiver of equipment and related service charges and trading license fees for NYSE Trading Floor-based member organizations that have been unable to resume their Floor operations to a certain capacity level, as discussed below. The Exchange proposes to implement the fee change effective February 1, 2021.

As proposed, the Exchange would continue to waive 50% of the Telephone System charges and Service Charges (except for the internet Equipment Monthly Hosting Fee) and trading license fees for member organizations that meet the waiver criteria set forth in footnotes 11 and 15 of the Price List, respectively, commencing January 1, 2021 through the earlier of the first full month of a full reopening of the Trading Floor facilities to Floor personnel or March 2021.

Background

Beginning on March 16, 2020, in order to slow the spread of the novel coronavirus (''COVID–19'') through social distancing measures, significant limitations were placed on large gatherings throughout the country. As a result, on March 18, 2020, the Exchange determined that beginning March 23, 2020, the physical Trading Floor facilities located at 11 Wall Street in New York City would close and that the Exchange would move, on a temporary basis, to fully electronic trading.[3] Following the temporary closure of the Trading Floor, the Exchange waived certain equipment fees for the booth telephone system on the Trading Floor and associated service charges for the months of April and May.[4]

On May 14, 2020, the Exchange announced that on May 26, 2020 trading operations on the Trading Floor would resume on a limited basis to a subset of Floor brokers, subject to health and safety measures designed to prevent the spread of COVID–19.[5] On June 15, 2020, the Exchange announced that on June 17, 2020, the Trading Floor would reintroduce a subset of DMMs, also subject to health and safety measures designed to prevent the spread of COVID–19.[6] Following this partial reopening of the Trading Floor, the Exchange extended the equipment fee waiver for the months of June 2020 through January 2021.[7] The Trading Floor continues to operate with reduced

[3] *See* Press Release, dated March 18, 2020, available here: *https://ir.theice.com/press/press-releases/allcategories/2020/03-18-2020-204202110* [sic].

[4] *See* Securities Exchange Act Release No. 88602 (April 8, 2020), 85 FR 20730 (April 14, 2020) (SR–NYSE–2020–27); Securities Exchange Act Release No. 88874 (May 14, 2020), 85 FR 30743 (May 20, 2020) (SR–NYSE–2020–29 [sic]). *See* footnote 11 of the Price List.

[5] *See* Trader Update, dated May 14, 2020, available here: *https://www.nyse.com/traderupdate/history#110000251588* [sic].

[6] *See* Trader Update, dated June 15, 2020, available here: *https://www.nyse.com/trader-update/history#110000272018.*

[7] *See* Securities Exchange Act Release No. 89050 (June 11, 2020), 85 FR 36637 (June 17, 2020) (SR–NYSE–2020–49); Securities Exchange Act Release No. 89324 (July 15, 2020), 85 FR 44129 (July 21, 2020) (SR–NYSE–2020–59); Securities Exchange Act Release No. 89754 (September 2, 2020), 85 FR 55550 (September 8, 2020) (SR–NYSE–2020–71); Securities Exchange Act Release No. 89798 (September 9, 2020), 85 FR 57263 (September 15, 2020) (SR–NYSE–2020–72); Securities Exchange Act Release No. 90161 (October 13, 2020), 85 FR 66370 (October 19, 2020) (SR–NYSE–2020–81); Securities Exchange Act Release No. 90391 (November 10, 2020), 85 FR 73326 (November 17, 2020) (SR–NYSE–2020–92); Securities Exchange Act Release No. 90744 (December 21, 2020), 85 FR 85712 (December 29, 2020) (SR–NYSE–2020–102).

headcount and additional health and safety precautions.[8]

Proposed Rule Change

In response to the unprecedented events surrounding the spread of COVID–19 in 2020, the Exchange waived certain equipment and related service charges and trading license fees for NYSE Trading Floor-based member organizations through January 2021. Specifically, the Exchange extended the waiver of 50% of the Annual Telephone Line Charge of $400 per phone number; the $129 fee for a single line phone, jack, and data jack; the related service charges ($161.25 to install single jack (voice or data); $107.50 to relocate a jack; $53.75 to remove a jack; $107.50 to install voice or data line; $53.75 to disconnect data line; $53.75 to change a phone line subscriber; and miscellaneous telephone charges billed at $106 per hour in 15 minute increments); and the monthly portion of all applicable annual fees through January 2021 for member organizations that

- meet the current requirements of having at least one trading license, a physical trading Floor presence and Floor broker executions accounting for 40% or more of the member organization's combined adding, taking, and auction volumes during March 1 to March 20, 2020 or, if not a member organization during March 1 to March 20, 2020, based on the member organization's combined adding, taking, and auction volumes during its first month as a member organization on or after May 26, 2020, and
- are unable to operate at more than 50% of their March 2020 on-Floor staffing levels or, for member organizations that began Floor operations after March 2020, are unable to operate at more than 50% of their Exchange-approved on-Floor staffing levels, both excluding part-time Floor brokers known as ''flex brokers'' (hereinafter, ''Qualifying Firms'').[9]

Because the Trading Floor continues to operate with reduced capacity, and in order to further reduce costs for member organizations with a Trading Floor presence, the Exchange proposes to extend the fee waiver for Qualifying Firms commencing January 1, 2021 through the earlier of the first full month of a full reopening of the Trading Floor facilities to Floor personnel or March 2021. The proposed fee change is designed to reduce monthly costs for all Qualifying Firms whose operations continue to be disrupted even though the Trading Floor has partially reopened. The Exchange does not propose any substantive changes to the current waivers set forth in footnotes 11 and 15 of the Price List. The Exchange believes that all Qualifying Firms would benefit from the proposed fee change.

The proposed changes are not otherwise intended to address other issues, and the Exchange is not aware of any significant problems that market participants would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[11] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. 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.'' [12]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [13] Indeed, equity trading is currently dispersed across 16 exchanges,[14] 31 alternative trading systems,[15] and numerous broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange has more than 16% market share.[16] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, the Exchange's market share of trading in Tape A, B and C securities combined is less than 12%.

The Proposed Change Is Reasonable

The proposed extension of the waiver of equipment and related service fees and the applicable monthly trading license fee for Qualified Firms commencing January 1, 2021 through the earlier of the first full month of a full reopening of the Trading Floor facilities to Floor personnel or March 2021 is reasonable in light of the continued partial closure of the NYSE Trading Floor as a result of spread of COVID–19. The proposed change is reasonable because it would extend reduction of monthly costs for all Qualifying Firms whose operations have been disrupted despite the fact that the Trading Floor has partially reopened because of the social distancing requirements and/or other health concerns related to resuming operation on the Trading Floor. In reducing this monthly financial burden, the proposed change would allow Qualifying Firms that that are unable to operate at more than 50% of their March 2020 or Exchange-approved on-Floor staffing levels to reallocate funds to assist with the cost of shifting and maintaining their prior fully-staffed on-Floor operations to off-Floor and recoup losses resulting from the partial reopening of the Trading Floor.

The Proposal Is an Equitable Allocation of Fees

The Exchange believes the proposed extension of the waiver of equipment and related service fees and the applicable monthly trading license fee for Qualified Members for the proposed time period is an equitable allocation of fees. The proposed waivers apply to all Trading Floor-based firms meeting specific requirements during the specified period that the Trading Floor

[8] *See* Trader Update, dated June 15, 2020, available here: *https://www.nyse.com/trader-update/history#110000272018.* DMMs continue to support a subset of NYSE-listed securities remotely.

[9] *See* Securities Exchange Act Release No. 90744 (December 21, 2020), 85 FR 85712 (December 29, 2020) (SR–NYSE–2020–102).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) & (5).

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS'').

[13] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[14] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[15] *See* FINRA ATS Transparency Data, available at *https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[16] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

remains partially open. The Exchange believes the proposed rule change is an equitable allocation of its fees and credits as it continues the previous fee waiver for Qualifying Firms, which affects fees charged only to Floor participants and does not apply to participants that conduct business off-Floor. The Exchange believes it is an equitable allocation of fees and credits to extend the fee waiver for Qualifying Firms because such firms have no more than half of their Floor staff (as measured by either the March 2020 or Exchange-approved) levels, and this reduction in staffing levels on the Trading Floor impacts the speed, volume and efficiency with which these firms can operate, to their financial detriment.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory because the proposed continuation of the fee waiver would affect all similarly-situated market participants on an equal and non-discriminatory basis. The Exchange is not proposing to waive the Trading Floor-related fees indefinitely, but rather during the specified period during which the Trading Floor is not fully open. As noted, the proposed fee change is designed to ease the financial burden on Trading Floor-based member organizations that cannot fully conduct Floor operations.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[17] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the continued participation of member organizations on the Exchange by providing certainty and fee relief during the ongoing pandemic. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [18]

Intramarket Competition. The proposed continued waiver of equipment and related service fees and the applicable monthly trading license fee for Qualified Firms is designed to reduce monthly costs for those Floor participants whose operations continue to be impacted by the COVID–19 pandemic despite the fact that the Trading Floor has partially reopened. In reducing this monthly financial burden, the proposed change would allow Qualifying Firms that had Floor operations in March 2020 to reallocate funds to assist with the cost of shifting and maintaining their previously on-Floor operations to off-Floor. Absent this change, all Qualifying Firms may experience an unintended increase in the cost of doing business on the Exchange, given that the Trading Floor has only reopened in a limited capacity. The Exchange believes that the proposed waiver of fees for Qualifying Firms would not impose a disparate burden on competition among market participants on the Exchange because off-Floor market participants are not subject to these Floor-based fixed fees. In addition, Floor-based firms that are not subject to the extent of staffing shortfalls as are Qualifying Firms, *i.e.,* firms that have more than 50% of their March 2020, or Exchange-approved staffing levels on the Trading Floor, do not face the same operational level of disruption and potential financial impact during the partial reopening of the Trading Floor. As noted, the proposal would apply to all similarly situated member organizations on the same and equal terms, who would benefit from the changes on the same basis. Accordingly, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. As described above, the Exchange operates in a highly competitive market in which market 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. The Exchange believes that the proposed rule change reflects this competitive environment because it permits impacted member organizations to continue to conduct market-making operations on the Exchange and avoid unintended costs of doing business on the Exchange while the Trading Floor is not fully open, which could make the Exchange a less competitive venue on which to trade as compared to other equities markets. In reducing this monthly financial burden, the proposed change would allow affected participants to reallocate funds to assist with the cost of shifting and maintaining their prior fully-staffed on-Floor operations to off-Floor. Absent this change, Qualifying Firms may experience an unintended increase in the cost of doing business on the Exchange, which would make the Exchange a less competitive venue on which to trade as compared to other options exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [19] of the Act and subparagraph (f)(2) of Rule 19b–4 [20] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [21] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2021–10 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.

[17] 15 U.S.C. 78f(b)(8).

[18] Regulation NMS, 70 FR at 37498–99.

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(2).

[21] 15 U.S.C. 78s(b)(2)(B).

All submissions should refer to File Number SR–NYSE–2021–10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2021–10, and should be submitted on or before March 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–02991 Filed 2–12–21; 8:45 am]

BILLING CODE 8011–01–P

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91089; File No. SR–NASDAQ–2021–007]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Proposed Rule Change To Adopt Additional Initial Listing Criteria for Companies Primarily Operating in Jurisdictions That Do Not Provide the PCAOB With the Ability To Inspect Public Accounting Firms

February 9, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 1, 2021, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt additional initial listing criteria for companies primarily operating in jurisdictions that do not currently provide the PCAOB with the ability to inspect public accounting firms.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

As described below, Nasdaq proposes to adopt additional initial listing criteria for companies primarily operating in jurisdictions that do not currently provide the Public Company Accounting Oversight Board (''PCAOB'') with the ability to inspect public accounting firms.[3]

Nasdaq rules[4] and federal securities laws[5] require a company's financial statements included in its initial registration statement or annual report to be audited by an independent public accountant that is registered with the PCAOB. Company management is responsible for preparing the company's financial statements and for establishing and maintaining disclosure controls and procedures and internal control over financial reporting. The company's auditor, based on its independent audit of the evidence supporting the amounts and disclosures in the financial statements, expresses an opinion on whether the financial statements present fairly, in all material respects, the company's financial position, results of operations and cash flows. ''To form an appropriate basis for expressing an opinion on the financial statements, the auditor must plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement due to error or fraud.''[6]

The auditor, in turn, is normally subject to inspection by the PCAOB,

[3] Nasdaq proposed a similar rule change in May 2020, which was withdrawn by Nasdaq on February, 1, 2021. Securities Exchange Act Release No. 89027 (June 8, 2020), 85 FR 35962 (June 12, 2020) (SR–Nasdaq–2020–027). The Commission issued an Order Instituting Proceedings to Determine Whether to Approve or Disapprove this proposal. Securities Exchange Act Release No. 89799 (September 9, 2020), 85 FR 57282 (September 15, 2020). This revised proposal addresses the concerns raised by the Commission in its Order.

[4] *See* Rule 5210(b) (''Each Company applying for initial listing must be audited by an independent public accountant that is registered as a public accounting firm with the Public Company Accounting Oversight Board, as provided for in Section 102 of the Sarbanes-Oxley Act of 2002 [15 U.S.C. 7212].'') and Rule 5250(c)(3) (''Each listed Company shall be audited by an independent public accountant that is registered as a public accounting firm with the Public Company Accounting Oversight Board, as provided for in Section 102 of the Sarbanes-Oxley Act of 2002 [15 U.S.C. 7212].'').

[5] *See* Section 4100—Qualifications of Accountants, *SEC Financial Reporting Manual* (June 30, 2009), available at *https://www.sec.gov/corpfin/cf-manual/topic-4/.*

[6] *See* PCAOB Auditing Standard 1101.03—Audit Risk, available at *https://pcaobus.org/Standards/Auditing/Pages/AS1101.aspx.*

which assesses compliance with PCAOB and SEC rules and professional standards in connection with the auditor's performance of audits. According to the PCAOB,

> PCAOB inspections may result in the identification of deficiencies in one or more of an audit firm's audits of issuers and/or in its quality control procedures which, in turn, can result in an audit firm carrying out additional procedures that should have been performed already at the time of the audit. Those procedures have sometimes led to the audited public company having to revise and refile its financial statements or its assessment of the effectiveness of its internal control over financial reporting. In addition, through the quality control remediation portion of the inspection process, inspected firms identify and implement practices and procedures to improve future audit quality.[7]

Nasdaq and investors rely on the work of auditors to provide reasonable assurances that the financial statements provided by a company are free of material misstatements. Nasdaq and investors further rely on the PCAOB's critical role in overseeing the quality of the auditor's work. The Chairman and the Chief Accountant of the Commission, along with the Chairman of the PCAOB, have raised concerns that national barriers on access to information can impede effective regulatory oversight of U.S.-listed companies with operations in certain countries, including the PCAOB's inability to inspect the audit work and practices of auditors in those countries.[8] Similar concerns have been expressed by Members of Congress,[9] the State Department [10] and the President's Working Group on Financial Markets.[11] In particular, the PCAOB is currently prevented from inspecting the audit work and practices of PCAOB-registered auditors in Belgium, France, China and Hong Kong (to the extent their audit clients have operations in mainland China).[12]

Nasdaq shares these concerns and believes that accurate financial statement disclosure is critical for investors to make informed investment decisions. Nasdaq believes the lack of transparency from certain markets raises concerns about the accuracy of disclosures, accountability, and access to information, particularly when a company is based in a jurisdiction that does not provide the PCAOB with access to conduct inspections of public accounting firms that audit Nasdaq-listed companies (a ''Restrictive Market'').

Nasdaq's listing requirements include a number of criteria which, in the aggregate, are designed to ensure that a security listed on Nasdaq has sufficient liquidity and public interest to support a listing on a U.S. national securities exchange. These requirements are intended to ensure that there are sufficient shares available for trading to facilitate proper price discovery in the secondary market. Nasdaq believes that concerns about the accuracy of disclosures, accountability, and access to information can be compounded when a company from a Restrictive Market lists on Nasdaq through an initial public offering (''IPO'') or business combination with a small offering size or a low public float percentage because such companies may not attract market attention and develop sufficient public float, investor base, and trading interest to provide the depth and liquidity necessary to promote fair and orderly trading. As a result, the securities may trade infrequently, in a more volatile manner and with a wider bid-ask spread, all of which may result in trading at a price that may not reflect their true market value. In addition, foreign issuers are more likely to issue a portion of an offering to investors in their home country, which raises concerns that such investors will not contribute to the liquidity of the security in the U.S. secondary market.

Less liquid securities may be more susceptible to price manipulation, as a relatively small amount of trading activity can have an inordinate effect on market prices. The risk of price manipulation due to insider trading is more acute when a company principally administers its business in a Restrictive Market (a ''Restrictive Market Company''), particularly if a company's financial statements contain undetected material misstatements due to error or fraud and the PCAOB is unable to inspect the company's auditor to determine if it complied with PCAOB and SEC rules and professional standards in connection with its performance of audits. The risk to investors in such cases may be compounded because regulatory investigations into price manipulation, insider trading and compliance concerns may be impeded and investor protections and remedies may be limited in such cases due to obstacles encountered by U.S. authorities in bringing or enforcing actions against the companies and insiders.[13]

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[7] *See* Public Company Accounting Oversight Board, *Public Companies that are Audit Clients of PCAOB-Registered Firms from Non-U.S. Jurisdictions where the PCAOB is Denied Access to Conduct Inspections* (October 1, 2020), available at *https://pcaobus.org/oversight/international/denied-access-to-inspections.*

[8] *See* SEC Chairman Jay Clayton, SEC Chief Accountant Wes Bricker and PCAOB Chairman William D. Duhnke III, *Statement on the Vital Role of Audit Quality and Regulatory Access to Audit and Other Information Internationally—Discussion of Current Information Access Challenges with Respect to U.S.-listed Companies with Significant Operations in China* (December 7, 2018), available at *https://www.sec.gov/news/public-statement/statement-vital-role-audit-quality-and-regulatory-access-audit-and-other* (''Positions taken by some foreign authorities currently prevent or significantly impair the PCAOB's ability to inspect non-U.S. audit firms in certain countries, even though these firms are registered with the PCAOB.''). On April 21, 2020, these concerns were reiterated by the Chairman and the Chief Accountant of the Commission, along with the Chairman of the PCAOB and the Directors of the SEC Divisions of Corporation Finance and Investment Management. *See* SEC Chairman Jay Clayton, PCAOB Chairman William D. Duhnke III, SEC Chief Accountant Sagar Teotia, SEC Division of Corporation Finance Director William Hinman, SEC Division of Investment Management Director Dalia Blass, *Emerging Market Investments Entail Significant Disclosure, Financial Reporting and Other Risks; Remedies are Limited* (April 21, 2020), available at *https://www.sec.gov/news/public-statement/emerging-market-investments-disclosure-reporting.* See also Chairman Jay Clayton's Statement at the SEC's Emerging Markets Roundtable (July 9, 2020), available at *https://www.sec.gov/news/public-statement/clayton-emerging-markets-roundtable-2020-07-09.*

[9] *See* Congress Passes Legislation to De-List Chinese Companies Unless U.S. Has Access to Audit Workpapers (December 2, 2020), available at *https://sherman.house.gov/media-center/press-releases/congress-passes-legislation-to-de-list-chinese-companies-unless-us-has*; *see also* SEC Chairman Jay Clayton, *Statement after the Enactment of the Holding Foreign Companies Accountable Act* (December 18, 2020), available at *https://www.sec.gov/news/public-statement/clayton-hfcaa-2020-12#_ftn5.*

[10] *See* Press Statement of Michael R. Pompeo, Secretary of State, New Nasdaq Restrictions Affecting Listing of Chinese Companies (June 4, 2020), available at *https://www.state.gov/new-nasdaq-restrictions-affecting-listing-of-chinese-companies/.*

[11] *See* President's Working Group on Financial Markets: Report on Protecting United States Investors from Significant Risks from Chinese Companies (July 24, 2020), available at *https://home.treasury.gov/system/files/136/PWG-Report-on-Protecting-United-States-Investors-from-Significant-Risks-from-Chinese-Companies.pdf.*

[12] *See supra* note 7. The PCAOB notes that ''[t]he position taken by authorities in mainland China may in some circumstances cause a registered firm located in another jurisdiction to attempt to resist PCAOB inspection of public company audit work that the firm has performed relating to the company's operations in mainland China. Only in mainland China and Hong Kong, however, is the position of the Chinese authorities effectively an obstacle to inspection of all, or nearly all, registered firms in the jurisdiction.'' In addition, the PCAOB's cooperative arrangement with the French audit authority expired in December 2019, preventing inspections of registered firms in France until a new arrangement is concluded. According to the PCAOB, it expects to enter into bilateral cooperative arrangements soon ''that will permit the PCAOB to commence inspections in Belgium and resume inspections in France.''

[13] *See* SEC Chairman Jay Clayton, PCAOB Chairman William D. Duhnke III, SEC Chief Accountant Sagar Teotia, SEC Division of Corporation Finance Director William Hinman, SEC Division of Investment Management Director Dalia Blass, *Emerging Market Investments Entail*

Currently, Nasdaq may rely upon its discretionary authority provided under Rule 5101 [14] to deny initial listing or to apply additional and more stringent criteria when Nasdaq is concerned that a small offering size for an IPO may not reflect the company's initial valuation or ensure sufficient liquidity to support trading in the secondary market. Nasdaq is proposing to adopt new Rules 5210(k)(i) and (ii) that would require a minimum offering size or public float for Restrictive Market Companies listing on Nasdaq in connection with an IPO or a business combination (as described in Rule 5110(a) or IM–5101–2). Nasdaq is also proposing to adopt a new Rule 5210(k)(iii) to provide that Restrictive Market Companies would be permitted to list on the Nasdaq Global Select or Nasdaq Global Markets if they are listing in connection with a Direct Listing (as defined in IM–5315–1), but would not be permitted to list on the Nasdaq Capital Market, which has lower requirements for Unrestricted Publicly Held Shares, in connection with a Direct Listing.

I. Definition of Restrictive Market

Nasdaq proposes to adopt a new definition of Restrictive Market in Rule 5005(a)(37) to define a Restrictive Market as a jurisdiction that does not provide the PCAOB with access to conduct inspections of public accounting firms that audit Nasdaq-listed companies. This is similar to the President's Working Group on Financial Markets definition of ''Non-Cooperating Jurisdictions,'' which observed that:

> Certain jurisdictions, however, do not currently provide the PCAOB with the ability to inspect public accounting firms, including sufficient access to conduct inspections and investigations of audits of public companies, or otherwise do not cooperate with U.S. regulators (''Non-Cooperating Jurisdictions,'' or ''NCJs''). The PCAOB has been unable to fulfill its statutory mandate under Sarbanes-Oxley to inspect audit firms in NCJs, including those in China, potentially exposing investors in U.S. capital markets to significant risks. The PCAOB has been unable to fulfill this mandate meaningfully with respect to audit firms based in China for more than a decade.[15]

The PCAOB maintains a map of where it can and cannot conduct oversight activities on its website.[16] In addition, the PCAOB publishes a list identifying the public companies for which a PCAOB-registered public accounting firm signed and issued an audit report and is located in a jurisdiction where obstacles to PCAOB inspections exist.[17]

Nasdaq will consider a company's business to be principally administered in a Restrictive Market if: (i) The company's books and records are located in that jurisdiction; (ii) at least 50% of the company's assets are located in such jurisdiction; or (iii) at least 50% of the company's revenues are derived from such jurisdiction. Nasdaq also proposes to renumber the remainder of Rule 5005(a) to ensure consistency in its rulebook.

For example, Company X's books and records could be located in Country Y, which is not a Restrictive Market, while 90% of its revenues are derived from operations in Country Z, which is a Restrictive Market. If Company X applies to list its Primary Equity Security on Nasdaq in connection with an IPO, Nasdaq would consider Company X's business to be principally administered in Country Z, and Company X would therefore be subject to the proposed additional requirements applicable to a Restrictive Market Company. Conversely, Company A's books and records could be located in Country B, which is a Restrictive Market, but 90% of its revenues are derived from Country C, which is not a Restrictive Market. Nasdaq would consider Company A's business to be principally administered in Country B, and Company A would therefore be subject to the proposed additional requirements applicable to a Restrictive Market Company.

II. Minimum Offering Size or Public Float Percentage for an IPO

As proposed, Rule 5210(k)(i) would require a company that is listing its Primary Equity Security [18] on Nasdaq in connection with its IPO, and that principally administers its business in a Restrictive Market, to offer a minimum amount of securities in a Firm Commitment Offering [19] in the U.S. to Public Holders [20] that: (a) Will result in gross proceeds to the company of at least $25 million; or (b) will represent at least 25% of the company's post-offering Market Value [21] of Listed Securities,[22] whichever is lower. For example, Company X is applying to list on Nasdaq Global Market. Company X principally administers its business in a Restrictive Market and its post-offering Market Value of Listed Securities is expected to be $75,000,000. Since 25% of $75,000,000 is $18,750,000, which is lower than $25,000,000, it would be eligible to list under the proposed rule based on a Firm Commitment Offering in the U.S. to Public Holders of at least $18,750,000. However, Company X would also need to comply with the other applicable listing requirements of the Nasdaq Global Market, including a Market Value of Unrestricted Publicly Held Shares [23] of at least $8 million.[24]

In contrast, Company Y, which also principally administers its business in a Restrictive Market, is applying to list on the Nasdaq Global Select Market and its post-offering Market Value of Listed Securities is expected to be $200,000,000. Since 25% of

Significant Disclosure, Financial Reporting and Other Risks; Remedies are Limited (April 21, 2020), available at *https://www.sec.gov/news/public-statement/emerging-market-investments-disclosure-reporting*; *see also* SEC Division of Corporation Finance, CF Disclosure Guidance: Topic No. 10: Disclosure Considerations for China-Based Issuers (November 23, 2020), available at *https://www.sec.gov/corpfin/disclosure-considerations-china-based-issuers.*

[14] Listing Rule 5101 provides Nasdaq with broad discretionary authority over the initial and continued listing of securities in Nasdaq in order to maintain the quality of and public confidence in its market, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and to protect investors and the public interest. Nasdaq may use such discretion to deny initial listing, apply additional or more stringent criteria for the initial or continued listing of particular securities, or suspend or delist particular securities based on any event, condition, or circumstance that exists or occurs that makes initial or continued listing of the securities on Nasdaq inadvisable or unwarranted in the opinion of Nasdaq, even though the securities meet all enumerated criteria for initial or continued listing on Nasdaq.

[15] *See supra* note 11 at 2.

[16] *See* Public Company Accounting Oversight Board, *Oversight: International* (last accessed January 29, 2020), available at *https://pcaobus.org/oversight/international.*

[17] *See supra* note 7.

[18] Rule 5005(a)(33) defines ''Primary Equity Security'' as ''a Company's first class of Common Stock, Ordinary Shares, Shares or Certificates of Beneficial Interest of Trust, Limited Partnership Interests or American Depositary Receipts (ADR) or Shares (ADS).''

[19] Rule 5005(a)(17) defines ''Firm Commitment Offering'' as ''an offering of securities by participants in a selling syndicate under an agreement that imposes a financial commitment on participants in such syndicate to purchase such securities.''

[20] Rule 5005(a)(36) defines ''Public Holders'' as ''holders of a security that includes both beneficial holders and holders of record, but does not include any holder who is, either directly or indirectly, an Executive Officer, director, or the beneficial holder of more than 10% of the total shares outstanding.''

[21] Rule 5005(a)(23) defines ''Market Value'' as ''the consolidated closing bid price multiplied by the measure to be valued (*e.g.,* a Company's Market Value of Publicly Held Shares is equal to the consolidated closing bid price multiplied by a Company's Publicly Held Shares).''

[22] Rule 5005(a)(22) defines ''Listed Securities'' as ''securities listed on Nasdaq or another national securities exchange.''

[23] *See* Rule 5005(a)(45) (definition of ''Unrestricted Publicly Held Shares''), Rule 5005(a)(46) (definition of ''Unrestricted Securities''), and Rule 5005(a)(37) (definition of ''Restricted Securities'').

[24] *See* Rule 5405(b)(1)(C).

$200,000,000 is $50,000,000, which is higher than $25,000,000, it would be eligible to list under the proposed rule based on a Firm Commitment Offering in the U.S. to Public Holders that will result in gross proceeds of at least $25,000,000. However, Company Y would also need to comply with the other applicable listing requirements of the Nasdaq Global Select Market, including a Market Value of Unrestricted Publicly Held Shares of at least $45 million.[25]

The Exchange believes that the proposal to require a Restrictive Market Company conducting an IPO to offer a minimum amount of securities in the U.S. to Public Holders in a Firm Commitment Offering will provide greater support for the company's price, as determined through the offering, and will help assure that there will be sufficient liquidity, U.S. investor interest and distribution to support price discovery once a security is listed. Nasdaq believes there is a risk that substantial participation by foreign investors in an offering, combined with insiders retaining significant ownership, does not promote sufficient investor base and trading interest to support trading in the secondary market. The risk to U.S. investors is compounded when a company is located in a Restrictive Market due to restrictions on the PCAOB's ability to inspect the audit work and practices of auditors in those countries, which may be accompanied by limitations on the ability of U.S. regulators to conduct investigations or bring or enforce actions against the company and non-U.S. persons. As a result, there are increased concerns about the accuracy of disclosures, accountability and access to information.

Further, the Exchange has observed that Restrictive Market Companies listing on Nasdaq in connection with an IPO with an offering size below $25 million or public float ratio below 25% have a high rate of compliance concerns. Nasdaq believes that these concerns may be mitigated by the company conducting a Firm Commitment Offering of at least $25 million or 25% of the company's post-offering Market Value of Listed Securities, whichever is lower. Firm Commitment Offerings typically involve a book building process that helps to generate an investor base and trading interest that promotes sufficient depth and liquidity to help support fair and orderly trading on the Exchange. Such offerings also typically involve more due diligence by the broker-dealer than would be done in connection with a best-efforts offering, which helps to ensure that third parties subject to U.S. regulatory oversight are conducting significant due diligence on the company, its registration statement and its financial statements. The Exchange believes that the proposal will help ensure that Restrictive Market Companies seeking to list on the Exchange have sufficient investor base and public float to support fair and orderly trading on the Exchange.

In developing the Proposal, Nasdaq analyzed the data behind its observations. An analysis of initial public offerings from January 1, 2015 to September 30, 2020, found that 113 Restrictive Market companies listed on Nasdaq through an IPO and 39 of such companies would not have qualified under proposed Rule 5210(k)(i) because they had offering amounts of $25 million or less.[26] Of those, 20, or 51%, were cited for a compliance issue, a significantly higher rate than other Restrictive Market Companies (16%).

During the period from January 1, 2015 to September 30, 2020, 84 Restrictive Market Companies had a ratio of offering size to Market Value of Listed Securities of 25% or less. Of these, 25, or 30%, failed to comply with one or more listing standards after listing, which is a significantly higher non-compliance rate than other foreign companies (11%) and other Restrictive Market Companies (21%) that had such listings. In some cases, when the ratio of offering size to Market Value of Listed Securities is low there may be concerns about whether there are sufficient freely tradable shares to meet investor demand.

Lastly, during the period from January 1, 2015 to September 30, 2020, 35 Restrictive Market Companies would not have qualified under either proposed Rule 5210(k)(i)(a) or (b). Of these companies, 18 were cited for a compliance concern.

III. Minimum Market Value of Publicly Held Shares for a Business Combination

Nasdaq believes that a business combination, as described in Rule 5110(a) or IM–5101–2, involving a Restrictive Market Company presents similar risks to U.S. investors as IPOs of Restrictive Market Companies. However, such a business combination would typically not involve an offering. Therefore, Nasdaq proposes to adopt a new Rule 5210(k)(ii) that would impose a similar new requirement as applicable to IPOs, but would reflect that the listing would not typically be accompanied by an offering. Specifically, proposed Rule 5210(k)(ii) would require the listed company to have a minimum Market Value of Unrestricted Publicly Held Shares following the business combination equal to the lesser of: (a) $25 million; or (b) 25% of the post-business combination entity's Market Value of Listed Securities.

For example, Company A is currently listed on the Nasdaq Capital Market and plans to acquire a company that principally administers its business in a Restrictive Market, in accordance with IM–5101–2. Following the business combination, Company A intends to transfer to the Nasdaq Global Select Market. Company A expects the post-business combination entity to have a Market Value of Listed Securities of $250,000,000. Since 25% of $250,000,000 is $62,500,000, which is higher than $25,000,000, to qualify for listing on the Nasdaq Global Select Market the post-business combination entity must have a minimum Market Value of Unrestricted Publicly Held Shares of at least $25,000,000. However, Company A would also need to comply with the other applicable listing requirements of the Nasdaq Global Select Market, including a Market Value of Unrestricted Publicly Held Shares of at least $45,000,000.[27]

In contrast, Company B is currently listed on Nasdaq Capital Market and plans to combine with a non-Nasdaq entity that principally administers its business in a Restrictive Market, resulting in a change of control as defined in Rule 5110(a), whereby the non-Nasdaq entity will become the Nasdaq-listed company. Following the change of control, Company B expects the listed company to have a Market Value of Listed Securities of $50,000,000. Since 25% of $50,000,000 is $12,500,000, which is lower than $25,000,000, the listed company must have a minimum Market Value of Unrestricted Publicly Held Shares following the change of control of at least $12,500,000. However, the company would also need to comply with the other applicable listing requirements of the Nasdaq Capital Market, including a Market Value of Unrestricted Publicly Held Shares of at least $5 million.[28]

[25] *See* Rule 5315(f)(2)(C).

[26] Two of these companies were considered to be principally administered in a Restrictive Market because they had at least 50% of the company's assets located in a Restrictive Market and 37 met the definition because they had at least 50% of the company's revenues derived from a Restrictive Market.

[27] *See* Rule 5315(f)(2)(C).

[28] *See* Rule 5505(b)(3)(C).

Market Value of Unrestricted Publicly Held Shares excludes securities subject to resale restrictions from the calculation of Publicly Held Shares because securities subject to resale restrictions are not freely transferrable or available for outside investors to purchase and therefore do not truly contribute to a security's liquidity upon listing. Nasdaq believes that requiring the post-business combination entity to have a minimum Market Value of Unrestricted Publicly Held Shares of at least $25 million or 25% of its Market Value of Listed Securities, whichever is lower, would help to provide an additional assurance that there are sufficient freely tradable shares and investor interest to support fair and orderly trading on the Exchange when the target company principally administers its business in a Restrictive Market. Nasdaq believes that this will help mitigate the unique risks that Restrictive Market Companies present to U.S. investors due to restrictions on the PCAOB's ability to inspect the audit work and practices of auditors in those countries, which create concerns about the accuracy of disclosures, accountability and access to information.

Nasdaq found that out of seven business combinations involving Restrictive Market Companies from 2015 through September 30, 2020, five would not have qualified under proposed Rule 5210(k)(ii). All five of these companies have been cited for a deficiency after the completion of their business combination. Of the two business combinations involving Restrictive Market Companies that would have qualified under proposed Rule 5210(k)(ii), one was cited for a compliance concern. As such, Nasdaq believes that a business combination, as described in Nasdaq Rule 5110(a) or IM–5101–2, involving a Restrictive Market Company presents similar risks to U.S. investors as an IPO of a Restrictive Market Company and, therefore, believes it is appropriate to apply similar thresholds to post-business combination entities to ensure that a company listing through a business combination would have satisfied equivalent standards that apply to an IPO.

IV. Direct Listings of Restrictive Market Companies

Nasdaq proposes to adopt Rule 5210(k)(iii) to provide that a Restrictive Market Company would be permitted to list on the Nasdaq Global Select Market or Nasdaq Global Market in connection with a Direct Listing (as defined in IM–5315–1), provided that the company meets all applicable listing requirements for the Nasdaq Global Select Market and the additional requirements of IM–5315–1, or the applicable listing requirements for the Nasdaq Global Market and the additional requirements of IM–5405–1. However, such companies would be not be permitted to list on the Nasdaq Capital Market in connection with a Direct Listing notwithstanding the fact that such companies may meet the applicable initial listing requirements for the Nasdaq Capital Market and the additional requirements of IM–5505–1.

Direct Listings are currently required to comply with enhanced listing standards pursuant to IM–5315–1 (Nasdaq Global Select Market) and IM–5405–1 (Nasdaq Global Market). If a company's security has had sustained recent trading in a Private Placement Market,[29] Nasdaq may attribute a Market Value of Unrestricted Publicly Held Shares equal to the lesser of (i) the value calculable based on a Valuation [30] and (ii) the value calculable based on the most recent trading price in the Private Placement Market.[31] Nasdaq believes that the price from such sustained trading in the Private Placement Market for the company's securities is predictive of the price in the market for the common stock that will develop upon listing of the securities on Nasdaq and that qualifying a company based on the lower of such trading price or the Valuation helps assure that the company satisfies Nasdaq's requirements.

Nasdaq may require a company listing on the Nasdaq Global Select Market that has not had sustained recent trading in a Private Placement Market to satisfy the applicable Market Value of Unrestricted Publicly Held Shares requirement and provide a Valuation evidencing a Market Value of Publicly Held Shares of at least $250,000,000.[32] For a company that has not had sustained recent trading in a Private Placement Market and that is applying to list on the Nasdaq Global Market, Nasdaq will generally require the company to provide a Valuation that demonstrates a Market Value of Listed Securities and Market Value of Unrestricted Publicly Held Shares that exceeds 200% of the otherwise applicable requirement.[33] Nasdaq believes that in the absence of recent sustained trading in the Private Placement Market, the requirement to demonstrate a Market Value of Publicly Held Shares of at least $250 million for a company seeking to list on Nasdaq Global Select Market, or that the company exceeds 200% of the otherwise applicable price-based requirement for a company seeking to list on Nasdaq Global Market, helps assure that the company satisfies Nasdaq's requirement by imposing a standard that is more than double the otherwise applicable standard.

Thus, companies listing in connection with a Direct Listing on the Nasdaq Global or Global Select Market tiers are already subject to enhanced listing requirements and Nasdaq believes it is appropriate to permit Restrictive Market Companies to list through a Direct Listing on the Nasdaq Global Select Market or Nasdaq Global Market. On the other hand, while companies listing in connection with a Direct Listing on the Capital Market are also subject to enhanced listing requirements, Nasdaq does not believe that these enhanced requirements are sufficient to overcome concerns regarding sufficient liquidity and investor interest to support fair and orderly trading on the Exchange with respect to Restrictive Market Companies.[34] Nasdaq believes that Restrictive Market Companies present unique risks to U.S. investors due to restrictions on the PCAOB's ability to inspect the audit work and practices of auditors in those countries, which create concerns about the accuracy of disclosures, accountability and access to information. Therefore, Nasdaq believes that precluding a Restrictive Market Company from listing through a Direct Listing on the Capital Market will help to ensure that the company has sufficient public float, investor base, and trading interest likely to generate depth and liquidity necessary to promote fair and orderly trading on the secondary market.

V. Conclusion

Nasdaq believes that the U.S. capital markets can provide Restrictive Market Companies with access to additional capital to fund ground-breaking research and technological advancements. Further, such companies provide U.S. investors with opportunities to diversify their portfolio by providing exposure to

[29] *See* Rule 5005(a)(34).

[30] *See* IM–5315–1(a)(1).

[31] *See* IM–5315–1(a)(1) (Nasdaq Global Select Market) and IM–5405–1(a)(1) (Nasdaq Global Market).

[32] *See* IM–5315–1(b).

[33] *See* IM–5405–1(a)(2) (Nasdaq Global Market).

[34] For example, the Nasdaq Global Select Market and Nasdaq Global Market require a company to have at least 1,250,000 and 1.1 million Unrestricted Publicly Held Shares, respectively, and a Market Value of Unrestricted Publicly Held Shares of at least $45 million and $8 million, respectively. In contrast, the Nasdaq Capital Market requires a company to have at least 1 million Unrestricted Publicly Held Shares and a Market Value of Unrestricted Publicly Held Shares of at least $5 million.

Restrictive Markets. However, as discussed above, Nasdaq believes that Restrictive Market Companies present unique potential risks to U.S. investors due to restrictions on the PCAOB's ability to inspect the audit work and practices of auditors in those countries, which create concerns about the accuracy of disclosures, accountability and access to information.[35] Nasdaq believes that the proposed rule changes will help to ensure that Restrictive Market Companies have sufficient investor base and public float to support fair and orderly trading on the Exchange.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[36] in general, and furthers the objectives of Section 6(b)(5) of the Act,[37] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. Further, the Exchange believes that this proposal is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission has previously opined on the importance of meaningful listing standards for the protection of investors and the public interest.[38] In particular, the Commission stated:

> Among other things, listing standards provide the means for an exchange to screen issuers that seek to become listed, and to provide listed status only to those that are bona fide companies with sufficient public float, investor base, and trading interest likely to generate depth and liquidity sufficient to promote fair and orderly markets. Meaningful listing standards also are important given investor expectations regarding the nature of securities that have achieved an exchange listing, and the role of an exchange in overseeing its market and assuring compliance with its listing standards.[39]

Nasdaq believes that requiring a minimum offering size or public float percentage for Restrictive Market Companies seeking to list on Nasdaq through an IPO or business combination will ensure that a security to be listed on Nasdaq has adequate liquidity, distribution and U.S. investor interest to support fair and orderly trading in the secondary market, which will reduce trading volatility and price manipulation, thereby protecting investors and the public interest.

Similarly, Nasdaq believes that permitting Restrictive Market Companies to list on Nasdaq Global Select Market or Nasdaq Global Market, rather than the Nasdaq Capital Market, in connection with a Direct Listing will ensure that such companies satisfy more rigorous listing requirements, including the minimum amount of Publicly Held Shares and Market Value of Publicly Held Shares, which will help to ensure that the security has sufficient public float, investor base, and trading interest likely to generate depth and liquidity sufficient to promote fair and orderly trading, thereby protecting investors and the public interest.

While the proposal applies only to Restrictive Market Companies, the Exchange believes that the proposal is not designed to permit unfair discrimination among companies because Nasdaq believes that Restrictive Market Companies present unique potential risks to U.S. investors due to restrictions on the PCAOB's ability to inspect the audit work and practices of auditors in those countries, which create concerns about the accuracy of disclosures, accountability and access to information.

Nasdaq and investors rely on the work of auditors to provide reasonable assurances that the financial statements provided by a company are free of material misstatements. The PCAOB states that ''[r]easonable assurance is obtained by reducing audit risk to an appropriately low level through applying due professional care, including obtaining sufficient appropriate audit evidence.''[40] Nasdaq believes that the PCAOB's inability to inspect the audit work and practices of auditors in certain countries weakens the assurance that the auditor obtained sufficient appropriate audit evidence to express its opinion on a company's financial statements, and decreases confidence that the auditor complied with PCAOB and SEC rules and professional standards in connection with the auditor's performance of audits. Nasdaq believes that without reasonable assurances from an auditor that a company's financial statements and related disclosures are free from material misstatements, there is a risk that a company that would otherwise not have qualified to list on Nasdaq may satisfy Nasdaq's listing standards by presenting financial statements that contain undetected material misstatements. In *In the Matter of the Tassaway, Inc.,* the Commission observed that

> Though exclusion from the system may hurt existing investors, primary emphasis must be placed on the interests of prospective future investors. The latter group is entitled to assume that the securities in the system meet the system's standards. Hence the presence in NASDAQ of non-complying securities could have a serious deceptive effect.[41]

The proposed rule change would provide greater assurances to investors that a company truly meets Nasdaq's financial listing requirements by imposing heightened listing criteria on a company that principally administers its business in a Restrictive Market, thereby preventing fraudulent and manipulative acts, protecting investors and promoting the public interest.

In addition, securities of Restrictive Market Companies may not develop sufficient public float, investor base, and trading interest to provide the depth and liquidity necessary to promote fair and orderly trading, resulting in a security that is illiquid. Nasdaq is concerned because illiquid securities may trade infrequently, in a more volatile manner and with a wider bid-ask spread, all of which may result in trading at a price that may not reflect their true market value.

Less liquid securities also may be more susceptible to price manipulation, as a relatively small amount of trading activity can have an inordinate effect on market prices. Price manipulation is a particular concern when insiders retain a significant ownership portion of the company. The risk of price manipulation due to insider trading is more acute when a company principally administers its business in a Restrictive Market and management lacks familiarity or experience with U.S. securities laws. Therefore, Nasdaq believes that it is not unfairly discriminatory to treat Restrictive Market Companies differently under this proposal because it will help ensure that securities of a Restrictive Market Company listed on Nasdaq have sufficient public float, investor base, and trading interest to provide the depth and liquidity necessary to promote fair and orderly markets, thereby promoting investor protection and the public interest.

[35] *See supra* note 8.

[36] 15 U.S.C. 78f(b).

[37] 15 U.S.C. 78f(b)(5).

[38] Securities Exchange Act Release No. 65708 (November 8, 2011), 76 FR 70799 (November 15, 2011) (approving SR–Nasdaq–2011–073 adopting additional listing requirements for companies applying to list after consummation of a ''reverse merger'' with a shell company).

[39] *Id* at 70802.

[40] *See supra* note 6.

[41] *See In the Matter of Tassaway, Inc.,* Securities Exchange Act Release No. 11291, 1975 WL 160383; 45 SEC 706 (March 13, 1975).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. While the proposed rule changes will apply only to companies primarily operating in Restrictive Markets, Nasdaq and the SEC have identified specific concerns with such companies that make the imposition of additional initial listing criteria on such companies appropriate to enhance investor protection, which is a central purpose of the Act. Any impact on competition, either among listed companies or between exchanges, is incidental to that purpose.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2021–007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2021–007. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*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–NASDAQ–2021–007 and should be submitted on or before March 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[42]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–02993 Filed 2–12–21; 8:45 am]

BILLING CODE 8011–01–P

[42] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91091; File No. SR–ICEEU–2021–003]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the ICE Clear Europe Delivery Procedures.

February 9, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 2, 2021, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II and III below, which Items have been prepared by ICE Clear Europe. ICE Clear Europe filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(4)(ii)[4] thereunder, such that the proposed rule was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed amendments is for ICE Clear Europe to amend its Delivery Procedures (the ''Delivery Procedures'') to add a new Section 11 and a new Part GG to address delivery relating to the ICE Futures Abu Dhabi Murban Crude Oil Futures Contracts (the ''ICE Murban Crude Oil Futures Contracts'' or the ''Contracts'').[5]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe is proposing to amend its Delivery Procedures to add a new Section 11 and a new Part GG to address delivery relating to the ICE Murban Crude Oil Futures Contracts. The Contracts will be traded on ICE Futures Abu Dhabi and cleared by ICE Clear Europe.

New Part GG would set out the delivery specifications and procedures for deliveries of Murban crude oil under the ICE Murban Crude Oil Futures

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(a).

[4] 17 CFR 240.19b–4(f)(4)(ii).

[5] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules (the ''Rules'').

Contract. The amended Delivery Procedures would specify the delivery mode (with reference to applicable requirements of the relevant delivery terminal in Fujairah, UAE) and delivery loading volume tolerances). Consistent with the exchange rules for the Contracts, delivery would take place on one or more consecutive Terminal Loading Days within the Delivery Range (which range must fall within the Delivery Period). The new Part GG would also address requirements as to delivery free of encumbrances, and determination of delivery quantity and price by reference to exchange rules for the Contract. The amendments would also establish certain timing requirements for exchange of futures for physical and swap transactions under exchange rules.

New Part GG would provide a detailed delivery timetable, from the last trading day of the Contract through final settlement, including procedures, deadlines and requirements for nominations or substitutions of delivery range and delivery day, loading programme, delivery confirmations, delivery margin, invoicing, receipt confirmations, and other matters. The procedures would also address invoice calculation with respect to the Contract and delivery loading volume tolerances. New Part GG would also specify the delivery documentation required of Buyers and Sellers.

New Section 11 of the Delivery Procedures would provide for an alternative delivery procedure for the Contracts if the Buyer and Seller agree to undertake delivery outside the ICE Futures Abu Dhabi Rules (similar to the alternative delivery procedure for other cleared F&O Contracts).

(b) Statutory Basis

Section 17A(b)(3)(F) of the Act [6] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest. The proposed amendments are designed to facilitate the clearing of a new physically settled crude oil futures contract being launched for trading by the ICE Futures Abu Dhabi exchange and that will be cleared by ICE Clear Europe. The amendments would set out the obligations and roles of the Clearing House and the relevant parties for delivery under the Contracts, supplementing the existing provisions of the Rules. ICE Clear Europe believes that its financial resources, risk management, systems and operational arrangements are sufficient to support clearing of such Contracts (and to address physical delivery under such Contracts) and to manage the risks associated with such Contracts. As a result, in ICE Clear Europe's view, the amendments would be consistent with the prompt and accurate clearance and settlement of the Contracts as set out in the proposed Delivery Procedures amendments, and the protection of investors and the public interest, consistent with the requirements of Section 17A(b)(3)(F) of the Act.[7] (In ICE Clear Europe's view, the amendments would not adversely affect the safeguarding of funds or securities in the custody or control of the clearing agency or for which it is responsible, within the meaning of Section 17A(b)(3)(F).[8])

In addition, Rule 17Ad–22(e)(10) [9] requires that each covered clearing agency establish and maintain transparent written standards that state its obligations with respect to the delivery of physical instruments, and establish and maintain operational practices that identify, monitor and manage the risks associated with such physical deliveries. As discussed above, the amendments to the Delivery Procedures relating to the delivery and settlement of Murban crude oil under the Contracts would set out the obligations and roles of Clearing Members and the Clearing House. The amendments would also specify the mode of delivery and adopt relevant procedures, deadlines and documentation requirements for such deliveries, which would facilitate identifying, monitoring and managing risks associated with delivery. As such, in ICE Clear Europe's view, the amendments are consistent with the requirements of Rule 17Ad–22(e)(10).[10]

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The changes are being proposed in order to update the Delivery Procedures in connection with the listing of the Contracts for trading on the ICE Futures Abu Dhabi market. ICE Clear Europe believes that the Contracts would provide additional opportunities for interested market participants to engage in trading activity in the Murban crude oil market. ICE Clear Europe does not believe the amendments would adversely affect competition among Clearing Members, materially affect the cost of clearing, adversely affect access to clearing in Contracts for Clearing Members or their customers, or otherwise adversely affect competition in clearing services. Accordingly, ICE Clear Europe does not believe that the amendments would impose any impact or burden on competition that is not appropriate in furtherance of the purpose of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any comments received with respect to 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 Act [11] and paragraph (f) of Rule 19b–4 [12] 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.

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–ICEEU–2021–003 on the subject line.

[6] 15 U.S.C. 78q–1(b)(3)(F).

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] 15 U.S.C. 78q–1(b)(3)(F).

[9] 17 CFR 240.17Ad–22(e)(10).

[10] 17 CFR 240.17Ad–22(e)(10).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f).

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–ICEEU–2021–003. 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 such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.*

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–ICEEU–2021–003 and should be submitted on or before March 9, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

J. Mathew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–02995 Filed 2–12–21; 8:45 am]

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[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91090; File No. SR–ICC–2021–004]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Relating to the ICC Governance Playbook

February 9, 2021.

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 29, 2021, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to update and formalize the ICC Governance Playbook. These revisions do not require any changes to the ICC Clearing Rules (the ''Rules'').

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change, security-based swap submission, or advance notice and discussed any comments it received on the proposed rule change, security-based swap submission, or advance notice. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICC proposes to update and formalize the Governance Playbook. ICC believes such changes will facilitate the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions for which it is responsible. ICC proposes to update and formalize the Governance Playbook following Commission approval of the proposed rule change. The proposed rule change is described in detail as follows.

The Governance Playbook consolidates governance arrangements set forth in ICC's Rules, operating agreement, and other ICC policies and procedures. The Governance Playbook contains information regarding the governance structure at ICC, which includes the Board, committees, and management. The document is divided in six parts and sets out (i) the purpose of the document, (ii) an introduction to the ICC governance structure, (iii) information on the ICC Board of Managers (the ''Board''; each member a ''Manager''); (iv) descriptions of the committees at ICC, (v) descriptions of the special purpose committees at ICC, and (vi) a revision history and appendix.

The Board has sole responsibility for the control and management of ICC's operations, subject only to prior consultation rights of the ICC Risk Committee and the ICC Risk Management Subcommittee as described in Chapter 5 of the ICC Rules. The Governance Playbook details reporting lines of relevant personnel to the Board as well as how the Board guides management with respect to strategic planning and priority setting. Additionally, the Governance Playbook describes the composition of the Board, and details the fitness standards required of each Board member and the Board as a whole. Such procedures are in place to ensure that the Board consists of suitable individuals having appropriate skills and incentives and that Managers have the appropriate experience, skills, and integrity necessary to discharge their Board responsibilities. The Governance Playbook describes the election procedures for new Managers and specifies who is responsible for electing new Managers and for ensuring such Managers meet the fitness standards. The Governance Playbook contains information regarding scheduling of meetings and meeting frequency, and lists all documents relevant to Board operations. The Governance Playbook sets forth the process for determining the independence of those Managers who are required to be independent. Additionally, the document lists the independence qualifications considered as part of such independence determinations and describes the annual questionnaire process each independent Manager is required to complete. The performance of the Board and its individual Managers is reviewed on an annual basis, through a self-evaluation

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

survey; the Governance Playbook describes this survey process.

The Governance Playbook also contains information on required disclosures under relevant regulations. The arrangements in place at ICC ensure that all major decisions of the Board are clearly disclosed to clearing members, other relevant stakeholders, and ICC's regulators. Further, major decisions of the Board having a broad market impact are clearly disclosed to the public. With respect to information made available to the public, ICC posts on its website relevant rules and material procedures and documents. ICC maintains a comprehensive public Disclosure Framework that describes its material rules, policies, and procedures regarding its legal, governance, risk management, and operating framework, which is updated every two years or more frequently following material changes to ICC's systems or environment in which it operates.

The Governance Playbook describes the Board's role in reviewing the performance and compensation of management, who are responsible for executing the Board's decisions throughout the year. As part of this process, the Board will consider whether management continues to have the appropriate experience, skills, and integrity necessary to discharge their responsibilities.

Additionally, the Governance Playbook contains information regarding the roles and responsibilities of the various committees at ICC, including the Audit Committee, Risk Committee, Risk Management Subcommittee, Advisory Committee, Futures Commission Merchant (''FCM'') Executive Council, Participant Review Committee, Credit Review Subcommittee, New Initiatives Approval Committee, Operations Working Group, Trading Advisory Group, Business Continuity Planning (''BCP'') and Disaster Recovery (''DR'') Oversight Committee of the Compliance Committee, Risk Working Group, Compliance Committee, and Steering Committee. The Governance Playbook further details the membership composition and meeting frequency for each committee and contains a listing of all relevant committee documents (including, as applicable, a charter, meeting minutes, and agendas). As applicable, the Governance Playbook details procedures for electing new members to a committee. The Governance Playbook also includes procedures for the annual Audit Committee performance review and the annual reconstitution of the Risk Committee.

Further, the Governance Playbook contains information regarding ICC's special purpose committees, including the Business Conduct Committee, Regional CDS Committees, and the CDS Default Committee. The Governance Playbook contains a brief description of each special purpose committee, details membership composition and meeting frequency, and lists relevant committee documents. As applicable, the Governance Playbook contains information regarding the appointment of new members.

Finally, the Governance Playbook includes a revision history and an appendix with relevant information, including a record of the roles, responsibilities, and required skills of key senior management and a template relating to the reconstitution of the Risk Committee.

(b) Statutory Basis

ICC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act [3] and the regulations thereunder applicable to it, including the applicable standards under Rule 17Ad–22.[4] In particular, Section 17A(b)(3)(F) of the Act [5] requires that the rule change be consistent with the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts and transactions cleared by ICC, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest. ICC believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to ICC, in particular, to Section 17(A)(b)(3)(F),[6] because the proposed rule change would promote governance of ICC that is effective and efficient and ensure that ICC has governance arrangements that are clear and transparent and promote its safety and efficiency. The proposed rule change details ICC's governance structure and assigns ownership to responsible parties of relevant governance procedures, including those responsible for electing new Managers, for ensuring such Managers meet fitness standards, and for ensuring that management has the appropriate experience and skills necessary to discharge their responsibilities. The document describes fitness standards required of each Board member and the Board as a whole, the review of management, and the roles and responsibilities of the various committees at ICC. ICC believes that the Governance Playbook augments its governance procedures and ensures that it has clear and transparent governance arrangements that support its ability to provide clearing services and effectively manage the risks associated with discharging its responsibilities, thereby promoting the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions; the safeguarding of securities and funds which are in the custody or control of ICC or for which it is responsible; and the protection of investors and the public interest. As such, the proposed rule change is designed to promote the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions; to contribute to the safeguarding of securities and funds associated with security-based swap transactions in ICC's custody or control, or for which ICC is responsible; and, in general, to protect investors and the public interest within the meaning of Section 17A(b)(3)(F) of the Act.[7]

The amendments would also satisfy relevant requirements of Rule 17Ad–22.[8] Rule 17Ad–22(e)(2) [9] requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for governance arrangements that are (i) clear and transparent; (ii) clearly prioritize the safety and efficiency of the covered clearing agency; (iii) support the public interest requirements in Section 17A of the Act [10] applicable to clearing agencies, and the objectives of owners and participants; (iv) establish that the board of directors and senior management have appropriate experience and skills to discharge their duties and responsibilities; (v) specify clear and direct lines of responsibility; and (vi) consider the interests of participants' customers, securities issuers and holders, and other relevant stakeholders of the covered clearing agency. The Governance Playbook clearly assigns and documents responsibility and accountability for governance actions and decisions and details reporting lines of relevant personnel to the Board. The Governance Playbook documents the role of the Board, relevant committees, and

[3] 15 U.S.C. 78q–1.

[4] 17 CFR 240.17Ad–22.

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] *Id.*

[7] *Id.*

[8] 17 CFR 240.17Ad–22.

[9] 17 CFR 240.17Ad–22(e)(2).

[10] 15 U.S.C. 78q–1.

management in the governance process in order to provide for clear and transparent governance arrangements that specify clear and direct lines of responsibility. Moreover, the governance arrangements set out in the document promote the safety and efficiency of ICC and support the public interest requirements in Section 17A of the Act [11] applicable to clearing agencies, and the objectives of owners and participants, by describing the roles, responsibilities, and required skills of the Board, committees, and management, thereby ensuring that such groups have the appropriate experience, skills, and integrity necessary to discharge their responsibilities and to ensure that ICC continues to provide safe and sound central counterparty services. Further, ICC's governance structure, as set out in the Governance Playbook, is designed to provide a forum for ICC to receive feedback from multiple stakeholders as ICC's committees are actively involved in the governance process to ensure that ICC's rules, strategy, and major decisions reflect appropriately the interests of market participants and other relevant stakeholders. As such, ICC believes that the proposed rule change is consistent with the requirements of Rule 17Ad–22(e)(2).[12]

Rule 17Ad–22(e)(23) [13] requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for (i) publicly disclosing all relevant rules and material procedures, including key aspects of its default rules and procedures; (ii) providing sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency; (iii) publicly disclosing relevant basic data on transaction volume and values; (iv) a comprehensive public disclosure that describes its material rules, policies, and procedures regarding its legal, governance, risk management, and operating framework, accurate in all material respects at the time of publication; and (v) updating the public disclosure every two years, or more frequently following changes to its system or the environment in which it operates to the extent necessary to ensure statements previously provided remain accurate in all material respects. The Governance Playbook contains procedures regarding required disclosures to ensure transparency and availability of sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in ICC. The document requires that ICC post on its website relevant rules and material procedures and maintain a comprehensive public Disclosure Framework that describes its material rules, policies, and procedures regarding its legal, governance, risk management, and operating framework, which is updated every two years or more frequently following material changes to ICC's systems or environment in which it operates. Therefore, ICC believes the proposed rule change is consistent with the requirements of Rule 17ad–22(e)(23) [sic].[14]

(B) Clearing Agency's Statement on Burden on Competition

ICC does not believe the proposed rule change would have any impact, or impose any burden, on competition. The proposed rule change to update and formalize the Governance Playbook will apply uniformly across all market participants. Therefore, ICC does not believe the proposed rule change would impose any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, security-based swap submission, or advance notice 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–ICC–2021–004 on the subject line.

Paper Comments

Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–ICC–2021–004. 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 such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's website at *https://www.theice.com/clear-credit/regulation.*

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–ICC–2021–004 and should be submitted on or before March 9, 2021.

[11] *Id.*

[12] 17 CFR 240.17Ad–22(e)(2).

[13] 17 CFR 240.17Ad–22(e)(23).

[14] *Id.*

[15] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–02994 Filed 2–12–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91092; File No. SR–FICC–2020–017]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Modify the Calculation of the MBSD VaR Floor To Incorporate a Minimum Margin Amount

February 9, 2021.

I. Introduction

On November 20, 2020, Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] proposed rule change SR–FICC–2020–017 to introduce a new ''Minimum Margin Amount'' to complement the existing VaR Floor calculation.[3] The proposed rule change was published for comment in the **Federal Register** on December 10, 2020.[4] The Commission has received comment letters on the proposed rule change.[5] On December 23, 2020, pursuant to Section 19(b)(2) of the Act,[6] the Commission designated a longer period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the proposed rule change and the Commission designated a longer period for comment on the proposed rule change.[7] This order institutes proceedings, pursuant to Section 19(b)(2)(B) of the Act,[8] to determine whether to approve or disapprove the proposed rule change.

II. Summary of the Proposed Rule Change

A. Background

FICC, through its Mortgage-Backed Securities Division (''MBSD''), serves as a central counterparty (''CCP'') and provider of clearance and settlement services for the non-private label mortgage-backed securities markets. A key tool that FICC uses to manage its respective credit exposures to its members is collecting margin from each member. The aggregated amounts of all members' margin constitutes the Clearing Fund, which FICC would access should a defaulted member's own margin be insufficient to satisfy losses to the CCP caused by the liquidation of that member's portfolio.

Each member's margin consists of a number of applicable components, including a value-at-risk (''VaR'') Charge designed to capture the potential market price risk associated with the securities in a member's portfolio. The VaR Charge is typically the largest of the margin components.

To determine the VaR Charge, FICC generally uses a risk-based calculation designed to quantify the risks related to the volatility of market prices associated with the securities in a member's portfolio. However, FICC also uses a haircut-based calculation to determine a VaR Floor, which replaces the risk-based calculation to become a member's VaR Charge in the event that the VaR Floor is greater than the amount determined by the risk-based calculation, operating as a minimum VaR Charge. FICC uses the VaR Floor to mitigate the risk that the risk-based calculation does not result in margin amounts that accurately reflect FICC's applicable credit exposure, which may occur in certain member portfolios containing long and short positions in different asset classes that share a high degree of historical price correlation.

B. Minimum Margin Amount

FICC is proposing to introduce a new calculation called the ''Minimum Margin Amount'' to complement the existing VaR Floor calculation. Under the proposal, FICC would revise the existing definition of the VaR Floor to be the greater of (1) the current VaR Floor calculation, and (2) the Minimum Margin Amount. The Minimum Margin Amount would enhance FICC's margin collection during periods of market volatility, particularly when TBA [9] price changes significantly exceed those implied by the VaR model risk factors, such as rates and option-adjusted spread. FICC observed this situation occur during March and April 2020, with the result that margin amounts collected were not sufficient to mitigate FICC's credit exposure to its members' portfolios.[10] The Minimum Margin

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On November 27, 2020, FICC also filed the proposal contained in the proposed rule change as advance notice SR–FICC–2020–804 with the Commission pursuant to Section 806(e)(1) of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act''), 12 U.S.C. 5465(e)(1), and Rule 19b–4(n)(1)(i) of the Act, 17 CFR 240.19b–4(n)(1)(i). Notice of filing of the advance notice and extension of the review period was published for comment in the **Federal Register** on January 6, 2021. Securities Exchange Act Release No. 90834 (December 31, 2020), 86 FR 584 (January 6, 2021) (SR–FICC–2020–804). The proposal contained in the proposed rule change and the advance notice shall not take effect until all regulatory actions required with respect to the proposal are completed.

[4] Securities Exchange Act Release No. 90568 (December 4, 2020), 85 FR 79541 (December 10, 2020) (SR–FICC–2020–017) (''Notice'').

[5] *See* Letter from Christopher Killian, Managing Director, Securities Industry and Financial Markets Association, dated January 29, 2021, to Vanessa Countryman, Secretary, Commission, *available at https://www.sec.gov/comments/sr-ficc-2020-017/srficc2020017-8154310-226759.pdf;* Letter from Christopher A. Iacovella, Chief Executive Officer, American Securities Association, dated January 28, 2021, to Vanessa Countryman, Secretary, Commission, *available at https://www.sec.gov/comments/sr-ficc-2020-804/srficc2020804-8302307-228379.pdf;* Letter from James Tabacchi, Chairman, Independent Dealer and Trader Association and Mike Fratantoni, Chief Economist, Senior Vice President, Mortgage Bankers Association, dated January 26, 2021, to Allison Herren Lee, Acting Chair, Commission, *available at https://www.sec.gov/comments/sr-ficc-2020-017/srficc2020017-8290678-228219.pdf;* Letter from Kelli McMorrow, Head of Government Affairs, American Securities Association, dated December 18, 2020, to Vanessa Countryman, Secretary, Commission, *available at https://www.sec.gov/comments/sr-ficc-2020-017/srficc2020017-8173139-227003.pdf;* Letter from Pete Mills, Senior Vice President, Mortgage Bankers Association, dated December 17, 2020, to Jay Clayton, Chairman, Commission, *available at https://www.sec.gov/comments/sr-ficc-2020-017/srficc2020017-8155338-226778.pdf;* Letter from Christopher Killian, Managing Director, Securities Industry and Financial Markets Association, dated December 16, 2020, to Vanessa Countryman, Secretary, Commission, *available at https://www.sec.gov/comments/sr-ficc-2020-017/srficc2020017-8154310-226759.pdf;* Letter from Curtis Richins, President & CEO, Mortgage Capital Trading, Inc., dated December 15, 2020, to Vanessa Countryman, Secretary, Commission, *available at https://www.sec.gov/comments/sr-ficc-2020-017/srficc2020017-8156568-226839.pdf;* and Letter from James Tabacchi, Chairman, Independent Dealer and Trader Association, dated December 10, 2020, to Vanessa Countryman, Secretary, Commission, *available at https://www.sec.gov/comments/sr-ficc-2020-017/srficc2020017-8127766-226454.pdf. See* comments on the proposed rule change (SR–FICC–2020–017), *available at https://www.sec.gov/comments/sr-ficc-2020-017/srficc2020017.htm.* Because the proposal contained in the proposed rule change was also filed as an advance notice, *supra* note 3, the Commission is considering all public comments received on the proposal regardless of whether the comments were submitted to the advance notice or the proposed rule change.

[6] 15 U.S.C. 78s(b)(2).

[7] Securities Exchange Act Release No. 90794 (December 23, 2020), 85 FR 86591 (December 30, 2020) (SR–FICC–2020–017).

[8] 15 U.S.C. 78s(b)(2)(B).

[9] The vast majority of agency MBS trading occurs in a forward market, on a ''to-be-announced'' or ''TBA'' basis. In a TBA trade, the seller of MBS agrees on a sale price, but does not specify which particular securities will be delivered to the buyer on settlement day. Instead, only a few basic characteristics of the securities are agreed upon, such as the MBS program, maturity, coupon rate, and the face value of the bonds to be delivered.

[10] Although FICC expects its margin methodology to cover projected liquidation losses at a 99 percent

Amount would be calculated based on historical price movements of the securities in the member's portfolio. Specifically, FICC would use a dynamic haircut method based on observed TBA price moves that would provide a more reliable estimate for the portfolios' risk level when current market conditions deviate from historical observations.

The Minimum Margin Amount would be a minimum volatility calculation for specified net unsettled positions, calculated [11] using the historical market price changes of such benchmark TBA securities determined by FICC. The Minimum Margin Amount would cover such range of historical market price moves and parameters using a look-back period of no less than one year and no more than three years.

C. Summary of the Effect of the Changes Proposed in the Proposed Rule Change

FICC performed an impact study on members' portfolios for the period beginning February 3, 2020 through June 30, 2020. On average, at the member level, FICC found that the Minimum Margin Amount would have increased the VaR Charge by $27 million during the period of the impact study.[12] The largest percent increase in VaR Charge for any member would have been 146%, or $22 million.[13] The largest dollar increase for any member would have been $333 million, or 37% increase in the VaR Charge.[14] The top 10 members based on the size of their VaR Charges would have contributed 69.3% of the aggregate VaR Charges had the Minimum Margin Amount been in place.[15] The same members would have contributed to 54% of the increase resulting from the Minimum Margin Amount.[16]

Backtesting studies indicate that average daily Backtesting Charges [17] would have decreased by approximately $450 million or 53% during the impact study period and the overall margin backtesting coverage (based on 12 month trailing backtesting) would have improved from approximately 97.3% to 98.5% through June 30, 2020 if the Minimum Margin Amount calculation had been in place.[18]

III. Proceedings To Determine Whether To Approve or Disapprove the Proposed Rule Change and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act [19] to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to comment on the proposed rule change, and provide the Commission with arguments to support the Commission's analysis as to whether to approve or disapprove the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[20] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the proposed rule change's consistency with Section 17A of the Act,[21] and the rules thereunder, including the following provisions:

- Section 17A(b)(3)(F) of the Act,[22] which requires, among other things, that the rules of a clearing agency must be designed to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible and to protect investors and the public interest;
- Section 17A(b)(3)(I) of the Act,[23] which requires that the rules of a clearing agency do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act;
- Rule 17Ad–22(e)(4)(i) under the Act,[24] which requires a covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence;
- Rule 17Ad–22(e)(6)(i) and (v) under the Act, which require a covered clearing agency to establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum (1) considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market, and (2) uses an appropriate method for measuring credit exposure that accounts for relevant product risk factors and portfolio effects across products; and
- Rule 17Ad–22(e)(23)(ii) under the Act,[25] which requires a covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to provide sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency.

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposed rule change. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act,[26] Section 17A(b)(3)(I) of the Act,[27] Rule 17Ad–22(e)(4)(i) under the Act,[28] Rule 17Ad–22(e)(6)(i) and (v),[29] Rule 17Ad–22(e)(23)(ii) under the Act,[30] or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4(g) under the Act,[31] any request for an opportunity to make an oral presentation.[32]

confidence level, MBSD's monthly backtesting coverage of the VaR Charge was 86.6 percent in March 2020 and 94.2 percent in April 2020.

[11] *See generally* Notice, *supra* note 4, 85 FR at 79543–44 for a more detailed description of the calculation.

[12] Notice, *supra* note 4, 85 FR at 79545.

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] The Backtesting Charge is an existing charge FICC adds to a member's VaR Charge when a member has 12-month trailing backtesting coverage below the 99 percent backtesting coverage target. The Backtesting Charge is generally equal to the member's third largest deficiency that occurred during the previous 12 months.

[18] Notice, *supra* note 4, 85 FR at 79545.

[19] 15 U.S.C. 78s(b)(2)(B).

[20] *Id.*

[21] 15 U.S.C. 78q–1.

[22] 15 U.S.C. 78q–1(b)(3)(F).

[23] 15 U.S.C. 78q–1(b)(3)(I).

[24] 17 CFR 240.17Ad–22(e)(4)(i).

[25] 17 CFR 240.17Ad–22(e)(23)(ii).

[26] 15 U.S.C. 78q–1(b)(3)(F).

[27] 15 U.S.C. 78q–1(b)(3)(I).

[28] 17 CFR 240.17Ad–22(e)(4)(i).

[29] 17 CFR 240.17Ad–22(e)(6)(i) and (v).

[30] 17 CFR 240.17Ad–23(e)(23)(ii).

[31] 17 CFR 240.19b–4(g).

[32] Section 19(b)(2) of the Act grants to the Commission flexibility to determine what type of

Continued

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by February 23, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by March 3, 2021.

The Commission asks that commenters address the sufficiency of FICC's statements in support of the proposed rule change, which are set forth in the Notice,[33] in addition to any other comments they may wish to submit about the proposed rule change.

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–FICC–2020–017 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–FICC–2020–017. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of FICC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). 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–FICC–2020–017 and should be submitted on or before February 23, 2021. Rebuttal comments should be submitted by March 3, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

J. Matthew DeLesDernier,

Assistant Secretary.

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proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[33] *See* Notice, *supra* note 3.

[34] 17 CFR 200.30–3(a)(31).

SMALL BUSINESS ADMINISTRATION

[Docket No: SBA–2020–0011]

SBA Lender Risk Rating System

AGENCY: Small Business Administration.

ACTION: Notice of revised Risk Rating System and Lender Portal definition of Confidential Information; request for comments.

SUMMARY: This notice implements changes to the Small Business Administration's (SBA's) Risk Rating System. The Risk Rating System is an internal tool to assist SBA in assessing the risk of the SBA loan operations and loan portfolio of each active 7(a) Lender and Certified Development Company (CDC). Consistent with industry best practices, SBA recently redeveloped the model used to calculate the composite Risk Ratings of lenders and the risk associated with each SBA loan to ensure that the Risk Rating System remains current and predictive as technologies, the economy, and available data evolve. In conjunction with the redevelopment of the Lender Risk Rating, SBA is updating the Lender Portal and its definition for Confidential Information. SBA is publishing this notice with a request for comments to provide the public with an opportunity to comment.

DATES: This notice is effective February 16, 2021.

Comment Date: Comments must be received on or before April 19, 2021.

ADDRESSES: You may submit comments, identified by Docket number SBA–2020–0011 by using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Identify comments by ''Docket Number SBA–2020–0011, SBA Lender Risk Rating System,'' and follow the instructions for submitting comments.
- *Email:* Eddie Ledford, Deputy Director, Office of Credit Risk Management, U.S. Small Business Administration, at *edward.ledford@sba.gov.*

All comments will be posted on *http://www.Regulations.gov.* If you wish to include within your comment confidential business information (CBI) as defined in the Privacy and Use Notice/User Notice at *http://www.Regulations.gov* and you do not want that information disclosed, you must submit the comment by either Mail or Hand Delivery and you must address the comment to the attention of Eddie Ledford, Deputy Director, Office of Credit Risk Management, U.S. Small Business Administration. In the submission, you must highlight the information that you consider is CBI and explain why you believe this information should be held confidential. SBA will make a final determination, in its discretion, of whether the information is CBI and, therefore, will be published or not.

FOR FURTHER INFORMATION CONTACT: Eddie Ledford, Deputy Director, Office of Credit Risk Management, U.S. Small Business Administration, 409 Third Street SW, 8th Floor, Washington, DC 20416, (202) 205–6402.

SUPPLEMENTARY INFORMATION:

I. Background Information

(A) Introduction to the Risk Rating System

The Risk Rating System is an internal tool that uses data in SBA's Loan and Lender Monitoring System (L/LMS), borrower data provided by Dun & Bradstreet (D&B), and certain macroeconomic factors to assist SBA in assessing the risk of the SBA loan performance of each 7(a) Lender and CDC (each, an SBA Lender) on a uniform basis and identifying those SBA Lenders whose portfolio performance, or other lender-specific risk-related factors, may demonstrate the need for additional SBA monitoring or other action. The Risk Rating System also serves as a vehicle to measure the aggregate strength of SBA's overall 7(a) loan and 504 loan portfolios and to assist SBA in managing the related risk. SBA uses the Risk Rating System to make more effective use of its lender review and assessment resources. The Risk Rating System is available to SBA Lenders through SBA's Lender Portal

and provides SBA Lenders feedback and timely insight into the expected performance of their SBA portfolio.

Under SBA's Risk Rating System, SBA calculates a Forecasted Purchase Rate (FPR) for each SBA Lender. The FPR projects the percent of an SBA Lender's SBA loan portfolio that will be purchased by SBA over the next 12 months. An SBA Lender's FPR can be used to predict the dollar amount of an SBA Lender's purchases. The FPR is calculated using several component variables or factors. The component variables were developed using step-wise regression analysis to determine the components that provided a linear regression formula that was most predictive of actual purchases over a one-year period. The FPR is also used to assign each SBA Lender a composite Risk Rating (Lender Risk Rating or Lender Purchase Rating) of 1 to 5 based on geometric sequencing. The rating reflects SBA's measurement of the SBA Lender's potential portfolio risk. In general, a rating of 1 indicates least risk and that the least degree of SBA oversight is likely needed, while a 5 rating indicates highest risk and that the highest degree of SBA oversight is likely needed.

SBA first introduced the Risk Rating System as a proposal for comment in the **Federal Register** on May 1, 2006 (72 FR 25624). SBA published the final notice in the **Federal Register** on May 16, 2007 (72 FR 27611). On March 1, 2010, SBA published a notice describing revisions to the Risk Rating System (75 FR 9257), with a correction notice published on March 18, 2010 (75 FR 13145). In 2014, SBA revised the system again and published a notice and request for comments on April 29, 2014 (79 FR 24053).

(B) Redevelopment

Typically, under industry best practices, custom credit scoring models are redeveloped approximately every three to five years to reflect changing conditions, portfolio shifts, and to incorporate additional data that may have become available. Accordingly, SBA redeveloped the Risk Rating System in 2010 and 2014 and completed the latest redevelopment in 2019. This most recent redevelopment, like the earlier ones, is consistent with best practices. Given the unprecedented economic impact caused by the pandemic in 2020, SBA will initiate the next redevelopment in late 2021 to ensure that SBA's Risk Rating System provides an accurate and up to date measurement of lenders' SBA portfolio performance.

The goals of this redevelopment were to: (i) Maintain or improve the accuracy of the current Lender Risk Rating (LRR) and FPR; (ii) maintain or increase transparency to the lender without sacrificing predictive power; (iii) incorporate the latest SBA performance data; and (iv) evaluate other variables that can provide additional insight into lender risk. During this redevelopment, SBA reviewed over 200 potential variables from SBA's L/LMS archive along with nearly 400 potential variables from D&B sources. SBA selected these potential variables for review based on its experience working with such models over the past several years. The D&B variables included attributes from its detailed trade repository providing the highest level of trade data resolution. The variables were then run through rigorous statistical techniques and the most predictive combinations of variables were chosen as components in the redeveloped Risk Rating model.

II. The Redeveloped Risk Rating Model

SBA followed common industry best practices and internal control standards when redeveloping and validating the Risk Rating model. The redeveloped model was independently validated by personnel other than the staff responsible for the redevelopment. The redeveloped model used to calculate the composite Risk Ratings is an updated version of the previous models. Like the previous models, it is a custom credit scoring model that predicts the likelihood of an SBA Lender's loan purchases over the next 12 months. Like the 2014 model, the redeveloped model uses a segmentation approach to loan scoring. The model groups the loans into loan segments [1] and then applies a formula to the loan predictive of purchase for that applicable segment. (See Section IV below for more information on the segments and their formulas). The new model thus predicts the probability of default for each loan in an SBA Lender's portfolio (Projected Purchase Rate or PPR) and then multiplies this probability by the outstanding loan amount at the time the ratings are formulated. The individual loan-level PPRs are then aggregated to obtain the SBA Lender's overall FPR, which is then used to calculate the SBA Lender's composite Risk Rating [1–5].

The most notable changes in the redeveloped Risk Rating System are:

1. Updated components in the regression formulas. The redeveloped model continues to use loan-level data (provided by the SBA Lenders and SBA's own data), external risk assessment data (provided by D&B) that is derived from third party business and consumer credit bureau data, and macroeconomic data. New loan level data components include, for example: (i) NAICs sector; (ii) new or existing business indicator; and (iii) whether sold on Secondary Market. The new external data components include, for example, (i) commercial credit score; (ii) number of UCC filings against business; and (iii) PAYDEX previous three months.[2] Only one macroeconomic data component continues to be used—the State Unemployment Rate. The updated components add predictive value to the Risk Rating model.

2. Slight Revisions in segmentation. The 2014 model used seven segments, each with its own rating formula (five for 7(a) Lenders; two for CDCs). The 2019 redeveloped model eliminated segmentation of 7(a) fixed-term loans based on loan size, collapsing the model's segmentation from seven to six (four for 7(a) Lenders and two for CDCs). Under the new model, loans are segmented by loan type (revolver-type or fixed-term) and current payment status. The segments are as follows: (i) 7(a) Segment 1—revolver type loans in current payment status; (ii) 7(a) Segment 2—revolver-type loans in non-current payment status; (iii) 7(a) Segment 3—fixed-term loans in current payment status; (iv) 7(a) Segment 4—fixed-term loans in non-current payment status; (v) 504 Segment 1—loans in current payment status; and (vi) 504 Segment 2—loans in non-current payment status. A loan's PPR formula is calculated based on a combination of components that is uniquely predictive for loans in that segment. See paragraph IV(B) for a detailed discussion of the six segments and the update of components used in each segment.

3. Evolution of the Lender Portal.

Since the 2014 redevelopment, SBA has been significantly expanding the content of the Lender Portal. In addition to the LRR/Lender Purchase Rating (LPR), the Lender Portal now includes the SBA Lender's FPR, the FPR's components or factors, SBA Lender's PARRiS or SMART Scores (as applicable) [3] and the PARRiS/SMART

[1] For example, 7(a) fixed term loans in current payment status or 504 fixed term loans in non-current payment status.

[2] D&B collects and aggregates all trade data provided to it by over 30,000 trade credit sources on a monthly basis for its entire global database of commercial entities.

[3] PARRiS and SMART refer to SBA's risk measurement methodologies and scoring guides used in conjunction with SBA's Risk-Based Review protocol. PARRiS is an acronym for the specific risk

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Score components. In addition, the Lender Portal now includes much of the information that is contained in SBA Lender's Lender Profile Assessment (LPA) (*e.g.,* loan vintage analysis, charting of loans by delivery method, Cumulative Net Yield chart, loan concentration chart, Secondary Market sales chart and other lender information). The Lender Portal provides SBA Lenders timely feedback on their expected portfolio performance. In conjunction with the redevelopment and expansion of Lender Portal content, SBA is updating its definition of Confidential Information. See Section IV for more information on the Lender Portal and the updated definition of Confidential Information.

The redeveloped Risk Rating System is one of several tools in SBA's oversight framework. SBA uses the Risk Rating, the FPR/LPR, SBA Lender Reviews/Examinations, and PARRiS and SMART components and scores in conjunction with other risk related information to assess SBA Lender risk and performance. For example, SBA may consider rapid growth in loan volume that may skew metrics and other factors in considering an SBA Lender's overall risk.

III. Request for Comments

This notice provides program participants and other parties with an explanation of the components and a description of other modeling enhancements. SBA is soliciting comments on all aspects of this notice, including but not limited to the components and enhancements. These changes will be effective upon publication of this notice and are expected to be incorporated in the Lender Portal update in February 2021 for the quarter ending December 31, 2020.

IV. SBA Lender Risk Rating System

(A) Overview

Under SBA's Risk Rating System, SBA assigns all SBA Lenders a composite Risk Rating. The composite rating reflects SBA's assessment of the SBA Lender's potential risk. It is based on the loan-level probability of purchase over the next 12 months, as calculated by SBA.

The Risk Rating System also assigns each SBA-guaranteed loan a Projected Purchase Rate (PPR) using a unique set of components that SBA has determined to be predictive for that loan's segment (see Section IV.B. on Segmentation for further details below). The individual loan-level PPR is then multiplied by the total outstanding balance of the loan in order to approximate the SBA Lender's exposure for that loan. The sum of all those values for Lender's SBA loans is an estimation of the total default dollars for the SBA portfolio of the SBA Lender in the next 12 months. That number is then divided by the total outstanding balances of all loans in the above calculation to obtain the SBA Lender's overall Forecasted Purchase Rate (FPR). SBA then assigns a composite rating of 1 to 5 based on the SBA Lender's overall FPR using geometrically sequenced category thresholds. Geometrically sequenced categories contain thresholds that are a multiple of the prior category. The category boundaries represent a doubling of the prior category (with the exception of the ''zero'' threshold). Geometric categorizations aim to delineate a non-linear distribution more evenly.

SBA updates the Lender Risk Ratings and FPRs on a quarterly basis, using refreshed SBA Lender data. The primary purpose of the Risk Rating and FPR is to focus SBA's oversight resources on those SBA Lenders whose portfolio performance or other lender-specific risk-related factors demonstrate a need for further review and evaluation by SBA. SBA generally does not intend to use the Risk Rating or FPR as the sole basis for taking a formal enforcement action against an SBA Lender.

All SBA Lenders have on-line access to their Risk Ratings, FPR (including its components or factors), PARRiS or SMART Score (and its components), and other risk related information through the Lender Portal. In addition, an SBA Lender can view the loan-level components utilized to generate each loan's PPR. For information on gaining access to the Lender Portal, see SBA SOP 50 10 and the Lender Portal log-on page at *https://sbalenderportal.dnb.com.*

(B) Segmentation

SBA's Risk Rating System uses a segmentation approach to calculate the PPR of each loan in an SBA Lender's SBA portfolio. The loan segments for the 7(a) Program are as follows:

1. Revolver-type loans in current payment status,
2. Revolver-type loans in non-current payment status,
3. Fixed-term loans in current payment status, and
4. Fixed-term loans in non-current payment status.

The loan segments for the 504 Loan Program are:

1. Loans in current payment status, and
2. Loans in non-current payment status.

A loan's PPR is calculated based on a combination of components that is uniquely predictive for the loans in that segment. Many of the segment components are the same as in the prior model, however, some are new. The components used in each segment are as follows:

7(a) Segment 1—Revolver-type loans in current payment status:
(a) Current Small Business Predictive Score (SBPS)
(b) Months on Book (MOB)
(c) Loan Term
(d) Percent of Accounts 30 Days or More Past Due
(e) Outstanding Loan Balance
(f) New or Existing Business Indicator
(g) Total Employees
(h) NAICS Sector
(i) 12-Month Originating Lender Purchase Rate
(j) Overall Interest Rate
(k) Average State-level Unemployment Rate

7(a) Segment 2—Revolver-type loans in non-current payment status:
(a) Current SBPS
(b) MOB
(c) Loan Term
(d) Loan Status
(e) SBA Share of Outstanding Loan Balance
(f) PAYDEX Previous 3 Months
(g) Average State-level Unemployment Rate

7(a) Segment 3—Fixed-term loans in current payment status:
(a) Current SBPS
(b) MOB
(c) Loan Term
(d) Number of Current Accounts
(e) Sold on Secondary Market Indicator
(f) Spread Interest Rate
(g) New or Existing Business Indicator
(h) 12-Month Originating Lender Purchase Rate

7(a) Segment 4—Fixed-term loans in non-current payment status:
(a) Current SBPS
(b) MOB
(c) Loan Status
(d) Percent of Accounts 30 Days or More Past Due
(e) 12-Month Originating Lender

areas or components that SBA reviews for 7(a) lenders. They are Performance, Asset Management, Regulatory Compliance, Risk Management, and Special Items. SMART is the acronym for the risk areas that SBA reviews in the 504 program. They are Solvency and Financial Condition, Management and Board Governance, Asset Quality and Servicing, Regulatory Compliance, and Technical Issues and Mission. For a more detailed discussion on PARRiS and SMART, see SOPs 50 53 2 and 50 10, which incorporate SBA Notices on Risk-Based Review Protocols.

Purchase Rate

504 Segment 1—Loans in current payment status:

(a) Current SBPS
(b) MOB
(c) Loan Term
(d) Commercial Credit Score
(e) NAICS Sector
(f) Number of UCC Filings
(g) 12-Month Lender Purchase Rate
(h) Average State-level Unemployment Rate

504 Segment 2—Loans in non-current payment status:

(a) Current SBPS
(b) Loan Status
(c) Viability Score

The components were selected through statistical analysis using step-wise logistic regression to identify the combination of variables that are the most predictive for each segment of loans. The model is ''multivariate,'' meaning that an SBA Lender's PPR (and thus its FPR and Risk Rating) is based on a combination of all components in the model. Each of the components is described in more detail in the Rating Components section below.

(C) Rating Components

SBA derives components from three types of data sources to calculate a loan's PPR: SBA loan data, D&B Borrower data,[4] and macroeconomic data. The first category includes detailed loan/borrower level information from SBA's database. The second category is information on the small business borrower from D&B's trade database. The third category includes state level unemployment data. Each of the components is defined in detail below. For those components that were also in the prior model, their definitions are generally the same.

(1) SBA Loan Data Components

Loan Status: The Loan Status component captures the payment status of loans as of the rating date. Loans are categorized as current, delinquent, past due, or deferred. If delinquent, this component indicates the delinquency ''bucket'' (*e.g.,* 30 days past due, 60 days past due, etc.) at the time of rating. A greater number of days past due contributes to a higher purchase risk.

Loan Term: The Loan Term is the length of the loan repayment period at origination. Loan Term is measured in months and purchase risk increases as the repayment term increases for 7(a) Revolver loans. For 7(a) Fixed loans, the purchase risk associated with the loan term is arch-shaped: Loans at either end of the spectrum (very short or very long term) have the lowest purchase risk. For 504 loans, the purchase risk is lower for longer term loans.

Months on Book (MOB): The MOB is the number of months between the rating date and the date of the first loan disbursement, up to a maximum of 120 months. For 7(a) loans, the purchase risk associated with MOB risk level is arch-shaped: Loans at either end of the spectrum (very low or very high MOB) have the lowest purchase risk. For 504 loans, a higher MOB is associated with a higher purchase risk.

NAICS Sector: The North American Industry Classification System (NAICS) is the standard used by Federal statistical agencies in classifying business establishments. For 7(a) Segment 1, revolver-type loans in current payment status, industries classified as information, transportation, or warehousing are associated with the highest purchase risk and those classified as education, finance, insurance, management, manufacturing, public administration, and utilities are associated with the lowest purchase risk. All other industry classifications are associated with a mid-range of purchase risk. For 504 Segment 1, current loans, industries classified as food services, administrative, educational, manufacturing, real estate, or retail are associated with the highest purchase risk and those classified as agriculture, forestry, fishing, construction, finance, insurance, information, or mining have the lowest purchase risk. All other industry classifications are associated with a mid-range of purchase risk.

New or Existing Business Indicator: This component indicates whether a borrower is a new or existing business. Start-ups and businesses in existence for 2 years or less are considered new businesses and those over 2 years old are considered existing businesses. An existing business is associated with a lower purchase risk.

Overall Interest Rate: The Overall Interest Rate is the interest rate of a loan at origination. A higher Overall Interest Rate is associated with a higher purchase risk.

Outstanding Loan Balance: The Outstanding Loan Balance is the outstanding gross loan balance at the time of the rating date. This component is only used for revolver-type accounts that are currently in active status. The purchase risk associated with Outstanding Loan Balance is arch-shaped: Loans at either end of the spectrum (very low or very high Outstanding Loan Balance) have the lowest purchase risk.

SBA Share of Outstanding Loan Balance: The SBA Share of Outstanding Loan Balance is the SBA guaranteed portion of the outstanding amount of the loan as of the rating date. Similar to the Outstanding Loan Balance, the purchase risk associated with SBA Share of Outstanding Loan Balance is arch-shaped: Loans at either end of the spectrum (very low or very high SBA Share of Outstanding Loan Balance) have the lowest purchase risk.

Sold on Secondary Market Indicator: This component indicates whether the SBA guaranteed portion of a loan was sold on the secondary market. This is a static field once a loan is sold on the secondary market. Loans sold on the secondary market have a higher purchase risk.

Spread Interest Rate: The Spread Interest Rate is the difference between the interest rate of the loan and the Prime interest rate in effect on the date of origination. A higher Spread Interest Rate is associated with a higher purchase risk.

12-Month Lender Purchase Rate: The 12-Month Lender Purchase Rate is a calculated field based on a lender's purchase rate over the past 12 months. A higher value for this attribute is associated with a higher purchase risk.

12-Month Originating Lender Purchase Rate: The 12-Month Originating Lender Purchase Rate is a calculated field based on the originating lender's purchase rate over the past 12 months. For loans that a lender has acquired from another SBA Lender, the originating lender's 12-Month Lender Purchase Rate will apply. For loans that have not been acquired from another SBA Lender, this component is the same as the 12-Month Lender Purchase Rate described above. If the originating lender does not have a 12-Month Lender Purchase Rate (for example, the lender is no longer participating in SBA's programs or is no longer in business), the 12-Month Overall Portfolio Purchase Rate will be used. The 12-Month Overall Portfolio Purchase Rate is the purchase rate of SBA's entire 7(a) or 504 portfolio, based on the last 12 months. A higher value for this attribute is associated with a higher purchase risk.

(2) D&B Borrower Data Components

Commercial Credit Score: The Commercial Credit Score (CCS) is a proprietary calculation from D&B that predicts the likelihood of a business paying its bills in a severely delinquent manner (91 days or more past terms), obtaining legal relief from its creditors, or ceasing operations without paying all creditors in full over the next 12 months. D&B defines severe

[4] D&B business bureau data is combined with FICO consumer data.

delinquency as a business with at least 10 percent of its payments 91 days or more past due, based on the information in D&B's commercial database. A high CCS value indicates a lower risk of delinquency. The CCS is calculated using statistical models derived from D&B's extensive database of U.S. businesses including payment, public filing, demographic, and financial information when available. A higher CCS is associated with a lower purchase risk.

Number of Current Accounts: The Number of Current Accounts is the number of a borrower's trade accounts, as reported to D&B, that have been current over the past 24 months. Higher values of this attribute are associated with lower purchase risk.

Number of UCC Filings: Number of UCC Filings is the number of Uniform Commercial Code (UCC) filings recorded against the borrower's business in the past 10 years, including initial filings, continuations, amendments, and terminations. A UCC filing is a legal form filed by a creditor to give notice that it has an interest in the property of a debtor. A higher value for this attribute is associated with a higher purchase risk.

PAYDEX Previous 3 Months: PAYDEX is a unique, dollar weighted indicator of a business's payment performance based on the total number of payment experiences in D&B's database over the past 3 months. Payment experiences are gathered by D&B from a business's suppliers and vendors. Higher PAYDEX scores indicate better payment performance. A higher value for this attribute is associated with a lower purchase risk.

Percent of Accounts 30 Days or More Past Due: The Percent of Accounts 30 Days or More Past Due is calculated using data from the D&B detail trade database for the last 4 months. This percentage results from dividing the total number of accounts which have been 30 days or more delinquent in the past 4 months by the total number of active accounts associated with a borrower. A higher value for this attribute is associated with a higher purchase risk.

SBPS: The SBPS, the Small Business Risk Portfolio Solution commercially known as SBRPS, is a portfolio management credit score based upon a borrower's business credit report and principal's consumer credit report and is updated quarterly. SBPS is a commercial score provided by Dun & Bradstreet (D&B), under contract with SBA. SBPS was developed by D&B and FICO and is compatible with FICO's ''Liquid Credit'' origination score. This component provides an indication of the relative creditworthiness of a given borrower with higher values indicating lower purchase risk. FICO recently updated SBPS to a new, more predictive version which will be used in this redeveloped Risk Rating version.

Total Employees: Total Employees is the number of people the borrower employs, as reported to D&B. A higher value for this attribute is associated with a lower purchase risk.

Viability Score: The Viability Score is a proprietary calculation from D&B that assesses the probability that the borrower will no longer be viable within the next 12 months compared to all the U.S. businesses within the D&B database. A business is no longer viable when it goes out of business, becomes dormant or inactive, or files for bankruptcy. The Viability Score is based on available financial data, trade payments, firmographics and other business activity. A higher Viability Score is associated with a higher purchase risk.

(3) Macroeconomic Data Component

Average State-level Unemployment Rate: The Average State-level Unemployment Rate is the ratio of unemployed to the civilian labor force in the borrower's State, expressed as a percent. The source is Bureau of Labor Statistics (BLS), Local Area Unemployment Statistics Database. The borrower's state is identified through borrower's address fields in the SBA's database. The unemployment rate is extracted directly from BLS reporting, which is updated monthly. A higher unemployment rate in the borrower's state contributes to a higher purchase risk.

(D) Lender Risk Rating

The SBA Lender Risk Rating (LRR) is a measure of predicted performance over the next 12 months. As described above, SBA uses its Risk Rating model to calculate a Forecasted Purchase Rate (FPR). The FPR predicts the percent of an SBA Lender's SBA loan portfolio that will be purchased over the next 12 months. An SBA Lender's FPR can be used to project the dollar amount of an SBA Lender's purchases. SBA then uses the FPR to assign a composite rating of 1 to 5 to each SBA Lender. This composite rating is the LRR. SBA may make adjustments to the composite rating based on results of reviews, third party information on an SBA Lender's operations, portfolio trends, and other information that could impact an SBA Lender's risk profile. (See section E ''Overriding Factors'' for further detail.) In general, a rating of 1 indicates least risk, and that the least degree of SBA oversight is likely needed, while a 5 rating indicates highest risk, and that the highest degree of SBA oversight is likely needed. Rating categories 2, 3, and 4 provide granularity for increasing levels of risk and the corresponding levels of necessary oversight.

(E) Overriding Factors

As with prior LRR models, the redeveloped Risk Rating System allows for consideration of additional factors. The occurrence of these factors may lead SBA to conclude that an individual SBA Lender's composite rating, as calculated by the Risk Rating model, is not fully reflective of its true risk. Therefore, the Risk Rating System provides for the consideration of overriding factors, which may only apply to a particular SBA Lender or group of SBA Lenders, and permit SBA to adjust an SBA Lender's calculated composite rating. The allowance of overriding factors in helping determine an SBA Lender's Risk Rating enables SBA to use key risk factors that are not necessarily applicable to all SBA Lenders but indicate a greater or lower level of risk from a particular SBA Lender than that which the calculated rating provides.

Overriding factors may result from SBA Lenders' risk-based reviews/examinations and evaluations. SBA routinely conducts reviews of SBA Lenders, performs safety and soundness examinations of SBA Small Business Lending Companies (SBLCs) and Non-Federally Regulated Lenders (NFRLs), and uses certain evaluation measures for other SBA Lenders. Examples of other overriding factors that may be considered include, but are not limited to: Enforcement or other actions of regulators or other authorities, including, but not limited to, Cease & Desist orders by, or related agreements with, Federal Financial Institution Regulators (FFIRs); capital adequacy levels not in conformity with FFIRs; secondary market issues and concerns; receipt of a Going Concern opinion issued by an independent auditor; early loan default trends; purchase rate or projected purchase rate trends; abnormally high default, purchase or liquidation rates; denial of liability occurrences; lending concentrations; rapid growth of SBA lending; net yield rate (or losses) significantly worse than average; violation of SBA Loan Program Requirements; inadequate, incomplete, or untimely reporting to SBA; fraud/indictment of lender, officers, or key employees; an identified condition that affects capital, solvency or prudent commercial lending ability; inaccurate

submission of required fees or amounts due SBA or the federal government; and other risk-related or program integrity concerns. Rapid growth, in particular, is a significant factor that can mask poor portfolio performance in a calculated Risk Rating. Consequently, SBA includes a rapid growth flag in its PARRiS and SMART assessments and in this override list.

(F) Confidential Information

Each SBA Lender must continue to handle its Reports, Risk Ratings and related Confidential Information in accordance with the confidentiality requirements set forth in 13 CFR 120.1060, Confidentiality of Reports, Risk Ratings, and related Confidential Information. Under this regulation, Reports, Risk Ratings, and Confidential Information are privileged, confidential, and the property of SBA. Further, the regulation states that such information may not be relied upon for any purpose other than SBA's lender oversight and SBA's portfolio management purposes. In addition, the SBA Lender is prohibited from disclosing its Report, Risk Rating, and Confidential Information, in full or in part, in any manner, without SBA's prior written permission, and the SBA Lender must not make any representations concerning the information (including Report findings, conclusions, and recommendations), the Risk Rating, or the Confidential Information.

13 CFR 120.1060(a) defines ''Report'' to mean ''the review or examination report and related documents.'' It also provides that Confidential Information ''is defined in the SBA Lender information portal and by notice issued from time to time.'' The SBA Lender information portal currently defines ''Confidential Information'' to mean ''all lender-related information contained in the Portal including ''Lender Results'', except for the ''Past 12 Month Actual Purchase Rate'' and the ''Past 12 Month Actual Charge-Off Rate''. SBA has expanded the information available to an SBA Lender in the Lender Portal. Therefore, SBA is updating the definition for ''Confidential Information'' to mean:

''Confidential Information includes all the SBA Lender-related information/data contained in the Lender Portal except the dollar amounts associated with SBA purchase of and charge off of SBA Lender's loans and information already publicly available related to the Lender's capital, non-performing assets, and regulatory actions (*e.g.,* from a bank's public Call Report). Confidential Information also includes any information related to SBA's supervision of the SBA Lender (*e.g.,* review or corrective action correspondence) and any actions taken by SBA related to enforcement (*e.g.,* informal enforcement actions as defined in SOP 50 53 or by regulation, notices of proposed enforcement action) unless made public by SBA (*e.g.,* in a Cease and Desist Order).''

SBA included the last sentence because it has long treated supervisory and enforcement information as confidential information and this information is generally related to a review or exam and, therefore, covered by the confidentiality provisions in 13 CFR 120.1060 and/or FOIA exemption 8. SBA may disclose Reports, Risk Ratings, and Confidential Information in its discretion; however, such disclosures do not waive SBA Lender's obligation under 13 CFR 120.1060 to maintain the confidentiality of the information.

(G) Conclusion

In conclusion, industry best practices and changes in the SBA portfolio, programs, and available data necessitate that SBA's Risk Rating model be periodically redeveloped. This notice marks the third redevelopment of SBA's Risk Rating model. In addition to this redevelopment, SBA has and will continue to perform annual validation testing on the calculated composite Risk Ratings and will further refine the model as necessary to maintain or improve the predictiveness of its risk scoring.

Authority: 15 U.S.C. 633(b)(3); 15 U.S.C. 634(b)(6) and (7); 15 U.S.C. 657t; 15 U.S.C. 687(f); and 13 CFR 120.10, 120.1015, 120.1025, 120.1050, and 120.1060.

Tami Perriello,

Acting Administrator.

[FR Doc. 2021–03053 Filed 2–12–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16869 and #16870; Washington Disaster Number WA–00089]

Administrative Declaration of a Disaster for the State of Washington

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Washington dated 02/09/2021.

Incident: Wildfires and Straight-line Winds.

Incident Period: 09/01/2020 through 09/19/2020.

DATES: Issued on 02/09/2021.

Physical Loan Application Deadline Date: 04/12/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 11/09/2021.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Whitman.

Contiguous Counties:

Washington: Adams, Asotin, Columbia, Franklin, Garfield, Lincoln, Spokane.

Idaho: Benewah, Latah, Nez Perce.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	2.375
Homeowners without Credit Available Elsewhere	1.188
Businesses with Credit Available Elsewhere	6.000
Businesses without Credit Available Elsewhere	3.000
Non-Profit Organizations with Credit Available Elsewhere	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	3.000
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 16869 5 and for economic injury is 16870 0.

The States which received an EIDL Declaration # are Washington, Idaho.

(Catalog of Federal Domestic Assistance Number 59008)

Tami Perriello,

Acting Administrator.

[FR Doc. 2021–03009 Filed 2–12–21; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice: 11357]

In the Matter of the Revocation of the Designation of Ansarallah (and Other Aliases) as a Foreign Terrorist Organization

In consultation with the Attorney General and the Secretary of the Treasury, I hereby revoke the designation of Ansarallah, and its aliases, as a Foreign Terrorist Organization pursuant to Section 219 (a)(6)(A) of the Immigration and Nationality Act, as amended (8 U.S.C. 1189(a)(6)(A)).

This determination shall be published in the **Federal Register**.

Authority: 8 U.S.C. 1189.

Dated: February 11, 2021.

Anthony J. Blinken,

Secretary of State.

[FR Doc. 2021–03191 Filed 2–12–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE

[Public Notice 11358]

Revocation of the Designations of Ansarallah, Abdul Malik al-Houthi, Abd al-Khaliq Badr al-Din al-Houthi, and Abdullah Yahya al Hakim (and Their Respective Aliases) as Specially Designated Global Terrorists

I hereby revoke the designations of the following persons as Specially Designated Global Terrorist, pursuant to section 1(a)(ii) of Executive Order 13224: Ansarallah, Abdul Malik al-Houthi, Abd al-Khaliq Badr al-Din al-Houthi, Abdullah Yahya al Hakim, and their respective aliases.

This determination shall be published in the **Federal Register**.

Authority: E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786.

Dated: February 11, 2021.

Antony J. Blinken,

Secretary of State.

[FR Doc. 2021–03192 Filed 2–12–21; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Permanent Closure

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration received written notice from the Alaska Department of Transportation (AKDOT) advising that infrastructure associated with Klawock, Alaska Seaplane Base (AQC) is permanently closed.

DATES: The permanent closure of the seaplane base is retroactively effective.

FOR FURTHER INFORMATION CONTACT: Molly Fierro, Compliance Manager, Federal Aviation Administration, Alaskan Region Airports District Office, 222 W 7th Avenue, Anchorage, AK 99513. Telephone Number: (907) 271–5439/FAX Number: (907) 271–2851.

SUPPLEMENTARY INFORMATION: Ownership of infrastructure associated with AQC was transferred to the City of Klawock in 2003. Subsequent to the ownership transfer, the seaplane dock became unfeasible to utilize and was removed. The FAA hereby retroactively publishes the AKDOTs and City of Klawock's notice of permanent closure of the Klawock Seaplane Base (AQC) in accordance with 49 U.S.C. 46319(b).

Issued in Anchorage, Alaska, on February 9, 2021.

Kristi A. Warden,

Director, Airports Division, FAA, Alaskan Region.

[FR Doc. 2021–02965 Filed 2–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Permanent Closure

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration received written notice from the Alaska Department of Transportation (AKDOT) advising that infrastructure associated with Haines, Alaska Seaplane Base (3Z9) is permanently closed.

DATES: The permanent closure of the seaplane base is retroactively effective.

FOR FURTHER INFORMATION CONTACT: Molly Fierro, Compliance Manager, Federal Aviation Administration, Alaskan Region Airports District Office, 222 W 7th Avenue, Anchorage, AK 99513. Telephone Number: (907) 271–5439/FAX Number: (907) 271–2851.

SUPPLEMENTARY INFORMATION: Ownership of infrastructure associated with 3Z9 was transferred to the City of Haines in 2006. Subsequent to the ownership transfer, the harbor was expanded and it is no longer feasible to accommodate floatplane traffic. The FAA hereby retroactively publishes the AKDOTs and City of Haines' notice of permanent closure of the Haines Seaplane Base (3Z9) in accordance with 49 U.S.C. 46319(b).

Issued in Anchorage, Alaska, on February 9, 2021.

Kristi A. Warden,

Director, Airports Division, FAA, Alaskan Region.

[FR Doc. 2021–02967 Filed 2–12–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Final Agency Actions on Proposed Railroad Project in California, on Behalf of the California High-Speed Rail Authority

Correction

In notice document 2020–27441 appearing on pages 80888 through 80889 in the issue of Monday, December 14, 2020, make the following correction:

On page 80888, in the second column, in the **DATES** section, change ''January 14, 2022'' to read ''December 14, 2022.''

[FR Doc. C1–2020–27441 Filed 2–12–21; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2021–0003]

Pipeline Safety: Information Collection Activities

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, PHMSA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew the following information collections that are scheduled to expire in 2021 under OMB control numbers: 2137–0632 Post-Accident Drug Testing for Operators (6/30/21); 2137–0594 Customer-Owned Service Lines (8/31/21); 2137–0622 Public Awareness Program (9/30/21); 2137–0048 Recordkeeping Requirements for Liquefied Natural Gas Facilities (9/30/21); 2137–0618 Periodic Underwater Inspection and Notification of Abandoned Underwater Pipelines (10/31/21); 2137–0600 Qualification of Pipeline Safety Training (10/31/21), and

2137–0634 Recordkeeping for Underground Natural Gas Storage Facilities (10/31/21). PHMSA has reviewed each of these collections and considers them vital to the continuity of promoting and maintaining pipeline safety. As such, PHMSA will request a renewal, without change, to each of the information collections detailed below.

DATES: Interested persons are invited to submit comments on or before April 19, 2021.

ADDRESSES: Comments may be submitted in the following ways:

E-Gov website: http://www.regulations.gov. This site allows the public to submit comments on any **Federal Register** notice issued by any agency.

Fax: 1–202–493–2251.

Mail: Docket Management Facility; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590–0001.

Hand Delivery: Room W12–140 on the ground level of DOT, West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: Identify the docket number, PHMSA–2021–0003, at the beginning of your comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. You should know that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). Therefore, you may want to review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, (65 FR 19477) or visit *http://www.regulations.gov* before submitting any such comments.

Docket: For access to the docket or to read background documents or comments, go to *http://www.regulations.gov* at any time or to Room W12–140 on the ground level of DOT, West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: ''Comments on: PHMSA–2021–0003.'' The Docket Clerk will date stamp the postcard prior to returning it to you via the U.S. mail. Please note that due to delays in the delivery of U.S. mail to Federal offices in Washington, DC, we recommend that persons consider an alternative method (internet, fax, or professional delivery service) of submitting comments to the docket and ensuring their timely receipt at DOT.

Privacy Act Statement: DOT may solicit comments from the public regarding certain general notices. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 CFR 190.343, you may ask PHMSA to give confidential treatment to information you give to the Agency by taking the following steps: (1) Mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this notice. Submissions containing CBI should be sent to Angela Hill, DOT, PHMSA, 1200 New Jersey Avenue SE, PHP–30, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this matter.

FOR FURTHER INFORMATION CONTACT: Angela Hill by telephone at 202–366–1246 or by email at *Angela.Hill@dot.gov.*

SUPPLEMENTARY INFORMATION: Section 1320.8(d), Title 5, Code of Federal Regulations, requires PHMSA to provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. This notice identifies information collection requests that PHMSA will submit to OMB for revision.

The following information is provided for these information collections: (1) Title of the information collection; (2) OMB control number; (3) Current expiration date; (4) Type of request; (5) Abstract of the information collection activity; (6) Description of affected public; (7) Estimate of total annual reporting and recordkeeping burden; and (8) Frequency of collection.

PHMSA will request a 3-year term of approval for each of the following information collection activities. PHMSA requests comments on the following information:

1. *Title:* Post-Accident Drug Testing for Pipeline Operators.

OMB Control Number: 2137–0632.

Current Expiration Date: 6/30/2021.

Type of Request: Renewal of a currently approved information collection.

Abstract: Pursuant to 49 CFR 199.227, operators are required to maintain records of its alcohol misuse prevention program. The Post-Accident Drug Testing for Pipeline Operators Information Collection pertains specifically to 49 CFR 199.227(b)(4), which requires operators to maintain records of decisions not to administer post-accident employee alcohol tests for a minimum of three years. Operators must make those records available to the Secretary of Transportation upon request.

Affected Public: Operators of PHMSA-regulated pipelines.

Annual Reporting and Recordkeeping Burden:

Total Annual Responses: 609.

Total Annual Burden Hours: 1,218.

Frequency of Collection: On occasion.

2. *Title:* Customer-Owned Service Lines.

OMB Control Number: 2137–0594.

Current Expiration Date: 8/31/2021.

Type of Request: Renewal of a currently approved information collection.

Abstract: Pursuant to 49 CFR 192.16, operators of gas service lines who do not maintain their customers' buried piping between service lines and building walls or gas utilization equipment are required to send written notices to their customers prescribing the proper maintenance of these gas lines and of the potential hazards of not properly maintaining these gas lines. Operators also must maintain records that include a copy of the notice currently in use and evidence that notices were sent to customers within the previous three years. The purpose of the collection is to provide the Office of Pipeline Safety

with adequate information about how customer-owned service lines are being maintained to prevent the potential hazards associated with not maintaining the lines. Examples of sufficient notification include a prepared notification with the customer's bill.

Affected Public: State and local governments.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 550,000.

Estimated annual burden hours: 9,167.

Frequency of Collection: On occasion.

3. *Title:* Public Awareness Program.

OMB Control Number: 2137–0622.

Current Expiration Date: 9/30/2021.

Type of Request: Renewal of a currently approved information collection.

Abstract: Pursuant to the Federal Pipeline Safety Regulations in 49 CFR 192.616 and 49 CFR 195.440 each pipeline operator is required to develop and implement a written continuing public education program that follows the guidance provided in the American Petroleum Institute's (API) Recommended Practice (RP) 1162. Upon request, operators must submit their completed programs to PHMSA or, in the case of an intrastate pipeline facility operator, the appropriate state agency. The operator's program documentation and evaluation results must also be available for periodic review by appropriate regulatory agencies ( ). The purpose of the collection is to educate the public, appropriate government organizations, and persons engaged in excavation activities on the use of a one-call notification system, possible hazards associated with unintended releases, physical indications that a release may have occurred, steps that should be taken for public safety in the event of a release and procedures for reporting releases.

Affected Public: Operators of natural gas and hazardous liquid pipelines.

Estimated number of responses: 45,000.

Estimated annual burden hours: 517,500 hours.

Frequency of collection: Annual.

Title: Recordkeeping Requirements for Liquefied Natural Gas Facilities.

OMB Control Number: 2137–0048.

Current Expiration Date: 09/30/2021.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: Pursuant to the Federal Pipeline Safety Regulations, liquefied natural gas facility owners and operators are required to maintain various records, make reports, and provide information regarding their liquefied natural gas facilities to the Secretary of Transportation at the Secretary's request.

Affected Public: Operators and owners of liquefied natural gas facilities.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 40,400.

Estimated annual burden hours: 12,120.

Frequency of Collection: On occasion.

Title: Qualification of Pipeline Safety Training.

OMB Control Number: 2137–0600.

Current Expiration Date: 10/31/2021.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: The Federal Pipeline Safety Regulations require that all individuals responsible for the operation and maintenance of pipeline facilities are required to be properly qualified to safely perform their tasks. 49 CFR 192.807 requires each operator to maintain records that demonstrate compliance with the mandated qualification criteria. Operators are required to maintain records demonstrating compliance and provide them to PHMSA upon request.

Affected Public: Operators of pipeline facilities.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 29,167.

Estimated annual burden hours: 7,292.

Frequency of collection: On occasion.

4. *Title:* Periodic Underwater Inspection and Notification of Abandoned Underwater Pipelines.

OMB Control Number: 2137–0618.

Current Expiration Date: 10/31/2021.

Type of Request: Renewal with no change of a currently approved information collection.

Abstract: The Federal Pipeline Safety Regulations at 49 CFR 192.612 and 49 CFR 195.413 require operators of pipelines in the Gulf of Mexico and its inlets in waters less than 15 feet (4.6 meters) deep to conduct appropriate periodic underwater inspections to determine whether the pipelines are exposed underwater pipelines or pose a hazard to navigation. If an operator discovers that its underwater pipeline is exposed or poses a hazard to navigation, among other remedial actions, the operator must contact the National Response Center by telephone within 24 hours of discovery and report the location of the exposed pipeline or hazardous pipeline.

PHMSA's regulations for reporting the abandonment of underwater pipelines can be found at 49 CFR 192.727 and 49 CFR 195.59. These provisions contain certain requirements for disconnecting and purging abandoned pipelines and require operators to notify PHMSA of each abandoned offshore pipeline facility and each abandoned onshore pipeline facility that crosses over, under, or through a commercially navigable waterway.

Affected Public: Operators of pipeline facilities (except master meter operators).

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 92.

Estimated annual burden hours: 1,372.

Frequency of collection: On occasion.

5. *Title:* Recordkeeping for Underground Natural Gas Storage Facilities.

OMB Control Number: 2137–0634.

Current Expiration Date: 10/31/2021.

Type of Request: Renewal of a currently approved information collection.

Abstract: The Federal Pipeline Safety Regulations at 49 CFR 192.12 requires operators of underground natural gas storage facilities to maintain documentation and provide information to the Secretary of Transportation at the Secretary's request. Examples of the required records include operations and maintenance procedures, results of required tests, records of inspections and repairs, and notifications to the public.

Affected Public: Operators of underground natural gas storage facilities.

Annual Reporting and Recordkeeping Burden:

Estimated number of responses: 136.

Estimated annual burden hours: 220.

Frequency of Collection: On occasion.

Comments are invited on:

(a) The need for the renewal and revision of these collections of information 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 the use of appropriate automated, electronic,

mechanical, or other technological collection techniques.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued in Washington, DC, on February 9, 2021, under authority delegated in 49 CFR 1.97.

John A. Gale,

Director, Standards and Rulemaking Division.

[FR Doc. 2021–02982 Filed 2–12–21; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Bank Appeals Follow-Up Questionnaire

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, 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 a new information collection as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning renewal of a collection of information titled, ''Bank Appeals Follow-Up Questionnaire.''

DATES: Comments must be submitted on or before April 19, 2021.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557–0332, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0332'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection [1] by the following method:

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Click on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0332'' or ''Bank Appeals Follow-Up Questionnaire.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include 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 title 44 requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each renewal of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the renewal of the collection of information set forth in this document.

Title: Bank Appeals Follow-Up Questionnaire.

OMB Control No.: 1557–0332.

Type of Review: Regular.

Description: The OCC's Office of the Ombudsman (Ombudsman) is committed to assessing its efforts to provide a fair and expeditious appeal process to institutions under OCC supervision. To perform this assessment, it is necessary to obtain feedback from individual appellant institutions on the effectiveness of the Ombudsman's efforts to provide a fair and expeditious appeals process and suggestions to enhance the bank appeals process. For each appeal submitted, the Ombudsman uses the information gathered to assess adherence to OCC Bulletin 2013–15, ''Bank Appeals Process,'' dated June 7, 2013, and to enhance its bank appeals program.

Affected Public: Businesses or other for-profit.

Burden Estimates:

Estimated Number of Respondents: 5.

Estimated Annual Burden: 0.85 hours.

Frequency of Response: On occasion.

Comments: Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collections of information are necessary for the proper performance of the OCC's functions, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the information collections, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections 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.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2021–02986 Filed 2–12–21; 8:45 am]

BILLING CODE 4810–33–P

[1] Following the close of this notice's 60-day comment period, the OCC will publish a second notice with a 30-day comment period.

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0265]

Agency Information Collection Activity: Personalized Career Planning and Guidance Application

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of a previously approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before April 19, 2021.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *Nancy.Kessinger@va.gov*. Please refer to ''OMB Control No. 2900–0265'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0265'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 3697A.

Title: Personalized Career Planning and Guidance Application, VAF 28–8832.

OMB Control Number: 2900–0265.

Type of Review: Reinstatement of a previously approved collection.

Abstract: A Veteran, Service member, or dependent may use VAF 28–8832 to apply for Personalized Career Planning and Guidance (PCPG) benefits and the information on the form assists program staff to determine a claimant's eligibility to PCPG benefits. Without the structured questions on this form, the application process could be delayed, particularly in instances where incomplete information is submitted under 38 U.S.C. 501(a).

Affected Public: Individuals and households.

Estimated Annual Burden: 2,750 hours.

Estimated Average Burden Per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 11,000.

By direction of the Secretary:

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–03026 Filed 2–12–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0390]

Agency Information Collection Activity: Application of Surviving Spouse or Child for REPS Benefits (Restored Entitlement Program for Survivors)

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veteran's Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before April 19, 2021.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0390'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0390'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 5101; 38 CFR 3.812.

Title: Application for Surviving Spouse or Child for REPS Benefits (Restored Entitlement Program for Survivors) (VA Form 21P–8924).

OMB Control Number: 2900–0390.

Type of Review: Extension of a currently approved collection.

Abstract: Restored Entitlement Program for Survivors (REPS) is a benefit payable to certain surviving spouses and dependent children of deceased Veterans who died in service prior to August 13, 1981 or died as a result of a service-connected disability incurred or aggravated prior to August 13, 1981. Survivors of the deceased Veteran complete VA Form 21P–8924 to apply for REPS benefits; without the information provided on the form, determination of eligibility would not be possible.

Affected Public: Individuals and households.

Estimated Annual Burden: 600 hours.

Estimated Average Burden Per Respondent: 20 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 1,800.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–03051 Filed 2–12–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0859]

Agency Information Collection Activity Under OMB Review: Request for Restoration of Educational Assistance

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection 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. Refer to ''OMB Control No. 2900–0859.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0859'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 115–48.

Title: Request for Restoration of Educational Assistance.

OMB Control Number: 2900–0859.

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 22–0989 will allow students to apply for restoration of entitlement for VA education benefits used at a school that closed, suspended, or had its approval to receive VA benefits withdrawn. Education Service requests approval of this information collection in order to carry out the implementation of the law which requires VA to immediately accept applications to restore education benefits for school closures and disapprovals beginning after January 1, 2015.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 85 FR 22929 on October 16, 2020, page 65902.

Affected Public: Individuals.

Estimated Annual Burden: 955 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: Once on occasion.

Estimated Number of Respondents: 3,821.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–03029 Filed 2–12–21; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 86 Tuesday,

No. 29 February 16, 2021

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910

Hazard Communication Standard; Proposed Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA–2019–0001]

RIN 1218–AC93

Hazard Communication Standard

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Proposed rule; request for comments.

SUMMARY: OSHA is proposing through this notice of proposed rulemaking (NPRM) to modify the Hazard Communication Standard (HCS) to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Revision 7 (GHS, Rev. 7), to address issues that arose during the implementation of the 2012 update to the HCS, and provide better alignment with other U.S. agencies and international trading partners, without lowering overall protections of the standard. OSHA has preliminarily determined that the proposed revisions to the HCS will reduce costs and burdens while also improving the quality and consistency of information provided to employers and employees regarding chemical hazards and associated protective measures. Consistent with the Executive order entitled ''Improving Regulation and Regulatory Review'' (January 18, 2011) and section 3(a) of the Regulatory Flexibility Act, which call for assessment and, where appropriate, modification and improvement of existing rules to minimize any significant economic impact upon a substantial number of small entities, OSHA has reviewed the existing HCS. The agency has preliminarily determined that the proposed revisions will enhance the effectiveness of the HCS by ensuring employees are appropriately apprised of the chemical hazards to which they may be exposed, thus reducing the incidence of chemical-related occupational illnesses and injuries. The proposed modifications to the standard include revised criteria for classification of certain health and physical hazards, revised provisions for updating labels, new labeling provisions for small containers, technical amendments related to the contents of safety data sheets (SDSs), and related revisions to definitions of terms used in the standard.

DATES: Comments on this NPRM (including requests for hearing) and other information must be submitted by April 19, 2021.

Informal public hearing: OSHA will schedule an informal public hearing on the proposed rule if requested during the comment period. If a hearing is requested, the location and date of the hearing, procedures for interested parties to notify the agency of their intention to participate, and procedures for participants to submit their testimony and documentary evidence will be announced in the **Federal Register**.

ADDRESSES:

Written comments: You may submit comments and attachments, identified by Docket No. OSHA–2019–0001, electronically at *http://www.regulations.gov*, which is the Federal e-Rulemaking Portal. Follow the instructions online for making electronic submissions. After accessing ''all documents and comments'' in the docket (Docket No. OSHA–2019–0001), check the ''proposed rule'' box in the column headed ''Document Type,'' find the document posted on the date of publication of this document, and click the ''Comment Now'' link. When uploading multiple attachments to *regulations.gov*, please number all of your attachments because *www.regulations.gov* will not automatically number the attachments. This will be very useful in identifying all attachments in the preamble. For example, Attachment 1—title of your document, Attachment 2—title of your document, Attachment 3—title of your document. For assistance with commenting and uploading documents, please see the Frequently Asked Questions on *regulations.gov*.

Instructions: All submissions must include the agency's name and the docket number for this rulemaking (Docket No. OSHA–2019–0001). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting information they do not want made available to the public, or submitting materials that contain personal information (either about themselves or others), such as Social Security Numbers and birthdates.

Docket: To read or download comments and materials submitted in response to this **Federal Register** document, go to Docket No. OSHA–2019–0001 at *http://www.regulations.gov.* All comments and submissions are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that website. All comments and submissions, including copyrighted material, are available for inspection through the OSHA Docket Office.[1]

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Contact Frank Meilinger, Director, Office of Communications, Occupational Safety and Health Administration, U.S. Department of Labor; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov*.

For general information and technical inquiries: Contact Maureen Ruskin, Acting Director, Directorate of Standards and Guidance, Occupational Safety and Health Administration, U.S. Department of Labor; telephone (202) 693–1950 or fax (202) 693–1678; email: *ruskin.maureen@dol.gov*.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) has been implemented around the world. In 2012, OSHA updated its Hazard Communication Standard (HCS), 29 CFR 1910.1200, to align with Revision 3 of the GHS (77 FR 17574).

[1] Documents submitted to the docket by OSHA or stakeholders are assigned document identification numbers (Document ID) for easy identification and retrieval. The full Document ID is the docket number plus a unique four-digit code. OSHA is identifying supporting information in this NPRM by author name, publication year, and the last four digits of the Document ID.

However, the GHS is updated with improvements and clarifications every two years. This proposed rulemaking would amend the HCS to align with Revision 7 of the GHS, published in 2017. OSHA is also proposing updates to address specific issues that have arisen since the 2012 rulemaking and to provide better alignment with international trading partners, without lowering the protections provided by the standard. This action is consistent with Executive Order 13563, ''Improving Regulation and Regulatory Review'' (January 18, 2011), and the Regulatory Flexibility Act, 5 U.S.C. 610, which requires periodic review of rules that may be out-of-date, ineffective, or excessively burdensome.

OSHA is required by the Occupational Safety and Health Act of 1970 (OSH Act) to assure, as far as possible, safe and healthful working conditions for the Nation's working men and women. As part of this effort, OSHA first promulgated the HCS in 1983 to provide a standardized approach to workplace hazard communications associated with exposure to hazardous chemicals. The HCS requires chemical manufacturers or importers to classify the hazards of chemicals they produce or import. The standard requires all employers to provide information to their employees about the hazardous chemicals to which they are exposed, by means of a hazard communication program, labels and other forms of warning, safety data sheets (SDSs), and information and training. OSHA is not proposing to change the fundamental structure of the HCS.

OSHA has preliminarily determined that the proposed amendments to the HCS would enhance the effectiveness of the standard by ensuring that employees are appropriately apprised of the chemical hazards to which they may be exposed. The proposed modifications to the standard include revised criteria for classification of certain health and physical hazards to better capture and communicate the hazards to downstream users, revised provisions for labels (including proposed provisions addressing the labeling of small containers and the relabeling of chemicals that have been released for shipment), technical amendments related to the contents of SDSs, and new provisions relating to concentrations or concentration ranges being claimed as trade secrets.

Additionally, in accordance with all applicable Executive Orders, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act, OSHA has prepared a Preliminary Economic Analysis (PEA), including a Preliminary Regulatory Flexibility Analysis Certification, for the proposed modifications to the HCS (see the full PEA in Section VII of this document). Supporting materials prepared by OSHA, such as spreadsheets, are available in the public docket for this rulemaking, Docket ID OSHA–2019–0001, through *www.regulations.gov*. OSHA invites comments on all aspects of the PEA.

In the PEA, OSHA estimates that the proposed rule would result in net cost savings of $26.8 million per year at a 7 percent discount rate, as shown in Table ES–1, below (a summary of annualized costs by affected industry). Annualized at a 3 percent discount rate, OSHA estimates that the proposed rule would result in net cost savings of $27.5 million per year. Under a perpetual time horizon to allow for cost comparisons under Executive Order 13771, OSHA estimates that the net cost savings of the proposed rule at a discount rate of 7 percent would be $19.6 million per year in 2016 dollars.[2] OSHA also expects that the proposed revisions to the HCS would result in modest improvements in worker health and safety above those already being achieved under the current HCS, but the agency was unable to quantify the magnitude of these health and safety benefits (see Section VII.D. Health and Safety Benefits and Unquantified Positive Economic Effects).

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[2] This calculation (a) converts the costs and cost savings of the rule from 2019 dollars to 2016 dollars using the BEA (2020) implicit price deflator for Gross Domestic Product, and (b) discounts the first year costs by five years, to reflect the five years between 2016 and 2021, the scheduled year of publication of this NPRM. For further details, see Document ID 0049, tab ''Tables'', E.O. 13771 Summary Table.

Table ES-1: Total Annualized Costs for All Entities Affected by the Proposed Revisions to the Hazard Communication Standard (by Industry and Provision, 7 Percent Discount Rate, 2019 Dollars)

NAICS Code	Industry	Rule Familiarization	Training	Revised SDS/Labels [a]	Released for Shipment	Labels for Very Small Containers	Total Costs
21	**Mining, Quarrying, and Oil and Gas Extraction**	**$39,410**	**$7,194**	**$264,973**	**$0**	**$0**	**$311,577**
211	Oil and Gas Extraction	$39,410	$7,194	$264,973	$0	$0	$311,577
31-33	**Manufacturing**	**$483,276**	**$112,964**	**$3,264,949**	**-$11,397,777**	**-$1,291,839**	**-$8,828,427**
324	Petroleum and Coal Products Manufacturing	$19,238	$11,539	$1,498,159	$0	$0	$1,528,936
325	Chemical Manufacturing	$137,810	$101,426	$1,587,629	-$11,397,777	-$1,291,839	-$10,862,751
326	Plastics and Rubber Products Manufacturing	$68,513	$0	$0	$0	$0	$68,513
327	Nonmetallic Mineral Product Manufacturing	$59,127	$0	$0	$0	$0	$59,127
331	Primary Metal Manufacturing	$25,831	$0	$0	$0	$0	$25,831
339	Miscellaneous Manufacturing	$172,756	$0	$179,161	$0	$0	$351,917
42	**Wholesale Trade**	**$213,209**	**$0**	**$0**	**-$18,450,070**	**$0**	**-$18,236,861**
423	Merchant Wholesalers, Durable Goods	$59,554	$0	$0	$0	$0	$59,554
424	Merchant Wholesalers, Nondurable Goods	$153,654	$0	$0	-$18,450,070	$0	-$18,296,415
Total		**$735,894**	**$120,158**	**$3,529,921**	**-$29,847,846**	**-$1,291,839**	**-$26,753,711**

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

[a] Figures in this column represent the sum of the costs for chemical reclassification and requirements in the appendices to the standard addressing precautionary statements and other mandatory language.

Note: Figures may not add to totals due to rounding.

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II. Introduction

This preamble to the proposal to modify the HCS includes a review of the events leading to the proposal, a discussion of the reasons why OSHA believes these modifications are necessary, the preliminary economic and regulatory flexibility analysis for the proposal, and an explanation of the specific revisions OSHA is proposing to make to the standard.

III. Events Leading to the Proposed Modifications to the Hazard Communication Standard

OSHA first promulgated the HCS in 1983, covering only the chemical manufacturing industry (48 FR 53280). The purpose of the standard was to provide a standardized approach for communicating workplace hazards associated with exposure to hazardous chemicals. OSHA updated the HCS in 1987 to expand coverage to all industries where workers are exposed to hazardous chemicals (52 FR 31852). In 1994, OSHA promulgated an additional update to the HCS with technical changes and amendments designed to ensure better comprehension and greater compliance with the standard (59 FR 6126). In adopting the original HCS in 1983, the agency noted the benefits of an internationally harmonized chemical hazard communication standard (48 FR 53287), and actively participated in efforts to develop one over the subsequent decades. In 2012, the agency officially harmonized the HCS with the third revision of the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UN GHS, Rev. 3, 2009, Document ID 0085) (77 FR 17574).

OSHA has always envisioned that the HCS would require periodic rulemakings to maintain consistency with the GHS and incorporate the progression of scientific principles and best approaches for classification and communication of workplace hazards related to hazardous chemical exposure (77 FR 17574). This section provides information on the events that have occurred since promulgation of the 2012 HCS, with additional information on the development of the GHS and its relationship to the HCS, and explains the impetus for this proposed rule.

Several international and domestic activities have impacted the direction of the HCS and led to the updates proposed in this NPRM, including negotiations at the UN, OSHA's participation in the U.S.–Canada Regulatory Cooperation Council (RCC) with Health Canada, and information OSHA has received from HCS stakeholders. These are discussed below.

A. International Events Affecting the Standard

The evolution of what was to become the GHS had its early beginnings with the work started in 1956 by the United Nations Economic and Social Council Committee of Experts on the Transport of Dangerous Goods (TDG) and continued in the 1990s through the United Nations Conference on Environment and Economic Development (UNCED), the United Nations International Labour Organization (ILO), and the Organization for Economic Cooperation and Development (OECD) (UN GHS, 2019, Document ID 0053). The overarching goal was to provide an internationally harmonized system to convey information to workers, consumers, and the general public on the physical, health, and environmental effects of hazardous chemicals across the globe, as well as to provide a foundation for the safe management of those chemicals.

Finalized by the UN in 2002, the GHS is intended to harmonize elements of hazard communication, including SDSs and labels, by providing a unified classification system of chemicals based on their physical and health-related hazards. The GHS is updated and revised every two years based on information and experience gained by regulatory agencies, industry, and non-governmental organizations (UN GHS, 2020, Document ID 0052). OSHA largely adopted the third revision to the GHS in 2012.

OSHA leads the U.S. Interagency GHS Coordinating Group, an interagency group that serves as a U.S. delegation to the UN. The Interagency Group works to ensure that modifications to the GHS continue to reflect U.S. agencies' key priorities and do not conflict with U.S. hazard communication and associated requirements. The group meets regularly to discuss issues related to the domestic implementation of the GHS, as well as international work being done at the United Nations Sub-Committee of Experts on the GHS (UNSCEGHS). The Interagency Group consists of representatives from OSHA, the Department of State, the Department of Transportation (DOT), the Environmental Protection Agency (EPA), the U.S. Coast Guard, the Consumer Product Safety Commission (CPSC), the Department of Energy (DOE), the Department of Defense (DOD), and the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF). To date, OSHA is the only U.S. agency to have implemented the GHS, although CPSC regulations contain elements of the GHS (*e.g.*, precautionary statements) (CPSC, 2006, Document ID 0175). The EPA (which initiated the U.S. working group) has proposed changes to its regulations governing significant new uses of chemical substances under the Toxic Substances Control Act that would align with the HCS and the GHS as well as OSHA's respiratory protection standard (29 CFR 1910.134) and National Institute for Occupational Safety and Health (NIOSH) respirator certification requirements (81 FR 49598).

Since OSHA's adoption of Revision 3 in 2012, the GHS has been updated five times; the latest revision, Revision 8, was published in July 2019 (UN GHS, Rev. 8, 2019, Document ID 0065). Updates to the GHS in Revision 4 (2011) included changes to hazard categories for chemically unstable gases and non-flammable aerosols and updates to, and clarification of, precautionary statements (UN GHS, 2011, Document ID 0240). Changes in Revision 5 of the GHS (2013) included a new test method for oxidizing solids; miscellaneous provisions intended to further clarify the criteria for some hazard classes (skin corrosion/irritation, severe eye damage/irritation, and aerosols) and to complement the information to be included in the SDS; revised and simplified classification and labeling summary tables; a new codification system for hazard pictograms; and revised precautionary statements (UN GHS, 2013, Document ID 0241).

Revision 6 of the GHS (2015) included a new hazard class for desensitized explosives and a new hazard category for pyrophoric gases; miscellaneous provisions intended to clarify the criteria for some hazard classes (explosives, specific target organ toxicity following single exposure, aspiration hazard, and hazardous to the aquatic environment); additional information to be included in section 9 of the SDS; revised precautionary statements; and a new example in Annex 7 addressing labelling of small packages (UN GHS, 2015, Document ID 0134). Changes in Revision 7 (2017) included revised criteria for categorization of flammable gases within Category 1; miscellaneous amendments intended to clarify the definitions of some health hazard classes; additional guidance regarding the coverage of section 14 of the SDS (which is non-mandatory under the HCS); and a new example in Annex 7 addressing labelling of small packages

with fold-out labels (UN GHS, 2017, Document ID 0094). Revision 8 (published July 2019) includes a change in classification criteria for aerosols (based on flammable properties, heat of combustion); minor changes to precautionary statements for skin irritation and serious eye damage; new provisions for use of non-animal test methods for the skin irritation/corrosion hazard class; and new precautionary pictograms for ''keep out of reach of children'' (UN GHS, Rev. 8, 2019, Document ID 0065). OSHA is proposing to revise the HCS to align with the GHS Revision 7; however, the agency has included select provisions from Revision 8 for consideration in this rulemaking. Major U.S. trading partners are also aligning with Revision 7. This is discussed in more detail in the introduction to Issues and Options (see Section XIV) and the introduction to Summary and Explanation (see Section XV).

The GHS model is comprehensive and forward-looking, embracing concepts defined in the principles of aggregate exposure and cumulative risk, which have been developed and/or adopted by agencies such as the U.S. EPA pesticides program and NIOSH (US EPA, 2017, Document ID 0054; Lentz, 2015, Document ID 0071). In brief, aggregate exposure considers the combined exposures of a single chemical from multiple pathways (*e.g.,* oral, dermal, inhalation), while cumulative risk evaluates the potential adverse effects from multiple chemicals or stressors (such as heat and noise). Because of its comprehensive approach, the GHS takes into consideration multiple aspects of the intrinsic hazards of a chemical (*e.g.,* physical, health, and environmental hazards) and makes this information available in a manner that facilitates the assessment of aggregate exposures from a single chemical and identifies factors that may contribute to cumulative risk from multiple chemical exposures. While the HCS requires employers to provide information on SDSs in sections 1–11 and 16 (12–15 are non-mandatory) for workplace settings (29 CFR 1910.1200(g)(2)), many consumer products have SDSs available to the public through the National Library of Medicine (NLM, 2020, *http://medlineplus.gov/householdproducts.html,* Document ID 0059). Thus, aggregate exposure information is available to the public for many chemicals where occupational, consumer, and environmental exposures are possible, as intended by the GHS.

An additional international activity impacting the HCS is OSHA's participation in the RCC. The RCC was established in 2011 to promote economic growth, job creation, and other benefits through increased regulatory coordination and transparency between the U.S. and Canada (US EOP, 2011, Document ID 0057). In June 2018, U.S.–Canada RCC principles were reaffirmed through a memorandum of understanding between the U.S. Office of Information and Regulatory Affairs (OIRA) within the White House Office of Management and Budget and the Treasury Board of Canada (US-Canada MOU, 2018, Document ID 0199). Since the RCC's inception, OSHA and Health Canada, Canada's corresponding governmental agency, have developed joint guidance products and consulted on respective regulatory activities. In keeping with the RCC's goal of regulatory cooperation, OSHA is proposing several updates to the HCS that will align with Canada's Hazardous Products Regulations (HPR), such as changes to exemptions for labeling small containers and using prescribed concentration ranges when claiming trade secrets (Health Canada, 2015, Document ID 0051).

B. Stakeholder Engagement

Since updating the HCS in 2012, OSHA has engaged stakeholders in various ways in order to keep them apprised of changes to the GHS that may have an impact on future updates to the HCS, as well as to gather information about stakeholders' experience implementing the standard. For example, in November 2016, OSHA convened a meeting (International/Globally Harmonized System (GHS), Docket No. OSHA–2016–0005) to inform the public that OSHA was beginning rulemaking efforts to maintain alignment of the HCS with more recent revisions of the GHS. Meeting attendees discussed topics and issues that OSHA should consider during the rulemaking. In addition, attendees provided suggestions as to the types of publications (such as guidance products) that would be helpful in complying with the standard and the topics they would like OSHA to address in future compliance assistance materials.

OSHA has also engaged stakeholders through Interagency Group public meetings, prior to each UNSCEGHS Session, to discuss the issues and proposals being presented at the UN. During this forum, stakeholders have the opportunity to provide comments or voice concerns regarding the various proposals under discussion. Stakeholders are also able to provide comments on these proposals in writing via OSHA's docket for International/Globally Harmonized System (GHS) (Docket No. OSHA–2016–0005). The Interagency Group considers the comments and information gathered at these public meetings and in the docket when developing the United States' position on issues before the UN.

Additionally, in December 2018, the RCC held a stakeholder forum in Washington, DC. The purpose of the forum was to conduct senior-level discussions to proactively identify and discuss challenges, opportunities, and lessons learned regarding Canada-U.S, regulatory cooperation'' (US EOP, 2018, Document ID 0252). OSHA led the session regarding chemicals management and workplace chemicals.

C. OSHA Guidance Products, Letters of Interpretation, and Directives

Since OSHA's publication of the HCS update in 2012, the agency has published guidance documents, issued letters of interpretation (LOI), and implemented an enforcement directive. To see the guidance documents, please go to OSHA's web page at: *https://www.osha.gov/dsg/hazcom/guidance.html.* OSHA will continue to develop guidance documents to assist employers and employees with their understanding of the HCS and is seeking comments in this NPRM on types of guidance documents that the public may find useful to understand the updated HCS. Any guidance provided will accord with the Department's regulation at 29 CFR part 89, with a primary aim of providing helpful, plain language explanations.

OSHA has issued several letters of interpretation (LOI) in response to questions from the regulated community. These LOI provide clarification on provisions in the 2012 update to the HCS, and how they apply in particular circumstances. Some of the major issues covered in the LOI include the labeling of small containers, the labeling of chemicals released for shipment, and the use of concentration ranges for trade secrets. OSHA's LOI on the HCS may be found at *https://www.osha.gov/laws-regs/standardinterpretations/standardnumber/1910/1910.1200%20-%20Index/result.* In addition, the agency has published a directive that provides guidance to enforcement compliance officers intended to ensure uniform enforcement of the standard by the OSHA field offices (CPL 02–02–079, OSHA, 2015, Document ID 0007; *https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-079.pdf*). Several of the updates in this proposal would codify specific elements of the enforcement guidance the agency has already

provided in the LOI and the directive (see Section XV: Summary and Explanation for Regulatory Text, Appendix B and Appendix D).

IV. Need and Support for the Proposed Modifications to the Hazard Communication Standard

The HCS is the cornerstone of OSHA's risk mitigation strategy for controlling hazardous chemicals in the workplace. The importance of hazard communication in general and the HCS specifically have been well established over the past few decades, ever since OSHA first established the HCS in 1983 as a worker's ''right to know'' standard (OSHA Publication 3021—Workers' Rights, 2017). However, even prior to OSHA's promulgation of the HCS, there was recognition that workers needed to know the hazards encountered in the workplace and the importance of communicating, classifying, and training how to address, those hazards. The foundational goal of the HCS is to identify, understand, and communicate the hazards associated with exposure to chemicals before workers experience chronic exposure to those hazards.

OSHA first established the need for the HCS in the 1983 standard (48 FR 53282–53284) and most recently reiterated the need for the standard in 2012, when OSHA adopted the GHS hazard communication framework (77 FR 17584–17600). The 2012 HCS emphasized the need for improved quality, consistency, and comprehensibility of information provided to workers. The improved information mandated by the current HCS enables employers and workers to further reduce risks associated with chemical hazards by enabling them to identify and determine the hazards and by providing a method to indicate the severity of the relevant hazards. The HCS, as updated in 2012, also mandates information on proper storage and handling and other information on risk mitigation and management. Numerous studies examined in the final rulemaking for the 2012 HCS supported the need for a hazard communication standard that was focused on ensuring the comprehensibility of the conveyed information (77 FR 17584–17585).

OSHA is now proposing additional changes to the HCS that will serve three primary purposes: (1) Maintaining alignment with the GHS and ensuring that the standard reflects the current state of science and knowledge on relevant topics; (2) cooperating with international trading partners and other Federal agencies; and (3) responding to stakeholder experiences implementing current HCS requirements. The proposed changes include clarifying the purpose and scope of the standard, adding definitions, codifying enforcement policies currently in OSHA's compliance directive, clarifying requirements related to the transport of hazardous chemicals, adding labeling provisions for small containers, and adopting new requirements related to preparation of SDSs and new provisions related to claiming concentration ranges as trade secrets. The agency believes that the changes proposed in this NPRM will further improve the comprehensibility and utility of the standard and allow the HCS to keep up with advances in relevant science and technology, thereby better protecting worker health and safety.

A. Maintaining Alignment With the GHS and Ensuring That the Standard Reflects the Current State of Science and Knowledge on Relevant Topics

Periodic updates to the HCS are needed to maintain pace with the general advancement of science, technology, and our understanding of the processes involved in effective communication. As stated in the 2008 ILO report, ''Continuous improvement of occupational safety and health must be promoted. This is necessary to ensure that national laws, regulations, and technical standards to prevent occupational injuries, disease, and deaths are adapted periodically to social, technical, and scientific progress and other changes in the world of work.'' (ILO, 2008, Document ID 0181). While the tools and protective measures in place to reduce or prevent chemical-related occupational injuries and illnesses are effective, such tools and systems become less effective as time goes by and new technologies and workplace hazards emerge. Therefore, there is a need for continual improvement in the systems and processes designed to identify, communicate about, and reduce workplace exposures to chemical hazards. OSHA has always intended for the HCS to be updated periodically to reflect these advancements, as is the GHS (for further discussion see Section XIV, Issues and Options).[3]

The proposed changes to the HCS will result in better alignment between the standard and the continually-evolving GHS. The first edition of the UN GHS, adopted in December 2002 and published in 2003, implemented the 16-section format for SDSs that is now standard across much of the globe. As information has improved, the GHS has updated the form and content of SDSs[4] to improve readability, minimize redundancies, and ensure hazards are communicated appropriately (UN GHS, 2017, Document ID 0060; ANS revises standard, 2005, Document ID 0237).

Information OSHA has collected since publication of the 2012 updates to the HCS indicates that aligning the HCS with the GHS has had a positive impact. Data from published studies indicate that the hazard communication approach taken in the 2012 HCS has been effective, when implemented appropriately, in enabling workers to understand, avoid, and mitigate exposures to hazardous chemicals in the workplace (Bechtoldt, 2014, Document ID 0061; Elliott, 2016, Document ID 0119). Industry representatives have indicated that workers responded positively to training on pictograms and hazard statements because it provided an opportunity to address distinctions between acute toxicity and chronic health effects (Bechtold, 2014, Document ID 0061). In reference to SDSs, one industry representative stated that ''[b]ecause the standardized hazard statements and classifications are so precisely disclosed, it'll be a lot easier for industrial hygienists to identify the more hazardous chemicals, decide where they may need to take action, and compare the hazards of one product versus another.'' (Bechtold, 2014,

[3] The ILO and the World Health Organization (WHO) have also adopted an evergreen approach to workplace hazard communication (*i.e.,* an approach that ensures systems for hazard communication remain relevant and up-to-date). The ILO and WHO produce international chemical safety cards (ICSC) and maintain a database of approximately 500 data sheets designed to provide safety and health information on hazardous chemicals in a format consistent with the GHS. While not exactly like SDSs, ICSCs use GHS precautionary statements to convey safety and health information about workplace chemicals in a consistent, internationally-accessible manner. With participation by experts from government agencies around the world, including the U.S. (CDC/NIOSH), Canada (Health Canada and Environment Canada), and the European Commission (ECHA), ICSCs are prepared and periodically updated to account for the most recent scientific developments. Due to the robust process of preparation and peer-review, the ICSCs are considered authoritative in nature and a significant asset for workers and health professionals across the globe, including in the United States (ILO, 2019, Document ID 0069).

[4] SDSs, as adopted by the HCS, are intended to provide comprehensive information about a substance or mixture for use in the workplace, including identification of the substance or mixture; hazard identification; composition/ingredient information; first aid measures; fire-fighting measures; accidental release measures; handling and storage; exposure controls/personal protective measures; physical and chemical properties; stability and reactivity; toxicological information; ecological information; disposal considerations; transport information; regulatory information; and other information that may be relevant to the workplace (*e.g.,* date the SDS was prepared, key literature references, and sources of data used to prepare the SDS).

Document ID 0061; Elliot, 2016, Document ID 0119). Consistent labeling requirements have also enabled employers to identify the most hazardous materials in the workplace, understand more about the health effects of these chemicals, and address which hazardous chemicals they may want to replace with safer alternatives (Bechtold, 2014, Document ID 0061).

Several studies published since the 2012 HCS adopted the 16-section SDS format indicate that the new format improves comprehension in the workplace (Elliott, 2016, Document ID 0119; Boelhouwer, 2013, Document ID 0107). However, other recent studies have shown that the system can still be improved upon. Multiple studies in various industries have demonstrated that while comprehension has improved, many SDSs lack information vital to worker protections. Problems include insufficient information on the identification of substances/mixtures; inadequate hazard identification and classification information (*e.g.,* missing information on carcinogens and sensitizers, incorrect chemical classifications); lack of precautionary statements on safe handling; missing information on exposure controls/personal protective equipment; and missing toxicological information (Jang, 2019, Document ID 0110; Allen, 2017, Document ID 0117; DiMare, 2017, Document ID 0118; Tsai, 2016, Document ID 0116; Friis, 2015, Document ID 0120; Saito, 2015, Document ID 0191; Suleiman, 2014, Document ID 0192; Lee, 2012, Document ID 0070). A 2014 study concluded that the contents of the SDSs evaluated were generic and incomplete, lacking important safety measures and health information (Suleiman, 2014, Document ID 0192). A study on mixtures found that information on individual ingredients within mixtures was sometimes completely missing and that information on hazard characterization and classification was ambiguous and almost entirely incorrect (LeBouf, 2019, Document ID 0183). Furthermore, a 2012 study conducted by NIOSH found that SDSs for certain classes of chemicals lacked sufficient information to communicate the appropriate hazards and remedies related to engineered nanomaterials (Eastlake, 2012, Document ID 0063). A follow-up NIOSH study found some improvement in SDS preparation since implementation of the 2012 HCS; however, the study also found that there are still serious deficiencies in providing adequate information on the inherent health and safety hazards of engineered nanomaterials, including handling and storage (Hodson, 2019, Document ID 0067).

Inadequate information on the chemical hazards and risk management practices required on SDSs can lead to overexposure to chemical hazards and puts workers at risk. The studies described above demonstrate the need for ongoing review and refinement to make certain the standard is addressing comprehensibility issues and staying relevant with current occupational safety and health tools, science, and technology. Using information gained through the experience of global stakeholders, the GHS is updated with revisions and improvements every two years. These changes have been outlined in brief in Section III (Events Leading to the Proposed Modifications to the Hazard Communication Standard) of this NPRM. The proposed updates to appendix D, which are based in part on recent revisions to the GHS, seek, among other things, to remedy the issues that have been identified by clarifying the information needed in the SDS. For example, the change in section 9 (physical characteristics to include particle characteristics) will identify exposure issues that are not addressed by the current format. This should, among other things, improve the hazard information required for nanomaterials.

Furthermore, the GHS has been updated to reflect the development of non-animal test methods for use in hazard determination and classification. The development of these test methods led to updates in Chapter 3.2 on skin corrosion/irritation that incorporated new in vitro test methods, and computational and *in silico* techniques, to classify chemicals for this category of hazard (UN GHS, 2018, Document ID 0242). And techniques and processes developed in the behavioral sciences have led to the development of more effective communication practices for occupational safety and health purposes (NIOSH, 2019, Document ID 0126).[5] Studies evaluating the effectiveness of precautionary statements and pictograms used in the GHS have led to their evolution and continued revisions (Fagotto, 2003, Document ID 0125; Ta, 2010, Document ID 0115; Ta, 2011, Document ID 0194; Chan, 2017, Document ID 0017).

In addition to directly enhancing worker protections through improved hazard communication, updating the HCS (based on the GHS) will also improve the availability of important information to support larger efforts to address workplace hazards. For example, NIOSH is exploring the use of aggregate exposures (exposures to a specific chemical or hazard from several different sources) and cumulative risk models for use in setting occupational exposure limits and assessing impacts on worker health (Lentz, 2015, Document ID 0071; Redingert, 2015, Document ID 0100). A real-world example of the potential effects of aggregate exposure comes from the increased use of nanosilver in consumer products. A recent NIOSH review of nanosilver indicates that the current OSHA PEL for silver is adequate to protect workers from silver's adverse health effects (NIOSH, 2018, Document ID 0188). However, a 2013 study looking at the increased presence of nanosilver in consumer products (*e.g.,* use of nanosilver as an antimicrobial in clothing and materials that come into contact with food), and the increased environmental exposures from the manufacture, use, and disposal of these consumer products, indicates that the OSHA PEL may be inadequate to protect workers if nanosilver continues to be added to new consumer products (Balcher, 2013, Document ID 0097). This example highlights the importance of an effective overarching hazard communication strategy in understanding and managing exposures and risk.

Regularly updating the HCS to align with international practices also eases compliance for regulated entities because it provides greater international consistency (Bechtold, 2014, Document ID 0061). Industry groups, such as the American Petroleum Institute (API), have indicated their support for regular HCS updates as long as there is sufficient input from stakeholders (API, 2009, Document ID 0167). During the 2012 rulemaking, numerous safety organizations (including NIOSH, the American Chemical Society (ACS), the American Industrial Hygiene Association (AIHA), the American Society of Safety Engineers (ASSE), and the Society for Chemical Hazard Communication (SCHC)) have publicly supported OSHA's continued updates to the HCS (see 77 FR 17585, 17603, 17604). The Society of Toxicology has also expressed support for updating the HCS to align with the GHS as this ''is ani important step toward creating consistent communication about the hazards of chemicals used around the world.'' (see 77 FR 17585).

[5] Holistic programs such as NIOSH's Total Worker Health (TWH) program, where behavioral science is integrated into more traditional risk-management practices, require robust hazard communication practices (Tamers, 2019, Document ID 0076).

B. Cooperating With International Trading Partners and Other Federal Agencies

In support of the second goal of this NPRM, OSHA expects that the proposed updates to the HCS will facilitate cooperation with international trading partners and other Federal agencies. With respect to the U.S. and Canada specifically, the two countries participate in the RCC, which has a goal to ''reduce, eliminate, or prevent unnecessary regulatory differences between both countries while maintaining high levels of protection for health, safety, and the environment'' (US-Canada MOU, 2018, Document ID 0252). OSHA continues to work with Health Canada through the RCC to develop guidance documents pertaining to hazard communication issues the two countries share and to work cooperatively through the UN GHS subcommittee (see Section III, Events Leading to the Proposed Modifications to the Hazard Communication Standard). In addition, OSHA and Health Canada share regular updates on regulatory activity. As explained in the Summary and Explanation (see Section XV), a number of the updates OSHA is proposing in this NPRM would align U.S. and Canadian hazard communication practices, thereby facilitating cooperation between the two countries, easing compliance for employers who participate in both markets, and strengthening worker protections by providing harmonized hazard communication standards across trade borders.

In addition, OSHA is proposing to update the requirements for bulk shipment under paragraph (f)(5), *Transportation* to provide additional clarity for shipments that are also regulated by the U.S. Department of Transportation (DOT). For bulk shipments, the proposed new paragraph would increase flexibility by allowing labels to be placed on the immediate container or transmitted with shipping papers, bills of lading, or by other technological or electronic means so that they are immediately available to workers in printed form on the receiving end of the shipment. And in another effort to facilitate inter-agency cooperation, OSHA is proposing new language for paragraph (f)(5) providing that where a pictogram required by the DOT appears on the label for a shipped container, the HCS pictogram for the same hazard may also be provided, but is not required.

C. Responding to Stakeholder Experiences Implementing the 2012 HCS

Finally, some of the proposed changes in this NPRM, those related to labeling of small containers and relabeling requirements for chemicals that have been released for shipment, were developed in response to feedback and comments received from stakeholders since the promulgation of the 2012 updates to the HCS (Collatz, 2015, Document ID 0174; Ghosh, 2015, Document ID 0180). With respect to the labeling of small containers, issues raised by stakeholders included concerns about insufficient space on the label to highlight the most relevant safety information, problems with the readability of information on small labels, and challenges associated with using fold-out labels for certain small containers that need special handling (Watters, 2013, Document ID 0200; Collaltz, 2015, Document ID 0174; Blankfield, 2017, Document ID 0170). The proposed updates to the HCS related to the labeling of small containers are designed to address these issues. Furthermore, OSHA believes that adopting a uniform standard for the labeling of small containers will enhance worker protections by providing more clarity and certainty about the hazards posed by the chemicals contained in such containers (see Section X Summary and Explanation for (f)(12), Small container labelling).

Similarly, the proposed revisions to paragraph (f)(11), which address the relabeling of chemicals that have been released for shipment, are designed to address stakeholder concerns about the difficulty some manufacturers have in complying with paragraph (f)(11), especially in the case of chemicals that travel through long distribution cycles (Kenyon, 2017, Document ID 0182). Many products have straightforward supply chains and are packaged, labeled, and promptly shipped downstream. Other products, for example in the agrochemical sector, are packaged and labeled when they leave the chemical manufacturer's facility, but may reside at a warehouse or distribution facility for extended periods of time (*e.g.,* several years) before being shipped downstream. There are also instances where products may be returned from the downstream users to the distribution facility and then shipped to other customers (NGFA, 2016, Document ID OSHA–2016–0005–0018; AFIA, 2016, Document ID OSHA–2016–0005–0017). OSHA believes the proposed revisions to paragraph (f)(11) to provide that relabeling is not required for chemicals that have been released for shipment and are awaiting future distribution will accommodate these concerns; the proposal would also maintain worker protections by requiring the chemical manufacturer or importer to provide an updated label for each individual container with each shipment.

V. Pertinent Legal Authority

A. Background

The purpose of the Occupational Safety and Health Act of 1970 (the ''OSH Act'' or ''Act'') (29 U.S.C. 651 *et seq.*) is ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. 651(b). To achieve this goal, Congress authorized the Secretary of Labor to promulgate occupational safety and health standards pursuant to notice and comment. 29 U.S.C. 655(b). An occupational safety and health standard is a standard ''which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.'' 29 U.S.C. 652(8).

The OSH Act also authorizes the Secretary to ''modify'' or ''revoke'' any occupational safety or health standard, 29 U.S.C. 655(b), and under the Administrative Procedure Act, regulatory agencies generally may revise their rules if the changes are supported by a reasoned analysis. See *Encino Motorcars, LLC* v. *Navarro,* U.S., 136 S. Ct. 2117, 2125–26 (2016); *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 42 (1983). In passing the OSH Act, Congress recognized that OSHA should revise and replace its standards as ''new knowledge and techniques are developed.'' S. Rep. 91–1282 at 6 (1970). The Supreme Court has observed that administrative agencies ''do not establish rules of conduct to last forever, and . . . must be given ample latitude to adapt their rules and policies to the demands of changing circumstances.'' *Motor Vehicle Mfrs. Ass'n,* 463 U.S. at 42 (internal quotation marks and citations omitted).

Before the Secretary can promulgate any permanent health or safety standard, he must make a threshold finding that significant risk is present and that such risk can be eliminated or lessened by a change in practices. *Indus. Union Dep't* v. *Am. Petroleum Inst.,* 448 U.S. 607, 642 (1980) (plurality opinion)

(''*Benzene*''). As explained more fully below, OSHA need not make additional findings on risk for this proposal because OSHA previously determined that the HCS addresses a significant risk. 77 FR 17603–17604.

In promulgating a standard under, and making the determinations required by, the OSH Act, OSHA's determinations will be deemed conclusive if they are ''supported by substantial evidence in the record considered as a whole.'' 29 U.S.C. 655(f). OSHA must use the ''best available evidence,'' which includes ''the latest available scientific data in the field''; ''research, demonstrations, experiments, and such other information as may be appropriate''; and ''experience gained under this and other health and safety laws.'' 29 U.S.C. 655(b)(5).

B. Authority—Section 6(b)(5)

The HCS is a health standard promulgated under the authority of section 6(b)(5) of the OSH Act. See *Associated Builders & Contractors, Inc.* v. *Brock,* 862 F.2d 63, 67–68 (3d Cir. 1988); *United Steelworkers of Am.* v. *Auchter,* 763 F.2d 728, 735 (3d Cir. 1985); 77 FR 17601. Section 6(b)(5) of the OSH Act provides that in promulgating health standards dealing with toxic materials or harmful physical agents, the Secretary must ''set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' 29 U.S.C. 655(b)(5). Thus, once OSHA determines that a significant risk due to a health hazard is present and that such risk can be reduced or eliminated by an OSHA standard, section 6(b)(5) requires OSHA to issue the standard, based on the best available evidence, that ''most adequately assures'' employee protection, subject only to feasibility considerations. As the Supreme Court has explained, in passing section 6(b)(5), Congress ''place[d] . . . worker health above all other considerations save those making attainment of this 'benefit' unachievable.'' *Am. Textile Mfrs. Inst., Inc.* v. *Donovan,* 452 U.S. 490, 509 (1981) (''*Cotton Dust*'').

C. Other Authority

The HCS is also promulgated under the authority of section 6(b)(7) of the OSH Act. See *United Steelworkers,* 763 F.2d at 730; 77 FR 17601. Section 6(b)(7) of the OSH Act provides in part: ''Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure.'' 29 U.S.C. 655(b)(7). Section 6(b)(7)'s labeling and employee warning requirements provide basic protections for employees in the absence of specific permissible exposure limits, particularly by providing employers and employees with information necessary to design work processes that protect employees against exposure to hazardous chemicals in the first instance.

The last sentence of section 6(b)(7) provides that the Secretary, in consultation with the Secretary of Health and Human Services, may by rule promulgated pursuant to section 553 of Title 5, make appropriate modifications in the foregoing requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations, as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard. 29 U.S.C. 655(b)(7). OSHA used the authority granted by this paragraph to promulgate the 2012 revisions to the HCS, 77 FR 17602, and this provision provides additional authority for the current proposal.

This proposal to update the HCS fits well within the authority granted by the last sentence of section 6(b)(7). The changes proposed would constitute a ''modification'' of the HCS regarding ''the use of labels or other forms of warning.'' As explained more fully elsewhere in this preamble, OSHA believes the proposed updates to be ''appropriate'' based on ''experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.'' The updates found in GHS Rev. 7 may be considered a ''technological development'' that has occurred since the promulgation of the HCS in 2012 and are also ''warranted by experience [and] information.'' The GHS was negotiated and drafted through the involvement of labor, industry, and governmental agencies, and thus represents the collective experience and information on hazard communication gathered by the participants in these sectors over the last several decades. See 71 FR 53617, 53618–53619.[6] See also Section III of this preamble, Events Leading to the Proposed Modifications to the Hazard Communication Standard.

Authority for the HCS is also found in section 8, paragraphs (c) and (g), of the OSH Act. Section 8(c)(1) of the OSH Act empowers the Secretary to require employers to make, keep, and preserve records regarding activities related to the OSH Act and to make such records available to the Secretary. 29 U.S.C. 657(c)(1). Section 8(g)(2) of the OSH Act empowers the Secretary to ''prescribe such rules and regulations as he may deem necessary to carry out [his] responsibilities'' under the Act. 29 U.S.C. 657(g)(2).

D. Significant Risk

As required for standards promulgated under section 6(b)(5) of the OSH Act, OSHA determined that the HCS would substantially reduce a significant risk of material harm. Most OSHA health standards protect employees by imposing requirements when employees are exposed to a concentration of a hazardous substance that OSHA has found creates a significant risk of material health impairment. Thus, in making the significant risk determination in these cases, OSHA measures and assesses the hazards of employee exposures in order to determine the level at which a significant risk arises.

OSHA took a different approach to its significant risk determination when first promulgating the HCS in 1983. Rather than attempting to assess the risk associated with exposures to each hazardous chemical in each industry to determine if that chemical posed a significant risk in that industry, OSHA took a more general approach. It relied on NIOSH data showing that about 25 million or about 25 percent of American employees were potentially exposed to one or more of 8,000 NIOSH-identified chemical hazards and that for the years 1977 and 1978 more than 174,000 illnesses were likely caused by exposure to hazardous chemicals. 48 FR 53282. OSHA then noted the consensus evident in the record among labor, industry, health professionals, and government that an ''effective [F]ederal standard requiring employers to identify workplace hazards, communicate hazard information to employees, and train employees in recognizing and avoiding those hazards'' was necessary to protect employee health. 48 FR

[6] The last sentence of section 6(b)(7) requires consultation with the Secretary of Health and Human Services. OSHA briefed NIOSH on this proposal during a collaboration meeting held in December 2018, which was attended by the Director of NIOSH, and NIOSH expressed its support. NIOSH also supported OSHA's update of the HCS in 2012. See 77 FR 17603.

53283. OSHA determined that the HCS addressed a significant risk because ''inadequate communication about serious chemical hazards endangers workers,'' and that the practices required by the standard were ''necessary or appropriate to the elimination or mitigation of these hazards.'' 48 FR 53321. The U.S. Court of Appeals for the Third Circuit agreed that ''inadequate communication is itself a hazard, which the standard can eliminate or mitigate.'' *United Steelworkers,* 763 F.2d at 735. That court has upheld OSHA's determination of significant risk as sufficient to justify the HCS. See *Associated Builders & Contractors,* 862 F.2d at 67–68 (discussing the history of its review of the issue).

OSHA reaffirmed its finding of significant risk in adopting revisions to the HCS in 1994. See 59 FR 6126–6133. When revising the HCS to adopt the GHS model in 2012, OSHA found that there remained a ''significant risk of inadequate communication'' of chemical hazards in the workplace and that adopting the standardized requirements of the GHS would substantially reduce that risk by improving chemical hazard communications. 77 FR 17603–17604.

In previous rulemakings, OSHA rejected suggestions that the hazard assessment and communication obligations of the HCS should arise only where the downstream use creates a significant risk because it is difficult, if not impossible, for OSHA or manufacturers and importers to know in advance where these risks might occur. See 48 FR 53295–53296; 59 FR 6132. Further, it is only by the provision of hazard information that downstream employers and employees can determine how to use the chemical so that exposure and risk may be minimized. See 48 FR 53295–53296; 59 FR 6132. Thus, the HCS protects employees from significant risk by requiring communications about all chemicals that may present a hazard to employees, regardless of the exposure or risk levels any particular downstream user might actually experience. See *Durez Div. of Occidental Chem. Corp.* v. *OSHA,* 906 F.2d 1, 3–4 (D.C. Cir. 1990); *Gen. Carbon Co.* v. *OSHRC,* 860 F.2d 479, 484–85 (D.C. Cir. 1988).

For the changes proposed in this NPRM, OSHA has not made a new preliminary finding of significant risk, but is proposing changes that are reasonably related to the purpose of the HCS as a whole. When, as here, OSHA has previously determined that its standard substantially reduces a significant risk, it is unnecessary for the agency to make additional findings on risk for every provision of that standard. See, *e.g., Pub. Citizen Health Research Grp.* v. *Tyson,* 796 F.2d 1479, 1502 n.16 (D.C. Cir. 1986) (rejecting the argument that OSHA must ''find that each and every aspect of its standard eliminates a significant risk''). Rather, once OSHA makes a general significant risk finding in support of a standard, the next question is whether a particular requirement is reasonably related to the purpose of the standard as a whole. See *Asbestos Info. Ass'n/N. Am.* v. *Reich,* 117 F.3d 891, 894 (5th Cir. 1997); *Forging Indus. Ass'n* v. *Sec'y of Labor,* 773 F.2d 1436, 1447 (4th Cir. 1985); *United Steelworkers of Am., AFL–CIO–CLC* v. *Marshall,* 647 F.2d 1189, 1237–38 (D.C. Cir. 1980) (''*Lead I*'').

Furthermore, the Supreme Court has recognized that protective measures like those called for by the HCS may be imposed in workplaces where chemical exposure levels are below that for which OSHA has found a significant risk. In *Benzene,* the Court recognized that the ''backstop'' provisions of section 6(b)(7) allow OSHA to impose information requirements even before the employee is exposed to the significant risk. See *Benzene,* 448 U.S. at 657–58 & n.66. Rather than requiring a finding of significant risk, the last sentence of section 6(b)(7) provides other assurances that OSHA is exercising its authority appropriately by requiring the involvement of the Secretary of Health and Human Services, and by limiting the authority only to modifications that are based on ''experience, information, or medical or technological developments'' acquired since the promulgation of the standard in the limited areas of hazard communication, monitoring, and medical examinations. Therefore, OSHA need not make any new significant risk findings; rather, the final rule is supported by the significant risk findings that OSHA made when it adopted the current HCS.[7] See 77 FR 17602.

[7] Section 6(b)(7) of the OSH Act also exempts modifications to hazard communication, monitoring, and medical examination requirements from the standard-setting requirements of section 6(b), and so evidences Congress' intent to provide OSHA with an expedited procedure to update these requirements. The last sentence of section 6(b)(7) merely allows these requirements to be updated to reflect the latest knowledge available. The authorization to use Administrative Procedure Act notice and comment procedures rather than the more elaborate framework established by section 6(b) demonstrates congressional intent to treat such modifications differently from rulemakings to adopt standards. Congress envisaged a simple, expedited process that is inconsistent with the idea that OSHA must undertake additional significant risk analyses before exercising this authority. See 77 FR 17602.

E. Feasibility

Because section 6(b)(5) of the OSH Act explicitly requires OSHA to set health standards that eliminate risk ''to the extent feasible,'' OSHA uses feasibility analysis to make standards-setting decisions dealing with toxic materials or harmful physical agents. 29 U.S.C. 655(b)(5); *Cotton Dust,* 452 U.S. at 509. Feasibility in this context means ''capable of being done, executed, or effected.'' *Cotton Dust,* 452 U.S. at 508–09. Feasibility has two aspects, economic and technological. *Lead I,* 647 F.2d at 1264. A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed. See id. at 1272. A standard is economically feasible if industry can absorb or pass on the cost of compliance without threatening its long-term profitability or competitive structure. See *Cotton Dust,* 452 U.S. at 530 n.55; *Lead I,* 647 F.2d at 1265. As discussed more fully in Section VII.E of this preamble, Technological Feasibility, OSHA has preliminarily determined that compliance with the proposed revisions to the HCS is technologically feasible for all affected industries because compliance can be achieved with readily and widely available technologies. As discussed more fully in Section VII.G, Economic Feasibility and Impacts, OSHA has preliminarily determined that the proposed changes to the HCS are economically feasible because employers can comply without threatening the long-term profitability or competitive structure of any affected industries.

VI. OMB Review Under the Paperwork Reduction Act of 1995

A. Overview

OSHA is proposing to revise the Hazard Communication Standard (HCS), 29 CFR 1910.1200, which contains collection of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* and OMB regulations at 5 CFR part 1320. The agency is planning to revise and update the existing previously-approved paperwork package under OMB control number 1218–0072.

The PRA defines ''collection of information'' to mean ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or

format.'' 44 U.S.C. 3502(3)(A). Under the PRA, a Federal agency cannot conduct or sponsor a collection of information unless OMB approves it and the agency displays a currently valid OMB control number. 44 U.S.C. 3507. Also, notwithstanding any other provision of law, no employer shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number. 44 U.S.C. 3512.

B. Solicitation of Comments

OSHA prepared and submitted an Information Collection Request (ICR) to OMB proposing to revise certain collection of information currently contained in that paperwork package in accordance with 44 U.S.C. 3507(d). The agency solicits comments on the revision of the collection of information requirements and reduction in estimated burden hours associated with these requirements, including comments on the following items:

- Whether the collection of information are necessary for the proper performance of the agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and cost) of the collection of information, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the compliance burden on employers, for example, by using automated or other technological techniques for collecting and transmitting information.

C. Proposed Information Collection Requirements

As required by 5 CFR 1320.5(a)(1)(iv) and 1320.8(d)(2), the following paragraphs provide information about the ICR.

1. *Title:* Hazard Communication Standard.

2. *Description of the ICR:* The proposal would revise the currently approved Hazard Communication ICR and change the existing collection of information requirements currently approved by OMB.

3. *Brief Summary of the Information Collection Requirements:* This proposal would revise and clarify the collection of information contained in the existing ICR. Specifically, OSHA is proposing to (1) add to paragraph (d)(1) that the chemical manufacturer or importer shall determine for each chemical the hazard classes, and where appropriate, the category of each class that apply to the chemical being classified under normal conditions of use and foreseeable emergencies; (2) add language to paragraph (f)(1) requiring that the chemical manufacturer, importer, or distributor ensure labels on shipped containers bear the date the chemical is released for shipment; (3) revise paragraph (f)(5) by adding two new provisions related to bulk shipments of chemicals; (4) revise paragraph (f)(11) by adding a provision related to release for shipment that requires updated labels accompany each shipment; and (5) add new labeling requirements for small containers at paragraph (f)(12). See Table 1.

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Table 1 -- Collection of Information Requirements Being Revised in the Hazard Communication Standard

Section number and title	Currently approved collection of information requirements	Proposed collection of information requirements
§1910.1200 (d)(1)	*§1910.1200(d)(1)* - Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to classify the chemicals in accordance with this section. For each chemical, the chemical manufacturer or importer shall determine the hazard classes, and, where appropriate, the category of each class that apply to the chemical being classified. Employers are not required to classify chemicals unless they choose not to rely on the classification performed by the chemical manufacturer or importer for the chemical to satisfy this requirement.	*§1910.1200(d)(1)* - Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to classify the chemicals in accordance with this section. For each chemical, the chemical manufacturer or importer shall determine the hazard classes, and, where appropriate, the category of each class that apply to the chemical being classified *under normal conditions of use and foreseeable emergencies. The hazard classification shall include any hazards associated with a change in the chemical's physical form or resulting from a reaction with other chemicals under normal conditions of use.* Employers are not required to classify chemicals unless they choose not to rely on the classification performed by the chemical manufacturer or importer for the chemical to satisfy this requirement.

Table 1, continued -- Collection of Information Requirements Being Revised in the Hazard Communication Standard

Section number and title	Currently approved collection of information requirements	Proposed collection of information requirements
§1910.1200 (f)(1) -- Labels on shipped containers	*§1910.1200(f)(1)* The chemical manufacturer, importer, or distributor shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked. Hazards not otherwise classified do not have to be addressed on the container. Where the chemical manufacturer or importer is required to label, tag, or mark the following information shall be provided: • Product identifier; • Signal word; • Hazard statement(s); • Pictogram(s); • Precautionary statement(s); and, • Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party.	*§1910.1200(f)(1)* The chemical manufacturer, importer, or distributor shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked. Hazards not otherwise classified *and hazards resulting from a reaction with other chemicals under normal conditions of use* do not have to be addressed on the container. Where the chemical manufacturer, importer or *distributor* is required to label, tag, or mark the following information shall be provided: • Product identifier; • Signal word; • Hazard statement(s); • Pictogram(s); • Precautionary statement(s); • Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party; *and,* • *Date chemical is released for shipment.*
§1910.1200 (f)(5) -- Transportation	*§1910.1200(f)(5)* Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 et seq.) and regulations issued under that Act by the Department of Transportation.	*§1910.1200(f)(5)* – ***Transportation.*** • Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 et seq.) and regulations issued under that Act by the Department of Transportation. • *The label for bulk shipments of hazardous chemicals may be on the*

Table 1, continued -- Collection of Information Requirements Being Revised in the Hazard Communication Standard

Section number and title	Currently approved collection of information requirements	Proposed collection of information requirements
		immediate container or may be transmitted with the shipping papers, bills of lading, or other technological or electronic means so that it is immediately available to workers in printed form on the receiving end of shipment. • *Where a pictogram required by the Department of Transportation under Title 49 of the Code of Federal Regulations appears on the label for a shipped container, the pictogram specified in appendix C.4 for the same hazard is not required on the label.*
§1910.1200 (f)(11)	*§1910.1200(f)(11)* - Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.	*§1910.1200(f)(11)* - Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. *Chemicals that have been released for shipment and are awaiting future distribution need not be relabeled; however, the chemical manufacturer or importer must provide the updated label for each individual container with each shipment.* If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.
§1910.1200 (f)(12) – Small container labeling	[none]	*§1910.1200(f)(12)* - Small container labelling • *Paragraph (f)(12) applies where the chemical manufacturer, importer, or distributor can demonstrate that it is not feasible to use pull-out labels, fold-*

Table 1, continued -- Collection of Information Requirements Being Revised in the Hazard Communication Standard

Section number and title	Currently approved collection of information requirements	Proposed collection of information requirements
		back labels, or tags containing the full label information required by (f)(1). • *For a container less than or equal to 100 ml capacity, the chemical manufacturer, importer, or distributor must include, at a minimum, the following information on the label of the container:* ○ *Product identifier;* ○ *Pictogram(s);* ○ *Signal word;* ○ *Chemical manufacturer's name and phone number; and* ○ *A statement that the full label information for the hazardous chemical is provided on the immediate outer package.* • *For a container less than or equal to 3 ml capacity, where the chemical manufacturer, importer, or distributor can demonstrate that any label interferes with the normal use of the container, no label is required, but the container must bear, at a minimum, the product identifier.* • *For all small containers covered by (f)(12)(ii) or (iii), the immediate outer package must include:* ○ *The full label information required by (f)(1) for each hazardous chemical in the immediate outer package. The label must not be removed or defaced, as required by (f)(9).* ○ *A statement that the small container(s) inside must be stored in the immediate outer package bearing the complete label when not in use.*

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4. *OMB Control Number:* 1218–0072.

5. *Affected Public:* Business or other for-profit.

6. *Number of Respondents:* 2,206,700.

7. *Frequency of Responses:* Varies.

8. *Number of Reponses:* 74,019,955.

9. *Average Time per Response:* Varies.

10. *Estimated Annual Total Burden Hours:* 7,023,513.

11. *Estimated Annual Total Cost (Operation and maintenance):* $45,676,443.

D. Submitting Comments

Members of the public who wish to comment on the revisions to the paperwork requirements in this proposal must send their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, OSHA (RIN–1218–AC93), Office of Management and Budget, Room 10235, Washington, DC 20503, email: *OIRA_submission@omb.eop.gov.* The agency encourages commenters also to submit their comments on the paperwork requirements to the rulemaking docket (Docket Number OSHA–2019–0001) along with comments on other parts of the proposed rule. For instructions on submitting these comments to the rulemaking docket, see the sections of this **Federal Register** document titled **DATES** and **ADDRESSES**. Comments submitted in response to this document are public records; therefore, OSHA cautions commenters about submitting personal information such as Social Security numbers and dates of birth.

E. Docket and Inquiries

To access the docket to read or download comments and other materials related to this paperwork determination, including the complete ICR (containing the Supporting Statement with attachments describing the paperwork determinations in detail) use the procedures described under the section of this document titled **ADDRESSES**.

You also may obtain an electronic copy of the complete ICR by visiting the web page at: *http://www.reginfo.gov/public/do/PRAMain,* scroll under ''Currently Under Review'' to ''Department of Labor (DOL)'' to view all of the DOL's ICRs, including those ICRs submitted for proposed rulemakings. To make inquiries, or to request other information, contact Ms. Seleda Perryman, Directorate of Standards and Guidance, telephone (202) 693–2222.

VII. Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis

A. Introduction and Summary

Under Executive Order 12866, OMB's Office of Information and Regulatory Affairs (OIRA) determines whether a regulatory action is significant and, therefore, subject to the requirements of Executive Order 12866 and OMB review. 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 entitlements, 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 Executive Order 12866. Upon review, OMB has determined that this proposed rule is a significant regulatory action (''Other Significant'') under Executive Order 12866. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), OIRA designated that this rule is not a ''major rule,'' as defined by 5 U.S.C. 804(2).

OSHA has made a preliminary determination that this action is not an economically significant regulatory action under section 3(f)(1) of Executive Order 12866 because it is not likely to have an annual effect on the economy of $100 million or more. This proposed rule is expected to be an Executive Order 13771 deregulatory action. Details on the estimated cost-savings of this rule can be found in the economic analysis below. Executive Order 13563 directs agencies to adopt a regulation only upon a reasoned determination that its benefits justify its costs; tailor the regulation to impose the least burden on society, consistent with obtaining the regulatory objectives; and in choosing among alternative regulatory approaches, select those approaches that maximize net benefits. Executive Order 13563 recognizes that some benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

OSHA has prepared this Preliminary Economic Analysis (PEA), including a Preliminary Regulatory Flexibility Analysis Certification, for the proposed modifications to the HCS. Supporting materials prepared by OSHA (including spreadsheets) are available in the public docket for this rulemaking, Docket ID OSHA–2019–0001, through *www.regulations.gov.* OSHA invites comment on any aspects of this PEA.

In this PEA, OSHA estimates that the proposed amendments to the HCS would result in annualized net cost savings of $26.8 million at a 7 percent discount rate. Annualized at a 3 percent discount rate, OSHA estimates that the proposed amendments to the rule would lead to net cost savings of $27.5 million per year. Under a perpetual time horizon to allow for cost comparisons under Executive Order 13771, OSHA estimates that at a discount rate of 7 percent the net cost savings of the proposed amendments to the HCS would be $19.6 million per year in 2016 dollars.[8] OSHA expects that the proposed revisions to the HCS would also result in modest improvements in worker health and safety above those already being achieved under the current HCS, but the agency is unable to quantify the magnitude of these benefits.

B. Need for Regulation

Employees in work environments covered by OSHA's HCS are exposed to a variety of significant hazards associated with chemicals used in the workplace that can and do cause serious injury, illness, and death. The HCS serves to ensure that both employers and employees are provided the information they need about these chemical hazards. The current HCS contains a set of requirements for chemical products, including mandatory hazard classification, labeling requirements, provisions for providing detailed information (in SDSs), and label updating requirements. These requirements are based on Revision 3 of the GHS, which was adopted by the UN Committee and Sub-Committee of Experts on the GHS in December 2008.

OSHA has preliminarily determined that the proposed revisions to the HCS would make employers' hazard communication programs more worker-protective, efficient, and effective through standardizing practices nationally and internationally. In addition, aligning with the GHS Rev. 7 would continue to facilitate

[8] This calculation (a) converts the costs and cost savings of the rule from 2019 dollars to 2016 dollars using the BEA (2020) implicit price deflator for Gross Domestic Product, and (b) discounts the first year costs by five years, to reflect the five years between 2016 and 2021, the scheduled year of publication of this NPRM. For further details, see Document ID 0049, tab Tables, E.O. 13771 Summary Table.

international trade, as a number of U.S. trading partners are also preparing to align with the GHS Rev. 7.

The proposed revisions to the HCS include the following notable changes to improve the U.S. hazard communication system:

- Maintain alignment with the GHS
  - Adding classification categories for aerosols, desensitized explosives, and flammable gases; and
  - Updating select hazard and precautionary statements for clearer and more precise hazard information.
- Address issues identified in implementing the HCS 2012
  - Updating labeling requirements for small containers; and
  - Updating labeling requirements for packaged containers that have been released for shipment.

As discussed in Section F of this PEA, the estimated costs and cost savings resulting from the proposed revisions to the HCS consist of five main categories: (1) The cost of reclassifying affected chemicals and revising the corresponding SDSs and labels to achieve consistency with the reclassification (per proposed changes to appendix B), and the cost of revising SDSs and labels to conform with new precautionary statements and other new mandatory language in the appendices to the HCS (per proposed changes to appendices C and D); (2) the cost of management familiarization and other management-related costs (associated with all of the proposed revisions to the standard); (3) the cost of training employees as necessitated by the proposed changes to the HCS (see existing 29 CFR 1910.1200(h)(1)); (4) the cost savings resulting from the new released-for-shipment provision (proposed revisions to 29 CFR 1910.1200(f)(11)); and (5) the cost savings from limiting labeling requirements for certain very small containers (proposed 29 CFR 1910.1200(f)(12)). The first three categories are considered to be one-time costs and the last two categories are cost savings that would accrue to employers annually.

The proposed changes to the HCS would maintain the uniformity of hazard information with the GHS and would, accordingly, serve to improve the efficiency and effectiveness of the existing hazard communication system in the U.S., ensure that updated and advanced HCS methods are recognized, and reduce unnecessary barriers to trade. In short, the GHS is a ''uniformity standard'' for the presentation of hazard information (Hemenway, 1975, Document ID 0050). Much like other uniformity standards, such as driving on the right side of the road (in the U.S.), screw threads for fire hose connectors, ''handshake'' protocols for communication between computers, and, for that matter, language, the GHS provides significant efficiencies and economies.[9]

Since publication of the update to the HCS in 2012, there continues to be movement by U.S. trading partners toward maintaining standardization, consistent with the revisions in the GHS. However, OSHA does not believe that full and comprehensive standardization in accordance with the GHS, or the goal of harmonizing the U.S. system with the international one, can be achieved voluntarily in the absence of regulation.

First, the market alone will not ensure alignment with the GHS Rev. 7. In some cases (*e.g.,* aerosols, desensitized explosives), the GHS Rev. 7 contains different hazard classes or classification criteria than the current HCS, and it would be impermissible for a manufacturer to comply with the GHS Rev. 7 rather than the criteria in the existing HCS. Moreover, making compliance with the latest revision of the GHS optional undermines the goal of harmonizing classification criteria and label elements. Second, while the costs of creating SDSs and labels are borne directly by the chemical producers, maintaining alignment with the GHS benefits the users of hazardous chemicals. These users include employers who are direct customers of chemical manufacturers, employees who use or are exposed to workplace chemicals, and emergency responders who typically have no market relationship with the chemical producers. Even if market forces could ensure the socially optimal approach to SDSs between chemical manufacturers and their customers, there are limited market forces at work between the chemical manufacturer and two key sets of users—the employees and the emergency response community. Therefore, the benefits achieved by maintaining alignment with the GHS are unlikely to be obtained in the private market without regulation.

OSHA recognizes that there will be *some* market pressure to align with the GHS Rev. 7 as its adoption expands internationally.[10] Some firms in the U.S. may think that they have no need to follow the GHS because they do not ship their products internationally. These firms may not realize the extent to which they are involved in international trade. There are probably few companies that have products that are never involved in international trade or that never import chemical products requiring hazard information.[11] Nonetheless, even the small percentage of U.S. companies that only conduct business domestically are required to identify and communicate hazards to workers under the HCS. Many chemical producers ship their products to distributors and are unaware of where their products are ultimately used. These distributors might well put pressure on their suppliers to maintain compliance with the GHS. Further, small companies sell chemicals to larger companies. The larger companies may use those chemicals to make other products that are exported. These larger companies might also pressure their small-firm suppliers to align with the GHS. Nevertheless, relying solely on market pressures would surely involve a long transition period, with attendant

[9] A specification standard, such as an engineering standard, would spell out, in detail, the equipment or technology that must be used to achieve compliance. The usual rationale for a specification standard is that compliance would be difficult to verify under a performance standard; hence, a specification standard would better protect employees against the risk in question. A specification standard would generally not provide the efficiencies or economies (such as easier, less expensive training on uniform pictograms and a uniform SDS format made possible by the GHS) to the regulated community that a uniformity standard would. On the contrary, a specification standard could impose additional costs on some firms that may be able to effectively protect workers using a cheaper alternative approach if such flexibility were permitted.

It is also worth noting that, for uniformity standards with technological implications, the benefits of reduced information costs, economies of uniformity, and facilitation of exchange may need to be weighed against possible losses of flexibility, experimentation, and innovation. However, because the GHS is limited to the presentation of hazard information and does not involve other than incidental technological or strategic considerations, the possible costs of uniformity here would be minuscule.

[10] See *https://www.unece.org/fileadmin/DAM/trans/doc/2018/dgac10c4/ST-SG-AC10-C4-70e.pdf,* pp. 12–13 (UN GHS, 2018, Document ID 0040).

[11] According to the U.S. International Trade Commission, U.S. imports of chemicals and related products increased 23 percent from 2015 ($260.4 billion) to 2019 ($320.1 billion); and U.S. exports of chemicals and related products increased 7 percent from 2015 ($227.7 billion) to 2019 ($243.7 billion). See *https://usitc.gov/research_and_analysis/trade_shifts_2019/chemicals.htm,* accessed October 2, 2020 (Document ID 0234). The International Trade Administration reported that the U.S. chemical industry accounted for 18 percent of global chemical shipments. See *https://www.selectusa.gov/chemical-industry-united-states,* accessed October 2, 2020 (Document ID 0236). The American Chemistry Council reported that in 2019, total U.S. chemical exports accounted for 10 percent of all U.S. goods exports and 10 percent of all global chemical exports. See *https://www.americanchemistry.com/Policy/Trade/US-Chemicals-Trade-by-the-Numbers.pdf,* accessed October 2, 2020 (Document ID 0235).

losses in worker protection and production efficiencies, and it is unlikely that the market alone will ensure full alignment with the GHS for reasons described above.

The proposed changes to the HCS would involve costs and cost savings mainly for manufacturers and importers. Manufacturers and importers of chemicals would also achieve benefits—in part because they themselves benefit as both producers and users, and in part as a result of foreign trade benefits. Some manufacturers may not obtain trade benefits unless they engage in chemical export. International harmonization of hazard communication requirements may also make it easier for small companies to engage in international trade if they so desire (see additional discussion below in VII.D. Health and Safety Benefits and Unquantified Positive Economic Effects).

Of more significance to the concerns of the OSH Act, the proposed changes would also provide health benefits from improved hazard classification and communication; although unquantified in this proposal, these benefits would include reductions in worker illnesses, injuries, and fatalities (see additional discussion below in VII.D. Health and Safety Benefits and Unquantified Positive Economic Effects).

Because many of the health and safety benefits and cost savings described in this analysis require uniformity and are dispersed among a network of producers and users, only some of which have direct market relationships with each other, OSHA believes maintaining a single, uniform standard can best achieve the full benefits available from a hazard communications system.

C. Profile of Affected Industries, Establishments, and Employees

The proposed modifications to the standard include revised criteria for classification of certain health and physical hazards; revised labeling provisions for small containers and packages that have been released for shipment; revised trade secret disclosure requirements; updates to certain aspects of SDSs and precautionary statements; and related revisions to definitions of terms used in the standard.

In this section, OSHA presents a preliminary profile of industries affected by this proposal to revise the HCS. The profile data in this section are based upon the 2012 HCS final economic analysis (FEA), updated in this PEA with the most recent data available.

As a first step, OSHA identifies the North American Industry Classification System (NAICS) industries affected by the proposed changes to the HCS. Next, OSHA provides statistical information on the affected industries, including the number of affected entities and establishments; the number of workers whose exposure to the chemicals subject to the HCS could result in injury, illness, or death (''affected relevant employees''); and the average revenues and profits for affected entities and establishments by six-digit NAICS industry.[12] This information is provided for each affected industry as a whole, as well as for small entities, as defined by the Small Business Administration (SBA), and for ''very small'' entities, defined by OSHA as those with fewer than 20 employees, in each affected industry (U.S. Census Bureau, 2020a, Document ID 0231; U.S. Census Bureau, 2020b, Document ID 0232).

The revisions to the HCS would affect establishments in a variety of different industries in which employees are exposed to hazardous chemicals or in which hazardous chemicals are produced. The proposed changes to the HCS are not expected to change the overall list of affected industries or establishments. However, the changes are expected to affect certain establishment groupings that manufacture aerosols, desensitized explosives, and flammable gases. These proposed changes are also expected to affect certain manufacturers of hazardous chemicals that are packaged in small containers and manufacturers of chemicals that are not immediately distributed after being released for shipment.

The proposed revisions define and revise specific classifications and categories of hazards, but the scope of the requirements under which a chemical (whether a substance or mixture of substances) becomes subject to the standard is not substantially different from the current version of the HCS. Therefore, OSHA believes that the revisions would have little or no effect on whether specific establishments fall within the scope of the standard. OSHA requests comments on its preliminary determinations about the scope of the proposed revisions to the HCS and the details within the industrial profile presented in this section.

OSHA's estimates of the number of employees who will require new training under the proposed revisions to the standard are based on BLS' (2020) Occupational Employment Statistics data for May 2019, specifically the estimates of the number of employees in SOC 51–0000 Production Occupations and SOC 13–1081 Logisticians working in firms in the NAICS industries that would be affected by the proposed requirements to reclassify aerosols, desensitized explosives, and flammable gases.[13] (See the analysis and discussion of training costs below in VII.F. Compliance Costs and Cost Savings.)

Table VII–1 provides an overview of the estimated numbers of firms, establishments, and employees in each covered NAICS industry; the estimated number of employees in covered occupations (*e.g.,* logistics personnel); and the estimated numbers of affected firms, affected establishments, and affected employees in covered occupations.[14] Tables VII–2 and VII–3, respectively, provide parallel information for all affected business entities defined as small by the SBA [15] and all affected very small business entities, defined by OSHA as those with fewer than 20 employees. The data in

[12] The Census Bureau defines an establishment as a single physical location at which business is conducted or services or industrial operations are performed. The Census Bureau defines a business firm or entity as a business organization consisting of one or more domestic establishments in the same state and industry that are specified under common ownership or control. The firm and the establishment are the same for single-establishment firms. For each multi-establishment firm, establishments in the same industry within a state will be counted as one firm; the firm employment and annual payroll are summed from the associated establishments. (U.S. Census Bureau, Document ID 0047).

[13] The NAICS industries estimated to be affected by the proposed requirement to reclassify aerosols, desensitized explosives, and flammable gases are the following: 211130 Natural Gas Extraction, 324110 Petroleum Refineries, 325110 Petrochemical Manufacturing, 325120 Industrial Gas Manufacturing, 325320 Pesticide and Other Agricultural Chemical Manufacturing, 325412 Pharmaceutical Preparation Manufacturing, 325510 Paint and Coating Manufacturing, 325520 Adhesive Manufacturing, 325611 Soap and Other Detergent Manufacturing, 325612 Polish and Other Sanitation Good Manufacturing, 325613 Surface Active Agent Manufacturing, 325620 Toilet Preparation Manufacturing, and 325920 Explosives Manufacturing. Bureau of Labor Statistics (BLS, 2020). Occupational Employment Statistics—May 2019 (Released March 3, 2020). Available at *https://www.bls.gov/oes/#data* (Accessed April 3, 2020) (Document ID 0223).

[14] The overall percentage of firms, establishments, or employees affected is based on the largest percentage affected for any single cost item—as shown in Table VI–10 later in this section. To estimate the overall number of affected firms, establishments, and employees, OSHA multiplied the total number of firms, establishments, and employees by the maximum percentage of firms, establishments, and/or employees affected by any single provision. Because most of the NAICS industries shown in the table would be affected by rule familiarization, this percentage is 100 percent for most of the NAICS industries shown.

[15] For the 2019 SBA U.S. Small Business Administration Table of Small Business Size Standards matched to North American Industry Classification System Codes (Effective August 19, 2019),(see SBA, 2019, Document ID 0225).

these tables update the estimates provided in the FEA in support of the 2012 HCS final rule (Document ID 0005, Section VI) and rely on the most recent comprehensive set of data (including revenues) available from the U.S. Census Bureau (2020a; 2020b).[16]

[16] U.S. Census Bureau, Statistics of U.S. Businesses, 2017 *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html* (Document ID 0231) and *https://www.census.gov/data/datasets/2017/econ/susb/2017-susb.html* (Document ID 0232) (accessed August 14, 2020).

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Table VII-1: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS - All Entities

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
21	**Mining, Quarrying, and Oil and Gas Extraction**	**15,437**	**19,150**	**394,604**	**23,203**	**5,200**	**6,405**	**7,389**
211	**Oil and Gas Extraction**	**5,200**	**6,405**	**108,985**	**7,389**	**5,200**	**6,405**	**7,389**
211120	Crude Petroleum Extraction	4,570	5,333	85,169	5,774	4,570	5,333	5,774
211130	Natural Gas Extraction	630	1,072	23,816	1,615	630	1,072	1,615
31-33	**Manufacturing**	**258,563**	**290,936**	**11,721,785**	**6,111,260**	**60,752**	**74,969**	**1,442,936**
324	**Petroleum and Coal Products Manufacturing**	**984**	**2,135**	**105,730**	**44,261**	**984**	**2,135**	**44,261**
324110	Petroleum Refineries	70	155	63,594	26,622	70	155	26,622
324121	Asphalt Paving Mixture and Block Manufacturing	472	1,361	15,991	6,694	472	1,361	6,694
324122	Asphalt Shingle and Coating Materials Manufacturing	123	217	10,662	4,463	123	217	4,463
324191	Petroleum Lubricating Oil and Grease Manufacturing	253	318	12,462	5,217	253	318	5,217
324199	All Other Petroleum and Coal Products Manufacturing	66	84	3,021	1,265	66	84	1,265
325	**Chemical Manufacturing**	**10,389**	**13,426**	**784,725**	**289,832**	**10,389**	**13,426**	**289,832**
325110	Petrochemical Manufacturing	28	44	9,369	3,727	28	44	3,727
325120	Industrial Gas Manufacturing	63	502	13,202	5,251	63	502	5,251
325130	Synthetic Dye and Pigment Manufacturing	112	146	8,963	3,565	112	146	3,565
325180	Other Basic Inorganic Chemical Manufacturing	363	626	39,878	15,861	363	626	15,861
325193	Ethyl Alcohol Manufacturing	121	210	11,276	4,485	121	210	4,485
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	53	78	6,079	2,418	53	78	2,418
325199	All Other Basic Organic Chemical Manufacturing	591	814	67,603	26,889	591	814	26,889
325211	Plastics Material and Resin Manufacturing	852	1,125	75,998	30,228	852	1,125	30,228
325212	Synthetic Rubber Manufacturing	140	154	9,661	3,842	140	154	3,842
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	109	132	14,220	5,656	109	132	5,656
325311	Nitrogenous Fertilizer Manufacturing	163	202	6,154	2,448	163	202	2,448
325312	Phosphatic Fertilizer Manufacturing	45	71	5,279	2,099	45	71	2,099
325314	Fertilizer (Mixing Only) Manufacturing	359	473	8,625	3,430	359	473	3,430
325320	Pesticide and Other Agricultural Chemical Manufacturing	188	229	10,798	4,295	188	229	4,295
325411	Medicinal and Botanical Manufacturing	451	492	27,160	8,381	451	492	8,381
325412	Pharmaceutical Preparation Manufacturing	1,007	1,280	147,442	45,497	1,007	1,280	45,497
325413	In-Vitro Diagnostic Substance Manufacturing	192	237	28,838	8,898	192	237	8,898
325414	Biological Product (except Diagnostic) Manufacturing	266	341	46,498	14,348	266	341	14,348
325510	Paint and Coating Manufacturing	998	1,197	39,139	15,567	998	1,197	15,567
325520	Adhesive Manufacturing	403	559	24,231	9,638	403	559	9,638

Table VII-1: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS - All Entities

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
325611	Soap and Other Detergent Manufacturing	618	675	25,387	10,097	618	675	10,097
325612	Polish and Other Sanitation Good Manufacturing	419	458	15,779	6,276	419	458	6,276
325613	Surface Active Agent Manufacturing	105	131	5,938	2,362	105	131	2,362
325620	Toilet Preparation Manufacturing	926	984	53,817	21,405	926	984	21,405
325910	Printing Ink Manufacturing	182	342	10,962	4,360	182	342	4,360
325920	Explosives Manufacturing	52	88	7,288	2,899	52	88	2,899
325991	Custom Compounding of Purchased Resins	330	402	19,529	7,768	330	402	7,768
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	189	204	8,712	3,465	189	204	3,465
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	1,064	1,230	36,900	14,677	1,064	1,230	14,677
326	**Plastics and Rubber Products Manufacturing**	**9,694**	**12,217**	**771,836**	**468,018**	**9,694**	**12,217**	**468,018**
326111	Plastics Bag and Pouch Manufacturing	271	339	31,188	18,528	271	339	18,528
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	299	396	33,748	20,049	299	396	20,049
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	429	529	35,951	21,358	429	529	21,358
326121	Unlaminated Plastics Profile Shape Manufacturing	326	375	20,033	11,901	326	375	11,901
326122	Plastics Pipe and Pipe Fitting Manufacturing	266	448	23,281	13,831	266	448	13,831
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	208	230	12,378	7,354	208	230	7,354
326140	Polystyrene Foam Product Manufacturing	308	438	26,968	16,021	308	438	16,021
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	445	653	32,428	19,265	445	653	19,265
326160	Plastics Bottle Manufacturing	195	470	31,243	18,560	195	470	18,560
326191	Plastics Plumbing Fixture Manufacturing	311	346	17,300	10,278	311	346	10,278
326199	All Other Plastics Product Manufacturing	5,187	6,156	374,862	222,698	5,187	6,156	222,698
326211	Tire Manufacturing (except Retreading)	81	114	45,509	30,294	81	114	30,294
326212	Tire Retreading	261	373	6,568	4,372	261	373	4,372
326220	Rubber and Plastics Hoses and Belting Manufacturing	196	273	19,713	13,123	196	273	13,123
326291	Rubber Product Manufacturing for Mechanical Use	346	411	30,895	20,567	346	411	20,567
326299	All Other Rubber Product Manufacturing	565	666	29,771	19,819	565	666	19,819
327	**Nonmetallic Mineral Product Manufacturing**	**9,636**	**15,126**	**392,588**	**152,192**	**9,636**	**15,126**	**152,192**
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	566	585	12,508	4,849	566	585	4,849
327120	Clay Building Material and Refractories Manufacturing	375	530	21,628	8,385	375	530	8,385
327211	Flat Glass Manufacturing	74	98	11,504	4,459	74	98	4,459

Table VII-1: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS - All Entities

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
327212	Other Pressed and Blown Glass and Glassware Manufacturing	387	410	13,501	5,234	387	410	5,234
327213	Glass Container Manufacturing	29	69	14,426	5,593	29	69	5,593
327215	Glass Product Manufacturing Made of Purchased Glass	983	1,119	53,450	20,720	983	1,119	20,720
327310	Cement Manufacturing	101	215	14,121	5,475	101	215	5,475
327320	Ready-Mix Concrete Manufacturing	2,098	5,747	80,802	31,324	2,098	5,747	31,324
327331	Concrete Block and Brick Manufacturing	430	686	16,575	6,426	430	686	6,426
327332	Concrete Pipe Manufacturing	98	240	5,958	2,309	98	240	2,309
327390	Other Concrete Product Manufacturing	1,560	1,903	54,904	21,284	1,560	1,903	21,284
327410	Lime Manufacturing	38	95	4,225	1,638	38	95	1,638
327420	Gypsum Product Manufacturing	127	202	9,618	3,729	127	202	3,729
327910	Abrasive Product Manufacturing	256	301	12,639	4,900	256	301	4,900
327991	Cut Stone and Stone Product Manufacturing	1,907	1,982	31,577	12,241	1,907	1,982	12,241
327992	Ground or Treated Mineral and Earth Manufacturing	154	257	7,986	3,096	154	257	3,096
327993	Mineral Wool Manufacturing	174	264	14,842	5,753	174	264	5,753
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	279	423	12,324	4,777	279	423	4,777
331	**Primary Metal Manufacturing**	**3,558**	**4,287**	**370,534**	**213,151**	**3,558**	**4,287**	**213,151**
331110	Iron and Steel Mills and Ferroalloy Manufacturing	369	522	93,552	44,565	369	522	44,565
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	180	241	23,495	13,100	180	241	13,100
331221	Rolled Steel Shape Manufacturing	170	204	8,126	4,531	170	204	4,531
331222	Steel Wire Drawing	210	252	14,585	8,133	210	252	8,133
331313	Alumina Refining and Primary Aluminum Production	31	41	4,224	2,314	31	41	2,314
331314	Secondary Smelting and Alloying of Aluminum	65	87	5,338	2,924	65	87	2,924
331315	Aluminum Sheet, Plate, and Foil Manufacturing	62	90	18,759	10,277	62	90	10,277
331318	Other Aluminum Rolling, Drawing, and Extruding	212	275	29,441	16,129	212	275	16,129
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	129	146	7,908	4,332	129	146	4,332
331420	Copper Rolling, Drawing, Extruding, and Alloying	164	247	24,375	13,354	164	247	13,354
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	227	255	15,488	8,486	227	255	8,486
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	183	220	9,305	5,098	183	220	5,098
331511	Iron Foundries	298	346	32,738	22,564	298	346	22,564
331512	Steel Investment Foundries	95	114	12,986	8,950	95	114	8,950

Table VII-1: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS - All Entities

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
331513	Steel Foundries (except Investment)	189	201	11,581	7,982	189	201	7,982
331523	Nonferrous Metal Die-Casting Foundries	351	396	33,674	23,209	351	396	23,209
331524	Aluminum Foundries (except Die-Casting)	371	390	14,593	10,058	371	390	10,058
331529	Other Nonferrous Metal Foundries (except Die-Casting)	252	260	10,366	7,145	252	260	7,145
339	**Miscellaneous Manufacturing**	**26,491**	**27,778**	**545,724**	**275,482**	**26,491**	**27,778**	**275,482**
339112	Surgical and Medical Instrument Manufacturing	1,063	1,234	109,121	55,410	1,063	1,234	55,410
339113	Surgical Appliance and Supplies Manufacturing	1,651	1,867	86,837	44,095	1,651	1,867	44,095
339114	Dental Equipment and Supplies Manufacturing	557	579	15,040	7,637	557	579	7,637
339115	Ophthalmic Goods Manufacturing	336	493	25,411	12,904	336	493	12,904
339116	Dental Laboratories	5,637	5,971	41,838	21,245	5,637	5,971	21,245
339910	Jewelry and Silverware Manufacturing	1,967	1,986	23,813	14,153	1,967	1,986	14,153
339920	Sporting and Athletic Goods Manufacturing	1,586	1,649	39,326	19,373	1,586	1,649	19,373
339930	Doll, Toy, and Game Manufacturing	503	509	6,120	3,015	503	509	3,015
339940	Office Supplies (except Paper) Manufacturing	423	449	11,689	5,758	423	449	5,758
339950	Sign Manufacturing	5,602	5,727	76,353	37,615	5,602	5,727	37,615
339991	Gasket, Packing, and Sealing Device Manufacturing	490	562	28,575	14,078	490	562	14,078
339992	Musical Instrument Manufacturing	585	606	11,412	5,622	585	606	5,622
339993	Fastener, Button, Needle, and Pin Manufacturing	103	110	3,992	1,966	103	110	1,966
339994	Broom, Brush, and Mop Manufacturing	168	184	9,748	4,802	168	184	4,802
339995	Burial Casket Manufacturing	82	97	3,514	1,731	82	97	1,731
339999	All Other Miscellaneous Manufacturing	5,738	5,755	52,935	26,078	5,738	5,755	26,078
42	**Wholesale Trade**	**266,333**	**369,466**	**5,824,018**	**332,642**	**49,806**	**71,053**	**60,455**
423	**Merchant Wholesalers, Durable Goods**	**168,238**	**239,812**	**3,460,468**	**193,962**	**13,697**	**19,588**	**15,604**
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	7,886	10,125	223,659	8,539	7,886	10,125	8,539
423840	Industrial Supplies Merchant Wholesalers	5,811	9,463	105,490	7,065	5,811	9,463	7,065
424	**Merchant Wholesalers, Nondurable Goods**	**98,095**	**129,654**	**2,363,550**	**138,680**	**36,109**	**51,465**	**44,851**
424210	Drugs and Druggists' Sundries Merchant Wholesalers	6,958	10,281	304,606	17,755	6,958	10,281	17,755
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	2,218	2,968	33,302	1,941	2,218	2,968	1,941
424690	Other Chemical and Allied Products Merchant Wholesalers	6,069	9,418	126,009	7,345	6,069	9,418	7,345
424710	Petroleum Bulk Stations and Terminals	2,334	3,950	66,261	3,862	2,334	3,950	3,862
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,857	2,463	33,558	1,956	1,857	2,463	1,956

Table VII-1: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS - All Entities

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
424910	Farm Supplies Merchant Wholesalers	4,965	9,216	107,655	6,275	4,965	9,216	6,275
424950	Paint, Varnish, and Supplies Merchant Wholesalers	1,012	1,916	20,851	1,216	1,012	1,916	1,216
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,696	11,253	77,225	4,501	10,696	11,253	4,501
Total								
Total	**Total**	**6,077,430**	**7,780,863**	**148,004,068**	**9,637,950**	**115,758**	**152,427**	**1,510,780**

Sources: U.S. Census Bureau, 2020a (Document ID 0231); U.S. Census Bureau, 2020b (Document ID 0232); U.S. Census Bureau, 2019a (Document ID 0227); BLS, 2020 (Document ID 0223); U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

Note: Figures may not add to totals due to rounding.

Note: "Affected" firms, establishments, employees, labels, and SDSs are based on the maximum number affected by any one provision of the rule.

[a] Figures in these columns for two-digit and three-digit NAICS codes represent totals for the entire industry at the specified level and may exceed the total sum of the data for the affected six-digit NAICS industries that fall within the aggregated levels. This occurs because two-digit and three-digit NAICS codes may encompass some six-digit NAICS industries not covered by OSHA. (For example, NAICS 21 encompasses Mining, which is not covered by OSHA regulations.)

Table VII-2: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS - Small Entities

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
21	**Mining, Quarrying, and Oil and Gas Extraction**	**13,480**	**14,512**	**19,094**	**1,230**	**5,111**	**5,529**	**940**
211	**Oil and Gas Extraction**	**5,111**	**5,529**	**13,852**	**940**	**5,111**	**5,529**	**940**
211120	Crude Petroleum Extraction	4,519	4,842	11,392	773	4,519	4,842	773
211130	Natural Gas Extraction	592	687	2,460	167	592	687	167
31-33	**Manufacturing**	**160,080**	**168,058**	**574,144**	**298,937**	**35,641**	**39,115**	**83,501**
324	**Petroleum and Coal Products Manufacturing**	**488**	**728**	**4,238**	**1,775**	**488**	**728**	**1,775**
324110	Petroleum Refineries	8	10	3,579	1,499	8	10	1,499
324121	Asphalt Paving Mixture and Block Manufacturing	422	644	0	0	422	644	0
324191	Petroleum Lubricating Oil and Grease Manufacturing	4	9	659	276	4	9	276
324199	All Other Petroleum and Coal Products Manufacturing	54	65	0	0	54	65	0
325	**Chemical Manufacturing**	**5,729**	**6,345**	**52,927**	**19,145**	**5,729**	**6,345**	**19,145**
325110	Petrochemical Manufacturing	3	4	754	299	3	4	299
325130	Synthetic Dye and Pigment Manufacturing	5	7	1,259	501	5	7	501
325180	Other Basic Inorganic Chemical Manufacturing	24	48	3,138	1,248	24	48	1,248
325193	Ethyl Alcohol Manufacturing	3	4	97	39	3	4	39
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	37	38	282	113	37	38	113
325199	All Other Basic Organic Chemical Manufacturing	515	576	6,356	2,528	515	576	2,528
325211	Plastics Material and Resin Manufacturing	771	881	8,359	3,325	771	881	3,325
325311	Nitrogenous Fertilizer Manufacturing	3	6	140	56	3	6	56
325312	Phosphatic Fertilizer Manufacturing	5	7	110	44	5	7	44
325314	Fertilizer (Mixing Only) Manufacturing	340	409	0	0	340	409	0
325411	Medicinal and Botanical Manufacturing	8	10	2,858	882	8	10	882
325412	Pharmaceutical Preparation Manufacturing	930	988	14,680	4,530	930	988	4,530
325413	In-Vitro Diagnostic Substance Manufacturing	167	179	289	90	167	179	90
325414	Biological Product (except Diagnostic) Manufacturing	221	243	3,577	1,104	221	243	1,104
325510	Paint and Coating Manufacturing	17	38	2,819	1,121	17	38	1,121
325520	Adhesive Manufacturing	350	387	0	0	350	387	0
325612	Polish and Other Sanitation Good Manufacturing	4	4	301	120	4	4	120
325620	Toilet Preparation Manufacturing	896	924	7,113	2,829	896	924	2,829
325910	Printing Ink Manufacturing	161	243	0	0	161	243	0
325991	Custom Compounding of Purchased Resins	292	312	0	0	292	312	0
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	3	9	794	316	3	9	316
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	974	1,028	0	0	974	1,028	0
326	**Plastics and Rubber Products Manufacturing**	**1,543**	**1,883**	**52,045**	**31,437**	**1,543**	**1,883**	**31,437**
326111	Plastics Bag and Pouch Manufacturing	5	9	2,026	1,204	5	9	1,204

Table VII-2: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS - Small Entities

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	8	15	2,375	1,411	8	15	1,411
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	11	22	2,718	1,615	11	22	1,615
326121	Unlaminated Plastics Profile Shape Manufacturing	286	309	0	0	286	309	0
326122	Plastics Pipe and Pipe Fitting Manufacturing	3	12	720	428	3	12	428
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	177	186	0	0	177	186	0
326140	Polystyrene Foam Product Manufacturing	8	26	2,469	1,467	8	26	1,467
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	11	20	2,081	1,237	11	20	1,237
326160	Plastics Bottle Manufacturing	183	246	3,706	2,201	183	246	2,201
326191	Plastics Plumbing Fixture Manufacturing	5	14	1,955	1,161	5	14	1,161
326199	All Other Plastics Product Manufacturing	73	141	26,775	15,906	73	141	15,906
326211	Tire Manufacturing (except Retreading)	3	4	3,064	2,040	3	4	2,040
326212	Tire Retreading	245	283	0	0	245	283	0
326220	Rubber and Plastics Hoses and Belting Manufacturing	7	12	1,633	1,087	7	12	1,087
326291	Rubber Product Manufacturing for Mechanical Use	7	12	2,523	1,680	7	12	1,680
326299	All Other Rubber Product Manufacturing	511	572	0	0	511	572	0
327	**Nonmetallic Mineral Product Manufacturing**	**6,636**	**8,532**	**10,294**	**3,991**	**6,636**	**8,532**	**3,991**
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	4	6	1,452	563	4	6	563
327120	Clay Building Material and Refractories Manufacturing	7	30	2,182	846	7	30	846
327212	Other Pressed and Blown Glass and Glassware Manufacturing	372	379	1,387	538	372	379	538
327213	Glass Container Manufacturing	21	25	0	0	21	25	0
327215	Glass Product Manufacturing Made of Purchased Glass	7	15	2,422	939	7	15	939
327310	Cement Manufacturing	4	8	775	300	4	8	300
327320	Ready-Mix Concrete Manufacturing	2,038	3,492	0	0	2,038	3,492	0
327331	Concrete Block and Brick Manufacturing	401	514	0	0	401	514	0
327332	Concrete Pipe Manufacturing	3	16	583	226	3	16	226
327390	Other Concrete Product Manufacturing	1,511	1,659	0	0	1,511	1,659	0
327410	Lime Manufacturing	3	13	846	328	3	13	328
327991	Cut Stone and Stone Product Manufacturing	1,886	1,929	0	0	1,886	1,929	0
327992	Ground or Treated Mineral and Earth Manufacturing	125	160	0	0	125	160	0
327993	Mineral Wool Manufacturing	4	6	647	251	4	6	251
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	250	280	0	0	250	280	0
331	**Primary Metal Manufacturing**	**1,219**	**1,327**	**30,252**	**16,037**	**1,219**	**1,327**	**16,037**
331110	Iron and Steel Mills and Ferroalloy Manufacturing	26	54	13,461	6,413	26	54	6,413
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	11	28	3,431	1,913	11	28	1,913
331221	Rolled Steel Shape Manufacturing	7	7	642	358	7	7	358

Table VII-2: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS - Small Entities

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
331222	Steel Wire Drawing	9	25	3,108	1,733	9	25	1,733
331315	Aluminum Sheet, Plate, and Foil Manufacturing	49	55	0	0	49	55	0
331318	Other Aluminum Rolling, Drawing, and Extruding	8	14	2,439	1,336	8	14	1,336
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	5	9	1,066	584	5	9	584
331420	Copper Rolling, Drawing, Extruding, and Alloying	7	11	2,507	1,374	7	11	1,374
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	3	3	533	292	3	3	292
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	3	3	550	301	3	3	301
331511	Iron Foundries	3	3	309	213	3	3	213
331512	Steel Investment Foundries	6	9	2,206	1,520	6	9	1,520
331513	Steel Foundries (except Investment)	172	176	0	0	172	176	0
331523	Nonferrous Metal Die-Casting Foundries	315	323	0	0	315	323	0
331524	Aluminum Foundries (except Die-Casting)	359	367	0	0	359	367	0
331529	Other Nonferrous Metal Foundries (except Die-Casting)	236	240	0	0	236	240	0
339	**Miscellaneous Manufacturing**	**20,026**	**20,300**	**22,091**	**11,116**	**20,026**	**20,300**	**11,116**
339112	Surgical and Medical Instrument Manufacturing	26	52	9,980	5,068	26	52	5,068
339113	Surgical Appliance and Supplies Manufacturing	10	13	2,802	1,422	10	13	1,422
339114	Dental Equipment and Supplies Manufacturing	5	10	1,593	809	5	10	809
339115	Ophthalmic Goods Manufacturing	4	16	1,062	539	4	16	539
339116	Dental Laboratories	5,623	5,682	0	0	5,623	5,682	0
339910	Jewelry and Silverware Manufacturing	1,954	1,964	0	0	1,954	1,964	0
339920	Sporting and Athletic Goods Manufacturing	9	21	3,351	1,651	9	21	1,651
339930	Doll, Toy, and Game Manufacturing	498	503	0	0	498	503	0
339940	Office Supplies (except Paper) Manufacturing	6	7	1,089	536	6	7	536
339950	Sign Manufacturing	5,571	5,668	0	0	5,571	5,668	0
339991	Gasket, Packing, and Sealing Device Manufacturing	450	469	0	0	450	469	0
339992	Musical Instrument Manufacturing	3	10	2,214	1,091	3	10	1,091
339994	Broom, Brush, and Mop Manufacturing	153	160	0	0	153	160	0
339999	All Other Miscellaneous Manufacturing	5,714	5,725	0	0	5,714	5,725	0
42	**Wholesale Trade**	**255,199**	**276,509**	**332,271**	**18,450**	**47,541**	**51,142**	**3,452**
423	**Merchant Wholesalers, Durable Goods**	**161,160**	**176,375**	**179,042**	**9,549**	**13,098**	**13,961**	**439**
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	7,652	7,886	11,502	439	7,652	7,886	439
423840	Industrial Supplies Merchant Wholesalers	5,446	6,075	0	0	5,446	6,075	0
424	**Merchant Wholesalers, Nondurable Goods**	**94,039**	**100,134**	**153,229**	**8,901**	**34,443**	**37,181**	**3,013**
424210	Drugs and Druggists' Sundries Merchant Wholesalers	6,663	6,938	23,039	1,343	6,663	6,938	1,343

Table VII-2: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS - Small Entities

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	2,090	2,325	2,408	140	2,090	2,325	140
424690	Other Chemical and Allied Products Merchant Wholesalers	5,760	6,274	5,505	321	5,760	6,274	321
424710	Petroleum Bulk Stations and Terminals	2,086	2,533	8,163	476	2,086	2,533	476
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,691	1,808	3,913	228	1,691	1,808	228
424910	Farm Supplies Merchant Wholesalers	4,777	5,564	7,612	444	4,777	5,564	444
424950	Paint, Varnish, and Supplies Merchant Wholesalers	958	1,157	1,050	61	958	1,157	61
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,418	10,582	0	0	10,418	10,582	0
Total								
Total	**Total**	**5,820,799**	**6,165,382**	**9,714,667**	**496,344**	**88,293**	**95,786**	**87,893**

Sources: U.S. Census Bureau, 2020a (Document ID 0231); U.S. Census Bureau, 2020b (Document ID 0232); U.S. Census Bureau, 2019a (Document ID 0227); BLS, 2020 (Document ID 0223); U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

Note: Figures may not add to totals due to rounding.

Note: "Affected" firms, establishments, employees, labels, and SDSs are based on the maximum number affected by any one provision of the rule.

[a] Figures in these columns for two-digit and three-digit NAICS codes represent totals for the entire industry at the specified level and may exceed the total sum of the data for the affected six-digit NAICS industries that fall within the aggregated levels. This occurs because two-digit and three-digit NAICS codes may encompass some six-digit NAICS industries not covered by OSHA. (For example, NAICS 21 encompasses Mining, which is not covered by OSHA regulations.)

Table VII-3: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS – Entities With <20 Employees

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
21	**Mining, Quarrying, and Oil and Gas Extraction**	**13,018**	**13,092**	**48,895**	**2,897**	**4,573**	**4,603**	**1,031**
211	**Oil and Gas Extraction**	**4,573**	**4,603**	**15,204**	**1,031**	**4,573**	**4,603**	**1,031**
211120	Crude Petroleum Extraction	4,112	4,137	13,048	885	4,112	4,137	885
211130	Natural Gas Extraction	461	466	2,156	146	461	466	146
31-33	**Manufacturing**	**185,713**	**186,202**	**1,005,403**	**540,919**	**42,571**	**42,735**	**105,843**
324	**Petroleum and Coal Products Manufacturing**	**482**	**488**	**2,827**	**1,183**	**482**	**488**	**1,183**
324110	Petroleum Refineries	11	11	67	28	11	11	28
324121	Asphalt Paving Mixture and Block Manufacturing	233	238	1,340	561	233	238	561
324122	Asphalt Shingle and Coating Materials Manufacturing	67	67	373	156	67	67	156
324191	Petroleum Lubricating Oil and Grease Manufacturing	134	134	887	371	134	134	371
324199	All Other Petroleum and Coal Products Manufacturing	37	38	160	67	37	38	67
325	**Chemical Manufacturing**	**6,028**	**6,048**	**34,076**	**13,044**	**6,028**	**6,048**	**13,044**
325110	Petrochemical Manufacturing	7	7	63	25	7	7	25
325120	Industrial Gas Manufacturing	39	39	231	92	39	39	92
325130	Synthetic Dye and Pigment Manufacturing	58	58	282	113	58	58	113
325180	Other Basic Inorganic Chemical Manufacturing	146	146	923	367	146	146	367
325193	Ethyl Alcohol Manufacturing	18	19	87	34	18	19	34
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	20	20	124	50	20	20	50
325199	All Other Basic Organic Chemical Manufacturing	260	261	1,676	667	260	261	667
325211	Plastics Material and Resin Manufacturing	349	349	2,542	1,012	349	349	1,012
325212	Synthetic Rubber Manufacturing	64	64	360	143	64	64	143
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	40	40	281	112	40	40	112
325311	Nitrogenous Fertilizer Manufacturing	101	101	532	212	101	101	212
325312	Phosphatic Fertilizer Manufacturing	11	11	73	29	11	11	29
325314	Fertilizer (Mixing Only) Manufacturing	235	237	1,401	557	235	237	557
325320	Pesticide and Other Agricultural Chemical Manufacturing	116	118	493	196	116	118	196
325411	Medicinal and Botanical Manufacturing	271	271	1,542	476	271	271	476
325412	Pharmaceutical Preparation Manufacturing	579	584	2,929	903	579	584	903
325413	In-Vitro Diagnostic Substance Manufacturing	91	93	495	153	91	93	153
325414	Biological Product (except Diagnostic) Manufacturing	136	136	773	238	136	136	238
325510	Paint and Coating Manufacturing	683	686	4,198	1,670	683	686	1,670
325520	Adhesive Manufacturing	214	214	1,379	549	214	214	549
325611	Soap and Other Detergent Manufacturing	454	454	2,387	950	454	454	950
325612	Polish and Other Sanitation Good Manufacturing	291	291	1,576	627	291	291	627

Table VII-3: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS – Entities With <20 Employees

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
325613	Surface Active Agent Manufacturing	59	59	320	127	59	59	127
325620	Toilet Preparation Manufacturing	623	624	3,069	1,221	623	624	1,221
325910	Printing Ink Manufacturing	111	111	737	293	111	111	293
325920	Explosives Manufacturing	19	19	146	58	19	19	58
325991	Custom Compounding of Purchased Resins	179	179	1,207	480	179	179	480
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	143	145	585	232	143	145	232
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	711	712	3,665	1,458	711	712	1,458
326	**Plastics and Rubber Products Manufacturing**	**5,073**	**5,078**	**33,115**	**20,015**	**5,073**	**5,078**	**20,015**
326111	Plastics Bag and Pouch Manufacturing	112	114	783	465	112	114	465
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	101	102	710	422	101	102	422
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	215	215	1,271	755	215	215	755
326121	Unlaminated Plastics Profile Shape Manufacturing	148	148	902	536	148	148	536
326122	Plastics Pipe and Pipe Fitting Manufacturing	115	115	778	462	115	115	462
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	113	113	698	415	113	113	415
326140	Polystyrene Foam Product Manufacturing	145	145	963	572	145	145	572
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	208	208	1,492	886	208	208	886
326160	Plastics Bottle Manufacturing	66	66	418	248	66	66	248
326191	Plastics Plumbing Fixture Manufacturing	182	182	1,374	816	182	182	816
326199	All Other Plastics Product Manufacturing	2,904	2,906	18,940	11,252	2,904	2,906	11,252
326211	Tire Manufacturing (except Retreading)	38	38	182	121	38	38	121
326212	Tire Retreading	156	156	979	652	156	156	652
326220	Rubber and Plastics Hoses and Belting Manufacturing	104	104	529	352	104	104	352
326291	Rubber Product Manufacturing for Mechanical Use	162	162	1,150	765	162	162	765
326299	All Other Rubber Product Manufacturing	304	304	1,946	1,296	304	304	1,296
327	**Nonmetallic Mineral Product Manufacturing**	**6,513**	**6,589**	**39,366**	**15,256**	**6,513**	**6,589**	**15,256**
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	462	462	1,821	706	462	462	706
327120	Clay Building Material and Refractories Manufacturing	199	199	1,194	462	199	199	462
327211	Flat Glass Manufacturing	29	29	138	53	29	29	53
327212	Other Pressed and Blown Glass and Glassware Manufacturing	312	313	1,392	540	312	313	540
327213	Glass Container Manufacturing	13	13	68	26	13	13	26
327215	Glass Product Manufacturing Made of Purchased Glass	736	737	3,309	1,283	736	737	1,283
327310	Cement Manufacturing	54	56	291	112	54	56	112
327320	Ready-Mix Concrete Manufacturing	1,275	1,325	9,138	3,542	1,275	1,325	3,542

Table VII-3: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS – Entities With <20 Employees

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
327331	Concrete Block and Brick Manufacturing	241	245	1,773	687	241	245	687
327332	Concrete Pipe Manufacturing	47	47	350	135	47	47	135
327390	Other Concrete Product Manufacturing	1,018	1,022	6,776	2,626	1,018	1,022	2,626
327410	Lime Manufacturing	17	18	111	43	17	18	43
327420	Gypsum Product Manufacturing	98	98	518	201	98	98	201
327910	Abrasive Product Manufacturing	159	159	1,156	448	159	159	448
327991	Cut Stone and Stone Product Manufacturing	1,506	1,516	9,185	3,560	1,506	1,516	3,560
327992	Ground or Treated Mineral and Earth Manufacturing	70	71	409	159	70	71	159
327993	Mineral Wool Manufacturing	99	99	663	257	99	99	257
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	178	180	1,074	416	178	180	416
331	**Primary Metal Manufacturing**	**1,802**	**1,806**	**11,156**	**6,831**	**1,802**	**1,806**	**6,831**
331110	Iron and Steel Mills and Ferroalloy Manufacturing	197	197	1,088	518	197	197	518
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	50	50	268	149	50	50	149
331221	Rolled Steel Shape Manufacturing	85	85	518	289	85	85	289
331222	Steel Wire Drawing	113	113	566	316	113	113	316
331313	Alumina Refining and Primary Aluminum Production	12	12	24	13	12	12	13
331314	Secondary Smelting and Alloying of Aluminum	19	19	77	42	19	19	42
331315	Aluminum Sheet, Plate, and Foil Manufacturing	31	31	217	119	31	31	119
331318	Other Aluminum Rolling, Drawing, and Extruding	98	98	572	314	98	98	314
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	76	77	434	238	76	77	238
331420	Copper Rolling, Drawing, Extruding, and Alloying	63	63	447	245	63	63	245
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	141	142	810	444	141	142	444
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	98	100	589	322	98	100	322
331511	Iron Foundries	138	138	932	643	138	138	643
331512	Steel Investment Foundries	26	26	292	201	26	26	201
331513	Steel Foundries (except Investment)	89	89	576	397	89	89	397
331523	Nonferrous Metal Die-Casting Foundries	180	180	1,201	828	180	180	828
331524	Aluminum Foundries (except Die-Casting)	227	227	1,404	967	227	227	967
331529	Other Nonferrous Metal Foundries (except Die-Casting)	159	159	1,141	786	159	159	786
339	**Miscellaneous Manufacturing**	**22,673**	**22,726**	**98,204**	**49,514**	**22,673**	**22,726**	**49,514**
339112	Surgical and Medical Instrument Manufacturing	651	651	3,655	1,856	651	651	1,856
339113	Surgical Appliance and Supplies Manufacturing	1,179	1,200	6,567	3,335	1,179	1,200	3,335
339114	Dental Equipment and Supplies Manufacturing	468	469	1,910	970	468	469	970
339115	Ophthalmic Goods Manufacturing	257	257	1,254	637	257	257	637

Table VII-3: Characteristics of Industries Affected by OSHA's Proposed Revisions to the HCS – Entities With <20 Employees

NAICS Code	Industry	Total Firms	Total Establishments	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
339116	Dental Laboratories	5,294	5,301	18,710	9,501	5,294	5,301	9,501
339910	Jewelry and Silverware Manufacturing	1,763	1,765	6,344	3,771	1,763	1,765	3,771
339920	Sporting and Athletic Goods Manufacturing	1,289	1,293	6,226	3,067	1,289	1,293	3,067
339930	Doll, Toy, and Game Manufacturing	434	434	1,793	884	434	434	884
339940	Office Supplies (except Paper) Manufacturing	328	333	1,751	863	328	333	863
339950	Sign Manufacturing	4,774	4,784	22,211	10,942	4,774	4,784	10,942
339991	Gasket, Packing, and Sealing Device Manufacturing	293	294	2,067	1,018	293	294	1,018
339992	Musical Instrument Manufacturing	504	504	2,217	1,093	504	504	1,093
339993	Fastener, Button, Needle, and Pin Manufacturing	76	76	343	169	76	76	169
339994	Broom, Brush, and Mop Manufacturing	96	96	688	339	96	96	339
339995	Burial Casket Manufacturing	59	60	264	131	59	60	131
339999	All Other Miscellaneous Manufacturing	5,208	5,209	22,204	10,938	5,208	5,209	10,938
42	**Wholesale Trade**	**218,009**	**221,402**	**963,936**	**56,187**	**41,030**	**41,674**	**9,616**
423	**Merchant Wholesalers, Durable Goods**	**137,679**	**140,001**	**623,928**	**36,113**	**11,469**	**11,624**	**2,448**
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	6,893	6,935	24,628	941	6,893	6,935	941
423840	Industrial Supplies Merchant Wholesalers	4,576	4,689	22,501	1,507	4,576	4,689	1,507
424	**Merchant Wholesalers, Nondurable Goods**	**80,330**	**81,401**	**340,008**	**20,074**	**29,561**	**30,050**	**7,168**
424210	Drugs and Druggists' Sundries Merchant Wholesalers	5,661	5,708	23,356	1,361	5,661	5,708	1,361
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	1,782	1,834	8,416	491	1,782	1,834	491
424690	Other Chemical and Allied Products Merchant Wholesalers	4,967	5,079	21,771	1,269	4,967	5,079	1,269
424710	Petroleum Bulk Stations and Terminals	1,334	1,398	8,878	517	1,334	1,398	517
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,301	1,315	5,697	332	1,301	1,315	332
424910	Farm Supplies Merchant Wholesalers	3,985	4,075	18,351	1,070	3,985	4,075	1,070
424950	Paint, Varnish, and Supplies Merchant Wholesalers	803	863	4,120	240	803	863	240
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	9,728	9,778	32,394	1,888	9,728	9,778	1,888
Total								
Total	**Total**	**5,305,646**	**5,348,612**	**21,017,269**	**900,039**	**88,174**	**89,012**	**116,490**

Sources: U.S. Census Bureau, 2020a (Document ID 0231); U.S. Census Bureau, 2020b (Document ID 0232); U.S. Census Bureau, 2019a (Document ID 0227); BLS, 2020 (Document ID 0223); U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

Note: Figures may not add to totals due to rounding.

Note: 'Affected" firms, establishments, employees, labels, and SDSs are based on the maximum number affected by any one provision of the rule.

[a] Figures in these columns for two-digit and three-digit NAICS codes represent totals for the entire industry at the specified level and may exceed the total sum of the data for the affected six-digit NAICS industries that fall within the aggregated levels. This occurs because two-digit and three-digit NAICS codes may encompass some six-digit NAICS industries not covered by OSHA. (For example, NAICS 21 encompasses Mining, which is not covered by OSHA regulations.)

The costs and cost savings of some of the proposed provisions (new classification criteria for select hazards and labels on very small containers) are

driven by the number of SDSs (and labels) that manufacturers must redesign as a result of the new criteria and the number of labels on very small containers. In support of the cost analysis to follow later in this PEA, Table VII–4 presents OSHA's preliminary estimate of the number of labels per container by container size (and type).[17] Starting with the fifth row (container type: 250 ml container), Table VII–4 is drawn from data in a table (Table VI–5) presented in the FEA in support of the 2012 HCS final rule (77 FR 17640), but OSHA has updated the data to include smaller containers to permit evaluation of the impacts of the small container and very small container labeling provisions proposed in paragraph (f)(12). Also, the term ''jug'' has been changed to the more generic term ''container.'' The figures in Table VII–4 are slightly different than some of the figures in Table VI–5 of the 2012 FEA due to a change in OSHA's approach to rounding and the reporting of more significant digits.

TABLE VII–4—CHEMICAL CONTAINER ESTIMATED TYPICAL SHIPMENT WEIGHTS

Container type	Estimated shipment weight (lbs.)			Number of labels per container [a]
	Minimum	Typical	Maximum	
3 ml container	0.01	0.01	0.01	1.13
30 ml container	0.06	0.08	0.13	1.13
60 ml container	0.12	0.16	0.26	1.13
125 ml container	0.25	0.33	0.54	1.13
250 ml container	0.50	0.67	1.08	1.13
500 ml container	0.92	1.26	2.08	1.13
1 liter container	1.84	2.51	4.16	1.25
2 liter container	3.57	4.92	8.22	1.25
1 gallon container	6.83	9.38	15.63	1.25
2.5 gallon container	18.00	24.38	40.00	1.50
5 gallon drum	34.95	47.71	78.95	1.00
30 gallon drum	202.00	278.56	466.00	1.00
55 gallon drum	371.00	511.37	855.00	1.00
275 gallon tote	1,830.00	2,531.84	4,250.00	1.00
330 gallon tote	2,196.00	3,038.21	5,100.00	1.00
Tank Truck—5.5k g	34,100.00	48,136.79	82,500.00	0.00
Tank Truck—7.0k g	43,400.00	61,265.00	105,000.00	0.00
Rail Car—20k g	128,805.00	181,825.77	311,625.00	0.00
Rail Car—30k g	186,000.00	262,564.29	450,000.00	0.00
Barge	2,670,774.00	3,770,160.58	6,461,550.00	0.00

[a] Assumes 8 units per package for containers smaller than 1 liter, 4 units per package for containers from 1 liter to 1 gallon in volume, and 2 units per package for 2.5-gallon containers.

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

As will be discussed at greater length below in Section VII.F. Compliance Costs and Cost Savings, it is OSHA's understanding that chemical manufacturers and importers periodically review, revise, and update the electronic templates they use to create SDSs and labels. Changes are made, for example, as information regarding specific hazards becomes available, new information about protective measures is ascertained, or revisions are made to product information and marketing materials. Labels and SDSs are also produced and modified when products are first introduced to the market or when products change. In this PEA, the terms ''electronic templates'' and ''electronic files'' are used interchangeably with, and as proxies for, the term ''SDS.'' All three terms refer to the electronic files that are used to generate SDSs and labels. Table VII–5 provides, by covered NAICS industry, estimates of the total number of labels, the number of labels on very small containers (containers of 3 ml capacity or less), the total number of SDSs, and the number of labels and SDSs affected by the proposed revisions to the HCS classification criteria. The term ''SDS'' in the column headers and in the discussion below represents the estimated number of electronic templates (files) that are used to create SDSs and labels. The derivation of these estimates is discussed below. OSHA invites public comment on its understanding about the use of electronic template files to create SDSs and labels.

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[17] As reflected in Table VI–4, OSHA assumes one outer packaging with an additional label for every two 2.5-gallon containers; one outer packaging with an additional label for every four 1-liter, 2-liter, and 1-gallon containers; and one outer packaging with an additional label for every eight containers smaller than 1 liter.

Table VII-5: Labels and SDSs Affected by OSHA's Proposed Revisions to the HCS - All Entities

NAICS Code	Industry	Total Labels [a]	Total Labels for Very Small Containers [a]	Total SDSs [a]	Labels Affected by Revision [a]	Affected Labels for Very Small Containers [a]	Affected SDSs [a]
21	**Mining, Quarrying, and Oil and Gas Extraction**	**109,265,032**	**31,076,423**	**60,975**	**109,265,032**	**0**	**60,975**
211	**Oil and Gas Extraction**	**109,265,032**	**31,076,423**	**60,975**	**109,265,032**	**0**	**60,975**
211120	Crude Petroleum Extraction	3,541,929	0	45,165	3,541,929	0	45,165
211130	Natural Gas Extraction	105,723,103	31,076,423	15,810	105,723,103	0	15,810
31-33	**Manufacturing**	**869,081,754**	**116,523,050**	**1,458,531**	**851,788,962**	**25,394,066**	**1,373,596**
324	**Petroleum and Coal Products Manufacturing**	**14,882,436**	**0**	**863,711**	**14,882,436**	**0**	**863,711**
324110	Petroleum Refineries	14,086,121	0	19,760	14,086,121	0	19,760
324121	Asphalt Paving Mixture and Block Manufacturing	288,308	0	133,225	288,308	0	133,225
324122	Asphalt Shingle and Coating Materials Manufacturing	78,955	0	17,140	78,955	0	17,140
324191	Petroleum Lubricating Oil and Grease Manufacturing	345,015	0	688,691	345,015	0	688,691
324199	All Other Petroleum and Coal Products Manufacturing	84,036	0	4,895	84,036	0	4,895
325	**Chemical Manufacturing**	**822,909,392**	**116,523,050**	**470,608**	**822,909,392**	**25,394,066**	**470,608**
325110	Petrochemical Manufacturing	84,164,339	24,739,404	4,075	84,164,339	0	4,075
325120	Industrial Gas Manufacturing	14,647,038	4,305,375	4,635	14,647,038	0	4,635
325130	Synthetic Dye and Pigment Manufacturing	11,012,449	3,237,017	3,564	11,012,449	0	3,564
325180	Other Basic Inorganic Chemical Manufacturing	50,242,702	14,768,423	4,744	50,242,702	5,907,369	4,744
325193	Ethyl Alcohol Manufacturing	3,329,934	0	4,955	3,329,934	0	4,955
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	22,604,370	0	3,635	22,604,370	0	3,635
325199	All Other Basic Organic Chemical Manufacturing	120,855,181	35,524,371	29,172	120,855,181	14,209,748	29,172
325211	Plastics Material and Resin Manufacturing	4,515,944	0	104,079	4,515,944	0	104,079
325212	Synthetic Rubber Manufacturing	416,487	0	1,803	416,487	0	1,803
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	1,219,708	0	198	1,219,708	0	198
325311	Nitrogenous Fertilizer Manufacturing	4,450,484	0	262	4,450,484	0	262
325312	Phosphatic Fertilizer Manufacturing	8,644,852	2,541,082	122	8,644,852	0	122
325314	Fertilizer (Mixing Only) Manufacturing	3,552,710	0	3,654	3,552,710	0	3,654
325320	Pesticide and Other Agricultural Chemical Manufacturing	23,587,843	6,933,449	4,939	23,587,843	0	4,939
325411	Medicinal and Botanical Manufacturing	17,371,394	5,106,176	4,735	17,371,394	2,042,471	4,735
325412	Pharmaceutical Preparation Manufacturing	24,482,293	6,471,452	15,930	24,482,293	2,588,581	15,930
325413	In-Vitro Diagnostic Substance Manufacturing	1,897,855	501,664	26,971	1,897,855	200,665	26,971
325414	Biological Product (except Diagnostic) Manufacturing	4,210,917	1,113,080	3,338	4,210,917	445,232	3,338
325510	Paint and Coating Manufacturing	79,598,930	0	77,290	79,598,930	0	77,290
325520	Adhesive Manufacturing	42,641,685	0	29,540	42,641,685	0	29,540
325611	Soap and Other Detergent Manufacturing	38,380,263	11,281,558	16,925	38,380,263	0	16,925
325612	Polish and Other Sanitation Good Manufacturing	17,808,975	0	10,887	17,808,975	0	10,887

Table VII-5: Labels and SDSs Affected by OSHA's Proposed Revisions to the HCS - All Entities

NAICS Code	Industry	Total Labels [a]	Total Labels for Very Small Containers [a]	Total SDSs [a]	Labels Affected by Revision [a]	Affected Labels for Very Small Containers [a]	Affected SDSs [a]
325613	Surface Active Agent Manufacturing	20,727,699	0	5,255	20,727,699	0	5,255
325620	Toilet Preparation Manufacturing	119,801,629	0	18,258	119,801,629	0	18,258
325910	Printing Ink Manufacturing	12,550,924	0	34,737	12,550,924	0	34,737
325920	Explosives Manufacturing	6,873,598	0	2,743	6,873,598	0	2,743
325991	Custom Compounding of Purchased Resins	565,592	0	3,978	565,592	0	3,978
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	19,478,621	0	1,475	19,478,621	0	1,475
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	63,274,976	0	48,515	63,274,976	0	48,515
339	**Miscellaneous Manufacturing**	**13,997,134**	**0**	**39,277**	**13,997,134**	**0**	**39,277**
339112	Surgical and Medical Instrument Manufacturing	3,710,501	0	2,885	3,710,501	0	2,885
339113	Surgical Appliance and Supplies Manufacturing	3,213,294	0	3,548	3,213,294	0	3,548
339114	Dental Equipment and Supplies Manufacturing	455,499	0	866	455,499	0	866
339115	Ophthalmic Goods Manufacturing	549,159	0	1,302	549,159	0	1,302
339116	Dental Laboratories	446,775	0	7,676	446,775	0	7,676
339910	Jewelry and Silverware Manufacturing	667,355	0	2,369	667,355	0	2,369
339920	Sporting and Athletic Goods Manufacturing	947,796	0	2,431	947,796	0	2,431
339930	Doll, Toy, and Game Manufacturing	152,994	0	644	152,994	0	644
339940	Office Supplies (except Paper) Manufacturing	295,239	0	715	295,239	0	715
339950	Sign Manufacturing	1,174,913	0	7,375	1,174,913	0	7,375
339991	Gasket, Packing, and Sealing Device Manufacturing	670,470	0	1,250	670,470	0	1,250
339992	Musical Instrument Manufacturing	181,405	0	825	181,405	0	825
339993	Fastener, Button, Needle, and Pin Manufacturing	82,942	0	198	82,942	0	198
339994	Broom, Brush, and Mop Manufacturing	263,932	0	395	263,932	0	395
339995	Burial Casket Manufacturing	52,961	0	191	52,961	0	191
339999	All Other Miscellaneous Manufacturing	1,131,899	0	6,607	1,131,899	0	6,607
Total							
Total	Total	**1,512,219,200**	**147,599,473**	**1,519,312**	**961,053,993**	**25,394,066**	**1,434,377**

Sources: U.S. Census Bureau, 2020a (Document ID 0231); U.S. Census Bureau, 2020b (Document ID 0232); U.S. Census Bureau, 2019a (Document ID 0227); BLS, 2020 (Document ID 0223); U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

Note: Figures may not add to totals due to rounding.

Note: "Affected" firms, establishments, employees, labels, and SDSs are based on the maximum number affected by any one provision of the rule.

[a] Figures in these columns for two-digit and three-digit NAICS codes represent totals for the entire industry at the specified level and may exceed the total sum of the data for the affected six-digit NAICS industries that fall within the aggregated levels. This occurs because two-digit and three-digit NAICS codes may encompass some six-digit NAICS industries not covered by OSHA. (For example, NAICS 21 encompasses Mining, which is not covered by OSHA regulations.)

OSHA's estimate of the total number of SDSs per NAICS industry, as presented in Table VII–5, was developed by its contractor to support

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the agency's FEA for the 2012 final standard.[18] The analysis started with the number of SDSs per establishment by establishment size, as originally derived in the economic analysis in support of the 2009 proposed HCS rule (Document ID 0029) using a sampling of company websites and the SDSs posted there.[19] The analysis then combined the estimated number of SDSs per establishment by establishment size with the estimated number of establishments to estimate the weighted average number of SDSs per establishment in a given NAICS industry. This estimate was then multiplied by the average number of establishments per firm to estimate the number of SDSs per firm for each NAICS industry. Multiplying by the number of firms per NAICS industry yields the total number of SDSs in each NAICS industry (as shown in Column 5 of Table VII–5). Although OSHA has preliminarily determined that this methodology remains sound, the agency invites public comment on the reasonableness of this methodology for the current analysis.

OSHA's estimate of the number of labels per NAICS industry is constructed using the same methodology developed in the 2012 HCS final rule (Document ID 0005, pp. 17634–17643), but with more recent data. The steps in the analysis, elaborated on below, can be summarized as follows:

- Begin with data on shipment weight by commodity code and shipment weight class.
- Estimate the average weight per container for containers of various sizes.
- Allocate the tons shipped in each shipment weight class for certain sizes of containers.
- Divide the tons shipped by the average container weight to estimate total containers.
- Multiply the containers by the average number of labels per container to estimate total labels.
- Allot the labels among NAICS codes using receipts data.

The label analysis begins with the U.S. Census Bureau and the U.S. Department of Transportation's jointly-produced Commodity Flow Survey (CFS) (U.S. Census Bureau, 2014a, Document ID 0024) data on shipment characteristics by commodity and shipment weight. This dataset includes the number of tons shipped for a range of shipment weight classes by Standard Classification of Transported Goods (SCTG) code. The number of tons is converted to pounds, and limited to hazardous non-consumer products (*i.e.,* those that would have the HCS labeling).[20] This estimate is used in conjunction with another CFS dataset (U.S. Census Bureau, 2014b, Document ID 0030) that has shipment data by NAICS industry (but not by shipment weight) to divide the detailed shipment weight data into shipments coming from manufacturers and distributors.

The next step in the methodology estimated the representative weight per container for a variety of types of containers (ranging in size from a 3-milliliter vial to a rail car) and substances (such as antifreeze, diesel fuel, paint). Using representative substances, OSHA estimated the shipment weight for one container of each size as *Shipment Weight = (Product Weight per gallon × Container Capacity) + Container Weight.* Because of a lack of available data establishing the percentage of products shipped by container type (*i.e.,* the breakdown of the types of products shipped by each container type), the calculation for each product and container type relied on professional judgment (by OSHA and its economic contractor, ERG) to select a ''typical'' product weight per gallon and container weight for each container type. Next, the analysis estimated shipment weight per container by multiplying the average product weight per gallon times the number of gallons per container, plus the container weight.

To convert the CFS data on tons (or pounds) shipped by container size into a number of containers, the analysis estimated the percentage of each shipment class likely to be shipped in certain sizes of containers. Shipments of lower weights are generally estimated to be shipped in smaller containers, and vice versa. Then the total non-consumer hazardous pounds shipped (from the CFS data) was multiplied by the estimated percentage shipped in each container type to yield the number of non-consumer hazardous pounds in each container type. Finally, the non-consumer hazardous pounds in each container type was divided by the average weight per container type to yield an estimate of the total number of containers.

To estimate the number of labels that would be used on these containers, the analysis first estimated the average number of labels on a single container for each container size (from Table VII–4 above). As previously noted, these estimates account for the fact that some containers have outer packaging that would require an additional label under this proposed rule (*e.g.,* kits containing containers less than 100 ml where tags and fold out labels are infeasible) or are shipped with several containers grouped into a single outer container with a label. This average number of labels per container for each shipment size class was then multiplied by the number of containers to estimate the total number of labels.

The final step in the analysis was to allocate the number of labels shipped from SCTG codes to NAICS codes. The NAICS-to-SCTG mapping was adapted from the mapping used in the FEA in support of the 2012 HCS final rule analysis, but with NAICS categories updated from 2007 to 2017 categories. U.S. Census (2020a; 2020b) Statistics of U.S. Businesses data was used to estimate each NAICS industry's share of total receipts for the SCTG code with which it corresponds, and then the number of labels in each SCTG was allocated proportionally. (This calculation was performed separately for shipments from manufacturers and from distributors for purposes of estimating cost savings due to the proposed released-for-shipment provision in paragraph (f)(11)). This resulted in the estimated number of labels shown in Column 3 of Table VII–5.[21]

To estimate the number of labels on very small containers (those on containers with a volume capacity of 3 ml or less), the same analysis was performed, but it was limited to containers in that size range. The resulting estimates of the number of

[18] Technical and analytical support for this preliminary economic analysis was provided by Eastern Research Group, Inc. under Contract No. DOL–OPS–16–D–0012.

[19] This methodology was not challenged by commenters during the rulemaking that resulted in the 2012 final rule.

[20] The estimated percentages for the transported goods identified as hazardous non-consumer products were presented in the 2012 HCS FEA cost model. See ERG/OSHA, 2012, Document ID 0029). At the time OSHA developed this PEA, the final 2017 CFS data was not yet available. Therefore, 2012 CFS data was the most recent information available. OSHA requests public comments on the estimated percentages for the transported goods identified as hazardous non-consumer products in this preliminary profile.

[21] For example, NAICS 211130—Natural Gas Extraction is categorized as a basic chemicals manufacturer, or Code 20 in the SCTG commodity coding system. Across the range of container types and container weights shown in Table VII–4, the analysis led to an estimate of the total number of labels (474,629,165) required by all SCTG Code 20 manufacturers (see Document ID 0049, tab ''Labels per NAICS'', cell O11). The percentage of receipts (22.3 percent) for NAICS 211130 relative to total receipts for SCTG Code 20 employers (Document ID 0049, tab ''Labels per NAICS'', cells N11–P11) was then applied to this total number of labels. The result, shown in Column 3 in Table VII–5, is an estimated 105,723,103 labels for NAICS 2111130. Note that multiplying factors may yield a slightly different total due to rounding of the factors in the table (but not in the spreadsheet).

labels on very small containers is shown in Column 4 of Table VII–5.

Not every SDS and label, and not every label on very small containers, would be affected by the proposed rule. Only SDSs and labels for certain products (aerosols, desensitized explosives, and flammable gases) would be affected by the new classification criteria. Only certain very small containers would be covered by proposed paragraph (f)(12)(iii), which would eliminate some labeling requirements in certain circumstances. In particular, under proposed paragraph (f)(12)(iii), only a product identifier would be required on the immediate outer package of very small containers (3 ml or less) where the manufacturer, importer, or distributor can demonstrate that a label would interfere with the normal use of the container and that it is not feasible to use pull-out labels, fold-back labels, or tags containing the full label information. Thus, in addition to the estimated total number of SDSs, labels, and labels on very small containers, Table VII–5 shows the number of each estimated to be affected by this proposed rule.[22]

Tables VII–6 and VII–7, respectively, provide information on total numbers of SDSs, labels, and labels on very small containers, and on the numbers of SDSs and labels (including labels on very small containers) affected by reclassification and the provisions for labels on very small containers, for all covered small entities and very small entities.

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[22] Note that OSHA's cost estimates for reclassifying affected chemicals and revising the corresponding SDSs and labels to achieve consistency with the reclassification (per proposed changes to Appendix B), and for revising SDSs and labels to conform with new precautionary statements and other new mandatory language in the appendices to the HCS (per proposed changes to Appendices C and D), are based on the costs associated with chemical manufacturers editing their electronic files (which are used to produce labels and SDSs) for each product for which reclassification would be required as a result of the proposed rule. They are not based on the number of labels or SDSs actually produced or used.

Table VII-6: Labels and SDSs Affected by OSHA's Proposed Revisions to the HCS - Small Entities

NAICS Code	Industry	Total Labels [a]	Total Labels for Very Small Containers [a]	Total SDSs [a]	Labels Affected by Revision [a]	Affected Labels for Very Small Containers [a]	Affected SDSs [a]
21	**Mining, Quarrying, and Oil and Gas Extraction**	**40,513,599**	**11,453,477**	**51,139**	**40,513,599**	**0**	**51,139**
211	**Oil and Gas Extraction**	**40,513,599**	**11,453,477**	**51,139**	**40,513,599**	**0**	**51,139**
211120	Crude Petroleum Extraction	1,548,460	0	41,007	1,548,460	0	41,007
211130	Natural Gas Extraction	38,965,139	11,453,477	10,132	38,965,139	0	10,132
31-33	**Manufacturing**	**154,650,912**	**13,026,348**	**296,902**	**152,383,341**	**5,031,528**	**272,736**
324	**Petroleum and Coal Products Manufacturing**	**951,525**	**0**	**48,486**	**951,525**	**0**	**48,486**
324110	Petroleum Refineries	760,797	0	1,275	760,797	0	1,275
324121	Asphalt Paving Mixture and Block Manufacturing	132,182	0	25,675	132,182	0	25,675
324191	Petroleum Lubricating Oil and Grease Manufacturing	25,936	0	19,491	25,936	0	19,491
324199	All Other Petroleum and Coal Products Manufacturing	32,610	0	2,045	32,610	0	2,045
325	**Chemical Manufacturing**	**147,916,748**	**13,026,348**	**200,290**	**147,916,748**	**5,031,528**	**200,290**
325110	Petrochemical Manufacturing	0	0	388	0	0	388
325130	Synthetic Dye and Pigment Manufacturing	1,371,499	403,141	171	1,371,499	0	171
325180	Other Basic Inorganic Chemical Manufacturing	3,389,492	996,313	364	3,389,492	398,525	364
325193	Ethyl Alcohol Manufacturing	32,507	0	94	32,507	0	94
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	3,561,423	0	1,771	3,561,423	0	1,771
325199	All Other Basic Organic Chemical Manufacturing	33,772,365	9,927,105	20,643	33,772,365	3,970,842	20,643
325211	Plastics Material and Resin Manufacturing	1,136,274	0	81,505	1,136,274	0	81,505
325311	Nitrogenous Fertilizer Manufacturing	0	0	8	0	0	8
325312	Phosphatic Fertilizer Manufacturing	151,003	44,386	12	151,003	0	12
325314	Fertilizer (Mixing Only) Manufacturing	2,521,919	0	2,054	2,521,919	0	2,054
325411	Medicinal and Botanical Manufacturing	1,080,369	317,565	96	1,080,369	127,026	96
325412	Pharmaceutical Preparation Manufacturing	3,950,891	1,044,347	12,296	3,950,891	417,739	12,296
325413	In-Vitro Diagnostic Substance Manufacturing	338,578	89,497	20,371	338,578	35,799	20,371
325414	Biological Product (except Diagnostic) Manufacturing	771,736	203,994	2,379	771,736	81,598	2,379
325510	Paint and Coating Manufacturing	5,957,343	0	2,454	5,957,343	0	2,454
325520	Adhesive Manufacturing	14,032,371	0	8,900	14,032,371	0	8,900
325612	Polish and Other Sanitation Good Manufacturing	336,955	0	95	336,955	0	95
325620	Toilet Preparation Manufacturing	46,326,620	0	17,145	46,326,620	0	17,145
325910	Printing Ink Manufacturing	3,879,379	0	9,987	3,879,379	0	9,987
325991	Custom Compounding of Purchased Resins	233,151	0	1,278	233,151	0	1,278
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	0	0	65	0	0	65
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	25,072,874	0	18,215	25,072,874	0	18,215
339	**Miscellaneous Manufacturing**	**3,515,068**	**0**	**23,960**	**3,515,068**	**0**	**23,960**
339112	Surgical and Medical Instrument Manufacturing	378,353	0	122	378,353	0	122

Table VII-6: Labels and SDSs Affected by OSHA's Proposed Revisions to the HCS - Small Entities

NAICS Code	Industry	Total Labels [a]	Total Labels for Very Small Containers [a]	Total SDSs [a]	Labels Affected by Revision [a]	Affected Labels for Very Small Containers [a]	Affected SDSs [a]
339113	Surgical Appliance and Supplies Manufacturing	86,950	0	25	86,950	0	25
339114	Dental Equipment and Supplies Manufacturing	60,444	0	15	60,444	0	15
339115	Ophthalmic Goods Manufacturing	17,565	0	42	17,565	0	42
339116	Dental Laboratories	333,595	0	6,231	333,595	0	6,231
339910	Jewelry and Silverware Manufacturing	349,044	0	2,259	349,044	0	2,259
339920	Sporting and Athletic Goods Manufacturing	109,838	0	31	109,838	0	31
339930	Doll, Toy, and Game Manufacturing	115,450	0	614	115,450	0	614
339940	Office Supplies (except Paper) Manufacturing	40,925	0	11	40,925	0	11
339950	Sign Manufacturing	957,512	0	7,080	957,512	0	7,080
339991	Gasket, Packing, and Sealing Device Manufacturing	222,738	0	785	222,738	0	785
339992	Musical Instrument Manufacturing	41,387	0	14	41,387	0	14
339994	Broom, Brush, and Mop Manufacturing	103,196	0	275	103,196	0	275
339999	All Other Miscellaneous Manufacturing	698,072	0	6,457	698,072	0	6,457
Total							
Total	Total	**316,792,075**	**24,479,825**	**348,040**	**192,896,939**	**5,031,528**	**323,875**

Sources: U.S. Census Bureau, 2020a (Document ID 0231); U.S. Census Bureau, 2020b (Document ID 0232); U.S. Census Bureau, 2019a (Document ID 0227); BLS, 2020 (Document ID 0223); U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

Note: Figures may not add to totals due to rounding.

Note: "Affected" firms, establishments, employees, labels, and SDSs are based on the maximum number affected by any one provision of the rule.

[a] Figures in these columns for two-digit and three-digit NAICS codes represent totals for the entire industry at the specified level and may exceed the total sum of the data for the affected six-digit NAICS industries that fall within the aggregated levels. This occurs because two-digit and three-digit NAICS codes may encompass some six-digit NAICS industries not covered by OSHA. (For example, NAICS 21 encompasses Mining, which is not covered by OSHA regulations.)

Table VII-7: Labels and SDSs Affected by OSHA's Proposed Revisions to the HCS – Entities with <20 Employees

NAICS Code	Industry	Total Labels [a]	Total Labels for Very Small Containers [a]	Total SDSs [a]	Labels Affected by Revision [a]	Affected Labels for Very Small Containers [a]	Affected SDSs [a]
21	**Mining, Quarrying, and Oil and Gas Extraction**	**3,442,500**	**962,003**	**23,015**	**3,442,500**	**0**	**23,015**
211	**Oil and Gas Extraction**	**3,442,500**	**962,003**	**23,015**	**3,442,500**	**0**	**23,015**
211120	Crude Petroleum Extraction	169,732	0	20,685	169,732	0	20,685
211130	Natural Gas Extraction	3,272,767	962,003	2,330	3,272,767	0	2,330
31-33	**Manufacturing**	**25,324,696**	**1,671,645**	**92,576**	**24,758,901**	**418,638**	**79,103**
324	**Petroleum and Coal Products Manufacturing**	**43,576**	**0**	**30,340**	**43,576**	**0**	**30,340**
324110	Petroleum Refineries	2,870	0	110	2,870	0	110
324121	Asphalt Paving Mixture and Block Manufacturing	25,467	0	2,380	25,467	0	2,380
324122	Asphalt Shingle and Coating Materials Manufacturing	2,067	0	670	2,067	0	670
324191	Petroleum Lubricating Oil and Grease Manufacturing	10,732	0	26,800	10,732	0	26,800
324199	All Other Petroleum and Coal Products Manufacturing	2,441	0	380	2,441	0	380
325	**Chemical Manufacturing**	**23,424,443**	**1,671,645**	**26,037**	**23,424,443**	**418,638**	**26,037**
325110	Petrochemical Manufacturing	81,759	24,032	70	81,759	0	70
325120	Industrial Gas Manufacturing	171,736	50,480	78	171,736	0	78
325130	Synthetic Dye and Pigment Manufacturing	231,464	68,037	464	231,464	0	464
325180	Other Basic Inorganic Chemical Manufacturing	874,414	257,027	584	874,414	102,811	584
325193	Ethyl Alcohol Manufacturing	24,475	0	95	24,475	0	95
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	225,874	0	140	225,874	0	140
325199	All Other Basic Organic Chemical Manufacturing	1,688,568	496,340	1,827	1,688,568	198,536	1,827
325211	Plastics Material and Resin Manufacturing	55,238	0	1,745	55,238	0	1,745
325212	Synthetic Rubber Manufacturing	8,822	0	128	8,822	0	128
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	18,222	0	40	18,222	0	40
325311	Nitrogenous Fertilizer Manufacturing	244,859	0	101	244,859	0	101
325312	Phosphatic Fertilizer Manufacturing	94,200	27,689	11	94,200	0	11
325314	Fertilizer (Mixing Only) Manufacturing	421,604	0	474	421,604	0	474
325320	Pesticide and Other Agricultural Chemical Manufacturing	566,329	166,468	826	566,329	0	826
325411	Medicinal and Botanical Manufacturing	695,866	204,544	1,355	695,866	81,818	1,355
325412	Pharmaceutical Preparation Manufacturing	245,447	64,879	2,920	245,447	25,952	2,920
325413	In-Vitro Diagnostic Substance Manufacturing	19,986	5,283	930	19,986	2,113	930
325414	Biological Product (except Diagnostic) Manufacturing	70,070	18,522	408	70,070	7,409	408
325510	Paint and Coating Manufacturing	4,308,873	0	3,430	4,308,873	0	3,430
325520	Adhesive Manufacturing	1,807,407	0	1,070	1,807,407	0	1,070
325611	Soap and Other Detergent Manufacturing	980,956	288,344	2,270	980,956	0	2,270
325612	Polish and Other Sanitation Good Manufacturing	1,175,050	0	582	1,175,050	0	582

Table VII-7: Labels and SDSs Affected by OSHA's Proposed Revisions to the HCS – Entities with <20 Employees

NAICS Code	Industry	Total Labels [a]	Total Labels for Very Small Containers [a]	Total SDSs [a]	Labels Affected by Revision [a]	Affected Labels for Very Small Containers [a]	Affected SDSs [a]
325613	Surface Active Agent Manufacturing	423,813	0	295	423,813	0	295
325620	Toilet Preparation Manufacturing	4,075,495	0	1,248	4,075,495	0	1,248
325910	Printing Ink Manufacturing	744,465	0	555	744,465	0	555
325920	Explosives Manufacturing	109,534	0	38	109,534	0	38
325991	Custom Compounding of Purchased Resins	26,583	0	358	26,583	0	358
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	458,814	0	435	458,814	0	435
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	3,574,522	0	3,560	3,574,522	0	3,560
339	**Miscellaneous Manufacturing**	**1,290,882**	**0**	**22,726**	**1,290,882**	**0**	**22,726**
339112	Surgical and Medical Instrument Manufacturing	81,805	0	651	81,805	0	651
339113	Surgical Appliance and Supplies Manufacturing	132,800	0	1,200	132,800	0	1,200
339114	Dental Equipment and Supplies Manufacturing	25,006	0	469	25,006	0	469
339115	Ophthalmic Goods Manufacturing	21,230	0	257	21,230	0	257
339116	Dental Laboratories	160,482	0	5,301	160,482	0	5,301
339910	Jewelry and Silverware Manufacturing	104,744	0	1,765	104,744	0	1,765
339920	Sporting and Athletic Goods Manufacturing	86,298	0	1,293	86,298	0	1,293
339930	Doll, Toy, and Game Manufacturing	31,802	0	434	31,802	0	434
339940	Office Supplies (except Paper) Manufacturing	23,048	0	333	23,048	0	333
339950	Sign Manufacturing	258,676	0	4,784	258,676	0	4,784
339991	Gasket, Packing, and Sealing Device Manufacturing	39,081	0	294	39,081	0	294
339992	Musical Instrument Manufacturing	22,736	0	504	22,736	0	504
339993	Fastener, Button, Needle, and Pin Manufacturing	4,662	0	76	4,662	0	76
339994	Broom, Brush, and Mop Manufacturing	10,893	0	96	10,893	0	96
339995	Burial Casket Manufacturing	3,087	0	60	3,087	0	60
339999	All Other Miscellaneous Manufacturing	284,532	0	5,209	284,532	0	5,209
Total							
Total	Total	**77,954,957**	**2,633,648**	**115,591**	**28,201,401**	**418,638**	**102,118**

Sources: U.S. Census Bureau, 2020a (Document ID 0231); U.S. Census Bureau, 2020b (Document ID 0232); U.S. Census Bureau, 2019a (Document ID 0227); BLS, 2020 (Document ID 0223); U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

Note: Figures may not add to totals due to rounding.

Note: "Affected" firms, establishments, employees, labels, and SDSs are based on the maximum number affected by any one provision of the rule.

[a] Figures in these columns for two-digit and three-digit NAICS codes represent totals for the entire industry at the specified level and may exceed the total sum of the data for the affected six-digit NAICS industries that fall within the aggregated levels. This occurs because two-digit and three-digit NAICS codes may encompass some six-digit NAICS industries not covered by OSHA. (For example, NAICS 21 encompasses Mining, which is not covered by OSHA regulations.)

Table VI–8 shows average estimated profit rates for affected NAICS industries based on IRS (2016) *SOI Tax Stats—Corporation Source Book* profit data for each of the 14 years 2000–

2013.[23] Table VII–9 presents estimates of total revenues and total profits by NAICS industry code for all entities, small entities, and very small entities affected by this proposed rule. OSHA calculated total profits per NAICS industry by multiplying the average profit rate (NAICS industry) (IRS, 2016, Document ID 0004) by total revenues (NAICS industry) (U.S. Census Bureau, 2020a, Document ID 0231; U.S. Census Bureau, 2020b, Document ID 0232).

[23] IRS, 2016, Document ID 0004.

Table VII–10 shows, by NAICS industry code, OSHA's best estimates of the percentage of establishments or entities estimated to be affected for each element of the proposed revisions to the HCS that is projected to result in costs (see Section VII.F. Compliance Costs and Cost Savings in this PEA for an explanation of the cost categories presented in this table).[24]

[24] Note that the provisions that are projected to result in cost savings are not included in Table VII–10 because, for those provisions, OSHA estimates a percentage of product, rather than a percentage of entities or establishments, that would be affected.

Finally, Table VII–11 summarizes key estimates for the combined covered industries, labels, and SDSs affected by this proposed rule. The data in this table are drawn from profile tables presented earlier in this PEA and summarize both the magnitude of the global profile metrics (within the scope of Federal OSHA jurisdiction) and the magnitude of affected inputs critical to the agency's analysis of preliminary economic impacts.

Table VII-8: Estimated Profit Rates for Industries Affected by the Proposed Revisions to the HCS – (Net Income (less Deficit) from IRS Table 1 [Returns with and without Net Income] / Total Receipts from IRS Table 1 [Returns with and without Net Income])

NAICS Code	Industry	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Average
21	**Mining, Quarrying, and Oil and Gas Extraction**															
211	**Oil and Gas Extraction**															
211120	Crude Petroleum Extraction	6.53%	5.55%	0.85%	5.50%	8.04%	14.89%	16.06%	11.11%	10.31%	-0.70%	4.68%	3.15%	-1.09%	2.36%	6.23%
211130	Natural Gas Extraction	6.53%	5.55%	0.85%	5.50%	8.04%	14.89%	16.06%	11.11%	10.31%	-0.70%	4.68%	3.15%	-1.09%	2.36%	6.23%
31-33	**Manufacturing**															
324	**Petroleum and Coal Products Manufacturing**															
324110	Petroleum Refineries	8.77%	7.99%	3.83%	6.49%	7.96%	8.57%	7.99%	7.35%	6.22%	6.59%	6.94%	5.20%	6.07%	5.39%	6.81%
324121	Asphalt Paving Mixture and Block Manufacturing	8.77%	7.99%	3.83%	6.49%	7.96%	8.57%	7.99%	7.35%	6.22%	7.63%	7.81%	5.47%	4.08%	6.40%	6.90%
324122	Asphalt Shingle and Coating Materials Manufacturing	8.77%	7.99%	3.83%	6.49%	7.96%	8.57%	7.99%	7.35%	6.22%	7.63%	7.81%	5.47%	4.08%	6.40%	6.90%
324191	Petroleum Lubricating Oil and Grease Manufacturing	8.77%	7.99%	3.83%	6.49%	7.96%	8.57%	7.99%	7.35%	6.22%	6.59%	6.95%	5.20%	6.05%	5.39%	6.81%
324199	All Other Petroleum and Coal Products Manufacturing	8.77%	7.99%	3.83%	6.49%	7.96%	8.57%	7.99%	7.35%	6.22%	6.59%	6.95%	5.20%	6.05%	5.39%	6.81%
325	**Chemical Manufacturing**															
325110	Petrochemical Manufacturing	1.93%	-1.88%	-0.92%	3.08%	1.16%	6.94%	5.82%	4.63%	2.18%	2.25%	5.76%	4.31%	5.71%	6.82%	3.41%
325120	Industrial Gas Manufacturing	1.93%	-1.88%	-0.92%	3.08%	1.16%	6.94%	5.82%	4.63%	2.18%	2.25%	5.76%	4.31%	5.71%	6.82%	3.41%
325130	Synthetic Dye and Pigment Manufacturing	1.93%	-1.88%	-0.92%	3.08%	1.16%	6.94%	5.82%	4.63%	2.18%	2.25%	5.76%	4.31%	5.71%	6.82%	3.41%
325180	Other Basic Inorganic Chemical Manufacturing	1.93%	-1.88%	-0.92%	3.08%	1.16%	6.94%	5.82%	4.63%	2.18%	2.25%	5.76%	4.31%	5.71%	6.82%	3.41%
325193	Ethyl Alcohol Manufacturing	1.93%	-1.88%	-0.92%	3.08%	1.16%	6.94%	5.82%	4.63%	2.18%	2.25%	5.76%	4.31%	5.71%	6.82%	3.41%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	1.93%	-1.88%	-0.92%	3.08%	1.16%	6.94%	5.82%	4.63%	2.18%	2.25%	5.76%	4.31%	5.71%	6.82%	3.41%
325199	All Other Basic Organic Chemical Manufacturing	1.93%	-1.88%	-0.92%	3.08%	1.16%	6.94%	5.82%	4.63%	2.18%	2.25%	5.76%	4.31%	5.71%	6.82%	3.41%
325211	Plastics Material and Resin Manufacturing	4.50%	10.28%	0.92%	1.98%	3.16%	23.55%	7.83%	7.23%	2.08%	-0.22%	4.91%	3.43%	4.83%	8.68%	5.94%
325212	Synthetic Rubber Manufacturing	4.50%	10.28%	0.92%	1.98%	3.16%	23.55%	7.83%	7.23%	2.08%	-0.22%	4.91%	3.43%	4.83%	8.68%	5.94%
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	4.50%	10.28%	0.92%	1.98%	3.16%	23.55%	7.83%	7.23%	2.08%	-0.22%	4.91%	3.43%	4.83%	8.68%	5.94%
325311	Nitrogenous Fertilizer Manufacturing	7.17%	6.83%	7.20%	8.32%	7.44%	20.64%	9.91%	9.08%	8.59%	13.43%	9.93%	8.63%	9.32%	9.51%	9.71%
325312	Phosphatic Fertilizer Manufacturing	7.17%	6.83%	7.20%	8.32%	7.44%	20.64%	9.91%	9.08%	8.59%	13.43%	9.93%	8.63%	9.32%	9.51%	9.71%
325314	Fertilizer (Mixing Only) Manufacturing	7.17%	6.83%	7.20%	8.32%	7.44%	20.64%	9.91%	9.08%	8.59%	13.43%	9.93%	8.63%	9.32%	9.51%	9.71%
325320	Pesticide and Other Agricultural Chemical Manufacturing	7.17%	6.83%	7.20%	8.32%	7.44%	20.64%	9.91%	9.08%	8.59%	13.43%	9.93%	8.63%	9.32%	9.51%	9.71%
325411	Medicinal and Botanical Manufacturing	11.96%	11.48%	11.32%	12.05%	11.84%	32.22%	14.50%	13.01%	12.42%	19.61%	12.08%	10.93%	10.88%	9.89%	13.87%
325412	Pharmaceutical Preparation Manufacturing	11.96%	11.48%	11.32%	12.05%	11.84%	32.22%	14.50%	13.01%	12.42%	19.61%	12.08%	10.93%	10.88%	9.89%	13.87%
325413	In-Vitro Diagnostic Substance Manufacturing	11.96%	11.48%	11.32%	12.05%	11.84%	32.22%	14.50%	13.01%	12.42%	19.61%	12.08%	10.93%	10.88%	9.89%	13.87%
325414	Biological Product (except Diagnostic) Manufacturing	11.96%	11.48%	11.32%	12.05%	11.84%	32.22%	14.50%	13.01%	12.42%	19.61%	12.08%	10.93%	10.88%	9.89%	13.87%
325510	Paint and Coating Manufacturing	3.64%	3.69%	3.79%	4.48%	4.85%	5.45%	5.11%	5.15%	2.66%	3.28%	4.01%	3.90%	3.92%	4.48%	4.17%
325520	Adhesive Manufacturing	3.64%	3.69%	3.79%	4.48%	4.85%	5.45%	5.11%	5.15%	2.66%	3.28%	4.01%	3.90%	3.92%	4.48%	4.17%
325611	Soap and Other Detergent Manufacturing	6.88%	7.60%	9.62%	9.68%	7.89%	10.60%	10.11%	8.42%	14.61%	19.77%	19.03%	16.21%	15.78%	16.61%	12.34%
325612	Polish and Other Sanitation Good Manufacturing	6.88%	7.60%	9.62%	9.68%	7.89%	10.60%	10.11%	8.42%	14.61%	19.77%	19.03%	16.21%	15.78%	16.61%	12.34%
325613	Surface Active Agent Manufacturing	6.88%	7.60%	9.62%	9.68%	7.89%	10.60%	10.11%	8.42%	14.61%	19.77%	19.03%	16.21%	15.78%	16.61%	12.34%

Table VII-8: Estimated Profit Rates for Industries Affected by the Proposed Revisions to the HCS – (Net Income (less Deficit) from IRS Table 1 [Returns with and without Net Income] / Total Receipts from IRS Table 1 [Returns with and without Net Income])

NAICS Code	Industry	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Average
325620	Toilet Preparation Manufacturing	6.88%	7.60%	9.62%	9.68%	7.89%	10.60%	10.11%	8.42%	14.61%	19.77%	19.03%	16.21%	15.78%	16.61%	12.34%
325910	Printing Ink Manufacturing	3.19%	2.02%	3.57%	0.86%	1.42%	5.03%	2.20%	6.33%	6.06%	5.89%	5.83%	8.92%	9.86%	9.81%	5.07%
325920	Explosives Manufacturing	3.19%	2.02%	3.57%	0.86%	1.42%	5.03%	2.20%	6.33%	6.06%	5.89%	5.83%	8.92%	9.86%	9.81%	5.07%
325991	Custom Compounding of Purchased Resins	3.19%	2.02%	3.57%	0.86%	1.42%	5.03%	2.20%	6.33%	6.06%	5.89%	5.83%	8.92%	9.86%	9.81%	5.07%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	3.19%	2.02%	3.57%	0.86%	1.42%	5.03%	2.20%	6.33%	6.06%	5.89%	5.83%	8.92%	9.86%	9.81%	5.07%
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	3.19%	2.02%	3.57%	0.86%	1.42%	5.03%	2.20%	6.33%	6.06%	5.89%	5.83%	8.92%	9.86%	9.81%	5.07%
326	**Plastics and Rubber Products Manufacturing**															
326111	Plastics Bag and Pouch Manufacturing	2.49%	1.24%	1.57%	1.50%	2.51%	3.62%	2.17%	2.74%	1.24%	2.32%	2.84%	3.00%	4.68%	4.01%	2.57%
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	2.49%	1.24%	1.57%	1.50%	2.51%	3.62%	2.17%	2.74%	1.24%	2.32%	2.84%	3.00%	4.68%	4.01%	2.57%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	2.49%	1.24%	1.57%	1.50%	2.51%	3.62%	2.17%	2.74%	1.24%	2.32%	2.84%	3.00%	4.68%	4.01%	2.57%
326121	Unlaminated Plastics Profile Shape Manufacturing	2.49%	1.24%	1.57%	1.50%	2.51%	3.62%	2.17%	2.74%	1.24%	2.32%	2.84%	3.00%	4.68%	4.01%	2.57%
326122	Plastics Pipe and Pipe Fitting Manufacturing	2.49%	1.24%	1.57%	1.50%	2.51%	3.62%	2.17%	2.74%	1.24%	2.32%	2.84%	3.00%	4.68%	4.01%	2.57%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	2.49%	1.24%	1.57%	1.50%	2.51%	3.62%	2.17%	2.74%	1.24%	2.32%	2.84%	3.00%	4.68%	4.01%	2.57%
326140	Polystyrene Foam Product Manufacturing	2.49%	1.24%	1.57%	1.50%	2.51%	3.62%	2.17%	2.74%	1.24%	2.32%	2.84%	3.00%	4.68%	4.01%	2.57%
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	2.49%	1.24%	1.57%	1.50%	2.51%	3.62%	2.17%	2.74%	1.24%	2.32%	2.84%	3.00%	4.68%	4.01%	2.57%
326160	Plastics Bottle Manufacturing	2.49%	1.24%	1.57%	1.50%	2.51%	3.62%	2.17%	2.74%	1.24%	2.32%	2.84%	3.00%	4.68%	4.01%	2.57%
326191	Plastics Plumbing Fixture Manufacturing	2.49%	1.24%	1.57%	1.50%	2.51%	3.62%	2.17%	2.74%	1.24%	2.32%	2.84%	3.00%	4.68%	4.01%	2.57%
326199	All Other Plastics Product Manufacturing	2.49%	1.24%	1.57%	1.50%	2.51%	3.62%	2.17%	2.74%	1.24%	2.32%	2.84%	3.00%	4.68%	4.01%	2.57%
326211	Tire Manufacturing (except Retreading)	1.61%	-0.88%	0.03%	0.58%	1.48%	1.82%	1.45%	4.41%	-2.00%	1.21%	1.94%	3.39%	4.68%	4.01%	1.69%
326212	Tire Retreading	1.61%	-0.88%	0.03%	0.58%	1.48%	1.82%	1.45%	4.41%	-2.00%	1.21%	1.94%	3.39%	4.68%	4.01%	1.69%
326220	Rubber and Plastics Hoses and Belting Manufacturing	1.61%	-0.88%	0.03%	0.58%	1.48%	1.82%	1.45%	4.41%	-2.00%	1.21%	1.94%	3.39%	4.68%	4.01%	1.69%
326291	Rubber Product Manufacturing for Mechanical Use	1.61%	-0.88%	0.03%	0.58%	1.48%	1.82%	1.45%	4.41%	-2.00%	1.21%	1.94%	3.39%	4.68%	4.01%	1.69%
326299	All Other Rubber Product Manufacturing	1.61%	-0.88%	0.03%	0.58%	1.48%	1.82%	1.45%	4.41%	-2.00%	1.21%	1.94%	3.39%	4.68%	4.01%	1.69%
327	**Nonmetallic Mineral Product Manufacturing**															
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	1.83%	0.88%	-0.38%	-0.03%	3.40%	6.29%	-2.15%	-5.12%	2.81%	1.77%	1.09%	3.50%	3.50%	4.62%	1.57%
327120	Clay Building Material and Refractories Manufacturing	1.83%	0.88%	-0.38%	-0.03%	3.40%	6.29%	-2.15%	-5.12%	2.81%	1.77%	1.09%	3.50%	3.50%	4.62%	1.57%
327211	Flat Glass Manufacturing	1.62%	2.63%	0.89%	0.20%	-0.34%	0.22%	2.12%	8.88%	0.22%	1.81%	7.03%	4.75%	4.09%	5.51%	2.83%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	1.62%	2.63%	0.89%	0.20%	-0.34%	0.22%	2.12%	8.88%	0.22%	1.81%	7.03%	4.75%	4.09%	5.51%	2.83%
327213	Glass Container Manufacturing	1.62%	2.63%	0.89%	0.20%	-0.34%	0.22%	2.12%	8.88%	0.22%	1.81%	7.03%	4.75%	4.09%	5.51%	2.83%
327215	Glass Product Manufacturing Made of Purchased Glass	1.62%	2.63%	0.89%	0.20%	-0.34%	0.22%	2.12%	8.88%	0.22%	1.81%	7.03%	4.75%	4.09%	5.51%	2.83%
327310	Cement Manufacturing	6.22%	3.38%	2.77%	3.05%	5.23%	10.26%	4.23%	4.70%	-2.69%	-7.44%	-5.71%	-4.26%	-1.15%	1.99%	1.47%
327320	Ready-Mix Concrete Manufacturing	6.22%	3.38%	2.77%	3.05%	5.23%	10.26%	4.23%	4.70%	-2.69%	-7.44%	-5.71%	-4.26%	-1.15%	1.99%	1.47%
327331	Concrete Block and Brick Manufacturing	6.22%	3.38%	2.77%	3.05%	5.23%	10.26%	4.23%	4.70%	-2.69%	-7.44%	-5.71%	-4.26%	-1.15%	1.99%	1.47%

Table VII-8: Estimated Profit Rates for Industries Affected by the Proposed Revisions to the HCS – (Net Income (less Deficit) from IRS Table 1 [Returns with and without Net Income] / Total Receipts from IRS Table 1 [Returns with and without Net Income])

NAICS Code	Industry	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Average
327332	Concrete Pipe Manufacturing	6.22%	3.38%	2.77%	3.05%	5.23%	10.26%	4.23%	4.70%	-2.69%	-7.44%	-5.71%	-4.26%	-1.15%	1.99%	1.47%
327390	Other Concrete Product Manufacturing	6.22%	3.38%	2.77%	3.05%	5.23%	10.26%	4.23%	4.70%	-2.69%	-7.44%	-5.71%	-4.26%	-1.15%	1.99%	1.47%
327410	Lime Manufacturing	3.98%	2.68%	1.71%	1.82%	3.65%	7.55%	2.64%	3.88%	-1.15%	-3.69%	-1.09%	-0.31%	1.12%	3.41%	1.87%
327420	Gypsum Product Manufacturing	3.98%	2.68%	1.71%	1.82%	3.65%	7.55%	2.64%	3.88%	-1.15%	-3.69%	-1.09%	-0.31%	1.12%	3.41%	1.87%
327910	Abrasive Product Manufacturing	3.98%	2.68%	1.71%	1.82%	3.65%	7.55%	2.64%	3.88%	-1.15%	-3.69%	-1.09%	-0.31%	1.12%	3.41%	1.87%
327991	Cut Stone and Stone Product Manufacturing	3.98%	2.68%	1.71%	1.82%	3.65%	7.55%	2.64%	3.88%	-1.15%	-3.69%	-1.09%	-0.31%	1.12%	3.41%	1.87%
327992	Ground or Treated Mineral and Earth Manufacturing	3.98%	2.68%	1.71%	1.82%	3.65%	7.55%	2.64%	3.88%	-1.15%	-3.69%	-1.09%	-0.31%	1.12%	3.41%	1.87%
327993	Mineral Wool Manufacturing	3.98%	2.68%	1.71%	1.82%	3.65%	7.55%	2.64%	3.88%	-1.15%	-3.69%	-1.09%	-0.31%	1.12%	3.41%	1.87%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	3.98%	2.68%	1.71%	1.82%	3.65%	7.55%	2.64%	3.88%	-1.15%	-3.69%	-1.09%	-0.31%	1.12%	3.41%	1.87%
331	**Primary Metal Manufacturing**															
331110	Iron and Steel Mills and Ferroalloy Manufacturing	-1.23%	-6.39%	-2.58%	-3.92%	7.34%	7.74%	8.96%	6.43%	5.80%	-6.26%	-0.65%	0.55%	1.79%	-0.23%	1.24%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	0.56%	-2.50%	-1.32%	-1.77%	5.58%	6.44%	7.55%	7.04%	4.38%	-3.37%	1.14%	1.77%	2.36%	1.29%	2.08%
331221	Rolled Steel Shape Manufacturing	0.56%	-2.50%	-1.32%	-1.77%	5.58%	6.44%	7.55%	7.04%	4.38%	-3.37%	1.14%	1.77%	2.36%	1.29%	2.08%
331222	Steel Wire Drawing	0.56%	-2.50%	-1.32%	-1.77%	5.58%	6.44%	7.55%	7.04%	4.38%	-3.37%	1.14%	1.77%	2.36%	1.29%	2.08%
331313	Alumina Refining and Primary Aluminum Production	2.50%	0.74%	-0.16%	1.39%	3.72%	4.88%	6.17%	7.76%	4.38%	-3.37%	1.14%	1.77%	2.36%	1.29%	2.47%
331314	Secondary Smelting and Alloying of Aluminum	2.50%	0.74%	-0.16%	1.39%	3.72%	4.88%	6.17%	7.76%	4.38%	-3.37%	1.14%	1.77%	2.36%	1.29%	2.47%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	2.50%	0.74%	-0.16%	1.39%	3.72%	4.88%	6.17%	7.76%	1.81%	-1.82%	2.25%	2.21%	1.33%	1.12%	2.42%
331318	Other Aluminum Rolling, Drawing, and Extruding	2.50%	0.74%	-0.16%	1.39%	3.72%	4.88%	6.17%	7.76%	4.38%	-3.37%	1.14%	1.77%	2.36%	1.29%	2.47%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	0.56%	-2.50%	-1.32%	-1.77%	5.58%	6.44%	7.55%	7.04%	4.38%	-3.37%	1.14%	1.77%	2.36%	1.29%	2.08%
331420	Copper Rolling, Drawing, Extruding, and Alloying	0.56%	-2.50%	-1.32%	-1.77%	5.58%	6.44%	7.55%	7.04%	4.38%	-3.37%	1.14%	1.77%	2.36%	1.29%	2.08%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	0.56%	-2.50%	-1.32%	-1.77%	5.58%	6.44%	7.55%	7.04%	4.38%	-3.37%	1.14%	1.77%	2.36%	1.29%	2.08%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	0.56%	-2.50%	-1.32%	-1.77%	5.58%	6.44%	7.55%	7.04%	4.38%	-3.37%	1.14%	1.77%	2.36%	1.29%	2.08%
331511	Iron Foundries	1.03%	1.46%	0.31%	-0.44%	1.65%	4.95%	5.78%	7.11%	6.39%	3.99%	7.09%	7.57%	9.76%	9.48%	4.72%
331512	Steel Investment Foundries	1.03%	1.46%	0.31%	-0.44%	1.65%	4.95%	5.78%	7.11%	6.39%	3.99%	7.09%	7.57%	9.76%	9.48%	4.72%
331513	Steel Foundries (except Investment)	1.03%	1.46%	0.31%	-0.44%	1.65%	4.95%	5.78%	7.11%	6.39%	3.99%	7.09%	7.57%	9.76%	9.48%	4.72%
331523	Nonferrous Metal Die-Casting Foundries	1.03%	1.46%	0.31%	-0.44%	1.65%	4.95%	5.78%	7.11%	6.39%	3.99%	7.09%	7.57%	9.76%	9.48%	4.72%
331524	Aluminum Foundries (except Die-Casting)	1.03%	1.46%	0.31%	-0.44%	1.65%	4.95%	5.78%	7.11%	6.39%	3.99%	7.09%	7.57%	9.76%	9.48%	4.72%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	1.03%	1.46%	0.31%	-0.44%	1.65%	4.95%	5.78%	7.11%	6.39%	3.99%	7.09%	7.57%	9.76%	9.48%	4.72%
339	**Miscellaneous Manufacturing**															
339112	Surgical and Medical Instrument Manufacturing	5.23%	4.45%	5.07%	3.98%	6.14%	15.65%	11.07%	7.53%	5.63%	7.65%	7.65%	7.72%	7.40%	7.48%	7.33%
339113	Surgical Appliance and Supplies Manufacturing	5.23%	4.45%	5.07%	3.98%	6.14%	15.65%	11.07%	7.53%	5.63%	7.65%	7.65%	7.72%	7.40%	7.48%	7.33%
339114	Dental Equipment and Supplies Manufacturing	5.23%	4.45%	5.07%	3.98%	6.14%	15.65%	11.07%	7.53%	5.63%	7.65%	7.65%	7.72%	7.40%	7.48%	7.33%
339115	Ophthalmic Goods Manufacturing	5.23%	4.45%	5.07%	3.98%	6.14%	15.65%	11.07%	7.53%	5.63%	7.65%	7.65%	7.72%	7.40%	7.48%	7.33%
339116	Dental Laboratories	5.23%	4.45%	5.07%	3.98%	6.14%	15.65%	11.07%	7.53%	5.63%	7.65%	7.65%	7.72%	7.40%	7.48%	7.33%

Table VII-8: Estimated Profit Rates for Industries Affected by the Proposed Revisions to the HCS – (Net Income (less Deficit) from IRS Table 1 [Returns with and without Net Income] / Total Receipts from IRS Table 1 [Returns with and without Net Income])

NAICS Code	Industry	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Average
339910	Jewelry and Silverware Manufacturing	3.26%	1.81%	2.91%	3.05%	3.19%	5.11%	5.41%	4.26%	3.63%	2.80%	4.68%	4.51%	6.37%	5.47%	4.03%
339920	Sporting and Athletic Goods Manufacturing	3.26%	1.81%	2.91%	3.05%	3.19%	5.11%	5.41%	4.26%	3.63%	2.80%	4.68%	4.51%	6.37%	5.47%	4.03%
339930	Doll, Toy, and Game Manufacturing	3.26%	1.81%	2.91%	3.05%	3.19%	5.11%	5.41%	4.26%	3.63%	2.80%	4.68%	4.51%	6.37%	5.47%	4.03%
339940	Office Supplies (except Paper) Manufacturing	3.26%	1.81%	2.91%	3.05%	3.19%	5.11%	5.41%	4.26%	3.63%	2.80%	4.68%	4.51%	6.37%	5.47%	4.03%
339950	Sign Manufacturing	3.26%	1.81%	2.91%	3.05%	3.19%	5.11%	5.41%	4.26%	3.63%	2.80%	4.68%	4.51%	6.37%	5.47%	4.03%
339991	Gasket, Packing, and Sealing Device Manufacturing	3.26%	1.81%	2.91%	3.05%	3.19%	5.11%	5.41%	4.26%	3.63%	2.80%	4.68%	4.51%	6.37%	5.47%	4.03%
339992	Musical Instrument Manufacturing	3.26%	1.81%	2.91%	3.05%	3.19%	5.11%	5.41%	4.26%	3.63%	2.80%	4.68%	4.51%	6.37%	5.47%	4.03%
339993	Fastener, Button, Needle, and Pin Manufacturing	3.26%	1.81%	2.91%	3.05%	3.19%	5.11%	5.41%	4.26%	3.63%	2.80%	4.68%	4.51%	6.37%	5.47%	4.03%
339994	Broom, Brush, and Mop Manufacturing	3.26%	1.81%	2.91%	3.05%	3.19%	5.11%	5.41%	4.26%	3.63%	2.80%	4.68%	4.51%	6.37%	5.47%	4.03%
339995	Burial Casket Manufacturing	3.26%	1.81%	2.91%	3.05%	3.19%	5.11%	5.41%	4.26%	3.63%	2.80%	4.68%	4.51%	6.37%	5.47%	4.03%
339999	All Other Miscellaneous Manufacturing	3.26%	1.81%	2.91%	3.05%	3.19%	5.11%	5.41%	4.26%	3.63%	2.80%	4.68%	4.51%	6.37%	5.47%	4.03%
42	**Wholesale Trade**															
423	**Merchant Wholesalers, Durable Goods**															
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	0.83%	0.32%	1.19%	1.01%	2.37%	2.56%	2.81%	2.51%	1.96%	2.27%	3.70%	3.73%	4.65%	4.86%	2.48%
423840	Industrial Supplies Merchant Wholesalers	2.05%	1.61%	0.82%	1.57%	2.92%	4.31%	4.28%	3.93%	3.42%	2.23%	3.47%	3.70%	4.49%	4.40%	3.09%
424	**Merchant Wholesalers, Nondurable Goods**															
424210	Drugs and Druggists' Sundries Merchant Wholesalers	1.82%	2.54%	3.73%	3.93%	3.20%	3.22%	3.47%	3.64%	2.98%	3.55%	4.02%	3.68%	4.33%	4.48%	3.47%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	2.58%	1.52%	2.11%	2.52%	2.21%	3.62%	3.28%	3.81%	3.37%	3.58%	3.30%	3.68%	3.73%	3.46%	3.05%
424690	Other Chemical and Allied Products Merchant Wholesalers	2.58%	1.52%	2.11%	2.52%	2.21%	3.62%	3.28%	3.81%	3.37%	3.58%	3.30%	3.68%	3.73%	3.46%	3.05%
424710	Petroleum Bulk Stations and Terminals	0.98%	0.42%	0.28%	1.18%	1.86%	2.54%	2.07%	2.01%	1.10%	0.82%	0.11%	-0.44%	0.46%	0.10%	0.96%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	0.98%	0.42%	0.28%	1.18%	1.86%	2.54%	2.07%	2.01%	1.10%	0.82%	0.11%	-0.44%	0.46%	0.10%	0.96%
424910	Farm Supplies Merchant Wholesalers	1.52%	1.36%	1.68%	2.63%	2.74%	2.98%	2.31%	1.99%	2.12%	2.37%	4.76%	4.21%	4.19%	3.09%	2.71%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	1.52%	1.36%	1.68%	2.63%	2.74%	2.98%	2.31%	1.99%	2.12%	2.47%	2.78%	2.23%	2.94%	2.76%	2.32%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	1.52%	1.36%	1.68%	2.63%	2.74%	2.98%	2.31%	1.99%	2.12%	2.47%	2.78%	2.23%	2.94%	2.76%	2.32%

Note: IRS profit data are available at varying NAICS levels; Where an estimate is not available we use the next-least granular NAICS with data available.

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health based on IRS, 2016 (Document ID 0004).

Table VII-9: Estimated Total Revenues and Profits for Industries Affected by the Proposed Revisions to the HCS, by Establishment Size

NAICS Code	Industry	All Entities		Small Entities		Very Small Entities (Fewer than 20 Employees)	
		Revenues	Profits	Revenues	Profits	Revenues	Profits
21	**Mining, Quarrying, and Oil and Gas Extraction**	**$326,848,327,601**	**$21,110,919,773**	**$126,641,777,686**	**$8,118,387,317**	**$17,191,968,980**	**$1,130,270,113**
211	**Oil and Gas Extraction**	**$240,298,917,934**	**$14,974,398,582**	**$100,248,982,771**	**$6,247,086,913**	**$10,327,453,313**	**$643,562,624**
211120	Crude Petroleum Extraction	$170,279,184,328	$10,611,068,906	$74,442,621,084	$4,638,945,066	$8,159,920,407	$508,491,264
211130	Natural Gas Extraction	$70,019,733,607	$4,363,329,676	$25,806,361,687	$1,608,141,848	$2,167,532,907	$135,071,360
31-33	**Manufacturing**	**$5,797,450,564,984**	**$264,415,656,740**	**$1,019,372,711,131**	**$46,934,620,433**	**$201,349,874,448**	**$8,599,149,973**
324	**Petroleum and Coal Products Manufacturing**	**$548,268,340,205**	**$37,365,772,412**	**$36,291,381,929**	**$2,477,359,321**	**$2,264,038,256**	**$155,524,865**
324110	Petroleum Refineries	$502,164,011,213	$34,203,490,777	$27,122,075,639	$1,847,343,982	$102,309,469	$6,968,522
324121	Asphalt Paving Mixture and Block Manufacturing	$13,860,504,187	$955,963,177	$6,354,692,152	$438,285,045	$1,224,335,797	$84,442,811
324122	Asphalt Shingle and Coating Materials Mfg.	$11,617,097,706	$801,234,752	$0	$0	$304,121,711	$20,975,367
324191	Petroleum Lubricating Oil and Grease Mfg.	$16,586,696,926	$1,129,878,602	$1,246,859,746	$84,935,545	$515,936,132	$35,145,346
324199	All Other Petroleum and Coal Products Mfg.	$4,040,030,172	$275,205,103	$1,567,754,391	$106,794,749	$117,335,147	$7,992,819
325	**Chemical Manufacturing**	**$789,429,171,514**	**$65,825,402,786**	**$133,195,382,934**	**$11,287,569,408**	**$15,398,580,338**	**$1,259,377,873**
325110	Petrochemical Manufacturing	$55,741,502,666	$1,902,021,496	$0	$0	$54,148,510	$1,847,665
325120	Industrial Gas Manufacturing	$9,700,639,626	$331,006,956	$0	$0	$113,739,490	$3,881,039
325130	Synthetic Dye and Pigment Manufacturing	$7,293,474,420	$248,869,235	$908,334,950	$30,994,367	$153,296,928	$5,230,825
325180	Other Basic Inorganic Chemical Manufacturing	$33,275,419,838	$1,135,429,811	$2,244,838,764	$76,598,789	$579,118,600	$19,760,788
325193	Ethyl Alcohol Manufacturing	$32,337,672,494	$1,103,431,829	$315,684,675	$10,771,849	$237,677,096	$8,110,060
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	$8,105,063,187	$276,562,412	$1,276,990,010	$43,573,681	$80,989,829	$2,763,549
325199	All Other Basic Organic Chemical Manufacturing	$80,041,612,356	$2,731,194,173	$22,367,221,007	$763,218,305	$1,118,327,492	$38,159,770
325211	Plastics Material and Resin Manufacturing	$94,876,413,479	$5,636,119,712	$23,872,209,387	$1,418,125,169	$1,160,497,774	$68,939,204
325212	Synthetic Rubber Manufacturing	$8,750,057,350	$519,795,900	$0	$0	$185,348,301	$11,010,589
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	$7,325,632,100	$435,178,122	$0	$0	$109,443,461	$6,501,473
325311	Nitrogenous Fertilizer Manufacturing	$6,178,183,955	$600,201,186	$0	$0	$339,914,652	$33,022,192
325312	Phosphatic Fertilizer Manufacturing	$5,725,430,291	$556,216,855	$100,008,328	$9,715,657	$62,388,297	$6,060,928
325314	Fertilizer (Mixing Only) Manufacturing	$4,931,889,637	$479,125,586	$3,500,940,093	$340,111,012	$585,272,906	$56,858,374
325320	Pesticide and Other Agricultural Chemical Mfg.	$15,622,076,997	$1,517,661,048	$0	$0	$375,076,009	$36,438,064
325411	Medicinal and Botanical Manufacturing	$11,504,963,235	$1,595,818,501	$715,521,577	$99,247,824	$460,867,342	$63,925,509
325412	Pharmaceutical Preparation Manufacturing	$186,027,072,841	$25,803,250,170	$30,020,579,790	$4,164,063,428	$1,865,009,961	$258,689,866
325413	In-Vitro Diagnostic Substance Manufacturing	$14,420,723,180	$2,000,254,706	$2,572,663,655	$356,846,361	$151,862,834	$21,064,432
325414	Biological Product (except Diagnostic) Manufacturing	$31,996,374,817	$4,438,119,954	$5,863,984,063	$813,375,416	$532,418,832	$73,850,199
325510	Paint and Coating Manufacturing	$28,755,602,915	$1,199,560,340	$2,152,126,723	$89,777,490	$1,556,606,813	$64,934,956
325520	Adhesive Manufacturing	$15,404,571,015	$642,612,589	$5,069,280,212	$211,468,614	$652,936,917	$27,237,726
325611	Soap and Other Detergent Manufacturing	$25,419,002,064	$3,137,684,958	$0	$0	$649,681,023	$80,195,689
325612	Polish and Other Sanitation Good Manufacturing	$6,433,601,711	$794,154,517	$121,727,113	$15,025,819	$424,493,885	$52,398,913

Table VII-9: Estimated Total Revenues and Profits for Industries Affected by the Proposed Revisions to the HCS, by Establishment Size

NAICS Code	Industry	All Entities		Small Entities		Very Small Entities (Fewer than 20 Employees)	
		Revenues	Profits	Revenues	Profits	Revenues	Profits
325613	Surface Active Agent Manufacturing	$7,488,008,843	$924,309,013	$0	$0	$153,105,159	$18,899,080
325620	Toilet Preparation Manufacturing	$43,279,075,380	$5,342,306,652	$16,735,776,539	$2,065,840,121	$1,472,297,515	$181,738,282
325910	Printing Ink Manufacturing	$4,534,098,456	$229,935,022	$1,401,449,523	$71,070,871	$268,942,637	$13,638,727
325920	Explosives Manufacturing	$2,483,129,453	$125,925,458	$0	$0	$39,569,945	$2,006,687
325991	Custom Compounding of Purchased Resins	$11,882,633,328	$602,596,873	$4,898,316,623	$248,405,400	$558,480,571	$28,321,891
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	$7,036,771,608	$356,851,588	$0	$0	$165,749,365	$8,405,548
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	$22,858,474,270	$1,159,208,126	$9,057,729,902	$459,339,236	$1,291,318,197	$65,485,847
326	**Plastics and Rubber Products Manufacturing**	**$247,748,726,309**	**$5,974,209,486**	**$29,139,202,553**	**$684,076,077**	**$8,440,100,253**	**$206,019,667**
326111	Plastics Bag and Pouch Manufacturing	$11,673,118,042	$299,485,288	$784,503,219	$20,127,199	$289,529,597	$7,428,166
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	$13,981,710,136	$358,714,481	$1,208,634,905	$31,008,713	$253,189,490	$6,495,825
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	$16,764,409,928	$430,107,373	$1,576,497,917	$40,446,600	$389,897,411	$10,003,200
326121	Unlaminated Plastics Profile Shape Manufacturing	$8,405,469,386	$215,650,558	$2,702,661,509	$69,339,431	$212,873,316	$5,461,474
326122	Plastics Pipe and Pipe Fitting Manufacturing	$11,149,151,610	$286,042,415	$225,529,681	$5,786,185	$319,401,690	$8,194,563
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	$4,558,892,856	$116,962,866	$1,742,170,853	$44,697,101	$175,678,590	$4,507,206
326140	Polystyrene Foam Product Manufacturing	$10,048,849,303	$257,813,081	$1,052,864,685	$27,012,276	$369,023,841	$9,467,668
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	$11,390,162,766	$292,225,793	$857,095,712	$21,989,631	$463,923,130	$11,902,403
326160	Plastics Bottle Manufacturing	$11,711,421,690	$300,468,006	$3,432,455,453	$88,063,010	$153,118,708	$3,928,411
326191	Plastics Plumbing Fixture Manufacturing	$4,393,033,016	$112,707,569	$550,566,149	$14,125,314	$246,216,000	$6,316,913
326199	All Other Plastics Product Manufacturing	$99,843,663,537	$2,561,587,076	$7,718,903,091	$198,036,027	$4,360,390,703	$111,870,098
326211	Tire Manufacturing (except Retreading)	$18,217,353,429	$308,595,467	$1,062,901,057	$18,005,165	$42,665,336	$722,736
326212	Tire Retreading	$1,750,825,443	$29,658,358	$878,258,502	$14,877,386	$226,970,376	$3,844,797
326220	Rubber and Plastics Hoses and Belting Manufacturing	$5,525,287,685	$93,596,402	$469,067,062	$7,945,829	$195,530,785	$3,312,222
326291	Rubber Product Manufacturing for Mechanical Use	$7,932,574,831	$134,374,987	$666,269,920	$11,286,375	$280,991,735	$4,759,900
326299	All Other Rubber Product Manufacturing	$10,402,802,651	$176,219,765	$4,210,822,837	$71,329,836	$460,699,545	$7,804,086
327	**Nonmetallic Mineral Product Manufacturing**	**$131,885,843,897**	**$2,461,308,698**	**$39,957,576,507**	**$648,610,549**	**$9,253,585,860**	**$160,254,290**
327110	Pottery, Ceramics, and Plumbing Fixture Mfg.	$2,319,233,154	$36,481,726	$277,050,335	$4,358,024	$240,529,651	$3,783,551
327120	Clay Building Material and Refractories Mfg.	$5,881,207,701	$92,511,875	$706,797,682	$11,117,985	$392,927,143	$6,180,776
327211	Flat Glass Mfg.	$4,388,366,999	$124,247,799	$0	$0	$34,821,593	$985,903
327212	Other Pressed and Blown Glass and Glassware Manufacturing	$3,522,384,800	$99,729,252	$1,168,942,607	$33,096,262	$200,184,295	$5,667,816
327213	Glass Container Manufacturing	$5,272,106,533	$149,269,109	$333,956,284	$9,455,302	$18,906,902	$535,311

Table VII-9: Estimated Total Revenues and Profits for Industries Affected by the Proposed Revisions to the HCS, by Establishment Size

NAICS Code	Industry	All Entities		Small Entities		Very Small Entities (Fewer than 20 Employees)	
		Revenues	Profits	Revenues	Profits	Revenues	Profits
327215	Glass Product Manufacturing Made of Purchased Glass	$13,900,601,495	$393,567,616	$686,676,277	$19,441,860	$694,354,717	$19,659,259
327310	Cement Manufacturing	$9,050,480,224	$133,073,152	$527,929,122	$7,762,372	$113,207,958	$1,664,546
327320	Ready-Mix Concrete Manufacturing	$32,398,760,101	$476,373,077	$17,735,436,381	$260,771,844	$3,102,958,186	$45,624,145
327331	Concrete Block and Brick Manufacturing	$4,879,471,211	$71,744,990	$2,979,630,278	$43,810,801	$448,924,550	$6,600,733
327332	Concrete Pipe Manufacturing	$1,708,315,398	$25,118,105	$157,861,666	$2,321,109	$84,751,199	$1,246,134
327390	Other Concrete Product Manufacturing	$12,334,383,335	$181,357,809	$7,821,743,134	$115,006,495	$1,265,924,521	$18,613,439
327410	Lime Manufacturing	$2,355,559,712	$44,069,981	$0	$0	$38,643,412	$722,977
327420	Gypsum Product Manufacturing	$6,468,574,425	$121,020,050	$0	$0	$168,446,629	$3,151,455
327910	Abrasive Product Manufacturing	$5,886,203,059	$110,124,510	$0	$0	$307,171,245	$5,746,843
327991	Cut Stone and Stone Product Manufacturing	$5,236,293,789	$97,965,408	$4,360,344,846	$81,577,349	$1,479,155,319	$27,673,400
327992	Ground or Treated Mineral and Earth Mfg.	$4,456,620,907	$83,378,570	$1,326,716,138	$24,821,428	$158,566,389	$2,966,606
327993	Mineral Wool Manufacturing	$6,445,499,687	$120,588,346	$246,343,878	$4,608,828	$162,470,543	$3,039,649
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	$5,381,781,367	$100,687,324	$1,628,147,880	$30,460,891	$341,641,610	$6,391,746
331	**Primary Metal Manufacturing**	**$232,471,614,560**	**$5,007,068,940**	**$30,289,721,564**	**$751,879,539**	**$3,862,267,143**	**$106,827,885**
331110	Iron and Steel Mills and Ferroalloy Manufacturing	$93,922,044,820	$1,165,821,393	$12,141,766,502	$150,711,488	$556,014,680	$6,901,615
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	$11,067,013,255	$230,377,817	$1,426,594,136	$29,696,869	$74,174,756	$1,544,068
331221	Rolled Steel Shape Manufacturing	$5,992,331,220	$124,740,086	$524,401,481	$10,916,267	$222,220,982	$4,625,890
331222	Steel Wire Drawing	$5,581,251,741	$116,182,800	$1,092,743,284	$22,747,222	$175,334,657	$3,649,875
331313	Alumina Refining and Primary Aluminum Production	$3,537,971,191	$87,352,773	$0	$0	$9,684,303	$239,106
331314	Secondary Smelting and Alloying of Aluminum	$6,039,040,368	$149,104,358	$0	$0	$85,089,920	$2,100,876
331315	Aluminum Sheet, Plate, and Foil Manufacturing	$15,749,488,321	$381,314,941	$1,812,679,081	$43,887,243	$138,958,073	$3,364,350
331318	Other Aluminum Rolling, Drawing, and Extruding	$11,879,785,984	$293,312,803	$1,042,425,463	$25,737,563	$179,057,465	$4,420,942
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	$9,746,852,678	$202,896,535	$1,513,416,451	$31,504,216	$334,535,758	$6,963,904
331420	Copper Rolling, Drawing, Extruding, and Alloying	$23,335,378,243	$485,763,717	$2,483,469,095	$51,697,434	$273,053,150	$5,684,044
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	$6,982,835,711	$145,359,042	$181,179,708	$3,771,549	$272,540,378	$5,673,370
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$7,574,445,310	$157,674,355	$0	$0	$422,211,424	$8,789,015
331511	Iron Foundries	$9,786,154,772	$462,217,269	$86,096,560	$4,066,492	$235,041,323	$11,101,414
331512	Steel Investment Foundries	$4,091,022,841	$193,226,191	$832,718,001	$39,330,733	$59,008,379	$2,787,069
331513	Steel Foundries (except Investment)	$3,451,310,647	$163,011,461	$1,520,040,544	$71,794,183	$158,529,911	$7,487,646
331523	Nonferrous Metal Die-Casting Foundries	$7,892,732,868	$372,787,629	$2,531,019,436	$119,544,491	$264,021,276	$12,470,188
331524	Aluminum Foundries (except Die-Casting)	$3,103,121,814	$146,565,891	$1,831,306,669	$86,495,829	$218,051,062	$10,298,934

Table VII-9: Estimated Total Revenues and Profits for Industries Affected by the Proposed Revisions to the HCS, by Establishment Size

NAICS Code	Industry	All Entities		Small Entities		Very Small Entities (Fewer than 20 Employees)	
		Revenues	Profits	Revenues	Profits	Revenues	Profits
331529	Other Nonferrous Metal Foundries (except Die-Casting)	$2,738,832,777	$129,359,880	$1,269,865,153	$59,977,960	$184,739,645	$8,725,578
339	**Miscellaneous Manufacturing**	**$157,410,019,449**	**$9,456,508,594**	**$39,530,013,204**	**$1,919,889,733**	**$14,517,096,167**	**$741,894,194**
339112	Surgical and Medical Instrument Manufacturing	$41,727,828,702	$3,059,643,748	$4,254,912,087	$311,986,403	$919,970,207	$67,455,729
339113	Surgical Appliance and Supplies Manufacturing	$36,136,301,720	$2,649,651,637	$977,823,332	$71,697,741	$1,493,451,442	$109,505,563
339114	Dental Equipment and Supplies Manufacturing	$5,122,480,302	$375,599,817	$679,750,171	$49,841,878	$281,217,897	$20,619,970
339115	Ophthalmic Goods Manufacturing	$6,175,778,513	$452,831,664	$197,531,165	$14,483,739	$238,750,582	$17,506,104
339116	Dental Laboratories	$5,024,370,977	$368,406,067	$3,751,568,850	$275,079,354	$1,804,762,383	$132,332,070
339910	Jewelry and Silverware Manufacturing	$7,504,994,935	$302,745,487	$3,925,308,912	$158,343,819	$1,177,940,358	$47,517,171
339920	Sporting and Athletic Goods Manufacturing	$10,658,798,838	$429,967,412	$1,235,218,821	$49,827,738	$970,497,005	$39,149,072
339930	Doll, Toy, and Game Manufacturing	$1,720,555,223	$69,405,820	$1,298,334,418	$52,373,771	$357,636,551	$14,426,772
339940	Office Supplies (except Paper) Manufacturing	$3,320,217,162	$133,934,902	$460,233,465	$18,565,450	$259,199,969	$10,455,919
339950	Sign Manufacturing	$13,212,923,236	$532,998,745	$10,768,055,741	$434,374,748	$2,909,036,588	$117,348,207
339991	Gasket, Packing, and Sealing Device Mfg.	$7,540,016,634	$304,158,235	$2,504,878,488	$101,044,793	$439,494,549	$17,728,858
339992	Musical Instrument Manufacturing	$2,040,059,050	$82,294,349	$465,435,364	$18,775,290	$255,684,563	$10,314,111
339993	Fastener, Button, Needle, and Pin Manufacturing	$932,759,282	$37,626,763	$0	$0	$52,427,806	$2,114,896
339994	Broom, Brush, and Mop Manufacturing	$2,968,149,189	$119,732,762	$1,160,531,125	$46,814,896	$122,499,344	$4,941,525
339995	Burial Casket Manufacturing	$595,589,836	$24,025,617	$0	$0	$34,718,413	$1,400,513
339999	All Other Miscellaneous Manufacturing	$12,729,195,852	$513,485,570	$7,850,431,266	$316,680,112	$3,199,808,510	$129,077,714
42	**Wholesale Trade**	**$8,241,112,357,137**	**$187,764,000,889**	**$2,029,694,592,065**	**$46,557,861,792**	**$662,069,497,910**	**$15,930,366,430**
423	**Merchant Wholesalers, Durable Goods**	**$3,730,586,842,837**	**$78,224,194,326**	**$1,038,998,940,330**	**$22,996,072,728**	**$358,307,048,518**	**$8,191,349,278**
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	$227,956,291,687	$5,659,037,892	$34,060,394,933	$845,552,734	$12,491,750,129	$310,108,955
423840	Industrial Supplies Merchant Wholesalers	$76,784,521,382	$2,369,037,938	$26,894,452,293	$829,776,323	$12,377,652,116	$381,888,523
424	**Merchant Wholesalers, Nondurable Goods**	**$4,510,525,514,300**	**$109,539,806,563**	**$990,695,651,735**	**$23,561,789,065**	**$303,762,449,392**	**$7,739,017,152**
424210	Drugs and Druggists' Sundries Merchant Wholesalers	$993,553,873,870	$34,478,605,779	$75,561,309,955	$2,622,151,336	$19,231,035,837	$667,361,198
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	$47,943,855,645	$1,464,284,802	$19,151,107,910	$584,906,572	$8,687,864,991	$265,341,794
424690	Other Chemical and Allied Products Merchant Wholesalers	$190,251,901,023	$5,810,608,336	$49,029,260,628	$1,497,434,869	$20,817,877,435	$635,812,476
424710	Petroleum Bulk Stations and Terminals	$553,795,115,137	$5,343,134,660	$116,687,155,895	$1,125,822,836	$19,778,343,816	$190,825,725
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	$589,029,156,042	$5,683,080,283	$110,304,296,920	$1,064,239,637	$21,107,021,411	$203,645,093
424910	Farm Supplies Merchant Wholesalers	$143,037,724,037	$3,880,616,514	$46,711,531,722	$1,267,284,855	$15,813,831,821	$429,029,596
424950	Paint, Varnish, and Supplies Merchant Wholesalers	$18,239,107,674	$423,672,981	$4,622,011,771	$107,363,888	$1,831,250,389	$42,537,789
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	$45,182,648,502	$1,049,539,689	$27,846,311,288	$646,837,002	$15,541,966,801	$361,021,577

Table VII-9: Estimated Total Revenues and Profits for Industries Affected by the Proposed Revisions to the HCS, by Establishment Size

NAICS Code	Industry	All Entities		Small Entities		Very Small Entities (Fewer than 20 Employees)	
		Revenues	Profits	Revenues	Profits	Revenues	Profits
Total							
Total	Total	$42,567,021,362,731	$5,795,377,657,021	$11,528,927,098,095	$1,258,949,490,569	$4,339,862,178,615	$165,526,269,969

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health based on U.S. Census Bureau, 2020a (Document ID 0231); U.S. Census Bureau, 2020b (Document ID 0232).

Table VII-10: Percentage of Establishments (or, for Training, Entities) Affected for Each Cost Provision in the Proposed Revisions to the HCS, by Industry

NAICS	NAICS Industry	Rule Familiarization - NAICS with Additional Costs[a]	Rule Familiarization - NAICS without Additional Costs	Training	Reclassification - Flammable Aerosols	Reclassification - Desensitized Explosives	Reclassification - Flammable Aerosols	Appendix
211120	Crude Petroleum Extraction	100%	0%	0%	0%	0%	0%	100%
211130	Natural Gas Extraction	100%	0%	50%	0%	0%	50%	100%
324110	Petroleum Refineries	100%	0%	50%	0%	0%	50%	100%
324121	Asphalt Paving Mixture and Block Manufacturing	100%	0%	0%	0%	0%	0%	100%
324122	Asphalt Shingle and Coating Materials Manufacturing	100%	0%	0%	0%	0%	0%	100%
324191	Petroleum Lubricating Oil and Grease Manufacturing	100%	0%	0%	0%	0%	0%	100%
324199	All Other Petroleum and Coal Products Manufacturing	100%	0%	0%	0%	0%	0%	100%
325110	Petrochemical Manufacturing	100%	0%	50%	0%	0%	50%	100%
325120	Industrial Gas Manufacturing	100%	0%	50%	0%	0%	50%	100%
325130	Synthetic Dye and Pigment Manufacturing	100%	0%	0%	0%	0%	0%	100%
325180	Other Basic Inorganic Chemical Manufacturing	100%	0%	0%	0%	0%	0%	100%
325193	Ethyl Alcohol Manufacturing	100%	0%	0%	0%	0%	0%	100%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	100%	0%	0%	0%	0%	0%	100%
325199	All Other Basic Organic Chemical Manufacturing	100%	0%	0%	0%	0%	0%	100%
325211	Plastics Material and Resin Manufacturing	100%	0%	0%	0%	0%	0%	100%
325212	Synthetic Rubber Manufacturing	100%	0%	0%	0%	0%	0%	100%
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	100%	0%	0%	0%	0%	0%	100%
325311	Nitrogenous Fertilizer Manufacturing	100%	0%	0%	0%	0%	0%	100%
325312	Phosphatic Fertilizer Manufacturing	100%	0%	0%	0%	0%	0%	100%
325314	Fertilizer (Mixing Only) Manufacturing	100%	0%	0%	0%	0%	0%	100%
325320	Pesticide and Other Agricultural Chemical Manufacturing	100%	0%	50%	50%	0%	0%	100%
325411	Medicinal and Botanical Manufacturing	100%	0%	0%	0%	0%	0%	100%
325412	Pharmaceutical Preparation Manufacturing	100%	0%	50%	50%	0%	0%	100%
325413	In-Vitro Diagnostic Substance Manufacturing	100%	0%	0%	0%	0%	0%	100%

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325414	Biological Product (except Diagnostic) Manufacturing	100%	0%	0%	0%	0%	0%	100%
325510	Paint and Coating Manufacturing	100%	0%	50%	50%	0%	0%	100%
325520	Adhesive Manufacturing	100%	0%	50%	50%	0%	0%	100%
325611	Soap and Other Detergent Manufacturing	100%	0%	50%	50%	0%	0%	100%
325612	Polish and Other Sanitation Good Manufacturing	100%	0%	50%	50%	0%	0%	100%
325613	Surface Active Agent Manufacturing	100%	0%	50%	50%	0%	0%	100%
325620	Toilet Preparation Manufacturing	100%	0%	50%	50%	0%	0%	100%
325910	Printing Ink Manufacturing	100%	0%	0%	0%	0%	0%	100%
325920	Explosives Manufacturing	100%	0%	50%	0%	50%	0%	100%
325991	Custom Compounding of Purchased Resins	100%	0%	0%	0%	0%	0%	100%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	100%	0%	0%	0%	0%	0%	100%
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	100%	0%	0%	0%	0%	0%	100%
326111	Plastics Bag and Pouch Manufacturing	0%	100%	0%	0%	0%	0%	0%
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	0%	100%	0%	0%	0%	0%	0%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	0%	100%	0%	0%	0%	0%	0%
326121	Unlaminated Plastics Profile Shape Manufacturing	0%	100%	0%	0%	0%	0%	0%
326122	Plastics Pipe and Pipe Fitting Manufacturing	0%	100%	0%	0%	0%	0%	0%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	0%	100%	0%	0%	0%	0%	0%
326140	Polystyrene Foam Product Manufacturing	0%	100%	0%	0%	0%	0%	0%
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	0%	100%	0%	0%	0%	0%	0%
326160	Plastics Bottle Manufacturing	0%	100%	0%	0%	0%	0%	0%
326191	Plastics Plumbing Fixture Manufacturing	0%	100%	0%	0%	0%	0%	0%
326199	All Other Plastics Product Manufacturing	0%	100%	0%	0%	0%	0%	0%
326211	Tire Manufacturing (except Retreading)	0%	100%	0%	0%	0%	0%	0%
326212	Tire Retreading	0%	100%	0%	0%	0%	0%	0%
326220	Rubber and Plastics Hoses and Belting Manufacturing	0%	100%	0%	0%	0%	0%	0%
326291	Rubber Product Manufacturing for Mechanical Use	0%	100%	0%	0%	0%	0%	0%
326299	All Other Rubber Product Manufacturing	0%	100%	0%	0%	0%	0%	0%
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	0%	100%	0%	0%	0%	0%	0%
327120	Clay Building Material and Refractories Manufacturing	0%	100%	0%	0%	0%	0%	0%
327211	Flat Glass Manufacturing	0%	100%	0%	0%	0%	0%	0%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	0%	100%	0%	0%	0%	0%	0%
327213	Glass Container Manufacturing	0%	100%	0%	0%	0%	0%	0%

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327215	Glass Product Manufacturing Made of Purchased Glass	0%	100%	0%	0%	0%	0%	0%
327310	Cement Manufacturing	0%	100%	0%	0%	0%	0%	0%
327320	Ready-Mix Concrete Manufacturing	0%	100%	0%	0%	0%	0%	0%
327331	Concrete Block and Brick Manufacturing	0%	100%	0%	0%	0%	0%	0%
327332	Concrete Pipe Manufacturing	0%	100%	0%	0%	0%	0%	0%
327390	Other Concrete Product Manufacturing	0%	100%	0%	0%	0%	0%	0%
327410	Lime Manufacturing	0%	100%	0%	0%	0%	0%	0%
327420	Gypsum Product Manufacturing	0%	100%	0%	0%	0%	0%	0%
327910	Abrasive Product Manufacturing	0%	100%	0%	0%	0%	0%	0%
327991	Cut Stone and Stone Product Manufacturing	0%	100%	0%	0%	0%	0%	0%
327992	Ground or Treated Mineral and Earth Manufacturing	0%	100%	0%	0%	0%	0%	0%
327993	Mineral Wool Manufacturing	0%	100%	0%	0%	0%	0%	0%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	0%	100%	0%	0%	0%	0%	0%
331110	Iron and Steel Mills and Ferroalloy Manufacturing	0%	100%	0%	0%	0%	0%	0%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	0%	100%	0%	0%	0%	0%	0%
331221	Rolled Steel Shape Manufacturing	0%	100%	0%	0%	0%	0%	0%
331222	Steel Wire Drawing	0%	100%	0%	0%	0%	0%	0%
331313	Alumina Refining and Primary Aluminum Production	0%	100%	0%	0%	0%	0%	0%
331314	Secondary Smelting and Alloying of Aluminum	0%	100%	0%	0%	0%	0%	0%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	0%	100%	0%	0%	0%	0%	0%
331318	Other Aluminum Rolling, Drawing, and Extruding	0%	100%	0%	0%	0%	0%	0%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	0%	100%	0%	0%	0%	0%	0%
331420	Copper Rolling, Drawing, Extruding, and Alloying	0%	100%	0%	0%	0%	0%	0%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	0%	100%	0%	0%	0%	0%	0%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	0%	100%	0%	0%	0%	0%	0%
331511	Iron Foundries	0%	100%	0%	0%	0%	0%	0%
331512	Steel Investment Foundries	0%	100%	0%	0%	0%	0%	0%
331513	Steel Foundries (except Investment)	0%	100%	0%	0%	0%	0%	0%
331523	Nonferrous Metal Die-Casting Foundries	0%	100%	0%	0%	0%	0%	0%
331524	Aluminum Foundries (except Die-Casting)	0%	100%	0%	0%	0%	0%	0%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	0%	100%	0%	0%	0%	0%	0%
339112	Surgical and Medical Instrument Manufacturing	100%	0%	0%	0%	0%	0%	100%

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339113	Surgical Appliance and Supplies Manufacturing	100%	0%	0%	0%	0%	0%	100%
339114	Dental Equipment and Supplies Manufacturing	100%	0%	0%	0%	0%	0%	100%
339115	Ophthalmic Goods Manufacturing	100%	0%	0%	0%	0%	0%	100%
339116	Dental Laboratories	100%	0%	0%	0%	0%	0%	100%
339910	Jewelry and Silverware Manufacturing	100%	0%	0%	0%	0%	0%	100%
339920	Sporting and Athletic Goods Manufacturing	100%	0%	0%	0%	0%	0%	100%
339930	Doll, Toy, and Game Manufacturing	100%	0%	0%	0%	0%	0%	100%
339940	Office Supplies (except Paper) Manufacturing	100%	0%	0%	0%	0%	0%	100%
339950	Sign Manufacturing	100%	0%	0%	0%	0%	0%	100%
339991	Gasket, Packing, and Sealing Device Manufacturing	100%	0%	0%	0%	0%	0%	100%
339992	Musical Instrument Manufacturing	100%	0%	0%	0%	0%	0%	100%
339993	Fastener, Button, Needle, and Pin Manufacturing	100%	0%	0%	0%	0%	0%	100%
339994	Broom, Brush, and Mop Manufacturing	100%	0%	0%	0%	0%	0%	100%
339995	Burial Casket Manufacturing	100%	0%	0%	0%	0%	0%	100%
339999	All Other Miscellaneous Manufacturing	100%	0%	0%	0%	0%	0%	100%
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	0%	100%	0%	0%	0%	0%	0%
423840	Industrial Supplies Merchant Wholesalers	0%	100%	0%	0%	0%	0%	0%
424210	Drugs and Druggists' Sundries Merchant Wholesalers	0%	100%	0%	0%	0%	0%	0%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	0%	100%	0%	0%	0%	0%	0%
424690	Other Chemical and Allied Products Merchant Wholesalers	0%	100%	0%	0%	0%	0%	0%
424710	Petroleum Bulk Stations and Terminals	0%	100%	0%	0%	0%	0%	0%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	0%	100%	0%	0%	0%	0%	0%
424910	Farm Supplies Merchant Wholesalers	0%	100%	0%	0%	0%	0%	0%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	0%	100%	0%	0%	0%	0%	0%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	0%	100%	0%	0%	0%	0%	0%

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

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TABLE VII–11—CHARACTERISTICS OF INDUSTRIES AND LABELS/SDSS AFFECTED BY OSHA'S PROPOSED REVISIONS TO THE HCS [a]

	Total	Percentage affected	Affected
Firms	6,077,430	1.91	115,758
Establishments	7,780,863	1.96	152,427
Relevant Employees	148,004,068	2.82	4,178,738
Labels Being Revised Due to Chemical Reclassification and Labels Revisions	1,512,219,200	63.55	961,053,993
Labels for Very Small Containers	147,599,473	17.21	25,394,066
Firms w/Warehoused Labels that Change	230	1.00	2.30
SDSs	1,519,506	94.40	1,434,377

Sources: U.S. Census Bureau, 2020a (Document ID 0231); U.S. Census Bureau, 2020b (Document ID 0232); U.S. Census Bureau, 2019a (Document ID 0227); BLS, 2020 (Document ID 0223); U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

Note: Due to rounding, data derived by applying the percentages shown in the table to the figures shown in the ''Total'' column may not be identical to the figures shown in the ''Affected'' column.

[a] The data in this table are drawn from tables presented earlier in this PEA (for firms, establishments and employees, see Table VII–1; for labels and SDSs, see Table VII–5).

D. Health and Safety Benefits and Unquantified Positive Economic Effects

As part of the rulemakings that resulted in promulgation of the original HCS in 1983, and the 1987 updates, OSHA conducted research to identify and estimate expected health and safety benefits, as described in the preambles to those final rules (48 FR 53327–53329; 52 FR 31868–31869). Combining the 1983 and 1987 rulemakings, OSHA estimated that the HCS would prevent 31,841 non-lost-workday injuries and illnesses, 20,263 lost-workday injuries and illnesses, 6,410 chronic illnesses, and 4,260 fatalities (77 FR 17621). In the 2012 final rule to modify the HCS to conform with the GHS, OSHA estimated that compliance with those revisions to the HCS would result in additional health and safety benefits equal to one percent of the previously-estimated health and safety benefits—that is, they would result in the prevention of an additional 318 non-lost-workday injuries and illnesses, 203 lost-workday injuries and illnesses, 64 chronic illnesses, and 43 fatalities annually (77 FR 17620–17624).

Relative to the HCS rulemakings that resulted in the promulgation of final rules in 1983, 1987, and 2012, these proposed revisions to the HCS are incremental and minor. Accordingly, OSHA expects that the proposed revisions to the standard will result in more modest improvements in employee health and safety than the estimated benefits OSHA attributed to the earlier rulemakings. But OSHA expects that the promulgation of the proposed revisions to the HCS *will* result in an increased degree of health and safety for affected employees and a corresponding reduction in the annual numbers of injuries, illnesses, and fatalities associated with workplace exposures to hazardous chemicals. Aligning with the GHS Rev. 7 will improve worker health and safety by ensuring the provision of more and better hazard information to employers and workers. For example, OSHA anticipates that the improved criteria for aerosols and flammable gases and the new hazard class for desensitized explosives, along with updated precautionary statements, will better differentiate the hazards associated with those chemicals. In addition, the proposed released-for-shipment provisions will remove the risk of injury and chemical exposures for employees who previously would have confronted the possibility of, for example, having to break down pallets of sealed, shrink-wrapped, packaged containers to replace labels when new hazards were identified.

Although OSHA expects that the proposed revisions to the HCS would reduce injuries, illnesses, and fatalities, the limited scope and nature of the changes being proposed have led OSHA to a preliminary determination that it cannot reasonably quantify an estimate of how many injuries, illnesses, and fatalities would be prevented. As the agency noted in the 2012 FEA, any assessment of benefits that are incremental to the original estimated benefits, *e.g.,* benefits associated with minor improvements to an existing standard, broaden the range of uncertainty associated with the original estimates (77 FR 17621).[25] OSHA invites interested parties to provide comments and evidence on how the proposed revisions to the HCS are likely to affect worker safety and health.

In addition to the aforementioned health and safety benefits, OSHA expects that the proposed revisions to the HCS would result in other positive economic effects. For example, being better aligned with the GHS would help facilitate international trade, thereby enhancing competition, increasing export opportunities for U.S. businesses, reducing costs for imported products, and generally expanding the selection of chemicals and products available to U.S. businesses and consumers. As a result of the direct savings expected to result from better harmonization and the associated increase in international competition, prices for the affected chemicals and products, and the corresponding goods and services that use them, should decline, even if only to a limited extent.

Similarly, better alignment between the HCS and the GHS would have the additional benefit of meeting the international goals for adoption and implementation of the GHS that have been supported by the U.S. government.[26] Maintaining alignment with the GHS in U.S. laws and policies through appropriate legislative and

[25] As described above, OSHA estimated that the 2012 revisions to the HCS would result in benefits equal to one percent of the health and safety benefits previously estimated for the standard (77 FR 17620–17624). In the 2012 rulemaking, OSHA and stakeholders collectively noted the considerable uncertainty inherent in estimating benefits that are additional (incremental) to the set of benefits associated with the original rule (see 77 FR 17620–17624). The agency stated: ''OSHA believes that a reasonable range for the magnitude of the health and safety benefits resulting from the proposed revisions would be between 0.5 percent and 5 percent of the benefits associated with the current HCS.'' (77 FR 17621 (n 14)). In addition, OSHA stated in the 2012 FEA that ''[i]t is conceivable that actual benefits might be somewhat lower, but because the GHS is expected to result, in some situations, in more timely and appropriate treatment of exposed workers, OSHA expects that actual benefits may be larger, perhaps several times larger.'' (77 FR 17621)

[26] The EU, Canada, Australia, and New Zealand have also indicated that they are proposing updates to align with the 7th revision to the GHS (Report of the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals on its thirty-fifth session ST/SG/AC.10/C.4/7, Document ID 0040).

regulatory action was anticipated by the U.S. when it supported international mandates regarding the GHS in the Intergovernmental Forum on Chemical Safety, the World Summit on Sustainable Development, and the United Nations. It is also consistent with the established goals of the Strategic Approach to International Chemical Management that the U.S. helped to craft.[27]

E. Technological Feasibility

In accordance with the OSH Act, OSHA is required to demonstrate that occupational safety and health standards promulgated by the agency are technologically feasible. A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed. See Lead I, 647 F.2d at 1272.

OSHA has reviewed the requirements that would be imposed by the proposed rule and has assessed their technological feasibility. As a result of this review, OSHA has preliminarily determined that compliance with the requirements of the rule is technologically feasible for all affected industries.

The proposed revisions to OSHA's HCS would require manufacturers and importers to reclassify aerosols, desensitized explosives, and flammable gases in accordance with the new classification criteria and make corresponding revisions to SDSs and labels. Compliance with these requirements would mainly involve revisions to the presentation of information and is not expected to involve any technological obstacles.

The proposed changes to the requirements for the labeling of very small containers, which would eliminate full labeling requirements for some containers with a volume capacity of 3 ml or less, is expected to address current feasibility issues related to labeling these small containers. When a label would interfere with the normal use of the container, and it is not feasible to use pullout labels, fold-back labels, or tags containing full label information, the proposal would require the container to bear only the product identifier, which could be etched onto the container itself. Similarly, the proposed released-for-shipment provisions would alleviate employer concerns regarding the practicability of breaking down pallets of sealed, shrink-wrapped packaged containers to replace labels when new hazards are identified. OSHA requests public comment on any employer concerns associated with the proposed provision for labeling very small containers or with the proposed provision addressing the relabeling of containers that have been released for shipment.

OSHA has preliminarily determined that compliance with all of the requirements of the proposed revisions to the HCS can be achieved with readily and widely available technologies. No new technologies are required for compliance with the proposed modifications to the HCS. Therefore, OSHA believes that there are no technological constraints associated with compliance with any of the proposed revisions to the HCS. OSHA invites comment on these preliminary findings of technological feasibility.

F. Compliance Costs and Cost Savings

Introduction

This section presents OSHA's estimates of the costs and cost savings expected to result from the proposed revisions to the HCS. The estimated costs and cost savings are based on employers achieving full compliance with the new requirements of the proposed rule. They do not include prior costs and cost savings associated with firms whose current practices are already in compliance with the proposed requirements (where prior compliance is possible).

The estimated costs and cost savings resulting from the proposed revisions to the HCS consist of five main categories: (1) The cost of revising SDSs and labels for select hazardous chemicals to reflect chemical reclassifications (per proposed changes to appendix B) and to conform to language criteria in precautionary statements and other mandatory language (per proposed changes to appendices C and D); (2) the cost of management familiarization and other management-related costs (associated with all of the proposed revisions to the standard); (3) the cost of training employees as necessitated by the proposed changes to the HCS (see existing 29 CFR 1910.1200(h)(1)); (4) the cost savings due to the new released-for-shipment provision (proposed revisions to 29 CFR 1910.1200(f)(11)); and (5) the cost savings from limiting labeling requirements for certain very small containers (proposed 29 CFR 1910.1200(f)(12)). The first three categories are considered to be one-time costs and the last two categories are cost savings that would accrue to employers annually. Although OSHA has preliminarily determined that these are the only elements of the proposed revisions to the HCS that are expected to result in more than *de minimis* costs or cost savings, OSHA requests comments on whether any other proposed changes to the standard could cause employers to incur costs or obtain cost savings.

The estimated compliance costs do not include any indirect costs or impacts that may result from the reclassification or relabeling of chemicals and products already subject to the HCS, such as possible changes in production or in demand for products. Theoretically, such impacts, if any, with regard to possible changes in the uses and applications of affected chemicals, could result in costs or cost savings. OSHA expects that such effects, if any, will not be significant, but the agency would welcome input from stakeholders. This is consistent with the determination OSHA made with regard to reclassification costs for the 2012 final rule (77 FR 17625).

In order to present compliance costs and cost savings on a consistent and comparable basis across various regulatory activities, they are expressed in annualized terms. Annualized costs and cost savings represent the most appropriate measure for assessing the longer-term potential impacts of this proposed rulemaking and for purposes of comparing net costs across diverse regulations with a consistent metric. In addition, annualized net costs are often used for accounting purposes to assess the cumulative net costs of regulations on the economy or specific parts of the economy across different regulatory programs or across years.

As presented in this PEA (unless otherwise specified), a seven percent discount rate was applied to costs and cost savings arising in future years to calculate the present value of these costs and cost savings for the base year in which the standard becomes effective, and the same discount rate was then applied to the total present value costs, over a 10-year period, to calculate the annualized cost.[28] The economic effects

[27] *https://2009-2017.state.gov/e/oes/eqt/chemicalpollution/83012.htm* (SAICM, 2006, Document ID 0039).

[28] OSHA annualized costs for this proposed rule over a 10-year period in accordance with Executive Order 13563, which directs agencies ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' In addition, OMB Circular A–4 states that analysis should include all future costs and benefits using a ''rule of reason'' to consider for how long it can reasonably predict the future and limit its analysis to this time period. The 10-year annualization period is the one OSHA has traditionally used in rulemakings. Note, however, that OSHA used a 20-year annualization period for the 2012 HCS final rule (77 FR 17625), but that was

using a three percent discount rate are also provided in the Excel spreadsheets that support this PEA, which are contained in the docket (OSHA, 2020, Document ID 0049).

For the purpose of calculating loaded wage rates, OSHA did not include an overhead labor cost in the FEA in support of the 2012 HCS final standard. The Department of Labor has since determined that it is appropriate, in some circumstances, to account for overhead expenses as part of the methodology used to estimate the costs and economic impacts of OSHA regulations. For this PEA, in addition to applying fringe benefits to hourly (''base'') wages, OSHA also applied an overhead rate when estimating the marginal cost of labor in its primary cost calculation.

Overhead costs are indirect expenses that cannot be tied to producing a specific product or service. Common examples include rent, utilities, and office equipment; however, there is no general consensus on the cost elements that fit the definition of overhead in the context of occupational safety and health. The lack of a common definition has led to a wide range of overhead estimates. Consequently, the treatment of overhead costs needs to be case-specific. For this PEA, OSHA has adopted an overhead rate of 17 percent of base wages, which is consistent with the overhead rate and methodology used for (1) sensitivity analyses in the FEA in support of the 2017 final rule delaying the deadline for submission of OSHA Form 300A data (82 FR 55761, 55765 (Nov. 24, 2017)); and (2) the FEA in support of OSHA's 2016 final standard on Occupational Exposure to Respirable Crystalline Silica (81 FR 16285, 16488–16492 (March 25, 2016)).[29]

To calculate the total labor cost for an occupational category, OSHA added together three components: Base wage + fringe benefits (derived as 45.8 percent of the base wage)[30] + applicable overhead costs (derived as 17 percent of the base wage). For example, the median hourly wage of an Occupational Health and Safety Specialist is $35.63. Applying a fringe markup of 45.8 percent (applied to the base wage) and an overhead rate of 17 percent (applied to the base wage) yields a fully-loaded hourly wage of $ $58.00 ($35.63 × .458 = $16.32; $35.63 × 0.17 = $6.11; $35.63 + $16.32 + $6.11 = $58.00). Note that, for this labor category, the fringe markup is equal to 28.13 percent of the fully-loaded hourly wage and that the overhead rate is equal to 10.53 percent of the fully-loaded hourly wage. Using this methodology, OSHA calculated the fully-loaded labor cost for four occupational categories: (1) Manager, Standard Occupational Classification (SOC) code 11–0000, $82.70; (2) Logistics Personnel, SOC code 13–1081, $58.51; (3) Production Worker, SOC code 51–0000, $28.18; and (4) Occupational Health and Safety Specialist, SOC code 19–5011, $58.00. (For further details, see Document ID 0049, tab ''Wages''.)

Table VII–12 shows the estimated annualized compliance costs and cost savings by cost category and by industry sector. All costs and cost savings are reported in 2019 dollars. As shown in Table VII–12, the total annualized net cost savings of compliance with the proposed rulemaking is estimated to be $26.8 million—consisting of about $4.4 million of annualized costs and $31.1 million of annual cost savings. Note that where tables in this PEA report estimated annualized costs, as in Table VII–12, cost savings appear as a negative number.

As shown by the three-digit NAICS Subsectors 325 (for Chemical Manufacturing) and 424 (for Merchant Wholesalers, Nondurable Goods) in Table VII–12, most of the estimated compliance costs and cost savings associated with the proposed rule would be incurred or realized by the chemical manufacturing industry and its distributors. However, the table also shows that familiarization costs would be spread across most manufacturing and wholesale industries in the U.S. economy subject to OSHA's jurisdiction, reflecting the fact that employee exposures to hazardous chemicals occur in many industry sectors.

OSHA expects that all compliance costs would be incurred in the first year, as the proposed rule would incorporate a one-year transition period into the compliance schedule for the standard. Specifically, for purposes of estimating the annualized compliance costs, OSHA assumed that the compliance costs associated with chemical reclassification, employee training, and management familiarization would be incurred in the first year following the effective date of the proposed revisions to the HCS.

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because of the 5-year phase-in of some provisions. This proposed rule does not have any lengthy phase-in provisions, supporting OSHA's decision to use a 10-year annualization period for this PEA.

[29] This methodology was modeled after an approach used by the Environmental Protection Agency. More information on this approach can be found at U.S. Environmental Protection Agency, ''Wage Rates for Economic Analyses of the Toxics Release Inventory Program,'' June 10, 2002 (Ex. 2066) (Document ID 0046). This analysis itself was based on a survey of several large chemical manufacturing plants: Heiden Associates, *Final Report: A Study of Industry Compliance Costs under the Final Comprehensive Assessment Information Rule,* prepared for the Chemical Manufacturers Association, December 14, 1989 (Ex. 2065) (Document ID 0048).

[30] In June of 2019, BLS reported: ''Employer costs for employee compensation for civilian workers averaged $36.77 per hour worked in March 2019 . . . Wages and salaries cost employers $25.22 while benefit costs were $11.55.'' The fringe markup of 31.4 percent of total compensation ($11.55/$36.77) is equivalent to a benefits markup of 45.8 percent in relation to the base wage ($11.55/$25.22). (BLS, 2019, Document ID 0224).

Table VII-12: Total Annualized Costs of Provisions, by Six-Digit NAICS for All Entities (7 Percent Discount Rate, 2019 Dollars)

NAICS Code	Industry	Rule Familiarization	Training	Revised SDS/ Labels [a]	Release for Shipment	Labels for Very Small Containers	Total Costs
21	**Mining, Quarrying, and Oil and Gas Extraction**	**$39,410**	**$7,194**	**$264,973**	**$0**	**$0**	**$311,577**
211	**Oil and Gas Extraction**	**$39,410**	**$7,194**	**$264,973**	**$0**	**$0**	**$311,577**
211120	Crude Petroleum Extraction	$31,535	$0	$166,838	$0	$0	$198,373
211130	Natural Gas Extraction	$7,875	$7,194	$98,135	$0	$0	$113,204
31-33	**Manufacturing**	**$483,276**	**$112,964**	**$3,264,949**	**-$11,397,777**	**-$1,291,839**	**-$8,828,427**
324	**Petroleum and Coal Products Manufacturing**	**$19,238**	**$11,539**	**$1,498,159**	**$0**	**$0**	**$1,528,936**
324110	Petroleum Refineries	$4,992	$11,539	$81,933	$0	$0	$98,464
324121	Asphalt Paving Mixture and Block Manufacturing	$7,969	$0	$163,804	$0	$0	$171,774
324122	Asphalt Shingle and Coating Materials Manufacturing	$2,383	$0	$23,837	$0	$0	$26,220
324191	Petroleum Lubricating Oil and Grease Manufacturing	$3,080	$0	$1,218,913	$0	$0	$1,221,994
324199	All Other Petroleum and Coal Products Manufacturing	$813	$0	$9,671	$0	$0	$10,485
325	**Chemical Manufacturing**	**$137,810**	**$101,426**	**$1,587,629**	**-$11,397,777**	**-$1,291,839**	**-$10,862,751**
325110	Petrochemical Manufacturing	$822	$1,808	$17,494	$0	$0	$20,123
325120	Industrial Gas Manufacturing	$4,270	$2,790	$18,258	$0	$0	$25,318
325130	Synthetic Dye and Pigment Manufacturing	$1,487	$0	$7,811	$0	$0	$9,298
325180	Other Basic Inorganic Chemical Manufacturing	$7,082	$0	$11,346	$0	-$300,518	-$282,090
325193	Ethyl Alcohol Manufacturing	$3,171	$0	$8,752	$0	$0	$11,923
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	$842	$0	$4,066	$0	$0	$4,908
325199	All Other Basic Organic Chemical Manufacturing	$10,001	$0	$46,752	$0	-$722,874	-$666,121
325211	Plastics Material and Resin Manufacturing	$13,899	$0	$141,086	$0	$0	$154,986
325212	Synthetic Rubber Manufacturing	$1,738	$0	$3,071	$0	$0	$4,809
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	$1,664	$0	$587	$0	$0	$2,251
325311	Nitrogenous Fertilizer Manufacturing	$1,656	$0	$942	-$1,544,546	$0	-$1,541,948
325312	Phosphatic Fertilizer Manufacturing	$628	$0	$265	-$1,431,358	$0	-$1,430,465
325314	Fertilizer (Mixing Only) Manufacturing	$3,609	$0	$9,794	-$1,232,972	$0	-$1,219,569
325320	Pesticide and Other Agricultural Chemical Manufacturing	$1,982	$3,691	$33,715	$0	$0	$39,388
325411	Medicinal and Botanical Manufacturing	$4,848	$0	$17,139	$0	-$103,904	-$81,917
325412	Pharmaceutical Preparation Manufacturing	$15,964	$28,984	$113,709	$0	-$131,685	$26,972
325413	In-Vitro Diagnostic Substance Manufacturing	$3,493	$0	$34,155	$0	-$10,208	$27,441
325414	Biological Product (except Diagnostic) Manufacturing	$4,877	$0	$6,306	$0	-$22,650	-$11,467
325510	Paint and Coating Manufacturing	$10,505	$16,645	$430,618	-$7,188,901	$0	-$6,731,133
325520	Adhesive Manufacturing	$5,711	$8,087	$169,541	$0	$0	$183,339
325611	Soap and Other Detergent Manufacturing	$5,475	$10,493	$109,220	$0	$0	$125,189
325612	Polish and Other Sanitation Good Manufacturing	$3,592	$6,882	$67,826	$0	$0	$78,300
325613	Surface Active Agent Manufacturing	$1,264	$2,046	$29,128	$0	$0	$32,437
325620	Toilet Preparation Manufacturing	$9,167	$18,280	$131,164	$0	$0	$158,612

Table VII-12: Total Annualized Costs of Provisions, by Six-Digit NAICS for All Entities (7 Percent Discount Rate, 2019 Dollars)

NAICS Code	Industry	Rule Familiarization	Training	Revised SDS/ Labels [a]	Release for Shipment	Labels for Very Small Containers	Total Costs
325910	Printing Ink Manufacturing	$2,742	$0	$50,591	$0	$0	$53,333
325920	Explosives Manufacturing	$838	$1,718	$13,195	$0	$0	$15,752
325991	Custom Compounding of Purchased Resins	$4,373	$0	$7,552	$0	$0	$11,925
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	$1,643	$0	$4,575	$0	$0	$6,218
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	$10,468	$0	$98,970	$0	$0	$109,437
326	**Plastics and Rubber Products Manufacturing**	**$68,513**	**$0**	**$0**	**$0**	**$0**	**$68,513**
326111	Plastics Bag and Pouch Manufacturing	$2,191	$0	$0	$0	$0	$2,191
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	$2,711	$0	$0	$0	$0	$2,711
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	$3,054	$0	$0	$0	$0	$3,054
326121	Unlaminated Plastics Profile Shape Manufacturing	$2,048	$0	$0	$0	$0	$2,048
326122	Plastics Pipe and Pipe Fitting Manufacturing	$2,800	$0	$0	$0	$0	$2,800
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	$1,121	$0	$0	$0	$0	$1,121
326140	Polystyrene Foam Product Manufacturing	$2,606	$0	$0	$0	$0	$2,606
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	$3,669	$0	$0	$0	$0	$3,669
326160	Plastics Bottle Manufacturing	$3,165	$0	$0	$0	$0	$3,165
326191	Plastics Plumbing Fixture Manufacturing	$1,724	$0	$0	$0	$0	$1,724
326199	All Other Plastics Product Manufacturing	$33,348	$0	$0	$0	$0	$33,348
326211	Tire Manufacturing (except Retreading)	$1,288	$0	$0	$0	$0	$1,288
326212	Tire Retreading	$1,390	$0	$0	$0	$0	$1,390
326220	Rubber and Plastics Hoses and Belting Manufacturing	$1,553	$0	$0	$0	$0	$1,553
326291	Rubber Product Manufacturing for Mechanical Use	$2,509	$0	$0	$0	$0	$2,509
326299	All Other Rubber Product Manufacturing	$3,339	$0	$0	$0	$0	$3,339
327	**Nonmetallic Mineral Product Manufacturing**	**$59,127**	**$0**	**$0**	**$0**	**$0**	**$59,127**
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	$1,963	$0	$0	$0	$0	$1,963
327120	Clay Building Material and Refractories Manufacturing	$2,740	$0	$0	$0	$0	$2,740
327211	Flat Glass Manufacturing	$597	$0	$0	$0	$0	$597
327212	Other Pressed and Blown Glass and Glassware Manufacturing	$1,534	$0	$0	$0	$0	$1,534
327213	Glass Container Manufacturing	$442	$0	$0	$0	$0	$442
327215	Glass Product Manufacturing Made of Purchased Glass	$4,844	$0	$0	$0	$0	$4,844
327310	Cement Manufacturing	$1,094	$0	$0	$0	$0	$1,094
327320	Ready-Mix Concrete Manufacturing	$19,738	$0	$0	$0	$0	$19,738
327331	Concrete Block and Brick Manufacturing	$3,058	$0	$0	$0	$0	$3,058
327332	Concrete Pipe Manufacturing	$1,195	$0	$0	$0	$0	$1,195
327390	Other Concrete Product Manufacturing	$8,244	$0	$0	$0	$0	$8,244
327410	Lime Manufacturing	$479	$0	$0	$0	$0	$479
327420	Gypsum Product Manufacturing	$987	$0	$0	$0	$0	$987

Table VII-12: Total Annualized Costs of Provisions, by Six-Digit NAICS for All Entities (7 Percent Discount Rate, 2019 Dollars)

NAICS Code	Industry	Rule Familiarization	Training	Revised SDS/ Labels [a]	Release for Shipment	Labels for Very Small Containers	Total Costs
327910	Abrasive Product Manufacturing	$1,317	$0	$0	$0	$0	$1,317
327991	Cut Stone and Stone Product Manufacturing	$6,594	$0	$0	$0	$0	$6,594
327992	Ground or Treated Mineral and Earth Manufacturing	$1,098	$0	$0	$0	$0	$1,098
327993	Mineral Wool Manufacturing	$1,369	$0	$0	$0	$0	$1,369
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	$1,833	$0	$0	$0	$0	$1,833
331	**Primary Metal Manufacturing**	**$25,831**	**$0**	**$0**	**$0**	**$0**	**$25,831**
331110	Iron and Steel Mills and Ferroalloy Manufacturing	$4,107	$0	$0	$0	$0	$4,107
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	$1,693	$0	$0	$0	$0	$1,693
331221	Rolled Steel Shape Manufacturing	$1,034	$0	$0	$0	$0	$1,034
331222	Steel Wire Drawing	$1,418	$0	$0	$0	$0	$1,418
331313	Alumina Refining and Primary Aluminum Production	$213	$0	$0	$0	$0	$213
331314	Secondary Smelting and Alloying of Aluminum	$572	$0	$0	$0	$0	$572
331315	Aluminum Sheet, Plate, and Foil Manufacturing	$861	$0	$0	$0	$0	$861
331318	Other Aluminum Rolling, Drawing, and Extruding	$1,718	$0	$0	$0	$0	$1,718
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	$650	$0	$0	$0	$0	$650
331420	Copper Rolling, Drawing, Extruding, and Alloying	$1,689	$0	$0	$0	$0	$1,689
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	$1,299	$0	$0	$0	$0	$1,299
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	$1,065	$0	$0	$0	$0	$1,065
331511	Iron Foundries	$2,275	$0	$0	$0	$0	$2,275
331512	Steel Investment Foundries	$898	$0	$0	$0	$0	$898
331513	Steel Foundries (except Investment)	$1,049	$0	$0	$0	$0	$1,049
331523	Nonferrous Metal Die-Casting Foundries	$2,463	$0	$0	$0	$0	$2,463
331524	Aluminum Foundries (except Die-Casting)	$1,726	$0	$0	$0	$0	$1,726
331529	Other Nonferrous Metal Foundries (except Die-Casting)	$1,100	$0	$0	$0	$0	$1,100
339	**Miscellaneous Manufacturing**	**$172,756**	**$0**	**$179,161**	**$0**	**$0**	**$351,917**
339112	Surgical and Medical Instrument Manufacturing	$14,300	$0	$8,697	$0	$0	$22,996
339113	Surgical Appliance and Supplies Manufacturing	$15,576	$0	$13,386	$0	$0	$28,962
339114	Dental Equipment and Supplies Manufacturing	$3,588	$0	$3,774	$0	$0	$7,362
339115	Ophthalmic Goods Manufacturing	$4,365	$0	$2,755	$0	$0	$7,119
339116	Dental Laboratories	$29,458	$0	$35,670	$0	$0	$65,129
339910	Jewelry and Silverware Manufacturing	$10,918	$0	$12,499	$0	$0	$23,417
339920	Sporting and Athletic Goods Manufacturing	$11,161	$0	$11,070	$0	$0	$22,231
339930	Doll, Toy, and Game Manufacturing	$2,924	$0	$3,323	$0	$0	$6,247
339940	Office Supplies (except Paper) Manufacturing	$3,076	$0	$3,120	$0	$0	$6,196
339950	Sign Manufacturing	$34,356	$0	$38,064	$0	$0	$72,420

Table VII-12: Total Annualized Costs of Provisions, by Six-Digit NAICS for All Entities (7 Percent Discount Rate, 2019 Dollars)

NAICS Code	Industry	Rule Familiarization	Training	Revised SDS/ Labels [a]	Release for Shipment	Labels for Very Small Containers	Total Costs
339991	Gasket, Packing, and Sealing Device Manufacturing	$5,715	$0	$4,104	$0	$0	$9,819
339992	Musical Instrument Manufacturing	$3,865	$0	$3,957	$0	$0	$7,822
339993	Fastener, Button, Needle, and Pin Manufacturing	$813	$0	$753	$0	$0	$1,567
339994	Broom, Brush, and Mop Manufacturing	$1,862	$0	$1,403	$0	$0	$3,266
339995	Burial Casket Manufacturing	$710	$0	$687	$0	$0	$1,397
339999	All Other Miscellaneous Manufacturing	$30,069	$0	$35,897	$0	$0	$65,966
42	**Wholesale Trade**	**$213,209**	**$0**	**$0**	**-$18,450,070**	**$0**	**-$18,236,861**
423	**Merchant Wholesalers, Durable Goods**	**$59,554**	**$0**	**$0**	**$0**	**$0**	**$59,554**
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	$32,883	$0	$0	$0	$0	$32,883
423840	Industrial Supplies Merchant Wholesalers	$26,671	$0	$0	$0	$0	$26,671
424	**Merchant Wholesalers, Nondurable Goods**	**$153,654**	**$0**	**$0**	**-$18,450,070**	**$0**	**-$18,296,415**
424210	Drugs and Druggists' Sundries Merchant Wholesalers	$35,832	$0	$0	$0	$0	$35,832
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	$8,475	$0	$0	$0	$0	$8,475
424690	Other Chemical and Allied Products Merchant Wholesalers	$28,715	$0	$0	$0	$0	$28,715
424710	Petroleum Bulk Stations and Terminals	$13,649	$0	$0	$0	$0	$13,649
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	$7,426	$0	$0	$0	$0	$7,426
424910	Farm Supplies Merchant Wholesalers	$26,634	$0	$0	-$14,911,683	$0	-$14,885,049
424950	Paint, Varnish, and Supplies Merchant Wholesalers	$5,100	$0	$0	-$3,538,387	$0	-$3,533,287
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	$27,823	$0	$0	$0	$0	$27,823
Total	**Total**	$735,894	$120,158	$3,529,921	-$29,847,846	-$1,291,839	-$26,753,711

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

[a] Figures in this column present the sum of the costs for chemical reclassification and requirements in the appendices to the standard addressing precautionary statements and other mandatory language.

Note: Figures reported for individual NAICS code and cost category may not add to totals due to rounding.

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Estimation of Compliance Costs and Cost Savings

The remainder of his section explains how OSHA calculated the estimated compliance costs and cost savings arising from the proposed rule by describing the data and methodology used.

The major elements of the proposed revisions to the HCS that involve compliance costs or cost savings are (1) the cost of revising SDSs and labels for select hazardous chemicals to reflect chemical reclassifications (per proposed changes to appendix B) and to conform to language criteria in precautionary statements and other mandatory language (per proposed changes to appendices C and D); (2) the cost of management familiarization and other management-related costs necessary to ensure compliance with the revised standard (associated with all of the proposed revisions to the standard); (3) the cost of training employees as necessitated by the proposed changes to the HCS (see existing 29 CFR 1910.1200(h)(1)); (4) cost savings from the new released-for-shipment provision (proposed revisions to 29 CFR 1910.1200(f)(11)); and (5) cost savings from limiting labeling requirements for certain very small containers (proposed 29 CFR 1910.1200(f)(12)).

The estimated compliance costs and cost savings presented in this analysis of the proposed revisions to the HCS are based partly on analysis conducted in support of the 2012 HCS final rule (77 FR 17605–17683) and partly on new analysis prepared with the assistance of OSHA's contractor, ERG.

The estimated costs of compliance with most provisions of the proposed rule involve wages paid for the labor hours required to fulfill the requirements. In some cases, compliance could be achieved by purchasing services or products in lieu of paying employees directly. The estimated compliance costs are intended to capture the resources required for compliance regardless of how individual establishments may choose to achieve compliance.

With the exception of the proposed revision to the standard addressing precautionary statements and other mandatory language, for this cost analysis OSHA estimated a baseline compliance of zero percent. The agency's estimate of baseline compliance for the revisions in appendices C and D addressing precautionary statements and other mandatory language are discussed below in the section, Revisions to SDSs and Labels Due to Revised Precautionary Statements.

Costs Associated With Reclassifications and Revisions to Safety Data Sheets and Labels

The proposed revisions to the HCS will not change the existing requirement for firms that sell hazardous chemicals to employers to provide information about the associated hazards. Information must be presented in an SDS in the format specified in the standard, and some information must also be presented on product labels. The proposed rule would require affected chemical manufacturers to revise SDSs and labels for select hazardous chemicals to reflect chemical reclassifications (appendix B) and to conform to language criteria in precautionary statements and other mandatory language (appendices C and D). Revisions to SDSs and labels would be required under provisions in the existing HCS, which require chemical manufacturers and importers to update SDSs and labels within three months and six months, respectively, of becoming aware of significant new information regarding the hazards of the chemicals they produce or import (see 29 CFR 1910.1200(f)(11), (g)(5)).

It is OSHA's understanding that chemical manufacturers and importers periodically review, revise, and update the electronic templates they use to create SDSs and labels. Changes are made, for example, as information regarding specific hazards becomes available, new information about protective measures is ascertained, or revisions are made to product information and marketing materials. Labels and SDSs are also produced and modified when products are first introduced to the market or when products change. Therefore, there is a regular cycle of change for these documents (see 77 FR 17634–17637 in the FEA of the 2012 final rule for a discussion of factors that compel employers to update SDSs and labels voluntarily). The proposed rule would require limited changes to some SDSs and labels. Given the phase-in period for the proposed changes to the standard,[31] OSHA expects that chemical manufacturers and importers would be able to phase in revisions to their labels and SDSs in accordance with the normal cycle of change, and therefore would not need to replace existing labels or SDSs. OSHA requests comments on this preliminary assumption.

OSHA has, however, estimated costs for the time it will take to update the electronic files that will be used to generate new SDSs and labels in accordance with the proposed revisions to the HCS. OSHA developed cost estimates based on the methodology used in its FEA in support of the 2012 HCS final rule (77 FR 17634–17637). The estimated compliance costs represent the incremental costs that would be incurred to achieve compliance with the proposed rule. These estimated costs, shown below in Tables VII–13 and VII–14, would be in addition to the costs that already need to be incurred to comply with applicable requirements of the existing HCS and represent the time it would take to identify the changes that need to be made to the relevant computer files (*i.e.,* the files that are used to generate SDSs and labels) and then to make those changes.

Producers of affected chemicals already have an obligation, under the existing HCS, to ensure that the information provided in their SDSs and labels is accurate and current (29 CFR 1910.1200(f)(2) and (g)(5)). They also are generally required to revise SDSs and labels in accordance with new information regarding hazards that may be associated with their products (29 CFR 1910.1200(f)(11) and (g)(5)). For every affected product that is newly created, reformulated, mixed with new ingredients, modified with new or different types of additives, or has any changes made in the proportions of the ingredients used, chemical manufacturers and importers are required, under the existing HCS, to review the available hazard information (29 CFR 1910.1200(d)(2)), to classify the chemical in accordance with applicable hazard criteria (29 CFR 1910.1200(d)(1)), and to develop corresponding SDSs (29 CFR 1910.1200(g)) and labels (29 CFR 1910.1200(f)). OSHA is not estimating costs for activities already required; rather, the agency is estimating costs for activities that would be newly conducted in conformance with the proposed revisions to chemical reclassifications (appendix B) and language criteria in precautionary statements and other mandatory language (appendices C and D).

[31] OSHA proposes that the revisions become effective 60 days after publication (paragraph (j)(1)) and that chemical manufacturers, importers, and distributors evaluating substances comply with all modified provisions within one year after the effective date (paragraph (j)(2)). OSHA also proposes that chemical manufacturers, importers, and distributors evaluating mixtures comply with all modified provisions within two years after the effective date (paragraph (j)(3)).

Revisions to SDSs and Labels Due to Chemical Reclassification

The NAICS industries listed in Columns 1 and 2 of Table VII–13 are those that OSHA expects would manufacture aerosols, desensitized explosives, or flammable gases. Of course, not all chemicals covered in these NAICS industries are aerosols, desensitized explosives, or flammable gases. Column 3 of Table VII–13 reflects OSHA's judgment that approximately 50 percent of the SDSs (or more specifically, 50 percent of the electronic templates (files) that are used to produce SDSs and labels) in these NAICS industries would be affected by the proposed requirements for aerosols, desensitized explosives, and flammable gases. OSHA invites public comments on its preliminary projection that 50 percent of the electronic files for SDSs and labels would be affected in these industries.

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Table VII-13: Total Costs Associated with Chemical Reclassifications and Related Revisions to Safety Data Sheets and Labels under the Proposed Revisions to the HCS (2019 Dollars)

NAICS	NAICS Industry	Percentage Affected	Affected Electronic Templates for SDSs/Labels	Hours per Electronic Template for SDS/Label	Unit cost of Health and Safety Specialist	Total One-Time Cost	Total Annualized Cost (7%)
SDSs at Establishments with < 20 Employees							
211130	Natural Gas Extraction	50%	1,165	1.75	$101.51	$118,257	$16,837
324110	Petroleum Refineries	50%	55	1.75	$101.51	$5,583	$795
325110	Petrochemical Manufacturing	50%	35	1.75	$101.51	$3,553	$506
325120	Industrial Gas Manufacturing	50%	39	1.75	$101.51	$3,959	$564
325320	Pesticide and Other Agricultural Chemical Manufacturing	50%	413	1.75	$101.51	$41,923	$5,969
325412	Pharmaceutical Preparation Manufacturing	50%	1,460	1.75	$101.51	$148,202	$21,101
325510	Paint and Coating Manufacturing	50%	1,715	1.75	$101.51	$174,086	$24,786
325520	Adhesive Manufacturing	50%	535	1.75	$101.51	$54,307	$7,732
325611	Soap and Other Detergent Manufacturing	50%	1,135	1.75	$101.51	$115,212	$16,404
325612	Polish and Other Sanitation Good Manufacturing	50%	291	1.75	$101.51	$29,539	$4,206
325613	Surface Active Agent Manufacturing	50%	148	1.75	$101.51	$14,972	$2,132
325620	Toilet Preparation Manufacturing	50%	624	1.75	$101.51	$63,341	$9,018
325920	Explosives Manufacturing	50%	19	1.75	$101.51	$1,929	$275
Subtotal		**–**	**7,634**	**1.75**	**$101.51**	**$774,861**	**$110,323**
SDSs at Establishments with 20-99 Employees							
211130	Natural Gas Extraction	50%	728	1.75	$101.51	$73,847	$10,514
324110	Petroleum Refineries	50%	75	1.75	$101.51	$7,613	$1,084
325110	Petrochemical Manufacturing	50%	0	1.75	$101.51	$0	$0
325120	Industrial Gas Manufacturing	50%	6	1.75	$101.51	$609	$87
325320	Pesticide and Other Agricultural Chemical Manufacturing	50%	203	1.75	$101.51	$20,555	$2,927
325412	Pharmaceutical Preparation Manufacturing	50%	970	1.75	$101.51	$98,463	$14,019
325510	Paint and Coating Manufacturing	50%	2,080	1.75	$101.51	$211,137	$30,061
325520	Adhesive Manufacturing	50%	1,605	1.75	$101.51	$162,920	$23,196
325611	Soap and Other Detergent Manufacturing	50%	728	1.75	$101.51	$73,847	$10,514
325612	Polish and Other Sanitation Good Manufacturing	50%	503	1.75	$101.51	$51,008	$7,262
325613	Surface Active Agent Manufacturing	50%	180	1.75	$101.51	$18,271	$2,601
325620	Toilet Preparation Manufacturing	50%	1,880	1.75	$101.51	$190,835	$27,171
325920	Explosives Manufacturing	50%	40	1.75	$101.51	$4,060	$578
Subtotal		**–**	**8,996**	**1.75**	**$101.51**	**$913,166**	**$130,014**
SDSs at Establishments with 100-499 Employees							
211130	Natural Gas Extraction	50%	525	1.25	$72.51	$38,065	$5,420
324110	Petroleum Refineries	50%	675	1.25	$72.51	$48,941	$6,968

Table VII-13: Total Costs Associated with Chemical Reclassifications and Related Revisions to Safety Data Sheets and Labels under the Proposed Revisions to the HCS (2019 Dollars)

NAICS	NAICS Industry	Percentage Affected	Affected Electronic Templates for SDSs/Labels	Hours per Electronic Template for SDS/Label	Unit cost of Health and Safety Specialist	Total One-Time Cost	Total Annualized Cost (7%)
325110	Petrochemical Manufacturing	50%	188	1.25	$72.51	$13,595	$1,936
325120	Industrial Gas Manufacturing	50%	23	1.25	$72.51	$1,631	$232
325320	Pesticide and Other Agricultural Chemical Manufacturing	50%	450	1.25	$72.51	$32,628	$4,645
325412	Pharmaceutical Preparation Manufacturing	50%	1,110	1.25	$72.51	$80,481	$11,459
325510	Paint and Coating Manufacturing	50%	8,175	1.25	$72.51	$592,734	$84,392
325520	Adhesive Manufacturing	50%	2,310	1.25	$72.51	$167,488	$23,847
325611	Soap and Other Detergent Manufacturing	50%	1,350	1.25	$72.51	$97,883	$13,936
325612	Polish and Other Sanitation Good Manufacturing	50%	1,425	1.25	$72.51	$103,321	$14,711
325613	Surface Active Agent Manufacturing	50%	400	1.25	$72.51	$29,002	$4,129
325620	Toilet Preparation Manufacturing	50%	1,975	1.25	$72.51	$143,199	$20,388
325920	Explosives Manufacturing	50%	213	1.25	$72.51	$15,407	$2,194
Subtotal		–	**18,818**	**1.25**	**$72.51**	**$1,364,376**	**$194,256**
SDSs at Establishments with 500+ Employees							
211130	Natural Gas Extraction	50%	5,488	0.75	$43.50	$238,725	$33,989
324110	Petroleum Refineries	50%	9,075	0.75	$43.50	$394,794	$56,210
325110	Petrochemical Manufacturing	50%	1,815	0.75	$43.50	$78,959	$11,242
325120	Industrial Gas Manufacturing	50%	2,250	0.75	$43.50	$97,883	$13,936
325320	Pesticide and Other Agricultural Chemical Manufacturing	50%	1,404	0.75	$43.50	$61,079	$8,696
325412	Pharmaceutical Preparation Manufacturing	50%	4,425	0.75	$43.50	$192,503	$27,408
325510	Paint and Coating Manufacturing	50%	26,675	0.75	$43.50	$1,160,454	$165,223
325520	Adhesive Manufacturing	50%	10,320	0.75	$43.50	$448,955	$63,921
325611	Soap and Other Detergent Manufacturing	50%	5,250	0.75	$43.50	$228,393	$32,518
325612	Polish and Other Sanitation Good Manufacturing	50%	3,225	0.75	$43.50	$140,299	$19,975
325613	Surface Active Agent Manufacturing	50%	1,900	0.75	$43.50	$82,657	$11,768
325620	Toilet Preparation Manufacturing	50%	4,650	0.75	$43.50	$202,291	$28,802
325920	Explosives Manufacturing	50%	1,100	0.75	$43.50	$47,854	$6,813
Subtotal		–	**77,577**	**0.75**	**$43.50**	**$3,374,843**	**$480,502**
Total/Average							
211130	Natural Gas Extraction	50%	7,905	1.02	$59.32	$468,894	$66,760
324110	Petroleum Refineries	50%	9,880	0.80	$46.25	$456,931	$65,057
325110	Petrochemical Manufacturing	50%	2,038	0.81	$47.17	$96,106	$13,683
325120	Industrial Gas Manufacturing	50%	2,318	0.77	$44.91	$104,082	$14,819
325320	Pesticide and Other Agricultural Chemical Manufacturing	50%	2,470	1.09	$63.25	$156,185	$22,237

Table VII-13: Total Costs Associated with Chemical Reclassifications and Related Revisions to Safety Data Sheets and Labels under the Proposed Revisions to the HCS (2019 Dollars)

NAICS	NAICS Industry	Percentage Affected	Affected Electronic Templates for SDSs/Labels	Hours per Electronic Template for SDS/Label	Unit cost of Health and Safety Specialist	Total One-Time Cost	Total Annualized Cost (7%)
325412	Pharmaceutical Preparation Manufacturing	50%	7,965	1.12	$65.24	$519,648	$73,986
325510	Paint and Coating Manufacturing	50%	38,645	0.95	$55.33	$2,138,411	$304,462
325520	Adhesive Manufacturing	50%	14,770	0.97	$56.44	$833,671	$118,696
325611	Soap and Other Detergent Manufacturing	50%	8,463	1.05	$60.90	$515,334	$73,372
325612	Polish and Other Sanitation Good Manufacturing	50%	5,444	1.03	$59.55	$324,166	$46,154
325613	Surface Active Agent Manufacturing	50%	2,628	0.95	$55.15	$144,903	$20,631
325620	Toilet Preparation Manufacturing	50%	9,129	1.13	$65.69	$599,666	$85,379
325920	Explosives Manufacturing	50%	1,372	0.87	$50.49	$69,250	$9,860
Total	–	–	**113,024**	**0.98**	**$56.87**	**$6,427,247**	**$915,095**

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

Note: Figures may not add to totals due to rounding.

OSHA derived the number of directly affected electronic files for SDSs and labels in Column 4 of Table VII–13 by applying the 50 percent factor to the overall number of affected SDSs (electronic files) from Table VII–5. For

example, in NAICS 211130, Table VII–5 shows the overall number of affected SDSs (technically, the number of electronic files) is 15,810. Applying a factor of 50 percent, OSHA estimated that 7,905 SDSs (electronic files) would be directly affected by the reclassification provision (see Table VII–13, NAICS 211130 within the section ''Total/Average''). All of the estimates of directly affected SDSs (electronic files) presented in Table VII–13 are similarly derived from Table VII–5, but only those NAICS industries with affected SDSs (electronic files) are reported in Table VII–13.

The estimated compliance costs associated with the reclassification of hazards and related changes to SDSs and labels are directly related to the number of chemicals for which electronic files will need to be updated in order to prepare updated SDSs and labels. OSHA developed estimates of the number of potentially affected SDSs for each of the industries producing the corresponding chemicals and products (based on estimates of the total number of SDSs (and the supporting electronic files) by industry as shown in Table VII–5 of this PEA). OSHA expects downstream users, distributors, and wholesalers would continue to rely on SDSs and labels provided by manufacturers to fulfill their obligations under the OSHA standard, and would not incur costs associated with chemical reclassification under the proposed revisions to the HCS. It is OSHA's understanding that this has been the practice for decades.

Table VII–13 also contains estimates of the amount of time OSHA expects it will take to update electronic files for SDSs and labels under the proposed revisions to the standard. OSHA believes that the estimates provided in Table VII–13 are reasonable because they reflect only the incremental time needed to identify affected labels and SDSs (electronic files) and to update electronic files through modification of the templates that are used to prepare labels and SDSs, without allocating costs to any time that would be spent updating files in the absence of any revisions to the HCS.

OSHA also believes that the estimated time to update SDSs and labels (electronic files) used in this analysis represents a reasonable average for most chemicals. In the FEA in support of the 2012 HCS final rule (77 FR 17635–17637), OSHA estimated that a Health and Safety Specialist would spend between three and seven hours per SDS requiring reclassification—with smaller entities, having fewer SDSs, incurring larger costs per SDS. The revisions to the HCS currently being proposed are significantly more limited in scope than the 2012 final rule, with fewer affected hazard categories and more limited changes; however, the proposed revisions to the standard still present opportunities for scale efficiencies in reclassification. As a result, OSHA estimates that a Health and Safety Specialist would spend about 25 percent as much time to reclassify a chemical as OSHA estimated for the 2012 HCS rule—depending on establishment size, from 0.75 hours to 1.75 hours per SDS (electronic file) requiring reclassification (1.75 hours per SDS for establishments with fewer than 100 employees; 1.25 hours per SDS for establishments with 100–499 employees; and 0.75 hours per SDS for establishments with 500 or more employees).[32] At a loaded hourly wage (including overhead) of $58.00 for a Health and Safety Specialist, this would result in unit costs of $101.51, $72.51, and $43.50 per SDS for small, medium, and large establishments, respectively. Multiplying these unit costs by the estimated number of affected chemicals (*i.e.,* electronic files) and summing the totals yields an undiscounted one-time estimated cost of $6.4 million for affected employers to comply with this provision. Annualizing this one-time cost using a 7 percent discount rate over a 10-year period results in estimated annualized costs of approximately $915,095 for reclassification in accordance with the criteria specified in the proposed revisions to the HCS. OSHA invites interested parties to comment on these cost estimates and the assumptions underlying them.

Revisions to SDSs and Labels Due to Revised Precautionary Statements, etc.

The proposed revisions to the HCS would require establishments to revise their electronic templates for SDSs and labels to conform to formatting and language criteria in precautionary statements and other mandatory language specified in appendices C and D. Under the proposed changes to the standard, affected establishments would have to update labels and SDSs for select hazardous chemicals to include updated signal word(s), hazard statement(s), pictogram(s), and precautionary statement(s) for each hazard class and associated hazard category (see existing 29 CFR 1910.1200(f) and (g)). The modification of SDSs and labels under the revisions proposed in appendices C and D would involve conforming to formatting and language standards, but would not require any additional testing, studies, or research. As previously stated, OSHA believes that chemical manufacturers and importers generally review, revise, and update their electronic templates for SDSs and labels periodically, such that there is a regular cycle of change for these documents.[33] The proposed changes to the appendices would require only limited changes to the electronic content of SDSs and labels, and, as explained previously, OSHA expects that the phase-in period for the proposed changes to the standard would allow chemical manufacturers and importers to take advantage of the normal cycle of change to phase in the revisions to their labels and SDSs, and therefore that it would not be necessary to replace existing labels or SDSs.[34] OSHA requests comments on this preliminary assumption.

The estimated compliance costs for revising electronic templates for SDSs and labels to conform to formatting and language criteria in precautionary statements and other mandatory language specified in the proposed revisions to appendices C and D represent the incremental costs that would be incurred to achieve compliance with the proposed changes to the appendices. These estimated costs, shown below in Table VII–14, would be in addition to the costs that are already incurred to comply with applicable requirements of the existing HCS.

[32] Note that OSHA estimated no baseline compliance for chemical manufacturers already having revised electronic files to reflect reclassified chemicals as specified in the proposed rule; the current HCS does not allow SDSs or labels to display chemical classifications that are not in conformance with the current rule.

[33] See discussion in the 2012 preamble (77 FR 17634).

[34] OSHA proposes that the revisions become effective 60 days after publication (paragraph (j)(1)) and that chemical manufacturers, importers, and distributors evaluating substances comply with all modified provisions within one year after the effective date (paragraph (j)(2)). OSHA also proposes that chemical manufacturers, importers, and distributors evaluating mixtures comply with all modified provisions within two years after the effective date (paragraph (j)(3)).

Table VII-14: Total Costs Associated with Proposed Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2019 Dollars)

NAICS	NAICS Industry	Affected Electronic Templates for SDSs/Labels	Hours per Electronic Template for SDS/Label	Unit cost of Health and Safety Specialist	Non-Compliance Rate	Total One-Time Cost	Total Annualized Cost (7%)
SDSs at Establishments with < 20 Employees							
211120	Crude Petroleum Extraction	20,685	0.7	$40.60	99%	$831,478	$118,384
211130	Natural Gas Extraction	2,330	0.7	$40.60	99%	$93,659	$13,335
324110	Petroleum Refineries	110	0.7	$40.60	99%	$4,422	$630
324121	Asphalt Paving Mixture and Block Manufacturing	2,380	0.7	$40.60	99%	$95,669	$13,621
324122	Asphalt Shingle and Coating Materials Manufacturing	670	0.7	$40.60	99%	$26,932	$3,835
324191	Petroleum Lubricating Oil and Grease Manufacturing	26,800	0.7	$40.60	99%	$1,077,284	$153,381
324199	All Other Petroleum and Coal Products Manufacturing	380	0.7	$40.60	99%	$15,275	$2,175
325110	Petrochemical Manufacturing	70	0.7	$40.60	99%	$2,814	$401
325120	Industrial Gas Manufacturing	78	0.7	$40.60	99%	$3,135	$446
325130	Synthetic Dye and Pigment Manufacturing	464	0.7	$40.60	99%	$18,651	$2,656
325180	Other Basic Inorganic Chemical Manufacturing	584	0.7	$40.60	99%	$23,475	$3,342
325193	Ethyl Alcohol Manufacturing	95	0.7	$40.60	99%	$3,819	$544
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	140	0.7	$40.60	99%	$5,628	$801
325199	All Other Basic Organic Chemical Manufacturing	1,827	0.7	$40.60	99%	$73,440	$10,456
325211	Plastics Material and Resin Manufacturing	1,745	0.7	$40.60	99%	$70,144	$9,987
325212	Synthetic Rubber Manufacturing	128	0.7	$40.60	99%	$5,145	$733
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	40	0.7	$40.60	99%	$1,608	$229
325311	Nitrogenous Fertilizer Manufacturing	101	0.7	$40.60	99%	$4,060	$578
325312	Phosphatic Fertilizer Manufacturing	11	0.7	$40.60	99%	$442	$63
325314	Fertilizer (Mixing Only) Manufacturing	474	0.7	$40.60	99%	$19,053	$2,713
325320	Pesticide and Other Agricultural Chemical Manufacturing	826	0.7	$40.60	99%	$33,203	$4,727
325411	Medicinal and Botanical Manufacturing	1,355	0.7	$40.60	99%	$54,467	$7,755
325412	Pharmaceutical Preparation Manufacturing	2,920	0.7	$40.60	99%	$117,376	$16,712
325413	In-Vitro Diagnostic Substance Manufacturing	930	0.7	$40.60	99%	$37,383	$5,323
325414	Biological Product (except Diagnostic) Manufacturing	408	0.7	$40.60	99%	$16,400	$2,335
325510	Paint and Coating Manufacturing	3,430	0.7	$40.60	99%	$137,876	$19,630
325520	Adhesive Manufacturing	1,070	0.7	$40.60	99%	$43,011	$6,124
325611	Soap and Other Detergent Manufacturing	2,270	0.7	$40.60	99%	$91,248	$12,992
325612	Polish and Other Sanitation Good Manufacturing	582	0.7	$40.60	99%	$23,395	$3,331
325613	Surface Active Agent Manufacturing	295	0.7	$40.60	99%	$11,858	$1,688
325620	Toilet Preparation Manufacturing	1,248	0.7	$40.60	99%	$50,166	$7,143

Table VII-14: Total Costs Associated with Proposed Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2019 Dollars)

NAICS	NAICS Industry	Affected Electronic Templates for SDSs/Labels	Hours per Electronic Template for SDS/Label	Unit cost of Health and Safety Specialist	Non-Compliance Rate	Total One-Time Cost	Total Annualized Cost (7%)
325910	Printing Ink Manufacturing	555	0.7	$40.60	99%	$22,309	$3,176
325920	Explosives Manufacturing	38	0.7	$40.60	99%	$1,527	$217
325991	Custom Compounding of Purchased Resins	358	0.7	$40.60	99%	$14,391	$2,049
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	435	0.7	$40.60	99%	$17,486	$2,490
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	3,560	0.7	$40.60	99%	$143,102	$20,374
339112	Surgical and Medical Instrument Manufacturing	651	0.7	$40.60	99%	$26,168	$3,726
339113	Surgical Appliance and Supplies Manufacturing	1,200	0.7	$40.60	99%	$48,237	$6,868
339114	Dental Equipment and Supplies Manufacturing	469	0.7	$40.60	99%	$18,852	$2,684
339115	Ophthalmic Goods Manufacturing	257	0.7	$40.60	99%	$10,331	$1,471
339116	Dental Laboratories	5,301	0.7	$40.60	99%	$213,085	$30,339
339910	Jewelry and Silverware Manufacturing	1,765	0.7	$40.60	99%	$70,948	$10,101
339920	Sporting and Athletic Goods Manufacturing	1,293	0.7	$40.60	99%	$51,975	$7,400
339930	Doll, Toy, and Game Manufacturing	434	0.7	$40.60	99%	$17,446	$2,484
339940	Office Supplies (except Paper) Manufacturing	333	0.7	$40.60	99%	$13,386	$1,906
339950	Sign Manufacturing	4,784	0.7	$40.60	99%	$192,303	$27,380
339991	Gasket, Packing, and Sealing Device Manufacturing	294	0.7	$40.60	99%	$11,818	$1,683
339992	Musical Instrument Manufacturing	504	0.7	$40.60	99%	$20,259	$2,884
339993	Fastener, Button, Needle, and Pin Manufacturing	76	0.7	$40.60	99%	$3,055	$435
339994	Broom, Brush, and Mop Manufacturing	96	0.7	$40.60	99%	$3,859	$549
339995	Burial Casket Manufacturing	60	0.7	$40.60	99%	$2,412	$343
339999	All Other Miscellaneous Manufacturing	5,209	0.7	$40.60	99%	$209,387	$29,812
Subtotal		**102,118**	**0.7**	**$40.60**	**99%**	**$4,104,854**	**$584,439**
SDSs at Establishments with 20-99 Employees							
211120	Crude Petroleum Extraction	5,490	0.7	$40.60	95%	$211,766	$30,151
211130	Natural Gas Extraction	1,455	0.7	$40.60	95%	$56,124	$7,991
324110	Petroleum Refineries	150	0.7	$40.60	95%	$5,786	$824
324121	Asphalt Paving Mixture and Block Manufacturing	4,770	0.7	$40.60	95%	$183,993	$26,197
324122	Asphalt Shingle and Coating Materials Manufacturing	1,020	0.7	$40.60	95%	$39,344	$5,602
324191	Petroleum Lubricating Oil and Grease Manufacturing	72,000	0.7	$40.60	95%	$2,777,259	$395,419
324199	All Other Petroleum and Coal Products Manufacturing	240	0.7	$40.60	95%	$9,258	$1,318
325110	Petrochemical Manufacturing	0	0.7	$40.60	95%	$0	$0
325120	Industrial Gas Manufacturing	12	0.7	$40.60	95%	$463	$66

Table VII-14: Total Costs Associated with Proposed Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2019 Dollars)

NAICS	NAICS Industry	Affected Electronic Templates for SDSs/Labels	Hours per Electronic Template for SDS/Label	Unit cost of Health and Safety Specialist	Non-Compliance Rate	Total One-Time Cost	Total Annualized Cost (7%)
325130	Synthetic Dye and Pigment Manufacturing	420	0.7	$40.60	95%	$16,201	$2,307
325180	Other Basic Inorganic Chemical Manufacturing	528	0.7	$40.60	95%	$20,367	$2,900
325193	Ethyl Alcohol Manufacturing	660	0.7	$40.60	95%	$25,458	$3,625
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	180	0.7	$40.60	95%	$6,943	$989
325199	All Other Basic Organic Chemical Manufacturing	2,295	0.7	$40.60	95%	$88,525	$12,604
325211	Plastics Material and Resin Manufacturing	6,204	0.7	$40.60	95%	$239,307	$34,072
325212	Synthetic Rubber Manufacturing	150	0.7	$40.60	95%	$5,786	$824
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	26	0.7	$40.60	95%	$1,003	$143
325311	Nitrogenous Fertilizer Manufacturing	41	0.7	$40.60	95%	$1,581	$225
325312	Phosphatic Fertilizer Manufacturing	9	0.7	$40.60	95%	$347	$49
325314	Fertilizer (Mixing Only) Manufacturing	500	0.7	$40.60	95%	$19,287	$2,746
325320	Pesticide and Other Agricultural Chemical Manufacturing	405	0.7	$40.60	95%	$15,622	$2,224
325411	Medicinal and Botanical Manufacturing	970	0.7	$40.60	95%	$37,416	$5,327
325412	Pharmaceutical Preparation Manufacturing	1,940	0.7	$40.60	95%	$74,832	$10,654
325413	In-Vitro Diagnostic Substance Manufacturing	980	0.7	$40.60	95%	$37,802	$5,382
325414	Biological Product (except Diagnostic) Manufacturing	290	0.7	$40.60	95%	$11,186	$1,593
325510	Paint and Coating Manufacturing	4,160	0.7	$40.60	95%	$160,464	$22,846
325520	Adhesive Manufacturing	3,210	0.7	$40.60	95%	$123,819	$17,629
325611	Soap and Other Detergent Manufacturing	1,455	0.7	$40.60	95%	$56,124	$7,991
325612	Polish and Other Sanitation Good Manufacturing	1,005	0.7	$40.60	95%	$38,766	$5,519
325613	Surface Active Agent Manufacturing	360	0.7	$40.60	95%	$13,886	$1,977
325620	Toilet Preparation Manufacturing	3,760	0.7	$40.60	95%	$145,035	$20,650
325910	Printing Ink Manufacturing	1,200	0.7	$40.60	95%	$46,288	$6,590
325920	Explosives Manufacturing	80	0.7	$40.60	95%	$3,086	$439
325991	Custom Compounding of Purchased Resins	410	0.7	$40.60	95%	$15,815	$2,252
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	250	0.7	$40.60	95%	$9,643	$1,373
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	6,030	0.7	$40.60	95%	$232,595	$33,116
339112	Surgical and Medical Instrument Manufacturing	454	0.7	$40.60	95%	$17,512	$2,493
339113	Surgical Appliance and Supplies Manufacturing	658	0.7	$40.60	95%	$25,381	$3,614
339114	Dental Equipment and Supplies Manufacturing	102	0.7	$40.60	95%	$3,934	$560
339115	Ophthalmic Goods Manufacturing	90	0.7	$40.60	95%	$3,472	$494
339116	Dental Laboratories	650	0.7	$40.60	95%	$25,072	$3,570

Table VII-14: Total Costs Associated with Proposed Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2019 Dollars)

NAICS	NAICS Industry	Affected Electronic Templates for SDSs/Labels	Hours per Electronic Template for SDS/Label	Unit cost of Health and Safety Specialist	Non-Compliance Rate	Total One-Time Cost	Total Annualized Cost (7%)
339910	Jewelry and Silverware Manufacturing	334	0.7	$40.60	95%	$12,883	$1,834
339920	Sporting and Athletic Goods Manufacturing	428	0.7	$40.60	95%	$16,509	$2,351
339930	Doll, Toy, and Game Manufacturing	110	0.7	$40.60	95%	$4,243	$604
339940	Office Supplies (except Paper) Manufacturing	132	0.7	$40.60	95%	$5,092	$725
339950	Sign Manufacturing	1,416	0.7	$40.60	95%	$54,619	$7,777
339991	Gasket, Packing, and Sealing Device Manufacturing	256	0.7	$40.60	95%	$9,875	$1,406
339992	Musical Instrument Manufacturing	126	0.7	$40.60	95%	$4,860	$692
339993	Fastener, Button, Needle, and Pin Manufacturing	32	0.7	$40.60	95%	$1,234	$176
339994	Broom, Brush, and Mop Manufacturing	94	0.7	$40.60	95%	$3,626	$516
339995	Burial Casket Manufacturing	36	0.7	$40.60	95%	$1,389	$198
339999	All Other Miscellaneous Manufacturing	888	0.7	$40.60	95%	$34,253	$4,877
Subtotal		**128,461**	**0.7**	**$40.60**	**95%**	**$4,955,131**	**$705,499**
SDSs at Establishments with 100-499 Employees							
211120	Crude Petroleum Extraction	2,640	0.5	$29.00	75%	$57,425	$8,176
211130	Natural Gas Extraction	1,050	0.5	$29.00	75%	$22,839	$3,252
324110	Petroleum Refineries	1,350	0.5	$29.00	75%	$29,365	$4,181
324121	Asphalt Paving Mixture and Block Manufacturing	18,525	0.5	$29.00	75%	$402,950	$57,371
324122	Asphalt Shingle and Coating Materials Manufacturing	1,950	0.5	$29.00	75%	$42,416	$6,039
324191	Petroleum Lubricating Oil and Grease Manufacturing	123,000	0.5	$29.00	75%	$2,675,461	$380,925
324199	All Other Petroleum and Coal Products Manufacturing	1,425	0.5	$29.00	75%	$30,996	$4,413
325110	Petrochemical Manufacturing	375	0.5	$29.00	75%	$8,157	$1,161
325120	Industrial Gas Manufacturing	45	0.5	$29.00	75%	$979	$139
325130	Synthetic Dye and Pigment Manufacturing	480	0.5	$29.00	75%	$10,441	$1,487
325180	Other Basic Inorganic Chemical Manufacturing	1,152	0.5	$29.00	75%	$25,058	$3,568
325193	Ethyl Alcohol Manufacturing	800	0.5	$29.00	75%	$17,401	$2,478
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	90	0.5	$29.00	75%	$1,958	$279
325199	All Other Basic Organic Chemical Manufacturing	3,300	0.5	$29.00	75%	$71,781	$10,220
325211	Plastics Material and Resin Manufacturing	15,130	0.5	$29.00	75%	$329,103	$46,857
325212	Synthetic Rubber Manufacturing	230	0.5	$29.00	75%	$5,003	$712
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	54	0.5	$29.00	75%	$1,175	$167
325311	Nitrogenous Fertilizer Manufacturing	26	0.5	$29.00	75%	$566	$81
325312	Phosphatic Fertilizer Manufacturing	36	0.5	$29.00	75%	$783	$111

Table VII-14: Total Costs Associated with Proposed Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2019 Dollars)

NAICS	NAICS Industry	Affected Electronic Templates for SDSs/Labels	Hours per Electronic Template for SDS/Label	Unit cost of Health and Safety Specialist	Non-Compliance Rate	Total One-Time Cost	Total Annualized Cost (7%)
325314	Fertilizer (Mixing Only) Manufacturing	1,080	0.5	$29.00	75%	$23,492	$3,345
325320	Pesticide and Other Agricultural Chemical Manufacturing	900	0.5	$29.00	75%	$19,577	$2,787
325411	Medicinal and Botanical Manufacturing	1,035	0.5	$29.00	75%	$22,513	$3,205
325412	Pharmaceutical Preparation Manufacturing	2,220	0.5	$29.00	75%	$48,289	$6,875
325413	In-Vitro Diagnostic Substance Manufacturing	3,200	0.5	$29.00	75%	$69,605	$9,910
325414	Biological Product (except Diagnostic) Manufacturing	300	0.5	$29.00	75%	$6,526	$929
325510	Paint and Coating Manufacturing	16,350	0.5	$29.00	75%	$355,640	$50,635
325520	Adhesive Manufacturing	4,620	0.5	$29.00	75%	$100,493	$14,308
325611	Soap and Other Detergent Manufacturing	2,700	0.5	$29.00	75%	$58,730	$8,362
325612	Polish and Other Sanitation Good Manufacturing	2,850	0.5	$29.00	75%	$61,992	$8,826
325613	Surface Active Agent Manufacturing	800	0.5	$29.00	75%	$17,401	$2,478
325620	Toilet Preparation Manufacturing	3,950	0.5	$29.00	75%	$85,919	$12,233
325910	Printing Ink Manufacturing	8,232	0.5	$29.00	75%	$179,060	$25,494
325920	Explosives Manufacturing	425	0.5	$29.00	75%	$9,244	$1,316
325991	Custom Compounding of Purchased Resins	510	0.5	$29.00	75%	$11,093	$1,579
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	90	0.5	$29.00	75%	$1,958	$279
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	8,625	0.5	$29.00	75%	$187,609	$26,711
339112	Surgical and Medical Instrument Manufacturing	555	0.5	$29.00	75%	$12,072	$1,719
339113	Surgical Appliance and Supplies Manufacturing	750	0.5	$29.00	75%	$16,314	$2,323
339114	Dental Equipment and Supplies Manufacturing	140	0.5	$29.00	75%	$3,045	$434
339115	Ophthalmic Goods Manufacturing	80	0.5	$29.00	75%	$1,740	$248
339116	Dental Laboratories	280	0.5	$29.00	75%	$6,090	$867
339910	Jewelry and Silverware Manufacturing	160	0.5	$29.00	75%	$3,480	$496
339920	Sporting and Athletic Goods Manufacturing	355	0.5	$29.00	75%	$7,722	$1,099
339930	Doll, Toy, and Game Manufacturing	70	0.5	$29.00	75%	$1,523	$217
339940	Office Supplies (except Paper) Manufacturing	135	0.5	$29.00	75%	$2,936	$418
339950	Sign Manufacturing	880	0.5	$29.00	75%	$19,142	$2,725
339991	Gasket, Packing, and Sealing Device Manufacturing	235	0.5	$29.00	75%	$5,112	$728
339992	Musical Instrument Manufacturing	105	0.5	$29.00	75%	$2,284	$325
339993	Fastener, Button, Needle, and Pin Manufacturing	35	0.5	$29.00	75%	$761	$108
339994	Broom, Brush, and Mop Manufacturing	85	0.5	$29.00	75%	$1,849	$263
339995	Burial Casket Manufacturing	35	0.5	$29.00	75%	$761	$108

Table VII-14: Total Costs Associated with Proposed Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2019 Dollars)

NAICS	NAICS Industry	Affected Electronic Templates for SDSs/Labels	Hours per Electronic Template for SDS/Label	Unit cost of Health and Safety Specialist	Non-Compliance Rate	Total One-Time Cost	Total Annualized Cost (7%)
339999	All Other Miscellaneous Manufacturing	360	0.5	$29.00	75%	$7,831	$1,115
Subtotal		**233,805**	**0.5**	**$29.00**	**75%**	**$5,085,659**	**$724,083**
SDSs at Establishments with 500+ Employees							
211120	Crude Petroleum Extraction	16,350	0.3	$17.40	25%	$71,128	$10,127
211130	Natural Gas Extraction	10,975	0.3	$17.40	25%	$47,745	$6,798
324110	Petroleum Refineries	18,150	0.3	$17.40	25%	$78,959	$11,242
324121	Asphalt Paving Mixture and Block Manufacturing	107,550	0.3	$17.40	25%	$467,879	$66,615
324122	Asphalt Shingle and Coating Materials Manufacturing	13,500	0.3	$17.40	25%	$58,730	$8,362
324191	Petroleum Lubricating Oil and Grease Manufacturing	466,891	0.3	$17.40	25%	$2,031,135	$289,188
324199	All Other Petroleum and Coal Products Manufacturing	2,850	0.3	$17.40	25%	$12,398	$1,765
325110	Petrochemical Manufacturing	3,630	0.3	$17.40	25%	$15,792	$2,248
325120	Industrial Gas Manufacturing	4,500	0.3	$17.40	25%	$19,577	$2,787
325130	Synthetic Dye and Pigment Manufacturing	2,200	0.3	$17.40	25%	$9,571	$1,363
325180	Other Basic Inorganic Chemical Manufacturing	2,480	0.3	$17.40	25%	$10,789	$1,536
325193	Ethyl Alcohol Manufacturing	3,400	0.3	$17.40	25%	$14,791	$2,106
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	3,225	0.3	$17.40	25%	$14,030	$1,998
325199	All Other Basic Organic Chemical Manufacturing	21,750	0.3	$17.40	25%	$94,620	$13,472
325211	Plastics Material and Resin Manufacturing	81,000	0.3	$17.40	25%	$352,378	$50,171
325212	Synthetic Rubber Manufacturing	1,295	0.3	$17.40	25%	$5,634	$802
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	78	0.3	$17.40	25%	$339	$48
325311	Nitrogenous Fertilizer Manufacturing	94	0.3	$17.40	25%	$409	$58
325312	Phosphatic Fertilizer Manufacturing	66	0.3	$17.40	25%	$287	$41
325314	Fertilizer (Mixing Only) Manufacturing	1,600	0.3	$17.40	25%	$6,961	$991
325320	Pesticide and Other Agricultural Chemical Manufacturing	2,808	0.3	$17.40	25%	$12,216	$1,739
325411	Medicinal and Botanical Manufacturing	1,375	0.3	$17.40	25%	$5,982	$852
325412	Pharmaceutical Preparation Manufacturing	8,850	0.3	$17.40	25%	$38,501	$5,482
325413	In-Vitro Diagnostic Substance Manufacturing	21,861	0.3	$17.40	25%	$95,103	$13,541
325414	Biological Product (except Diagnostic) Manufacturing	2,340	0.3	$17.40	25%	$10,180	$1,449
325510	Paint and Coating Manufacturing	53,350	0.3	$17.40	25%	$232,091	$33,045
325520	Adhesive Manufacturing	20,640	0.3	$17.40	25%	$89,791	$12,784
325611	Soap and Other Detergent Manufacturing	10,500	0.3	$17.40	25%	$45,679	$6,504
325612	Polish and Other Sanitation Good Manufacturing	6,450	0.3	$17.40	25%	$28,060	$3,995

Table VII-14: Total Costs Associated with Proposed Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2019 Dollars)

NAICS	NAICS Industry	Affected Electronic Templates for SDSs/Labels	Hours per Electronic Template for SDS/Label	Unit cost of Health and Safety Specialist	Non-Compliance Rate	Total One-Time Cost	Total Annualized Cost (7%)
325613	Surface Active Agent Manufacturing	3,800	0.3	$17.40	25%	$16,531	$2,354
325620	Toilet Preparation Manufacturing	9,300	0.3	$17.40	25%	$40,458	$5,760
325910	Printing Ink Manufacturing	24,750	0.3	$17.40	25%	$107,671	$15,330
325920	Explosives Manufacturing	2,200	0.3	$17.40	25%	$9,571	$1,363
325991	Custom Compounding of Purchased Resins	2,700	0.3	$17.40	25%	$11,746	$1,672
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	700	0.3	$17.40	25%	$3,045	$434
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	30,300	0.3	$17.40	25%	$131,815	$18,768
339112	Surgical and Medical Instrument Manufacturing	1,225	0.3	$17.40	25%	$5,329	$759
339113	Surgical Appliance and Supplies Manufacturing	940	0.3	$17.40	25%	$4,089	$582
339114	Dental Equipment and Supplies Manufacturing	155	0.3	$17.40	25%	$674	$96
339115	Ophthalmic Goods Manufacturing	875	0.3	$17.40	25%	$3,807	$542
339116	Dental Laboratories	1,445	0.3	$17.40	25%	$6,286	$895
339910	Jewelry and Silverware Manufacturing	110	0.3	$17.40	25%	$479	$68
339920	Sporting and Athletic Goods Manufacturing	355	0.3	$17.40	25%	$1,544	$220
339930	Doll, Toy, and Game Manufacturing	30	0.3	$17.40	25%	$131	$19
339940	Office Supplies (except Paper) Manufacturing	115	0.3	$17.40	25%	$500	$71
339950	Sign Manufacturing	295	0.3	$17.40	25%	$1,283	$183
339991	Gasket, Packing, and Sealing Device Manufacturing	465	0.3	$17.40	25%	$2,023	$288
339992	Musical Instrument Manufacturing	90	0.3	$17.40	25%	$392	$56
339993	Fastener, Button, Needle, and Pin Manufacturing	55	0.3	$17.40	25%	$239	$34
339994	Broom, Brush, and Mop Manufacturing	120	0.3	$17.40	25%	$522	$74
339995	Burial Casket Manufacturing	60	0.3	$17.40	25%	$261	$37
339999	All Other Miscellaneous Manufacturing	150	0.3	$17.40	25%	$653	$93
Subtotal		**969,993**	**0.3**	**$17.40**	**25%**	**$4,219,801**	**$600,805**
Total/Average							
211120	Crude Petroleum Extraction	45,165	0.5	$31.53	82%	$1,171,797	$166,838
211130	Natural Gas Extraction	15,810	0.4	$23.73	59%	$220,367	$31,375
324110	Petroleum Refineries	19,760	0.3	$18.50	32%	$118,531	$16,876
324121	Asphalt Paving Mixture and Block Manufacturing	133,225	0.3	$20.26	43%	$1,150,492	$163,804
324122	Asphalt Shingle and Coating Materials Manufacturing	17,140	0.4	$21.01	46%	$167,422	$23,837
324191	Petroleum Lubricating Oil and Grease Manufacturing	688,691	0.4	$22.80	55%	$8,561,138	$1,218,913
324199	All Other Petroleum and Coal Products Manufacturing	4,895	0.4	$23.72	59%	$67,927	$9,671

Table VII-14: Total Costs Associated with Proposed Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2019 Dollars)

NAICS	NAICS Industry	Affected Electronic Templates for SDSs/Labels	Hours per Electronic Template for SDS/Label	Unit cost of Health and Safety Specialist	Non-Compliance Rate	Total One-Time Cost	Total Annualized Cost (7%)
325110	Petrochemical Manufacturing	4,075	0.3	$18.87	35%	$26,762	$3,810
325120	Industrial Gas Manufacturing	4,635	0.3	$17.96	29%	$24,154	$3,439
325130	Synthetic Dye and Pigment Manufacturing	3,564	0.4	$24.72	62%	$54,864	$7,811
325180	Other Basic Inorganic Chemical Manufacturing	4,744	0.4	$25.66	65%	$79,689	$11,346
325193	Ethyl Alcohol Manufacturing	4,955	0.4	$22.81	54%	$61,469	$8,752
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	3,635	0.3	$19.73	40%	$28,558	$4,066
325199	All Other Basic Organic Chemical Manufacturing	29,172	0.4	$21.99	51%	$328,366	$46,752
325211	Plastics Material and Resin Manufacturing	104,079	0.4	$20.86	46%	$990,932	$141,086
325212	Synthetic Rubber Manufacturing	1,803	0.4	$22.46	53%	$21,568	$3,071
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	198	0.5	$28.30	74%	$4,125	$587
325311	Nitrogenous Fertilizer Manufacturing	262	0.5	$31.13	81%	$6,616	$942
325312	Phosphatic Fertilizer Manufacturing	122	0.4	$24.63	62%	$1,860	$265
325314	Fertilizer (Mixing Only) Manufacturing	3,654	0.5	$27.01	70%	$68,792	$9,794
325320	Pesticide and Other Agricultural Chemical Manufacturing	4,939	0.4	$25.30	65%	$80,617	$11,478
325411	Medicinal and Botanical Manufacturing	4,735	0.5	$31.33	81%	$120,378	$17,139
325412	Pharmaceutical Preparation Manufacturing	15,930	0.4	$26.10	67%	$278,997	$39,723
325413	In-Vitro Diagnostic Substance Manufacturing	26,971	0.4	$20.42	44%	$239,893	$34,155
325414	Biological Product (except Diagnostic) Manufacturing	3,338	0.4	$23.30	57%	$44,292	$6,306
325510	Paint and Coating Manufacturing	77,290	0.4	$22.13	52%	$886,071	$126,157
325520	Adhesive Manufacturing	29,540	0.4	$22.58	54%	$357,114	$50,845
325611	Soap and Other Detergent Manufacturing	16,925	0.4	$24.36	61%	$251,780	$35,848
325612	Polish and Other Sanitation Good Manufacturing	10,887	0.4	$23.82	59%	$152,213	$21,672
325613	Surface Active Agent Manufacturing	5,255	0.4	$22.06	51%	$59,677	$8,497
325620	Toilet Preparation Manufacturing	18,258	0.5	$26.28	67%	$321,578	$45,785
325910	Printing Ink Manufacturing	34,737	0.4	$21.32	48%	$355,328	$50,591
325920	Explosives Manufacturing	2,743	0.3	$20.20	42%	$23,429	$3,336
325991	Custom Compounding of Purchased Resins	3,978	0.4	$23.37	57%	$53,045	$7,552
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	1,475	0.5	$28.88	75%	$32,132	$4,575
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	48,515	0.4	$24.05	60%	$695,121	$98,970
339112	Surgical and Medical Instrument Manufacturing	2,885	0.5	$28.52	74%	$61,082	$8,697
339113	Surgical Appliance and Supplies Manufacturing	3,548	0.6	$32.00	83%	$94,021	$13,386
339114	Dental Equipment and Supplies Manufacturing	866	0.6	$34.58	89%	$26,506	$3,774

Table VII-14: Total Costs Associated with Proposed Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2019 Dollars)

NAICS	NAICS Industry	Affected Electronic Templates for SDSs/Labels	Hours per Electronic Template for SDS/Label	Unit cost of Health and Safety Specialist	Non-Compliance Rate	Total One-Time Cost	Total Annualized Cost (7%)
339115	Ophthalmic Goods Manufacturing	1,302	0.4	$24.30	61%	$19,349	$2,755
339116	Dental Laboratories	7,676	0.6	$35.81	91%	$250,534	$35,670
339910	Jewelry and Silverware Manufacturing	2,369	0.7	$38.74	96%	$87,790	$12,499
339920	Sporting and Athletic Goods Manufacturing	2,431	0.6	$35.52	90%	$77,750	$11,070
339930	Doll, Toy, and Game Manufacturing	644	0.7	$38.26	95%	$23,342	$3,323
339940	Office Supplies (except Paper) Manufacturing	715	0.6	$34.68	88%	$21,914	$3,120
339950	Sign Manufacturing	7,375	0.7	$38.29	95%	$267,348	$38,064
339991	Gasket, Packing, and Sealing Device Manufacturing	1,250	0.5	$29.79	77%	$28,827	$4,104
339992	Musical Instrument Manufacturing	825	0.6	$36.60	92%	$27,795	$3,957
339993	Fastener, Button, Needle, and Pin Manufacturing	198	0.6	$32.11	83%	$5,290	$753
339994	Broom, Brush, and Mop Manufacturing	395	0.5	$31.06	80%	$9,856	$1,403
339995	Burial Casket Manufacturing	191	0.5	$31.19	81%	$4,823	$687
339999	All Other Miscellaneous Manufacturing	6,607	0.7	$39.44	97%	$252,123	$35,897
Subtotal		**1,434,377**	**0.4**	**$23.02**	**56%**	**$18,365,445**	**$2,614,826**

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

Note: Figures may not add to totals due to rounding.

Table VII–14 shows the estimated costs associated with modifications to electronic templates for SDSs and labels to conform to formatting and language

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criteria in precautionary statements and other mandatory language specified in the proposed revisions to appendices C and D by NAICS industry and establishment size. The NAICS industries listed in Columns 1 and 2 of Table VII–14 are those that OSHA expects would need to update SDSs and labels under the proposed revisions to appendices C and D. The industries included are the ones OSHA identified as incurring costs for SDSs in the FEA in support of OSHA's 2012 HCS final rule (77 FR 17644–17650). The estimated costs associated with the proposed revisions to the appendices are directly related to the number of SDSs (or, in other words, the number of electronic templates) affected. These numbers were previously derived and presented in Tables VII–5, VII–6, and VII–7.[35]

OSHA estimates that the time needed to revise electronic templates for labels and SDSs to comply with the proposed revisions to appendices C and D would vary by establishment size and would be equal to 10 percent of the unit time (from 3 to 7 hours per SDS (electronic template)) estimated in the 2012 FEA (77 FR 17635–17637), as the changes the proposed revisions would require are relatively minor in comparison to the types of changes costed in 2012.[36] As shown in Column 4 of Table VII–14, OSHA estimates that Health and Safety Specialists would spend 0.7 hours per SDS (electronic template) in small establishments with fewer than 100 employees; 0.5 hours per SDS in medium establishments with 100 to 499 employees; and 0.3 hours per SDS in large establishments with 500 or more employees to comply with the proposed mandatory changes to appendices C and D. Multiplying these labor burdens by the loaded hourly wage of $58.00 results in unit costs for Health and Safety Specialists of $40.60, $29.00, and $17.40 per SDS for small, medium, and large establishments, respectively.

As in the FEA for the 2012 HCS final rule, OSHA anticipates that some manufacturers, particularly larger ones heavily involved in international trade, have already adopted the mandatory language proposed in appendices C and D. For the affected NAICS industries, OSHA estimates baseline compliance rates of 75 percent for establishments with 500 or more employees, 25 percent for establishments with 100 to 499 employees, 5 percent for establishments with 20 to 99 employees, and 1 percent for establishments with fewer than 20 employees.[37] These baseline compliance rates are the same ones OSHA used in the 2012 FEA (77 FR 17636).

Multiplying the number of affected SDSs (electronic files) by the unit cost of Health and Safety Specialists, and accounting for the relevant non-compliance rates,[38] results in an estimated total one-time cost associated with revising SDSs and labels to conform to the proposed appendix language on precautionary statements and other mandatory language. As shown in Column 7 of Table VII–14, this total one-time cost is estimated to be about $18.4 million. Annualizing this one-time cost using a 7 percent discount rate over a 10-year period results in estimated annualized costs of approximately $2.6 million for affected employers to revise SDSs and labels to comply with the proposed revisions to appendices C and D. OSHA invites interested parties to provide comments on these cost estimates and the assumptions underlying them.

The estimates of total costs in Table VII–14 are included within a broader cost category shown earlier in the aggregate costs presented in Table VII–12. Column 5 of Table VII–12 displays, by NAICS code, the combined annualized cost estimates for reclassifying chemicals (from Table VII–13) and revising SDSs and labels to be consistent with the precautionary statements and other language specified in the proposed revisions to the mandatory appendices (from Table VII–14).

Management Familiarization and Other Management-Related Costs

In order to implement the proposed new requirements in the HCS, or determine whether they need to implement any of the revisions to the standard, all employers currently covered by the standard would need to become familiar with the updates OSHA is making as part of this rulemaking. The nature and extent of the familiarization required would vary depending on the employer's business.

In the 2012 HCS final rule (77 FR 17637–17638), OSHA estimated that eight hours of time per manager, or an equivalent cost, would be associated with the necessary familiarization and implementation of revisions to hazard communication programs in affected establishments in the manufacturing sector.[39] This proposed rule would require some changes to hazard communication programs in affected establishments, but those changes would be significantly less extensive than those required by the 2012 rule. Therefore, OSHA believes that much less time would be needed for familiarization and implementation under this proposed rule than was necessary under the 2012 rule.

For the present proposed rule, OSHA estimates that management familiarization time would vary by establishment size. It would also vary depending on whether an establishment would simply be familiarizing itself with the proposed rule or would also need to take further action because it would be affected by one or more of the proposed changes to the standard. Above in Section VII.C Profile of Affected Industries, Establishments, and Employees, Table VII–10 presents, by NAICS industry, the percentage of establishments (and for training,

[35] As described above in the discussion explaining Table VI–5, OSHA's estimate of the total number of SDSs per NAICS industry was developed to support the agency's FEA for the 2012 final standard. The analysis started with the number of SDSs per establishment by establishment size, as originally derived in the economic analysis in support of the 2009 proposed revisions to the HCS using a sampling of company websites and the SDSs posted there. (ERG, 2012, Document ID 0029). The analysis then combined the estimated number of SDSs per establishment by establishment size with the estimated number of establishments to estimate the weighted average number of SDSs per establishment in a given NAICS industry. This estimate was then multiplied by the average number of establishments per firm to estimate the number of SDSs per firm for each NAICS industry. Multiplying by the number of firms per NAICS industry yields the total number of SDSs in each NAICS industry (as shown in Column 5 of Table VI–5). Although OSHA has preliminarily determined that this methodology remains sound, the agency invites public comment on the reasonableness of this methodology for the current analysis.

[36] 36 By comparison, the 2012 rule changes included completely revised SDS formats, the addition of pictograms, and various other revisions for specific SDS sections and chemical designations. Note that there are no estimated new software costs associated with the proposed revisions to the standard, as there were for the 2012 final rule, because OSHA expects that the necessary software is already in place in those larger firms for which the software is economically justified.

[37] As noted above, because the current HCS does not allow SDSs or labels to display chemical classifications that are not in conformance with the current rule, OSHA estimated no baseline compliance for chemical manufacturers already having revised electronic files to reflect reclassified chemicals as specified in the proposed rule. With respect to the mandatory language proposed in Appendices C and D, however, SDSs and labels could present standards stricter than seen under previous GHS revisions (for example, if mandatory language is adopted internationally by consensus) and still remain in conformance with the current HCS standard. Therefore, baseline compliance can be non-zero for industry practices involving use of precautionary statements and other mandatory language.

[38] That is, mathematically, (1—the relevant baseline compliance rate). Estimated non-compliance rates are shown in Column 6 of Table VI–14 by employment size for each affected NAICS industry.

[39] Larger employers were estimated to have greater familiarization costs for the 2012 HCS final rule because they have more managers.

entities) expected to be affected by rule familiarization and whether those establishments or entities would incur additional costs or no additional costs—that is, whether those establishments or entities would or would not incur additional costs for revising SDSs/labels or for training employees as a result of the proposed rule.[40] In terms of manufacturing establishments that would have costs in addition to management familiarization costs resulting from the provisions of the proposed rule, OSHA estimates that there are 38,018 small establishments (those with fewer than 20 employees), 11,273 medium establishments (those with 20 to 499 employees), and 394 large establishments (those with 500 or more employees). In terms of establishments that would not have costs other than management familiarization costs resulting from the provisions of this proposed rule, OSHA estimates that there are 79,500 small establishments, 22,657 medium establishments, and 467 large establishments; their only costs associated with this proposal would be as a result of rule familiarization.[41]

To estimate unit costs, OSHA first considered establishments that would incur costs, in addition to rule familiarization costs, because of the proposed rule. As noted earlier, for the 2012 FEA OSHA applied a Manager hourly wage to estimate familiarization costs. For this PEA, because the new requirements found within this proposed standard would be significantly less extensive than those required by the 2012 rule, OSHA expects that the employer will delegate to a Health and Safety Specialist the responsibility for management familiarization of the new requirements found within this proposed standard. OSHA requests public comment on the agency's preliminary assumptions for estimating the cost of management familiarization.

For small establishments, OSHA estimated management familiarization costs of 0.5 hours of a Health and Safety Specialist's labor time. For medium establishments, OSHA estimated 2 hours of a Health and Safety Specialist's labor time. For large establishments, OSHA estimated 8 hours of a Health and Safety Specialist's labor time. Multiplying these labor burdens by the loaded hourly wage of $58.00 results in estimated management familiarization costs per establishment of $29.00, $116.01, and $464.04 for small, medium, and large establishments, respectively.

For establishments that would not incur other costs as a result of the proposed rule, OSHA estimates that rule familiarization will take half as long; in those cases, management will not need to devote as much time to considering (or making compliance decisions about) the provisions in the proposed rule that are expected to result in costs. Therefore, OSHA adopted estimates of 0.25 hours, 1 hour, and 4 hours of a Health and Safety Specialist's labor time for small, medium, and large establishments, respectively. Multiplying these labor burdens by the loaded hourly wage of $58.00 results in management familiarization costs per establishment of $14.50 for small establishments, $58.00 for medium establishments, and $232.02 for large establishments.

These management familiarization costs per establishment are multiplied by the relevant number of small, medium, and large establishments, resulting in an estimated undiscounted one-time familiarization cost of $5.2 million. Annualizing this one-time cost using a 7 percent discount rate over a 10-year period results in an estimate of annualized costs of $735,894. Table VII–15 presents the detailed unit values factoring into OSHA's estimate of management-related costs. The distribution of these management-familiarization costs by NAICS code is displayed in Column 3 of Table VII–12. OSHA invites interested parties to provide comments on these cost estimates and the assumptions underlying them.

TABLE VII–15—TOTAL COSTS ASSOCIATED WITH MANAGEMENT FAMILIARIZATION WITH THE PROPOSED REVISIONS TO THE HCS

[by establishments size, 2019 dollars]

	Small establishments (<20 employees) affected	Medium establishments (20–499 employees) affected	Large establishments (≥ 500 employees) affected	Total
Directly Affected Establishments				
Total Establishments	38,018	11,273	394	49,685
Wage	$58.00	$58.00	$58.00	.....
Hours	0.50	2.00	8.00	.....
Unit Cost Per Establishment	$29.00	$116.01	$464.04	.....
Total One-Time Cost	$1,102,609	$1,307,771	$182,830	$2,593,210
Total Annualized Cost (7%)	$156,987	$186,197	$26,031	$369,215
Indirectly Affected Establishments				
Total Establishments	79,500	22,657	467	102,624
Wage	$58.00	$58.00	$58.00	.....
Hours	0.25	1.00	4.00	.....
Unit Cost Per Establishment	$14.50	$58.00	$232.02	.....
Total One-Time Cost	$1,152,841	$1,314,209	$108,353	$2,575,403
Total Annualized Cost (7%)	$164,139	$187,114	$15,427	$366,679
Total				
Total Establishments	117,518	33,930	861	152,309
Total One-Time Cost	$2,255,450	$2,621,980	$291,183	$5,168,613
Total Annualized Cost (7%)	$321,125	$373,311	$41,458	$735,894

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

[40] Wholesalers in NAICS 424910 and NAICS 424950 are not expected to incur costs for revising SDSs/labels or for training employees, but OSHA expects that they will be affected by the provisions of the proposed rule that are anticipated to result in cost savings.

[41] Note that the numbers of small, medium, and large establishments reported above are derived in the ''Rule Fam'' tab of the OSHA spreadsheet in support of this proposed rule (see Document ID 0049).

Note: Figures may not add to totals due to rounding.

Costs Associated With Training Employees

For this preliminary economic analysis, OSHA estimated the incremental costs to train chemical production employees who are covered by, and are already trained in accordance with, the existing standard but would need to receive additional training to become familiar with the updates to SDSs and labels for impacted aerosols, desensitized explosives, and flammable gases.[42] This analysis is described below. OSHA is not estimating any training costs for users of aerosols, desensitized explosives, or flammable gases in the workplace. OSHA does not believe that these users would need to dedicate more than a trivial amount of time to training associated with the reclassification of these chemicals. This is because the hazards associated with these chemicals have not changed. The only thing that would change under the proposed revisions to the HCS is the way the hazards are classified. For example, users of pyrophoric gases should already have received training on the fire and explosive-related hazards associated with these chemicals. At most, such users might require notification of a change in the classification of those chemicals.

Similarly, even though desensitized explosives is a new hazard classification, the explosion hazards were and are well-known and should have been included in prior hazard training. For example, should the water or other wetting solution dry out, an explosion could occur. In this case, even the hazard pictogram (flames) remains unchanged.

OSHA considered whether some increase in user training might be required for non-flammable aerosols not under pressure, since a small portion of these may not currently be classified as either flammable aerosols or gas under pressure; as noted in the Summary and Explanation section for appendix B, such aerosol containers differ from pressurized gas cylinders in terms of container characteristics and failure mechanisms. Training for non-flammable aerosols might include their revised classification and hazard avoidance measures (such as: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources; no smoking; do not pierce or burn, even after use). However, based on observation of the industry over time, OSHA believes that non-flammable aerosols not under pressure are fairly uncommon and, therefore, OSHA has preliminarily concluded that the total user training time required for non-flammable aerosols not under pressure would also be negligible. The agency requests comments on its preliminary conclusions regarding training time for users of reclassified chemicals.

As discussed above, under the proposed revisions to the HCS, some chemical production employees who are covered by, and are already trained in accordance with, the existing standard would need to receive additional training to become familiar with the updates to SDSs and labels for impacted aerosols, desensitized explosives, and flammable gases. OSHA expects that the incremental training costs for these employees to become familiar with the revisions to the HCS will be small. In certain cases, affected employers will be able to integrate the necessary training into existing training programs and related methods of distributing safety and health information to employees; those employers would not incur any meaningful additional costs.

OSHA estimates that each affected chemical manufacturing firm[43] would need to devote 2.5 hours of a Health and Safety Specialist's time to preparing new training under the proposed rule, and that each affected logistics or production worker would spend 12 minutes receiving the training. Multiplying the labor burden for each labor category by the loaded hourly wages of $58.00 for a Health and Safety Specialist, $58.51 for logistics personnel, and $28.18 for production workers, results in unit costs of $145.01, $11.70, and $5.64, respectively.

Multiplying these unit costs by the 2,754 affected firms, 1,179 affected logistics managers, and 76,447 affected production workers yields an undiscounted estimated one-time cost of $843,940.[44] Annualizing this one-time cost using a 7 percent discount rate over a 10-year period results in estimated annualized costs of $120,158. The unit values that factored into OSHA's estimate of training costs are shown in Table VII–16. The distribution of these training costs by NAICS code is displayed in Column 4 of Table VII–12. OSHA invites interested parties to provide comments on these cost estimates and the assumptions underlying them.

TABLE VII–16—TRAINING COSTS ASSOCIATED WITH THE PROPOSED REVISIONS TO THE HCS STANDARD

[2019 Dollars]

	Health & safety specialist hours per firm to prepare training	Logistics personnel hours per emp. to receive training	Production worker hours per emp. to receive training	Total
Affected Firms	2,754			2,754
Employees Needing Training		1,179	76,447	78,489
Wage	$58.00	$58.51	$28.18	
Hours	2.5	0.2	0.2	2.9
Unit Cost	$145.01	$11.70	$5.64	$162.35
Total One-Time Cost	$399,289	$13,796	$430,855	$843,940
Total Annualized Cost (7%)	$56,850	$1,964	$61,344	$120,158

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.
Note: Figures may not add to totals due to rounding.

[42] OSHA has preliminarily concluded that these would be the only training costs associated with the proposed revisions to the HCS. The agency requests comments on this determination.

[43] OSHA anticipates that, in practice, training would be organized more efficiently at the corporate (firm) level than at the establishment level.

[44] The estimated number of affected firms, logistics managers and production workers are derived in Document ID 0049, tab ''Training''. The affected number of firms (2,754) can also be calculated by matching the NAICS codes with training costs from Table VI–12 with the number of affected firms in the identical NAICS codes in Table VI–1 and multiplying by 50 percent (only 50 percent are estimated to require training).

Released for Shipment

In paragraph (f)(11) of the current HCS, chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical must revise the labels for the chemical within six months of becoming aware of the new information and ensure that labels on containers of hazardous chemicals shipped thereafter contain the new information. OSHA proposes to modify paragraph (f)(11) such that chemicals that have been released for shipment and are awaiting future distribution need not be relabeled; however, the manufacturer or importer must provide an updated label for each individual container with each shipment.

OSHA anticipates that these proposed modifications to paragraph (f)(11) would provide cost savings to manufacturers and distributors of certain products—those with large (and typically infrequent) production runs and lengthy shelf lives (often five years or longer) that, during production, are labeled, boxed, palletized, and shipped, and then go through the distribution chain usually without the chemical contents, packaging, or label being disturbed. In Columns 1 and 2 of Table VII–17, OSHA has identified the six industries (four manufacturing and two wholesale) that it expects would be impacted by the proposed modifications to paragraph (f)(11).[45] These are primarily fertilizer manufacturers, paint manufacturers, and wholesalers of related farm and paint supplies. OSHA invites comments on whether other industries are potentially affected by this proposed modification to paragraph (f)(11) and whether there might be other health or economic effects of this proposed modification that OSHA has not considered in this proposal.

The first factor used to estimate the cost savings resulting from the proposed changes to paragraph (f)(11) is the avoided economic loss for affected manufacturers or wholesalers who would otherwise have to relabel products being held in storage. To estimate the potential economic loss avoided, OSHA relied on comments submitted to the agency by the Council of Producers & Distributors of Agrotechnology (CPDA) on April 21, 2017.[46] The CPDA comments included a summary of cost estimates associated with relabeling non-pesticide agricultural chemical products in distribution. Those estimates were obtained from an industry survey and were based on the following unit costs: Shipping costs to move product out of and back into the warehouse (for off-site package opening and replacement); relabeling space per square foot per month; safety equipment and training per employee involved in relabeling; labor and materials to break down pallets and shrink-wrap and redo product packaging in new plastic bags; and labor and materials to move liquid to new containers and dispose of old containers (CPDA, 2017, pp. 4–5, Document ID 0006).

For OSHA's purposes, the critical costing information from CPDA is the estimate of summary relabeling costs presented as a percentage of the value of the products requiring relabeling. According to the CPDA survey results, these summary costs range from 1.5 percent to 204 percent of the value of the product, depending on product type (*e.g.,* liquid versus dry), container type (plastic bags, etc.), and the volume and value of the product (CPDA, 2017, p. 8, Document ID 0006). As a practical matter, OSHA expects that manufacturers and wholesalers would simply discard a product rather than incur relabeling costs *in excess* of the value of the product. Of course, there may be some disposal costs for the discarded material, but there may also be some salvage value for the improperly-labeled product. If one assumes that the disposal cost and the salvage value are relatively minor and, on net, offset each other, then the upper limit on the relabeling costs for any product would be approximately 100 percent of the value of the product. Furthermore, with an effective range of labeling costs from 1.5 percent to 100 percent of the value of the product, OSHA estimates, without further information on the distribution of the costs, that the average labeling cost would be approximately 50 percent of the value of the products requiring relabeling. While this cost estimate as a percentage of the value of the product was developed from data on relabeling non-pesticide agricultural chemical products in distribution, OSHA has assumed that this same estimate would also apply to relabeling paints and related chemical products in distribution. The agency invites comments on this assumption.

The 50 percent average cost savings estimate would apply only to those products requiring relabeling. In order to estimate the expected cost savings for all products in the NAICS codes affected by the proposed revisions to paragraph (f)(11), OSHA also needs to estimate three other factors (in addition to the average cost savings of 50 percent): (1) What percentage of the products in these NAICS industries would be warehoused for more than six months; (2) what percentage of products warehoused for more than six months would be relabeled in any particular year due to a manufacturer-initiated labeling change;[47] and (3) the percentage of all products in the NAICS industries that are covered by this proposed rule.

OSHA was unable to identify data relevant to factors (1) and (2) above and instead worked with its contractor, ERG, to develop estimates of both of these factors. For (1) above, OSHA expected that the percentage of products warehoused for more than six months would be quite low because it is expensive to hold inventory over long periods of time. Therefore, OSHA estimated that just five percent of the products in the six NAICS industries potentially impacted by the proposed modifications to paragraph (f)(11) would be warehoused for more than six months. For (2) above, OSHA anticipates that manufacturer-initiated relabeling would be rare, and estimated that only one percent of products warehoused for more than six months would be relabeled in any particular year due to a manufacturer-initiated labeling change to one or more of its chemical ingredients. See existing 29 CFR 1910.1200(f)(11). OSHA invites comments on these estimates.

For factor (3) above, OSHA assumed that 100 percent of the products in the four NAICS manufacturing industries are covered by the HCS.[48] For the two wholesale industries, however, some substantial portion of the covered products do not qualify as hazardous chemicals covered by the HCS or are not subject to the HCS labeling requirements. For NAICS 424910: Farm Supplies Merchant Wholesalers, a significant majority of the wholesale

[45] In principle, pesticide manufacturers would also be affected by the proposed revision to the standard, but pesticide labeling in the United States is covered by the U.S. Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). For that reason, any cost savings due to OSHA's proposed revisions to paragraph (f)(11) would not apply to manufacturers in NAICS 325320: Pesticide and other agricultural chemical manufacturing.

[46] Email to Maureen Ruskin of OSHA Re: Comments Supplementing a Petition Submitted to OSHA on May 24, 2016 Requesting a Revision of Paragraph (f)(11) of 29 CFR 1910.1200 (CPDA, 2017, Document ID 0006).

[47] These labeling changes occur when the manufacturer becomes newly aware of significant information regarding the hazards of a chemical. See existing 29 CFR 1910.1200(f)(11).

[48] A review of the products covered under the manufacturing NAICS codes reveals they are all, or almost all, chemicals.

supplies are non-fertilizers, such as grains (*e.g.,* alfalfa, hay, livestock feeds) and nursery stock (*e.g.,* plant seeds and plant bulbs). Based on data from the 2012 Economic Census,[49] ERG estimated that 41.7 percent of the wholesale supplies in NAICS 424910 would be fertilizers affected by the proposed released-for-shipment provision (Document ID 0049, tab ''RF Shipment''). For NAICS 424950: Paint, Varnish, and Supplies Merchant Wholesalers, some proportion of the wholesale supply consists of non-paints and non-chemicals, such as wallpaper and painting supplies such as paintbrushes, rollers, and spray-painting equipment. Based on data from the 2012 Economic Census, ERG estimated that 77.6 percent of the wholesale supplies in NAICS 424950 would be paints and related chemicals affected by the proposed released-for-shipment provision (Document ID 0049, tab ''RF Shipment''). OSHA used ERG's estimates to develop the expected cost savings attributable to the proposed revisions to paragraph (f)(11). The agency invites comments on these estimates.[50]

Column 3 of Table VII–18 shows the average product value (revenue) for each of the six NAICS industries that OSHA expects would be affected by the proposed modification to paragraph (f)(11).[51] Column 4 of Table VII–18 shows the number of affected firms (entities) for each of these six NAICS industries.[52] Column 5 of Table VII–18 shows the estimated loss avoided due to the proposed released-for-shipment provision for each of these six NAICS industries as a percentage of that industry's revenues. That percentage is the product of the four factors estimated above: (1) The costs of relabeling as a percentage of the value of the products requiring relabeling; (2) the percentage of the products in these NAICS industries that would be warehoused for more than six months; (3) the percentage of products warehoused for more than six months that would require relabeling in any particular year due to a manufacturer-initiated labeling change; and (4) the percentage of all products in the NAICS industries covered by this proposed rule.

Table VII–17 presents, by NAICS industry, these four factors and the calculated percentage loss in revenue OSHA anticipates would be avoided under the proposed released-for-shipment provision.

TABLE VII–17—CALCULATION OF THE PERCENTAGE LOSS AVOIDED DUE TO THE PROPOSED RELEASED-FOR-SHIPMENT PROVISION

[2019 Dollars]

NAICS	NAICS industry	Percentage cost savings (A)	Percentage of products warehoused ≥ six months (B)	Percentage of products warehoused ≥ six months and require relabeling (C)	Percentage of products covered by the proposed rule (D)	Product of percentages (A), (B), (C), and (D)
325311	Nitrogenous Fertilizer Manufacturing	50	5	1	100	0.03
325312	Phosphatic Fertilizer Manufacturing	50	5	1	100	0.03
325314	Fertilizer (Mixing Only) Manufacturing	50	5	1	100	0.03
325510	Paint and Coating Manufacturing	50	5	1	100	0.03
424910	Farm Supplies Merchant Wholesalers	50	5	1	41.70	0.01
424950	Paint, Varnish, and Supplies Merchant Wholesalers	50	5	1	77.60	0.02

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

The estimated cost savings for each of the six affected industries arising from the proposed modifications to paragraph (f)(11) then is simply the product of Columns 3, 4, and 5 in Table VII–18. Summing the cost savings for each of the six industries yields an estimated annual cost savings of $29.8 million. OSHA requests comments on the reasonableness of this estimate and the assumptions underlying it (including the various factor percentage estimates listed in Table VII–17).

TABLE VII–18—COST SAVINGS ASSOCIATED WITH THE PROPOSED RELEASED-FOR-SHIPMENT PROVISION

[2019 Dollars]

NAICS	NAICS industry	Average product value (revenue)	Affected firms	Loss avoided as a % of revenue	Loss avoided
325311	Nitrogenous Fertilizer Manufacturing	$37,902,969	163	0.03	$1,544,546
325312	Phosphatic Fertilizer Manufacturing	127,231,784	45	0.03	1,431,358
325314	Fertilizer (Mixing Only) Manufacturing	13,737,854	359	0.03	1,232,972
325510	Paint and Coating Manufacturing	28,813,229	998	0.03	7,188,901
424910	Farm Supplies Merchant Wholesalers	28,809,209	4,965	0.01	14,911,683
424950	Paint, Varnish, and Supplies Merchant Wholesalers	18,022,834	1,012	0.02	3,538,387

[49] 2012 Economic Census of the United States, Table EC1242SLLS1—Wholesale Trade: Subject Series—Product Lines: Product Lines Statistics by Industry for the U.S. and States: 2012 (Document ID 0043).

[50] Under the proposed revisions to paragraph (f)(11), when relabeling is not required for chemicals that have been released for shipment, the chemical manufacturer or importer would still be required to provide an updated label for each individual container with each shipment. The agency estimates that any incremental costs associated with providing updated labels are likely to be negligible, as OSHA believes this is already standard industry practice.

[51] Derived for each NAICS by dividing Column 3 of Table VII–9 (total industry revenues) by Column 7 of Table VII–1 (number of affected firms).

[52] Obtained from Column 7 of Table VII–1.

TABLE VII–18—COST SAVINGS ASSOCIATED WITH THE PROPOSED RELEASED-FOR-SHIPMENT PROVISION—Continued

[2019 Dollars]

NAICS	NAICS industry	Average product value (revenue)	Affected firms	Loss avoided as a % of revenue	Loss avoided
Total	.....	.....	7,542	.....	29,847,846

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.
Note: Figures may not add to totals due to rounding.

Labels on Very Small Containers

Proposed paragraph (f)(12), which addresses the labeling of small containers, would limit labeling requirements for chemical manufacturers, importers, or distributors where they can demonstrate that it is not feasible to use pull-out labels, fold-back labels, or tags to provide the full label information as required by paragraph (f)(1). As proposed in paragraph (f)(12)(ii), manufacturers, importers, and distributors would be able to use an abbreviated label (requiring only the product identifier, pictogram(s), signal word, chemical manufacturer's name and phone number, and a statement that the full label information is provided on the immediate outer package) on containers with a volume capacity of 100 ml or less—referred to as ''small containers'' in this PEA. As proposed in paragraph (f)(12)(iii), manufacturers, importers, and distributors would need to put only the product identifier on containers with a volume capacity of 3 ml or less—referred to as ''very small containers'' in this PEA—if they can demonstrate that any label would interfere with the normal use of the container.

Following publication of the 2012 updates to the HCS, stakeholders requested that OSHA clarify its enforcement policy on labels for small containers. In response, through letters of interpretation, OSHA adopted practical accommodations that specified: (1) The minimum information required for a label on the immediate container of the shipped chemical; and (2) the minimum information required for the outer packaging of shipped small containers (see, *e.g.,* Collatz, 2015, Document ID 0174; Watters, 2013, Document ID 0200; Blankfield, 2017, Document ID 0170). Proposed paragraph (f)(12)(ii) would incorporate into the HCS the accommodations for small containers described in these letters of interpretation; however, the letters did not contain any guidance unique to very small containers, which would be covered by proposed paragraph (f)(12)(iii).

For costing purposes, OSHA estimates that no cost savings will arise from proposed paragraph (f)(12)(ii) (small containers); OSHA expects that employers are already benefitting from the practical accommodations on the labeling of small packages described in the aforementioned letters of interpretation. OSHA invites public comments on this preliminary determination and the magnitude of any cost savings that should be attributed to proposed paragraph (f)(12)(ii).

OSHA has estimated cost savings under proposed paragraph (f)(12)(iii) for manufacturers, importers, and distributors of very small containers (volume capacity of 3 ml or less) where the use of any label (even an abbreviated label as specified in proposed paragraph (f)(12)(ii)) would interfere with the normal use of the container and only the product identifier would be required. OSHA has preliminarily determined that affected manufacturers would fall in only a few NAICS industries: Other Basic Chemical Manufacturing, Inorganic and Organic (NAICS 325180 and 325199, respectively) and Pharmaceutical and Medical Manufacturing (NAICS 3254—encompassing 6-digit NAICS 325411, 325412, 325413, and 325414). As shown in Column 3 of Table VII–19, OSHA estimates that there are approximately 63.5 million labels on very small containers in these six 6-digit NAICS manufacturing industries that OSHA anticipates could be affected by this part of the proposed rule.[53]

Even in these six NAICS industries, however, manufacturers would not be able to take advantage of proposed paragraph (f)(12)(iii) in all cases because that provision applies only when the manufacturer, importer, or distributor can demonstrate that it is not feasible to use pull-out labels, fold-back labels, or tags containing the full label information and that even an abbreviated label would interfere with the normal use of the container. Of the 63.5 million potentially affected labels on very small containers, OSHA estimates that for only 40 percent of them, or for an estimated total of 25.4 million very small containers, would manufacturers fall under proposed paragraph (f)(12)(iii) (see Column 5 of Table VII–19 and, equivalently, Column 7 of Table VII–5).

Manufacturers with containers falling under proposed paragraph (f)(12)(iii) could expect to obtain cost savings from avoided labeling costs on very small containers (with only the product identifier required) versus the labeling costs of abbreviated labels (requiring the product identifier, pictogram(s), signal word, manufacturer's name and phone number, and a statement that the full label information is provided on the immediate outer packaging). OSHA estimates an incremental unit cost savings of $0.051 per label for very small containers.[54] That unit cost savings is expected to be net of the cost of providing a full label on the immediate outer package (containing a set of very small containers) per proposed paragraph (f)(12)(iv)(A). As shown in Table VII–19, multiplying the number of affected labels by the unit cost savings of $0.051 per label for very

[53] The number of very small containers in Column 3 of Table VII–19 for each of these six NAICS industries was obtained from Column 4 of Table VII–5.

[54] The Flavor and Extract Manufacturers Association of the United States (FEMA) provided OSHA (in a letter to Robert Stone of OSHA, dated April 27, 2018) (Document ID 0257) a summary of survey results obtained from member companies concerning how they might benefit from relaxed OSHA labeling requirements on small containers. Those results included an estimate of $0.85 per label for small capacity containers compliant with the 2012 HCS. However, this estimate applies to expensive labels—such as pull-out labels, fold-back labels, and full-information tags—and therefore is not applicable to the cost savings associated with using only the product identifier in lieu of the abbreviated labeling specified in proposed paragraph (f)(12)(ii). OSHA believes it is likely that most of the cost savings reported from the FEMA survey would be attributable to the expensive types of labels.

Based on the unit cost data provided by FEMA, OSHA estimated a unit cost savings of $0.05 in 2018 dollars for the use of labels with the minimum information—the product identifier—required for very small containers (versus abbreviated labels). Updating the 2018 estimate to 2019 dollars using the BEA (2020) implicit price deflator for Gross Domestic Product, OSHA derived an estimate of $0.05087 in cost savings per label (with the unrounded estimate used in the analysis).

small containers yields estimated annual cost savings of $1.3 million. OSHA invites interested parties to provide comments on these cost estimates and the assumptions underlying them.

TABLE VII–19—ESTIMATED COST SAVINGS ASSOCIATED WITH ABBREVIATED LABELS ON VERY SMALL CONTAINERS UNDER THE PROPOSED HCS STANDARD

[2019 Dollars]

NAICS	NAICS industry	Labels—very small containers	Percentage of labels with cost savings	Labels w/cost savings	Annual cost savings
325180	Other Basic Inorganic Chemical Manufacturing	14,768,423	40	5,907,369	$300,518
325199	All Other Basic Organic Chemical Manufacturing	35,524,371	40	14,209,748	722,874
325411	Medicinal and Botanical Manufacturing	5,106,176	40	2,042,471	103,904
325412	Pharmaceutical Preparation Manufacturing	6,471,452	40	2,588,581	131,685
325413	In-Vitro Diagnostic Substance Manufacturing	501,664	40	200,665	10,208
325414	Biological Product (except Diagnostic) Manufacturing	1,113,080	40	445,232	22,650
Total		63,485,165	40	25,394,066	1,291,839

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.
Note: Figures may not add to totals due to rounding.

Sensitivity Analysis

In this section, OSHA presents the results of a sensitivity analysis to demonstrate how robust the estimates of net cost savings are to changes in various cost parameters. In this analysis, OSHA made a series of isolated changes to individual cost input parameters in order to determine their effects on the agency's estimates of annualized net cost savings, with a seven-percent discount rate as the reference point. The agency has conducted these calculations for informational purposes only.

The methodology and calculations underlying the cost estimates associated with this rulemaking are generally linear and additive in nature. Thus, the sensitivity of the results and conclusions of the analysis will generally be proportional to isolated variations in a particular input parameter. For example, if the estimated time that employees will need to devote to attending new training doubles, the corresponding labor costs would double as well.

OSHA evaluated a series of such changes in input parameters to test whether and to what extent the general conclusions of the preliminary economic analysis held up. OSHA considered changes to input parameters that affected only costs and cost savings and determined that each of the sensitivity tests on cost parameters had only a very minor effect on total costs or net costs. On the whole, OSHA found that the conclusions of the analysis are robust, as changes in any of the cost input parameters still show significant net cost savings for the final rule. The results of the individual sensitivity tests are summarized and are described in more detail in Table VII–20.

In the first of these sensitivity tests, OSHA reduced from 1 percent to 0.5 percent its estimate of the percentage of products warehoused for more than six months that require relabeling in any particular year. The effect of this change would be to reduce by 50 percent the estimated cost savings associated with the proposed released-for-shipment provision. Table VII–20 shows that the estimated net cost savings from the proposed rule would decline by $14.9 million annually, from $26.8 million to $11.8 million annually, or by about 56 percent.

In a second sensitivity test, OSHA reversed the first sensitivity test, that is, the agency increased from 1 percent to 2 percent the percentage of products warehoused for more than six months that require relabeling in any particular year. The effect of this change would be to increase by 100 percent the estimated cost savings associated with the proposed released-for-shipment provision. Table VII–20 shows that the estimated net cost savings from the proposed rule would increase by $29.8 million annually, from $26.8 million to $56.6 million annually, or by about 112 percent.

In a third sensitivity test, OSHA reduced from 40 percent to 20 percent the percentage of very small containers that would be affected by proposed paragraph (f)(12). As shown in Table VII–20, if OSHA's estimates of other input parameters remained unchanged, the estimated net cost savings from the proposed rule would decline by $0.6 million annually, from $26.8 million to $26.1 million annually, or by about 2 percent.

In a fourth sensitivity test, OSHA applied the same rule familiarization costs to all firms regardless of whether they are affected by other provisions of this proposal, *i.e.,* OSHA did not reduce estimated familiarization time for firms that are not affected by other parts of the proposal. The effect of this change would be to raise compliance costs for 102,624 establishments in manufacturing and wholesale trade; the estimated net cost savings from the proposed rule would be reduced by $0.4 million annually, from $26.8 million to $26.4 million annually, or by about 1 percent.

In a fifth sensitivity test, OSHA doubled the estimated labor hours assigned to revising SDSs and labels due to the reclassification of chemicals and revised mandatory language in the appendices of the HCS (from Tables VII–13 and VII–14). The effect of this change would be to double labor costs for the affected six-digit NAICS industries; estimated net cost savings would be reduced by $3.5 million annually, from $26.8 million to $23.2 million, or by 13.2 percent.

In a sixth sensitivity test, OSHA excluded overhead costs from the fully loaded hourly wage rates used throughout the PEA. Overhead costs were not applied in the 2012 FEA and this sensitivity test provides consistency with the treatment of overhead in the 2012 analysis. The effect of this change would be to remove the factor of 17 percent of base wages from the hourly costs for the four job categories used in the cost analysis. Applying this change, the estimated net cost savings from the proposed rule would increase by $0.5 million annually, or by 1.7 percent, resulting in a total estimate of annualized net cost savings of $27.2 million.

TABLE VII–20—SENSITIVITY TESTS AND REGULATORY ALTERNATIVES—IMPACTS ON NET COST SAVINGS
[7 Percent discount rate, 2019 dollars]

Uncertainty (cost) scenarios	Change from OSHA's best estimate	Difference from proposed rule	Percentage impact on net cost savings	Net cost savings
Proposed Rule—OSHA's midpoint estimate	N/A	$0	0.0	$26,753,711
Reduce from 1 percent to 0.5 percent the percentage of products warehoused for more than six months that would require relabeling in any particular year.	Halves cost savings associated with proposed released-for-shipment provision.	−$14,923,923	−55.8	11,829,788
Increase from 1 percent to 2 percent the percentage of products warehoused for more than six months that would require relabeling in any particular year.	Doubles cost savings associated with proposed released-for-shipment provision.	29,847,846	111.6	56,601,557
Reduce from 40% to 20% the percentage of very small containers that would be affected by proposed paragraph (f)(12).	Halves cost savings for affected firms	−645,919	−2.4	26,107,792
Rule familiarization time would not be reduced for firms that are not affected by any other cost provisions; it would be identical to rule familiarization time for those that are affected by other provisions.	Raises costs for the 31,577 establishments in NAICS 31–33—Manufacturing, and the 71,047 establishments in NAICS 42—Wholesale Trade not affected by other provisions.	−366,679	−1.4	26,387,032
Doubles labor hours for the reclassification of chemicals and compliance with the new mandatory language in the appendices to the proposed standard.	Doubles labor costs for the approximately 13 six-digit NAICS industries affected by proposed changes to paragraph (d) and appendices B, C, and D.	−3,529,921	−13.2	23,223,790
Excludes overhead costs from fully loaded hourly wage rates.	For the four job categories in the cost model, overhead costs (17 percent of base wages) are not applied and estimated wage rates are correspondingly lower.	458,003	1.7	27,211,714
Remove the proposed provisions that result in cost savings for very small labels.	Eliminates cost savings for affected employers	−1,291,839	−4.8	25,461,873
Eliminate the proposed released-for-shipment provisions and associated cost savings.	Eliminates cost savings for affected employers	−29,847,846	−111.6	−3,094,135

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0049, tab "Tables").

Not part of this table, but discussed in A. Introduction and Summary, the agency examined the effect of lowering the discount rate for annualizing costs from 7 percent to 3 percent. Lowering the discount rate to 3 percent would yield annualized net cost savings of $27.5 million, approximately $700,000 more in annual cost savings than the net cost savings at a 7 percent discount rate.

Regulatory Alternatives

This section discusses two regulatory alternatives to the changes OSHA is proposing in this NPRM: (1) Removing the proposed changes to paragraph (f)(12) regarding labeling of very small containers, which would eliminate cost savings for manufacturers, importers, and distributors that label such containers; and (2) removing the proposed changes to paragraph (f)(11) regarding labeling of containers that have been released-for-shipment, which would eliminate cost savings for manufacturers, importers, and distributors that have such containers. In Table VII–20, each regulatory alternative is described and analyzed relative to the proposed revisions to the HCS. Midpoint estimates are presented in all cases. Under Regulatory Alternative (1) (elimination of changes related to labeling of very small containers), cost impacts total $1.3 million (4.8 percent of baseline cost savings), resulting in a reduction of estimated annualized net cost savings to a total of $25.5 million. Under Regulatory Alternative (2) (elimination of changes related to labels on packages that have been released for shipment), cost impacts on employers total $29.8 million (112 percent of baseline cost savings), resulting in an overall estimate of annualized net costs of $3.1 million.

In summary, these regulatory alternatives would result in a reduction of cost savings—a significant reduction in the case of the second alternative (resulting in positive, but modest, overall net costs). The elimination of neither alternative, however, would alter the agency's determination of economic feasibility for the proposed revisions to the HCS as a whole. Nor would the elimination of these alternatives result in a significant impact on a substantial number of small entities (see Section VII. G. Economic Feasibility and Impacts).

G. Economic Feasibility and Impacts

This section presents OSHA's analysis of the potential economic impacts of the proposed rule and an assessment of economic feasibility. A separate analysis of the potential economic impacts on small entities (as defined in accordance with SBA criteria) and on very small entities (those with fewer than 20 employees) is presented in the following section as part of the Initial Regulatory Flexibility Screening Analysis, conducted in accordance with the criteria laid out in the Regulatory Flexibility Act.

A standard is economically feasible ''if it does not threaten massive dislocation to, or imperil the existence of, [an] industry.'' *Lead I,* 647 F.2d at 1265 (internal citations and quotation marks omitted). To determine whether a rule is economically feasible, OSHA begins with two screening tests to consider minimum threshold effects of the rule under two extreme cases: (1) A scenario in which all costs are passed through to customers in the form of higher prices (consistent with a price elasticity of demand of zero); and (2) a scenario in which all costs are absorbed by the firm in the form of reduced profits (consistent with an infinite price elasticity of demand).

In profit-earning entities, compliance costs can generally be expected to be absorbed through a combination of increases in prices and reductions in profits. The extent to which the impacts of cost increases affect prices or profits depends on the price elasticity of demand for the products or services produced and sold by the entity.

The price elasticity of demand refers to the relationship between changes in the price charged for a product and the resulting changes in the demand for that product. A larger price elasticity of demand implies that an entity or industry is less able to pass increases in costs through to its customers in the form of a price increase and must absorb more of the cost increase through a reduction in profits.

If the price elasticity of demand is zero, and all costs can be passed to customers in the form of higher prices, the immediate impact of the rule would be observed in the form of increased industry revenues. In the absence of evidence to the contrary, OSHA generally considers a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of one percent of annual revenues. Common-sense considerations indicate that potential impacts of such a small magnitude are unlikely to eliminate an industry or significantly alter its competitive structure, particularly since most industries have at least some ability to raise prices to reflect increased costs and normal price variations for products typically exceed three percent a year (OSHA, 2016, Chapter VI, pp. VI–20/VI–23 and Table VI–3). [55] Of course, OSHA recognizes that even when costs are within this range, there could be unusual circumstances requiring further analysis.

If, however, there is infinite price elasticity of demand, and all costs are absorbed by affected firms, the immediate impact of the rule would be observed in reduced industry profits. OSHA uses the ratio of annualized costs to annual profits as a second check on economic feasibility. In the absence of evidence to the contrary, OSHA generally considers a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of ten percent of annual profits. This is a fairly modest threshold level, given that normal year-to-year variations in profit rates in an industry can exceed 40 percent or more (OSHA, 2016, Chapter VI, pp. VI–20/VI–23 and Table VI–5).[56]

In order to assess the nature and magnitude of the economic impacts associated with compliance with the proposed rule, OSHA developed quantitative estimates of the potential economic impact of the requirements on each of the affected industry sectors. The estimated costs of compliance presented in Section VII.F of this preamble were compared with industry revenues and profits to provide a measure of potential economic impacts. Table VII–21 presents data on revenues and profits for each affected industry sector at the six-digit NAICS industry level, along with the corresponding estimated annualized costs of compliance in each sector. Potential impacts in the table are represented by the ratios of compliance costs to revenues and compliance costs to profits.

The nature of the proposed revisions to the HCS is such that all affected firms would incur some costs, but only a small subset would derive the cost savings that are monetized in this PEA (although most or all would enjoy non-monetized benefits, *e.g.,* in foreign trade). To examine the economic impacts of the proposed revisions to the standard for those affected establishments that obtain no monetized cost savings from any of the proposed revisions to the HCS, OSHA estimated the ratio of compliance costs to revenues and the ratio of compliance costs to profits using only gross positive costs (*i.e.,* costs exclusive of cost savings) as the numerator in the ratio. Table VII–22 presents this part of the agency's screening analysis.

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[55] Document ID OSHA–2010–0034–4247, Attachment ''Silica FEA Chapter VI: Economic Feasibility Analysis and Regulatory Flexibility Determination'' (Document ID 0045).

[56] Document ID OSHA–2010–0034–4247, Attachment ''Silica FEA Chapter VI: Economic Feasibility Analysis and Regulatory Flexibility Determination'' (Document ID 0045).

Table VII-21: Screening Analysis for Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2019 Dollars)

NAICS Code	Industry	Total Firms	Affected Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
21	**Mining, Quarrying, and Oil and Gas Extraction**	**15,437**	**5,200**	**$311,577**	**$326,848,327,601**	**$21,110,919,773**	**0.00%**	**0.00%**
211	**Oil and Gas Extraction**	**5,200**	**5,200**	**$311,577**	**$240,298,917,934**	**$14,974,398,582**	**0.00%**	**0.00%**
211120	Crude Petroleum Extraction	4,570	4,570	$198,373	$170,279,184,328	$10,611,068,906	0.00%	0.00%
211130	Natural Gas Extraction	630	630	$113,204	$70,019,733,607	$4,363,329,676	0.00%	0.00%
31-33	**Manufacturing**	**258,563**	**60,752**	**-$8,828,427**	**$5,797,450,564,984**	**$264,415,656,740**	**0.00%**	**0.00%**
324	**Petroleum and Coal Products Manufacturing**	**984**	**984**	**$1,528,936**	**$548,268,340,205**	**$37,365,772,412**	**0.00%**	**0.00%**
324110	Petroleum Refineries	70	70	$98,464	$502,164,011,213	$34,203,490,777	0.00%	0.00%
324121	Asphalt Paving Mixture and Block Manufacturing	472	472	$171,774	$13,860,504,187	$955,963,177	0.00%	0.02%
324122	Asphalt Shingle and Coating Materials Manufacturing	123	123	$26,220	$11,617,097,706	$801,234,752	0.00%	0.00%
324191	Petroleum Lubricating Oil and Grease Manufacturing	253	253	$1,221,994	$16,586,696,926	$1,129,878,602	0.01%	0.11%
324199	All Other Petroleum and Coal Products Manufacturing	66	66	$10,485	$4,040,030,172	$275,205,103	0.00%	0.00%
325	**Chemical Manufacturing**	**10,389**	**10,389**	**-$10,862,751**	**$789,429,171,514**	**$65,825,402,786**	**0.00%**	**-0.02%**
325110	Petrochemical Manufacturing	28	28	$20,123	$55,741,502,666	$1,902,021,496	0.00%	0.00%
325120	Industrial Gas Manufacturing	63	63	$25,318	$9,700,639,626	$331,006,956	0.00%	0.01%
325130	Synthetic Dye and Pigment Manufacturing	112	112	$9,298	$7,293,474,420	$248,869,235	0.00%	0.00%
325180	Other Basic Inorganic Chemical Manufacturing	363	363	-$282,090	$33,275,419,838	$1,135,429,811	0.00%	-0.02%
325193	Ethyl Alcohol Manufacturing	121	121	$11,923	$32,337,672,494	$1,103,431,829	0.00%	0.00%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	53	53	$4,908	$8,105,063,187	$276,562,412	0.00%	0.00%
325199	All Other Basic Organic Chemical Manufacturing	591	591	-$666,121	$80,041,612,356	$2,731,194,173	0.00%	-0.02%
325211	Plastics Material and Resin Manufacturing	852	852	$154,986	$94,876,413,479	$5,636,119,712	0.00%	0.00%
325212	Synthetic Rubber Manufacturing	140	140	$4,809	$8,750,057,350	$519,795,900	0.00%	0.00%
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	109	109	$2,251	$7,325,632,100	$435,178,122	0.00%	0.00%
325311	Nitrogenous Fertilizer Manufacturing	163	163	-$1,541,948	$6,178,183,955	$600,201,186	-0.02%	-0.26%
325312	Phosphatic Fertilizer Manufacturing	45	45	-$1,430,465	$5,725,430,291	$556,216,855	-0.02%	-0.26%
325314	Fertilizer (Mixing Only) Manufacturing	359	359	-$1,219,569	$4,931,889,637	$479,125,586	-0.02%	-0.25%
325320	Pesticide and Other Agricultural Chemical Manufacturing	188	188	$39,388	$15,622,076,997	$1,517,661,048	0.00%	0.00%
325411	Medicinal and Botanical Manufacturing	451	451	-$81,917	$11,504,963,235	$1,595,818,501	0.00%	-0.01%
325412	Pharmaceutical Preparation Manufacturing	1,007	1,007	$26,972	$186,027,072,841	$25,803,250,170	0.00%	0.00%
325413	In-Vitro Diagnostic Substance Manufacturing	192	192	$27,441	$14,420,723,180	$2,000,254,706	0.00%	0.00%
325414	Biological Product (except Diagnostic) Manufacturing	266	266	-$11,467	$31,996,374,817	$4,438,119,954	0.00%	0.00%
325510	Paint and Coating Manufacturing	998	998	-$6,731,133	$28,755,602,915	$1,199,560,340	-0.02%	-0.56%
325520	Adhesive Manufacturing	403	403	$183,339	$15,404,571,015	$642,612,589	0.00%	0.03%
325611	Soap and Other Detergent Manufacturing	618	618	$125,189	$25,419,002,064	$3,137,684,958	0.00%	0.00%
325612	Polish and Other Sanitation Good Manufacturing	419	419	$78,300	$6,433,601,711	$794,154,517	0.00%	0.01%
325613	Surface Active Agent Manufacturing	105	105	$32,437	$7,488,008,843	$924,309,013	0.00%	0.00%

Table VII-21: Screening Analysis for Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2019 Dollars)

NAICS Code	Industry	Total Firms	Affected Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
325620	Toilet Preparation Manufacturing	926	926	$158,612	$43,279,075,380	$5,342,306,652	0.00%	0.00%
325910	Printing Ink Manufacturing	182	182	$53,333	$4,534,098,456	$229,935,022	0.00%	0.02%
325920	Explosives Manufacturing	52	52	$15,752	$2,483,129,453	$125,925,458	0.00%	0.01%
325991	Custom Compounding of Purchased Resins	330	330	$11,925	$11,882,633,328	$602,596,873	0.00%	0.00%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	189	189	$6,218	$7,036,771,608	$356,851,588	0.00%	0.00%
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	1,064	1,064	$109,437	$22,858,474,270	$1,159,208,126	0.00%	0.01%
326	**Plastics and Rubber Products Manufacturing**	**9,694**	**9,694**	**$68,513**	**$247,748,726,309**	**$5,974,209,486**	**0.00%**	**0.00%**
326111	Plastics Bag and Pouch Manufacturing	271	271	$2,191	$11,673,118,042	$299,485,288	0.00%	0.00%
326112	Plastics Packaging Film and Sheet (including Laminated) Mfg.	299	299	$2,711	$13,981,710,136	$358,714,481	0.00%	0.00%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Mfg.	429	429	$3,054	$16,764,409,928	$430,107,373	0.00%	0.00%
326121	Unlaminated Plastics Profile Shape Manufacturing	326	326	$2,048	$8,405,469,386	$215,650,558	0.00%	0.00%
326122	Plastics Pipe and Pipe Fitting Manufacturing	266	266	$2,800	$11,149,151,610	$286,042,415	0.00%	0.00%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	208	208	$1,121	$4,558,892,856	$116,962,866	0.00%	0.00%
326140	Polystyrene Foam Product Manufacturing	308	308	$2,606	$10,048,849,303	$257,813,081	0.00%	0.00%
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	445	445	$3,669	$11,390,162,766	$292,225,793	0.00%	0.00%
326160	Plastics Bottle Manufacturing	195	195	$3,165	$11,711,421,690	$300,468,006	0.00%	0.00%
326191	Plastics Plumbing Fixture Manufacturing	311	311	$1,724	$4,393,033,016	$112,707,569	0.00%	0.00%
326199	All Other Plastics Product Manufacturing	5,187	5,187	$33,348	$99,843,663,537	$2,561,587,076	0.00%	0.00%
326211	Tire Manufacturing (except Retreading)	81	81	$1,288	$18,217,353,429	$308,595,467	0.00%	0.00%
326212	Tire Retreading	261	261	$1,390	$1,750,825,443	$29,658,358	0.00%	0.00%
326220	Rubber and Plastics Hoses and Belting Manufacturing	196	196	$1,553	$5,525,287,685	$93,596,402	0.00%	0.00%
326291	Rubber Product Manufacturing for Mechanical Use	346	346	$2,509	$7,932,574,831	$134,374,987	0.00%	0.00%
326299	All Other Rubber Product Manufacturing	565	565	$3,339	$10,402,802,651	$176,219,765	0.00%	0.00%
327	**Nonmetallic Mineral Product Manufacturing**	**9,636**	**9,636**	**$59,127**	**$131,885,843,897**	**$2,461,308,698**	**0.00%**	**0.00%**
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	566	566	$1,963	$2,319,233,154	$36,481,726	0.00%	0.01%
327120	Clay Building Material and Refractories Manufacturing	375	375	$2,740	$5,881,207,701	$92,511,875	0.00%	0.00%
327211	Flat Glass Manufacturing	74	74	$597	$4,388,366,999	$124,247,799	0.00%	0.00%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	387	387	$1,534	$3,522,384,800	$99,729,252	0.00%	0.00%
327213	Glass Container Manufacturing	29	29	$442	$5,272,106,533	$149,269,109	0.00%	0.00%
327215	Glass Product Manufacturing Made of Purchased Glass	983	983	$4,844	$13,900,601,495	$393,567,616	0.00%	0.00%
327310	Cement Manufacturing	101	101	$1,094	$9,050,480,224	$133,073,152	0.00%	0.00%
327320	Ready-Mix Concrete Manufacturing	2,098	2,098	$19,738	$32,398,760,101	$476,373,077	0.00%	0.00%
327331	Concrete Block and Brick Manufacturing	430	430	$3,058	$4,879,471,211	$71,744,990	0.00%	0.00%
327332	Concrete Pipe Manufacturing	98	98	$1,195	$1,708,315,398	$25,118,105	0.00%	0.00%

Table VII-21: Screening Analysis for Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2019 Dollars)

NAICS Code	Industry	Total Firms	Affected Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
327390	Other Concrete Product Manufacturing	1,560	1,560	$8,244	$12,334,383,335	$181,357,809	0.00%	0.00%
327410	Lime Manufacturing	38	38	$479	$2,355,559,712	$44,069,981	0.00%	0.00%
327420	Gypsum Product Manufacturing	127	127	$987	$6,468,574,425	$121,020,050	0.00%	0.00%
327910	Abrasive Product Manufacturing	256	256	$1,317	$5,886,203,059	$110,124,510	0.00%	0.00%
327991	Cut Stone and Stone Product Manufacturing	1,907	1,907	$6,594	$5,236,293,789	$97,965,408	0.00%	0.01%
327992	Ground or Treated Mineral and Earth Manufacturing	154	154	$1,098	$4,456,620,907	$83,378,570	0.00%	0.00%
327993	Mineral Wool Manufacturing	174	174	$1,369	$6,445,499,687	$120,588,346	0.00%	0.00%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	279	279	$1,833	$5,381,781,367	$100,687,324	0.00%	0.00%
331	**Primary Metal Manufacturing**	**3,558**	**3,558**	**$25,831**	**$232,471,614,560**	**$5,007,068,940**	**0.00%**	**0.00%**
331110	Iron and Steel Mills and Ferroalloy Manufacturing	369	369	$4,107	$93,922,044,820	$1,165,821,393	0.00%	0.00%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	180	180	$1,693	$11,067,013,255	$230,377,817	0.00%	0.00%
331221	Rolled Steel Shape Manufacturing	170	170	$1,034	$5,992,331,220	$124,740,086	0.00%	0.00%
331222	Steel Wire Drawing	210	210	$1,418	$5,581,251,741	$116,182,800	0.00%	0.00%
331313	Alumina Refining and Primary Aluminum Production	31	31	$213	$3,537,971,191	$87,352,773	0.00%	0.00%
331314	Secondary Smelting and Alloying of Aluminum	65	65	$572	$6,039,040,368	$149,104,358	0.00%	0.00%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	62	62	$861	$15,749,488,321	$381,314,941	0.00%	0.00%
331318	Other Aluminum Rolling, Drawing, and Extruding	212	212	$1,718	$11,879,785,984	$293,312,803	0.00%	0.00%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	129	129	$650	$9,746,852,678	$202,896,535	0.00%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	164	164	$1,689	$23,335,378,243	$485,763,717	0.00%	0.00%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	227	227	$1,299	$6,982,835,711	$145,359,042	0.00%	0.00%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal	183	183	$1,065	$7,574,445,310	$157,674,355	0.00%	0.00%
331511	Iron Foundries	298	298	$2,275	$9,786,154,772	$462,217,269	0.00%	0.00%
331512	Steel Investment Foundries	95	95	$898	$4,091,022,841	$193,226,191	0.00%	0.00%
331513	Steel Foundries (except Investment)	189	189	$1,049	$3,451,310,647	$163,011,461	0.00%	0.00%
331523	Nonferrous Metal Die-Casting Foundries	351	351	$2,463	$7,892,732,868	$372,787,629	0.00%	0.00%
331524	Aluminum Foundries (except Die-Casting)	371	371	$1,726	$3,103,121,814	$146,565,891	0.00%	0.00%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	252	252	$1,100	$2,738,832,777	$129,359,880	0.00%	0.00%
339	**Miscellaneous Manufacturing**	**26,491**	**26,491**	**$351,917**	**$157,410,019,449**	**$9,456,508,594**	**0.00%**	**0.00%**
339112	Surgical and Medical Instrument Manufacturing	1,063	1,063	$22,996	$41,727,828,702	$3,059,643,748	0.00%	0.00%
339113	Surgical Appliance and Supplies Manufacturing	1,651	1,651	$28,962	$36,136,301,720	$2,649,651,637	0.00%	0.00%
339114	Dental Equipment and Supplies Manufacturing	557	557	$7,362	$5,122,480,302	$375,599,817	0.00%	0.00%
339115	Ophthalmic Goods Manufacturing	336	336	$7,119	$6,175,778,513	$452,831,664	0.00%	0.00%
339116	Dental Laboratories	5,637	5,637	$65,129	$5,024,370,977	$368,406,067	0.00%	0.02%
339910	Jewelry and Silverware Manufacturing	1,967	1,967	$23,417	$7,504,994,935	$302,745,487	0.00%	0.01%
339920	Sporting and Athletic Goods Manufacturing	1,586	1,586	$22,231	$10,658,798,838	$429,967,412	0.00%	0.01%

Table VII-21: Screening Analysis for Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2019 Dollars)

NAICS Code	Industry	Total Firms	Affected Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
339930	Doll, Toy, and Game Manufacturing	503	503	$6,247	$1,720,555,223	$69,405,820	0.00%	0.01%
339940	Office Supplies (except Paper) Manufacturing	423	423	$6,196	$3,320,217,162	$133,934,902	0.00%	0.00%
339950	Sign Manufacturing	5,602	5,602	$72,420	$13,212,923,236	$532,998,745	0.00%	0.01%
339991	Gasket, Packing, and Sealing Device Manufacturing	490	490	$9,819	$7,540,016,634	$304,158,235	0.00%	0.00%
339992	Musical Instrument Manufacturing	585	585	$7,822	$2,040,059,050	$82,294,349	0.00%	0.01%
339993	Fastener, Button, Needle, and Pin Manufacturing	103	103	$1,567	$932,759,282	$37,626,763	0.00%	0.00%
339994	Broom, Brush, and Mop Manufacturing	168	168	$3,266	$2,968,149,189	$119,732,762	0.00%	0.00%
339995	Burial Casket Manufacturing	82	82	$1,397	$595,589,836	$24,025,617	0.00%	0.01%
339999	All Other Miscellaneous Manufacturing	5,738	5,738	$65,966	$12,729,195,852	$513,485,570	0.00%	0.01%
42	**Wholesale Trade**	**266,333**	**49,806**	**-$18,236,861**	**$8,241,112,357,137**	**$187,764,000,889**	**0.00%**	**-0.01%**
423	**Merchant Wholesalers, Durable Goods**	**168,238**	**13,697**	**$59,554**	**$3,730,586,842,837**	**$78,224,194,326**	**0.00%**	**0.00%**
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	7,886	7,886	$32,883	$227,956,291,687	$5,659,037,892	0.00%	0.00%
423840	Industrial Supplies Merchant Wholesalers	5,811	5,811	$26,671	$76,784,521,382	$2,369,037,938	0.00%	0.00%
424	**Merchant Wholesalers, Nondurable Goods**	**98,095**	**36,109**	**-$18,296,415**	**$4,510,525,514,300**	**$109,539,806,563**	**0.00%**	**-0.02%**
424210	Drugs and Druggists' Sundries Merchant Wholesalers	6,958	6,958	$35,832	$993,553,873,870	$34,478,605,779	0.00%	0.00%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	2,218	2,218	$8,475	$47,943,855,645	$1,464,284,802	0.00%	0.00%
424690	Other Chemical and Allied Products Merchant Wholesalers	6,069	6,069	$28,715	$190,251,901,023	$5,810,608,336	0.00%	0.00%
424710	Petroleum Bulk Stations and Terminals	2,334	2,334	$13,649	$553,795,115,137	$5,343,134,660	0.00%	0.00%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,857	1,857	$7,426	$589,029,156,042	$5,683,080,283	0.00%	0.00%
424910	Farm Supplies Merchant Wholesalers	4,965	4,965	-$14,885,049	$143,037,724,037	$3,880,616,514	-0.01%	-0.38%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	1,012	1,012	-$3,533,287	$18,239,107,674	$423,672,981	-0.02%	-0.83%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,696	10,696	$27,823	$45,182,648,502	$1,049,539,689	0.00%	0.00%
Total								
Total	**Total**	**6,077,430**	**115,758**	**-$26,753,711**	**$42,567,021,362,731**	**$5,795,377,657,021**	**0.00%**	**0.00%**

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

Note: "Affected" firms, establishments, employees, labels, and SDSs are based on the maximum number affected by any one provision of the rule.

Table VII-22: Screening Analysis for Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	Total Firms	Affected Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
21	**Mining, Quarrying, and Oil and Gas Extraction**	**15,437**	**5,200**	**$311,577**	**$326,848,327,601**	**$21,110,919,773**	**0.00%**	**0.00%**
211	**Oil and Gas Extraction**	**5,200**	**5,200**	**$311,577**	**$240,298,917,934**	**$14,974,398,582**	**0.00%**	**0.00%**
211120	Crude Petroleum Extraction	4,570	4,570	$198,373	$170,279,184,328	$10,611,068,906	0.00%	0.00%
211130	Natural Gas Extraction	630	630	$113,204	$70,019,733,607	$4,363,329,676	0.00%	0.00%
31-33	**Manufacturing**	**258,563**	**60,752**	**$3,861,188**	**$5,797,450,564,984**	**$264,415,656,740**	**0.00%**	**0.00%**
324	**Petroleum and Coal Products Manufacturing**	**984**	**984**	**$1,528,936**	**$548,268,340,205**	**$37,365,772,412**	**0.00%**	**0.00%**
324110	Petroleum Refineries	70	70	$98,464	$502,164,011,213	$34,203,490,777	0.00%	0.00%
324121	Asphalt Paving Mixture and Block Manufacturing	472	472	$171,774	$13,860,504,187	$955,963,177	0.00%	0.02%
324122	Asphalt Shingle and Coating Materials Manufacturing	123	123	$26,220	$11,617,097,706	$801,234,752	0.00%	0.00%
324191	Petroleum Lubricating Oil and Grease Manufacturing	253	253	$1,221,994	$16,586,696,926	$1,129,878,602	0.01%	0.11%
324199	All Other Petroleum and Coal Products Manufacturing	66	66	$10,485	$4,040,030,172	$275,205,103	0.00%	0.00%
325	**Chemical Manufacturing**	**10,389**	**10,389**	**$1,826,865**	**$789,429,171,514**	**$65,825,402,786**	**0.00%**	**0.00%**
325110	Petrochemical Manufacturing	28	28	$20,123	$55,741,502,666	$1,902,021,496	0.00%	0.00%
325120	Industrial Gas Manufacturing	63	63	$25,318	$9,700,639,626	$331,006,956	0.00%	0.01%
325130	Synthetic Dye and Pigment Manufacturing	112	112	$9,298	$7,293,474,420	$248,869,235	0.00%	0.00%
325180	Other Basic Inorganic Chemical Manufacturing	363	363	$18,428	$33,275,419,838	$1,135,429,811	0.00%	0.00%
325193	Ethyl Alcohol Manufacturing	121	121	$11,923	$32,337,672,494	$1,103,431,829	0.00%	0.00%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Mfg.	53	53	$4,908	$8,105,063,187	$276,562,412	0.00%	0.00%
325199	All Other Basic Organic Chemical Manufacturing	591	591	$56,753	$80,041,612,356	$2,731,194,173	0.00%	0.00%
325211	Plastics Material and Resin Manufacturing	852	852	$154,986	$94,876,413,479	$5,636,119,712	0.00%	0.00%
325212	Synthetic Rubber Manufacturing	140	140	$4,809	$8,750,057,350	$519,795,900	0.00%	0.00%
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	109	109	$2,251	$7,325,632,100	$435,178,122	0.00%	0.00%
325311	Nitrogenous Fertilizer Manufacturing	163	163	$2,598	$6,178,183,955	$600,201,186	0.00%	0.00%
325312	Phosphatic Fertilizer Manufacturing	45	45	$892	$5,725,430,291	$556,216,855	0.00%	0.00%
325314	Fertilizer (Mixing Only) Manufacturing	359	359	$13,403	$4,931,889,637	$479,125,586	0.00%	0.00%
325320	Pesticide and Other Agricultural Chemical Manufacturing	188	188	$39,388	$15,622,076,997	$1,517,661,048	0.00%	0.00%
325411	Medicinal and Botanical Manufacturing	451	451	$21,987	$11,504,963,235	$1,595,818,501	0.00%	0.00%
325412	Pharmaceutical Preparation Manufacturing	1,007	1,007	$158,657	$186,027,072,841	$25,803,250,170	0.00%	0.00%
325413	In-Vitro Diagnostic Substance Manufacturing	192	192	$37,649	$14,420,723,180	$2,000,254,706	0.00%	0.00%
325414	Biological Product (except Diagnostic) Manufacturing	266	266	$11,183	$31,996,374,817	$4,438,119,954	0.00%	0.00%
325510	Paint and Coating Manufacturing	998	998	$457,768	$28,755,602,915	$1,199,560,340	0.00%	0.04%
325520	Adhesive Manufacturing	403	403	$183,339	$15,404,571,015	$642,612,589	0.00%	0.03%
325611	Soap and Other Detergent Manufacturing	618	618	$125,189	$25,419,002,064	$3,137,684,958	0.00%	0.00%

Table VII-22: Screening Analysis for Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	Total Firms	Affected Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
325612	Polish and Other Sanitation Good Manufacturing	419	419	$78,300	$6,433,601,711	$794,154,517	0.00%	0.01%
325613	Surface Active Agent Manufacturing	105	105	$32,437	$7,488,008,843	$924,309,013	0.00%	0.00%
325620	Toilet Preparation Manufacturing	926	926	$158,612	$43,279,075,380	$5,342,306,652	0.00%	0.00%
325910	Printing Ink Manufacturing	182	182	$53,333	$4,534,098,456	$229,935,022	0.00%	0.02%
325920	Explosives Manufacturing	52	52	$15,752	$2,483,129,453	$125,925,458	0.00%	0.01%
325991	Custom Compounding of Purchased Resins	330	330	$11,925	$11,882,633,328	$602,596,873	0.00%	0.00%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	189	189	$6,218	$7,036,771,608	$356,851,588	0.00%	0.00%
325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	1,064	1,064	$109,437	$22,858,474,270	$1,159,208,126	0.00%	0.01%
326	**Plastics and Rubber Products Manufacturing**	**9,694**	**9,694**	**$68,513**	**$247,748,726,309**	**$5,974,209,486**	**0.00%**	**0.00%**
326111	Plastics Bag and Pouch Manufacturing	271	271	$2,191	$11,673,118,042	$299,485,288	0.00%	0.00%
326112	Plastics Packaging Film and Sheet (including Laminated) Mfg.	299	299	$2,711	$13,981,710,136	$358,714,481	0.00%	0.00%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Mfg.	429	429	$3,054	$16,764,409,928	$430,107,373	0.00%	0.00%
326121	Unlaminated Plastics Profile Shape Mfg.	326	326	$2,048	$8,405,469,386	$215,650,558	0.00%	0.00%
326122	Plastics Pipe and Pipe Fitting Mfg.	266	266	$2,800	$11,149,151,610	$286,042,415	0.00%	0.00%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Mfg.	208	208	$1,121	$4,558,892,856	$116,962,866	0.00%	0.00%
326140	Polystyrene Foam Product Manufacturing	308	308	$2,606	$10,048,849,303	$257,813,081	0.00%	0.00%
326150	Urethane and Other Foam Product (except Polystyrene) Mfg.	445	445	$3,669	$11,390,162,766	$292,225,793	0.00%	0.00%
326160	Plastics Bottle Manufacturing	195	195	$3,165	$11,711,421,690	$300,468,006	0.00%	0.00%
326191	Plastics Plumbing Fixture Manufacturing	311	311	$1,724	$4,393,033,016	$112,707,569	0.00%	0.00%
326199	All Other Plastics Product Manufacturing	5,187	5,187	$33,348	$99,843,663,537	$2,561,587,076	0.00%	0.00%
326211	Tire Manufacturing (except Retreading)	81	81	$1,288	$18,217,353,429	$308,595,467	0.00%	0.00%
326212	Tire Retreading	261	261	$1,390	$1,750,825,443	$29,658,358	0.00%	0.00%
326220	Rubber and Plastics Hoses and Belting Manufacturing	196	196	$1,553	$5,525,287,685	$93,596,402	0.00%	0.00%
326291	Rubber Product Manufacturing for Mechanical Use	346	346	$2,509	$7,932,574,831	$134,374,987	0.00%	0.00%
326299	All Other Rubber Product Manufacturing	565	565	$3,339	$10,402,802,651	$176,219,765	0.00%	0.00%
327	**Nonmetallic Mineral Product Manufacturing**	**9,636**	**9,636**	**$59,127**	**$131,885,843,897**	**$2,461,308,698**	**0.00%**	**0.00%**
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	566	566	$1,963	$2,319,233,154	$36,481,726	0.00%	0.01%
327120	Clay Building Material and Refractories Manufacturing	375	375	$2,740	$5,881,207,701	$92,511,875	0.00%	0.00%
327211	Flat Glass Manufacturing	74	74	$597	$4,388,366,999	$124,247,799	0.00%	0.00%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	387	387	$1,534	$3,522,384,800	$99,729,252	0.00%	0.00%
327213	Glass Container Manufacturing	29	29	$442	$5,272,106,533	$149,269,109	0.00%	0.00%
327215	Glass Product Manufacturing Made of Purchased Glass	983	983	$4,844	$13,900,601,495	$393,567,616	0.00%	0.00%
327310	Cement Manufacturing	101	101	$1,094	$9,050,480,224	$133,073,152	0.00%	0.00%
327320	Ready-Mix Concrete Manufacturing	2,098	2,098	$19,738	$32,398,760,101	$476,373,077	0.00%	0.00%
327331	Concrete Block and Brick Manufacturing	430	430	$3,058	$4,879,471,211	$71,744,990	0.00%	0.00%

Table VII-22: Screening Analysis for Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	Total Firms	Affected Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
327332	Concrete Pipe Manufacturing	98	98	$1,195	$1,708,315,398	$25,118,105	0.00%	0.00%
327390	Other Concrete Product Manufacturing	1,560	1,560	$8,244	$12,334,383,335	$181,357,809	0.00%	0.00%
327410	Lime Manufacturing	38	38	$479	$2,355,559,712	$44,069,981	0.00%	0.00%
327420	Gypsum Product Manufacturing	127	127	$987	$6,468,574,425	$121,020,050	0.00%	0.00%
327910	Abrasive Product Manufacturing	256	256	$1,317	$5,886,203,059	$110,124,510	0.00%	0.00%
327991	Cut Stone and Stone Product Manufacturing	1,907	1,907	$6,594	$5,236,293,789	$97,965,408	0.00%	0.01%
327992	Ground or Treated Mineral and Earth Manufacturing	154	154	$1,098	$4,456,620,907	$83,378,570	0.00%	0.00%
327993	Mineral Wool Manufacturing	174	174	$1,369	$6,445,499,687	$120,588,346	0.00%	0.00%
327999	All Other Miscellaneous Nonmetallic Mineral Product Mfg.	279	279	$1,833	$5,381,781,367	$100,687,324	0.00%	0.00%
331	**Primary Metal Manufacturing**	**3,558**	**3,558**	**$25,831**	**$232,471,614,560**	**$5,007,068,940**	**0.00%**	**0.00%**
331110	Iron and Steel Mills and Ferroalloy Manufacturing	369	369	$4,107	$93,922,044,820	$1,165,821,393	0.00%	0.00%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	180	180	$1,693	$11,067,013,255	$230,377,817	0.00%	0.00%
331221	Rolled Steel Shape Manufacturing	170	170	$1,034	$5,992,331,220	$124,740,086	0.00%	0.00%
331222	Steel Wire Drawing	210	210	$1,418	$5,581,251,741	$116,182,800	0.00%	0.00%
331313	Alumina Refining and Primary Aluminum Production	31	31	$213	$3,537,971,191	$87,352,773	0.00%	0.00%
331314	Secondary Smelting and Alloying of Aluminum	65	65	$572	$6,039,040,368	$149,104,358	0.00%	0.00%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	62	62	$861	$15,749,488,321	$381,314,941	0.00%	0.00%
331318	Other Aluminum Rolling, Drawing, and Extruding	212	212	$1,718	$11,879,785,984	$293,312,803	0.00%	0.00%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	129	129	$650	$9,746,852,678	$202,896,535	0.00%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	164	164	$1,689	$23,335,378,243	$485,763,717	0.00%	0.00%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	227	227	$1,299	$6,982,835,711	$145,359,042	0.00%	0.00%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal	183	183	$1,065	$7,574,445,310	$157,674,355	0.00%	0.00%
331511	Iron Foundries	298	298	$2,275	$9,786,154,772	$462,217,269	0.00%	0.00%
331512	Steel Investment Foundries	95	95	$898	$4,091,022,841	$193,226,191	0.00%	0.00%
331513	Steel Foundries (except Investment)	189	189	$1,049	$3,451,310,647	$163,011,461	0.00%	0.00%
331523	Nonferrous Metal Die-Casting Foundries	351	351	$2,463	$7,892,732,868	$372,787,629	0.00%	0.00%
331524	Aluminum Foundries (except Die-Casting)	371	371	$1,726	$3,103,121,814	$146,565,891	0.00%	0.00%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	252	252	$1,100	$2,738,832,777	$129,359,880	0.00%	0.00%
339	**Miscellaneous Manufacturing**	**26,491**	**26,491**	**$351,917**	**$157,410,019,449**	**$9,456,508,594**	**0.00%**	**0.00%**
339112	Surgical and Medical Instrument Manufacturing	1,063	1,063	$22,996	$41,727,828,702	$3,059,643,748	0.00%	0.00%
339113	Surgical Appliance and Supplies Manufacturing	1,651	1,651	$28,962	$36,136,301,720	$2,649,651,637	0.00%	0.00%
339114	Dental Equipment and Supplies Manufacturing	557	557	$7,362	$5,122,480,302	$375,599,817	0.00%	0.00%
339115	Ophthalmic Goods Manufacturing	336	336	$7,119	$6,175,778,513	$452,831,664	0.00%	0.00%
339116	Dental Laboratories	5,637	5,637	$65,129	$5,024,370,977	$368,406,067	0.00%	0.02%
339910	Jewelry and Silverware Manufacturing	1,967	1,967	$23,417	$7,504,994,935	$302,745,487	0.00%	0.01%

Table VII-22: Screening Analysis for Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	Total Firms	Affected Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
339920	Sporting and Athletic Goods Manufacturing	1,586	1,586	$22,231	$10,658,798,838	$429,967,412	0.00%	0.01%
339930	Doll, Toy, and Game Manufacturing	503	503	$6,247	$1,720,555,223	$69,405,820	0.00%	0.01%
339940	Office Supplies (except Paper) Manufacturing	423	423	$6,196	$3,320,217,162	$133,934,902	0.00%	0.00%
339950	Sign Manufacturing	5,602	5,602	$72,420	$13,212,923,236	$532,998,745	0.00%	0.01%
339991	Gasket, Packing, and Sealing Device Manufacturing	490	490	$9,819	$7,540,016,634	$304,158,235	0.00%	0.00%
339992	Musical Instrument Manufacturing	585	585	$7,822	$2,040,059,050	$82,294,349	0.00%	0.01%
339993	Fastener, Button, Needle, and Pin Manufacturing	103	103	$1,567	$932,759,282	$37,626,763	0.00%	0.00%
339994	Broom, Brush, and Mop Manufacturing	168	168	$3,266	$2,968,149,189	$119,732,762	0.00%	0.00%
339995	Burial Casket Manufacturing	82	82	$1,397	$595,589,836	$24,025,617	0.00%	0.01%
339999	All Other Miscellaneous Manufacturing	5,738	5,738	$65,966	$12,729,195,852	$513,485,570	0.00%	0.01%
42	**Wholesale Trade**	**266,333**	**49,806**	**$213,209**	**$8,241,112,357,137**	**$187,764,000,889**	**0.00%**	**0.00%**
423	**Merchant Wholesalers, Durable Goods**	**168,238**	**13,697**	**$59,554**	**$3,730,586,842,837**	**$78,224,194,326**	**0.00%**	**0.00%**
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	7,886	7,886	$32,883	$227,956,291,687	$5,659,037,892	0.00%	0.00%
423840	Industrial Supplies Merchant Wholesalers	5,811	5,811	$26,671	$76,784,521,382	$2,369,037,938	0.00%	0.00%
424	**Merchant Wholesalers, Nondurable Goods**	**98,095**	**36,109**	**$153,654**	**$4,510,525,514,300**	**$109,539,806,563**	**0.00%**	**0.00%**
424210	Drugs and Druggists' Sundries Merchant Wholesalers	6,958	6,958	$35,832	$993,553,873,870	$34,478,605,779	0.00%	0.00%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	2,218	2,218	$8,475	$47,943,855,645	$1,464,284,802	0.00%	0.00%
424690	Other Chemical and Allied Products Merchant Wholesalers	6,069	6,069	$28,715	$190,251,901,023	$5,810,608,336	0.00%	0.00%
424710	Petroleum Bulk Stations and Terminals	2,334	2,334	$13,649	$553,795,115,137	$5,343,134,660	0.00%	0.00%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,857	1,857	$7,426	$589,029,156,042	$5,683,080,283	0.00%	0.00%
424910	Farm Supplies Merchant Wholesalers	4,965	4,965	$26,634	$143,037,724,037	$3,880,616,514	0.00%	0.00%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	1,012	1,012	$5,100	$18,239,107,674	$423,672,981	0.00%	0.00%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,696	10,696	$27,823	$45,182,648,502	$1,049,539,689	0.00%	0.00%
Total								
Total	**Total**	**6,077,430**	**115,758**	**$4,385,974**	**$42,567,021,362,731**	**$5,795,377,657,021**	**0.00%**	**0.00%**

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health.

Note: “"Affected” firms, establishments, employees, labels, and SDSs are based on the maximum number affected by any one provision of the rule.

In the case of costs that may be incurred due to the requirements of the proposed revisions to the HCS, all businesses within each of the covered industry sectors would be subject to the same requirements. Thus, to the extent

potential price increases correspond to costs associated with achieving compliance with the revised standard, the elasticity of demand for each entity will approach that faced by the industry as a whole.

Furthermore, if OSHA adopts the proposed revisions to the HCS, hazardous chemicals distributed in the United States will have to be in compliance with the updated provisions, and chemical producers and users in most advanced economies will be operating under comparable requirements based on the GHS specific to their own country or economic union. For this reason, affected domestic establishments should not be susceptible to a loss of domestic market share resulting from the competition of foreign commercial entities not bound by the requirements of the HCS or similar GHS requirements.

Given the small increases in prices potentially resulting from compliance with the proposed revisions to the HCS in any particular industry, and the lack of readily available substitutes for the products and services provided by the covered industry sectors, demand is expected to be sufficiently inelastic in each affected industry to enable entities to substantially offset compliance costs through minor price increases without experiencing any significant reduction in revenues or profits. For example, for NAICS 324191: Petroleum Lubricating Oil and Grease Manufacturing, even if zero cost savings are obtained and gross positive costs reach OSHA's estimated total ($1,221,994; see Table VII–22), revenue impacts (0.0074 percent, rounded to 0.01 percent) and profit impacts (0.108 percent, rounded to 0.11 percent) fall well below OSHA's screening criteria associated with economic feasibility concerns. OSHA therefore preliminarily concludes that the proposed rule, if implemented, would be economically feasible. The agency invites comments on this preliminary conclusion.

H. Preliminary Regulatory Flexibility Act Certification

To determine whether the proposed revisions to the HCS will have a significant economic impact on a substantial number of small entities, OSHA evaluated the impact of compliance costs on the revenues and profits of small entities in affected industries. As discussed previously, the proposed rule would impose costs on impacted industries for training; for reclassification of aerosols, desensitized explosives, and flammable gases; and for becoming familiar with the proposed changes to the standard. The proposed rule would also result in cost savings to the extent it would limit employers' duties with respect to the labeling of some very small containers and provide more flexible relabeling requirements for packaged chemicals released for shipment.

OSHA believes that the estimated costs are one-time costs that would be incurred during the first-year transition period after the rule is promulgated. In addition, as mentioned above, there will be annual cost savings due to the flexibilities introduced in the proposed provision related to the labeling of very small containers and in the proposed released-for-shipment provision.

Tables VII–23 and VII–24 present OSHA's screening analysis of the impact of compliance costs and cost savings on revenues and profits of small and very small entities. Tables VII–25 and VII–26 present OSHA's screening analysis of impacts on revenues and profits for small and very small entities under the scenario that zero-cost savings are realized, *i.e.,* only positive costs are incurred by affected employers. OSHA's screening criteria for determining whether there are significant economic impacts on small firms assesses whether, for small entities in any given industry, the annualized costs exceed one percent of revenues or five percent of profits.[57]

The total annualized cost savings resulting from the proposed revisions to the HCS for small entities and very small entities are estimated to be approximately $17.1 million and $1.7 million, respectively (see Tables VII–23 and VII–24). To assess the potential economic impact of the proposed rule on small entities and very small entities, OSHA calculated the ratios of compliance costs to profits and to revenues. These ratios are presented for each affected industry in Tables VII–23 (small entities) and VII–24 (very small entities). Those tables show that in no industries do the annualized costs of the proposed revisions to the standard exceed one percent of annual revenues or five percent of annual profits, either for small entities or for very small entities. Similarly, under a cost scenario exclusive of cost savings (shown in Tables VII–25 and VII–26), in no industries do the annualized costs of the proposed rule exceed one percent of annual revenues or five percent of annual profits. Because no adverse revenue and profit impacts are expected to result from this proposed revision to the HCS, OSHA preliminarily certifies that the proposed changes to the standard will not have a significant economic impact on a substantial number of small entities. The agency invites comments on this preliminary certification.

[57] OSHA's screening criteria underlying the determination of significant economic impacts were developed in accordance with published guidelines for implementation of the Small Business Regulatory Enforcement Fairness Act amendment to the Regulatory Flexibility Act; Executive Orders 12866, 13563, and 13771; and the Unfunded Mandates Reform Act. For a recent example of the application of these screening criteria, see the Final Economic Analysis and Final Regulatory Flexibility Analysis for the Final Rule for Occupational Exposure to Respirable Crystalline Silica, Chapter VI: Economic Feasibility Analysis and Regulatory Flexibility Determination, Document ID 0045.

Table VII-23: Screening Analysis for SBA-Defined Small Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2019 Dollars)

NAICS Code	Industry	Total Small Firms	Affected Small Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
21	**Mining, Quarrying, and Oil and Gas Extraction**	**13,480**	**5,111**	**$254,229**	**$126,641,777,686**	**$8,118,387,317**	**0.00%**	**0.00%**
211	**Oil and Gas Extraction**	**5,111**	**5,111**	**$254,229**	**$100,248,982,771**	**$6,247,086,913**	**0.00%**	**0.00%**
211120	Crude Petroleum Extraction	4,519	4,519	$180,109	$74,442,621,084	$4,638,945,066	0.00%	0.00%
211130	Natural Gas Extraction	592	592	$74,120	$25,806,361,687	$1,608,141,848	0.00%	0.00%
31-33	**Manufacturing**	**160,080**	**35,641**	**-$307,017**	**$1,019,372,711,131**	**$46,934,620,433**	**0.00%**	**0.00%**
324	**Petroleum and Coal Products Manufacturing**	**488**	**488**	**$80,914**	**$36,291,381,929**	**$2,477,359,321**	**0.00%**	**0.00%**
324110	Petroleum Refineries	8	8	$6,300	$27,122,075,639	$1,847,343,982	0.00%	0.00%
324121	Asphalt Paving Mixture and Block Manufacturing	422	422	$35,347	$6,354,692,152	$438,285,045	0.00%	0.01%
324191	Petroleum Lubricating Oil and Grease Manufacturing	4	4	$34,585	$1,246,859,746	$84,935,545	0.00%	0.04%
324199	All Other Petroleum and Coal Products Manufacturing	54	54	$4,683	$1,567,754,391	$106,794,749	0.00%	0.00%
325	**Chemical Manufacturing**	**5,729**	**5,729**	**-$669,340**	**$133,195,382,934**	**$11,287,569,408**	**0.00%**	**-0.01%**
325110	Petrochemical Manufacturing	3	3	$1,893	$0	$0	0.00%	0.00%
325130	Synthetic Dye and Pigment Manufacturing	5	5	$446	$908,334,950	$30,994,367	0.00%	0.00%
325180	Other Basic Inorganic Chemical Manufacturing	24	24	-$18,861	$2,244,838,764	$76,598,789	0.00%	-0.02%
325193	Ethyl Alcohol Manufacturing	3	3	$227	$315,684,675	$10,771,849	0.00%	0.00%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	37	37	$2,391	$1,276,990,010	$43,573,681	0.00%	0.01%
325199	All Other Basic Organic Chemical Manufacturing	515	515	-$161,844	$22,367,221,007	$763,218,305	0.00%	-0.02%
325211	Plastics Material and Resin Manufacturing	771	771	$121,371	$23,872,209,387	$1,418,125,169	0.00%	0.01%
325311	Nitrogenous Fertilizer Manufacturing	3	3	$77	$0	$0	0.00%	0.00%
325312	Phosphatic Fertilizer Manufacturing	5	5	-$24,914	$100,008,328	$9,715,657	-0.02%	-0.26%
325314	Fertilizer (Mixing Only) Manufacturing	340	340	-$866,594	$3,500,940,093	$340,111,012	-0.02%	-0.25%
325411	Medicinal and Botanical Manufacturing	8	8	-$6,015	$715,521,577	$99,247,824	0.00%	-0.01%
325412	Pharmaceutical Preparation Manufacturing	930	930	$90,292	$30,020,579,790	$4,164,063,428	0.00%	0.00%
325413	In-Vitro Diagnostic Substance Manufacturing	167	167	$26,614	$2,572,663,655	$356,846,361	0.00%	0.01%
325414	Biological Product (except Diagnostic) Manufacturing	221	221	$3,818	$5,863,984,063	$813,375,416	0.00%	0.00%
325510	Paint and Coating Manufacturing	17	17	-$107,820	$2,152,126,723	$89,777,490	-0.01%	-0.12%
325520	Adhesive Manufacturing	350	350	$58,659	$5,069,280,212	$211,468,614	0.00%	0.03%
325612	Polish and Other Sanitation Good Manufacturing	4	4	$714	$121,727,113	$15,025,819	0.00%	0.00%
325620	Toilet Preparation Manufacturing	896	896	$142,177	$16,735,776,539	$2,065,840,121	0.00%	0.01%
325910	Printing Ink Manufacturing	161	161	$16,517	$1,401,449,523	$71,070,871	0.00%	0.02%
325991	Custom Compounding of Purchased Resins	292	292	$5,705	$4,898,316,623	$248,405,400	0.00%	0.00%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	3	3	$274	$0	$0	0.00%	0.00%
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	974	974	$45,534	$9,057,729,902	$459,339,236	0.00%	0.01%
326	**Plastics and Rubber Products Manufacturing**	**1,543**	**1,543**	**$9,864**	**$29,139,202,553**	**$684,076,077**	**0.00%**	**0.00%**
326111	Plastics Bag and Pouch Manufacturing	5	5	$58	$784,503,219	$20,127,199	0.00%	0.00%

Table VII-23: Screening Analysis for SBA-Defined Small Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2019 Dollars)

NAICS Code	Industry	Total Small Firms	Affected Small Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	8	8	$103	$1,208,634,905	$31,008,713	0.00%	0.00%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	11	11	$127	$1,576,497,917	$40,446,600	0.00%	0.00%
326121	Unlaminated Plastics Profile Shape Manufacturing	286	286	$1,694	$2,702,661,509	$69,339,431	0.00%	0.00%
326122	Plastics Pipe and Pipe Fitting Manufacturing	3	3	$75	$225,529,681	$5,786,185	0.00%	0.00%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	177	177	$920	$1,742,170,853	$44,697,101	0.00%	0.00%
326140	Polystyrene Foam Product Manufacturing	8	8	$155	$1,052,864,685	$27,012,276	0.00%	0.00%
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	11	11	$112	$857,095,712	$21,989,631	0.00%	0.00%
326160	Plastics Bottle Manufacturing	183	183	$1,657	$3,432,455,453	$88,063,010	0.00%	0.00%
326191	Plastics Plumbing Fixture Manufacturing	5	5	$70	$550,566,149	$14,125,314	0.00%	0.00%
326199	All Other Plastics Product Manufacturing	73	73	$764	$7,718,903,091	$198,036,027	0.00%	0.00%
326211	Tire Manufacturing (except Retreading)	3	3	$45	$1,062,901,057	$18,005,165	0.00%	0.00%
326212	Tire Retreading	245	245	$1,054	$878,258,502	$14,877,386	0.00%	0.01%
326220	Rubber and Plastics Hoses and Belting Manufacturing	7	7	$68	$469,067,062	$7,945,829	0.00%	0.00%
326291	Rubber Product Manufacturing for Mechanical Use	7	7	$73	$666,269,920	$11,286,375	0.00%	0.00%
326299	All Other Rubber Product Manufacturing	511	511	$2,889	$4,210,822,837	$71,329,836	0.00%	0.00%
327	**Nonmetallic Mineral Product Manufacturing**	**6,636**	**6,636**	**$31,859**	**$39,957,576,507**	**$648,610,549**	**0.00%**	**0.00%**
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	4	4	$20	$277,050,335	$4,358,024	0.00%	0.00%
327120	Clay Building Material and Refractories Manufacturing	7	7	$155	$706,797,682	$11,117,985	0.00%	0.00%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	372	372	$1,418	$1,168,942,607	$33,096,262	0.00%	0.00%
327213	Glass Container Manufacturing	21	21	$160	$333,956,284	$9,455,302	0.00%	0.00%
327215	Glass Product Manufacturing Made of Purchased Glass	7	7	$65	$686,676,277	$19,441,860	0.00%	0.00%
327310	Cement Manufacturing	4	4	$41	$527,929,122	$7,762,372	0.00%	0.00%
327320	Ready-Mix Concrete Manufacturing	2,038	2,038	$11,993	$17,735,436,381	$260,771,844	0.00%	0.00%
327331	Concrete Block and Brick Manufacturing	401	401	$2,291	$2,979,630,278	$43,810,801	0.00%	0.01%
327332	Concrete Pipe Manufacturing	3	3	$80	$157,861,666	$2,321,109	0.00%	0.00%
327390	Other Concrete Product Manufacturing	1,511	1,511	$7,194	$7,821,743,134	$115,006,495	0.00%	0.01%
327410	Lime Manufacturing	3	3	$66	$0	$0	0.00%	0.00%
327991	Cut Stone and Stone Product Manufacturing	1,886	1,886	$6,442	$4,360,344,846	$81,577,349	0.00%	0.01%
327992	Ground or Treated Mineral and Earth Manufacturing	125	125	$689	$1,326,716,138	$24,821,428	0.00%	0.00%
327993	Mineral Wool Manufacturing	4	4	$31	$246,343,878	$4,608,828	0.00%	0.00%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	250	250	$1,214	$1,628,147,880	$30,460,891	0.00%	0.00%
331	**Primary Metal Manufacturing**	**1,219**	**1,219**	**$6,983**	**$30,289,721,564**	**$751,879,539**	**0.00%**	**0.00%**
331110	Iron and Steel Mills and Ferroalloy Manufacturing	26	26	$425	$12,141,766,502	$150,711,488	0.00%	0.00%

Table VII-23: Screening Analysis for SBA-Defined Small Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2019 Dollars)

NAICS Code	Industry	Total Small Firms	Affected Small Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	11	11	$197	$1,426,594,136	$29,696,869	0.00%	0.00%
331221	Rolled Steel Shape Manufacturing	7	7	$35	$524,401,481	$10,916,267	0.00%	0.00%
331222	Steel Wire Drawing	9	9	$141	$1,092,743,284	$22,747,222	0.00%	0.00%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	49	49	$526	$1,812,679,081	$43,887,243	0.00%	0.00%
331318	Other Aluminum Rolling, Drawing, and Extruding	8	8	$87	$1,042,425,463	$25,737,563	0.00%	0.00%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	5	5	$40	$1,513,416,451	$31,504,216	0.00%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	7	7	$75	$2,483,469,095	$51,697,434	0.00%	0.00%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	3	3	$15	$181,179,708	$3,771,549	0.00%	0.00%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	3	3	$15	$0	$0	0.00%	0.00%
331511	Iron Foundries	3	3	$20	$86,096,560	$4,066,492	0.00%	0.00%
331512	Steel Investment Foundries	6	6	$71	$832,718,001	$39,330,733	0.00%	0.00%
331513	Steel Foundries (except Investment)	172	172	$933	$1,520,040,544	$71,794,183	0.00%	0.00%
331523	Nonferrous Metal Die-Casting Foundries	315	315	$1,733	$2,531,019,436	$119,544,491	0.00%	0.00%
331524	Aluminum Foundries (except Die-Casting)	359	359	$1,632	$1,831,306,669	$86,495,829	0.00%	0.00%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	236	236	$1,039	$1,269,865,153	$59,977,960	0.00%	0.00%
339	**Miscellaneous Manufacturing**	**20,026**	**20,026**	**$232,702**	**$39,530,013,204**	**$1,919,889,733**	**0.00%**	**0.01%**
339112	Surgical and Medical Instrument Manufacturing	26	26	$969	$4,254,912,087	$311,986,403	0.00%	0.00%
339113	Surgical Appliance and Supplies Manufacturing	10	10	$202	$977,823,332	$71,697,741	0.00%	0.00%
339114	Dental Equipment and Supplies Manufacturing	5	5	$127	$679,750,171	$49,841,878	0.00%	0.00%
339115	Ophthalmic Goods Manufacturing	4	4	$231	$197,531,165	$14,483,739	0.00%	0.00%
339116	Dental Laboratories	5,623	5,623	$57,004	$3,751,568,850	$275,079,354	0.00%	0.02%
339910	Jewelry and Silverware Manufacturing	1,954	1,954	$22,552	$3,925,308,912	$158,343,819	0.00%	0.01%
339920	Sporting and Athletic Goods Manufacturing	9	9	$283	$1,235,218,821	$49,827,738	0.00%	0.00%
339930	Doll, Toy, and Game Manufacturing	498	498	$6,090	$1,298,334,418	$52,373,771	0.00%	0.01%
339940	Office Supplies (except Paper) Manufacturing	6	6	$97	$460,233,465	$18,565,450	0.00%	0.00%
339950	Sign Manufacturing	5,571	5,571	$70,576	$10,768,055,741	$434,374,748	0.00%	0.02%
339991	Gasket, Packing, and Sealing Device Manufacturing	450	450	$6,975	$2,504,878,488	$101,044,793	0.00%	0.01%
339992	Musical Instrument Manufacturing	3	3	$129	$465,435,364	$18,775,290	0.00%	0.00%
339994	Broom, Brush, and Mop Manufacturing	153	153	$2,424	$1,160,531,125	$46,814,896	0.00%	0.01%
339999	All Other Miscellaneous Manufacturing	5,714	5,714	$65,044	$7,850,431,266	$316,680,112	0.00%	0.02%
42	**Wholesale Trade**	**255,199**	**47,541**	**-$17,547,454**	**$2,029,694,592,065**	**$46,557,861,792**	**0.00%**	**-0.04%**
423	**Merchant Wholesalers, Durable Goods**	**161,160**	**13,098**	**$41,544**	**$1,038,998,940,330**	**$22,996,072,728**	**0.00%**	**0.00%**
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	7,652	7,652	$24,512	$34,060,394,933	$845,552,734	0.00%	0.00%
423840	Industrial Supplies Merchant Wholesalers	5,446	5,446	$17,032	$26,894,452,293	$829,776,323	0.00%	0.00%

Table VII-23: Screening Analysis for SBA-Defined Small Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2019 Dollars)

NAICS Code	Industry	Total Small Firms	Affected Small Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
424	**Merchant Wholesalers, Nondurable Goods**	**94,039**	**34,443**	**-$17,588,998**	**$990,695,651,735**	**$23,561,789,065**	**0.00%**	**-0.07%**
424210	Drugs and Druggists' Sundries Merchant Wholesalers	6,663	6,663	$22,759	$75,561,309,955	$2,622,151,336	0.00%	0.00%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	2,090	2,090	$6,639	$19,151,107,910	$584,906,572	0.00%	0.00%
424690	Other Chemical and Allied Products Merchant Wholesalers	5,760	5,760	$18,937	$49,029,260,628	$1,497,434,869	0.00%	0.00%
424710	Petroleum Bulk Stations and Terminals	2,086	2,086	$8,705	$116,687,155,895	$1,125,822,836	0.00%	0.00%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,691	1,691	$5,361	$110,304,296,920	$1,064,239,637	0.00%	0.00%
424910	Farm Supplies Merchant Wholesalers	4,777	4,777	-$14,331,031	$46,711,531,722	$1,267,284,855	-0.03%	-1.13%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	958	958	-$3,346,555	$4,622,011,771	$107,363,888	-0.07%	-3.12%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,418	10,418	$26,187	$27,846,311,288	$646,837,002	0.00%	0.00%
Total								
Total	**Total**	**5,820,799**	**88,293**	**-$17,600,242**	**$11,528,927,098,095**	**$1,258,949,490,569**	**0.00%**	**0.00%**

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0049).

Note: "Affected" firms, establishments, employees, labels, and SDSs are based on the maximum number affected by any one provision of the rule.

Table VII-24: Screening Analysis for Very Small Entities (with Fewer than 20 Employees) Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2019 Dollars)

NAICS Code	Industry	<20 Firms	Affected <20 Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
21	**Mining, Quarrying, and Oil and Gas Extraction**	**13,018**	**4,573**	**$172,384**	**$17,191,968,980**	**$1,130,270,113**	**0.00%**	**0.02%**
211	**Oil and Gas Extraction**	**4,573**	**4,573**	**$172,384**	**$10,327,453,313**	**$643,562,624**	**0.00%**	**0.03%**
211120	Crude Petroleum Extraction	4,112	**4,112**	$135,467	$8,159,920,407	$508,491,264	0.00%	0.03%
211130	Natural Gas Extraction	461	**461**	$36,918	$2,167,532,907	$135,071,360	0.00%	0.03%
31-33	**Manufacturing**	**185,713**	**42,571**	**$72,088**	**$201,349,874,448**	**$8,599,149,973**	**0.00%**	**0.00%**
324	**Petroleum and Coal Products Manufacturing**	**482**	**482**	**$176,576**	**$2,264,038,256**	**$155,524,865**	**0.01%**	**0.11%**
324110	Petroleum Refineries	11	**11**	$1,595	$102,309,469	$6,968,522	0.00%	0.02%
324121	Asphalt Paving Mixture and Block Manufacturing	233	**233**	$14,604	$1,224,335,797	$84,442,811	0.00%	0.02%
324122	Asphalt Shingle and Coating Materials Manufacturing	67	**67**	$4,111	$304,121,711	$20,975,367	0.00%	0.02%
324191	Petroleum Lubricating Oil and Grease Manufacturing	134	**134**	$153,934	$515,936,132	$35,145,346	0.03%	0.44%
324199	All Other Petroleum and Coal Products Manufacturing	37	**37**	$2,332	$117,335,147	$7,992,819	0.00%	0.03%
325	**Chemical Manufacturing**	**6,028**	**6,028**	**-$356,211**	**$15,398,580,338**	**$1,259,377,873**	**0.00%**	**-0.03%**
325110	Petrochemical Manufacturing	7	**7**	$1,018	$54,148,510	$1,847,665	0.00%	0.06%
325120	Industrial Gas Manufacturing	39	**39**	$1,611	$113,739,490	$3,881,039	0.00%	0.04%
325130	Synthetic Dye and Pigment Manufacturing	58	**58**	$2,895	$153,296,928	$5,230,825	0.00%	0.06%
325180	Other Basic Inorganic Chemical Manufacturing	146	**146**	-$1,285	$579,118,600	$19,760,788	0.00%	-0.01%
325193	Ethyl Alcohol Manufacturing	18	**18**	$622	$237,677,096	$8,110,060	0.00%	0.01%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	20	**20**	$884	$80,989,829	$2,763,549	0.00%	0.03%
325199	All Other Basic Organic Chemical Manufacturing	260	**260**	$1,434	$1,118,327,492	$38,159,770	0.00%	0.00%
325211	Plastics Material and Resin Manufacturing	349	**349**	$11,428	$1,160,497,774	$68,939,204	0.00%	0.02%
325212	Synthetic Rubber Manufacturing	64	**64**	$997	$185,348,301	$11,010,589	0.00%	0.01%
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	40	**40**	$394	$109,443,461	$6,501,473	0.00%	0.01%
325311	Nitrogenous Fertilizer Manufacturing	101	**101**	-$83,984	$339,914,652	$33,022,192	-0.02%	-0.25%
325312	Phosphatic Fertilizer Manufacturing	11	**11**	-$15,489	$62,388,297	$6,060,928	-0.02%	-0.26%
325314	Fertilizer (Mixing Only) Manufacturing	235	**235**	-$142,627	$585,272,906	$56,858,374	-0.02%	-0.25%
325320	Pesticide and Other Agricultural Chemical Manufacturing	116	**116**	$12,461	$375,076,009	$36,438,064	0.00%	0.03%
325411	Medicinal and Botanical Manufacturing	271	**271**	$4,712	$460,867,342	$63,925,509	0.00%	0.01%
325412	Pharmaceutical Preparation Manufacturing	579	**579**	$45,249	$1,865,009,961	$258,689,866	0.00%	0.02%
325413	In-Vitro Diagnostic Substance Manufacturing	91	**91**	$5,599	$151,862,834	$21,064,432	0.00%	0.03%
325414	Biological Product (except Diagnostic) Manufacturing	136	**136**	$2,520	$532,418,832	$73,850,199	0.00%	0.00%
325510	Paint and Coating Manufacturing	683	**683**	-$334,171	$1,556,606,813	$64,934,956	-0.02%	-0.51%
325520	Adhesive Manufacturing	214	**214**	$17,172	$652,936,917	$27,237,726	0.00%	0.06%
325611	Soap and Other Detergent Manufacturing	454	**454**	$36,344	$649,681,023	$80,195,689	0.01%	0.05%
325612	Polish and Other Sanitation Good Manufacturing	291	**291**	$11,998	$424,493,885	$52,398,913	0.00%	0.02%
325613	Surface Active Agent Manufacturing	59	**59**	$4,725	$153,105,159	$18,899,080	0.00%	0.02%

Table VII-24: Screening Analysis for Very Small Entities (with Fewer than 20 Employees) Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2019 Dollars)

NAICS Code	Industry	<20 Firms	Affected <20 Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
325620	Toilet Preparation Manufacturing	623	**623**	$25,667	$1,472,297,515	$181,738,282	0.00%	0.01%
325910	Printing Ink Manufacturing	111	**111**	$3,635	$268,942,637	$13,638,727	0.00%	0.03%
325920	Explosives Manufacturing	19	**19**	$790	$39,569,945	$2,006,687	0.00%	0.04%
325991	Custom Compounding of Purchased Resins	179	**179**	$2,788	$558,480,571	$28,321,891	0.00%	0.01%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	143	**143**	$3,088	$165,749,365	$8,405,548	0.00%	0.04%
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	711	**711**	$23,315	$1,291,318,197	$65,485,847	0.00%	0.04%
326	**Plastics and Rubber Products Manufacturing**	**5,073**	**5,073**	**$10,484**	**$8,440,100,253**	**$206,019,667**	**0.00%**	**0.01%**
326111	Plastics Bag and Pouch Manufacturing	112	**112**	$235	$289,529,597	$7,428,166	0.00%	0.00%
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	101	**101**	$211	$253,189,490	$6,495,825	0.00%	0.00%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	215	**215**	$444	$389,897,411	$10,003,200	0.00%	0.00%
326121	Unlaminated Plastics Profile Shape Manufacturing	148	**148**	$306	$212,873,316	$5,461,474	0.00%	0.01%
326122	Plastics Pipe and Pipe Fitting Manufacturing	115	**115**	$237	$319,401,690	$8,194,563	0.00%	0.00%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	113	**113**	$233	$175,678,590	$4,507,206	0.00%	0.01%
326140	Polystyrene Foam Product Manufacturing	145	**145**	$299	$369,023,841	$9,467,668	0.00%	0.00%
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	208	**208**	$429	$463,923,130	$11,902,403	0.00%	0.00%
326160	Plastics Bottle Manufacturing	66	**66**	$136	$153,118,708	$3,928,411	0.00%	0.00%
326191	Plastics Plumbing Fixture Manufacturing	182	**182**	$376	$246,216,000	$6,316,913	0.00%	0.01%
326199	All Other Plastics Product Manufacturing	2,904	**2,904**	$6,000	$4,360,390,703	$111,870,098	0.00%	0.01%
326211	Tire Manufacturing (except Retreading)	38	**38**	$78	$42,665,336	$722,736	0.00%	0.01%
326212	Tire Retreading	156	**156**	$322	$226,970,376	$3,844,797	0.00%	0.01%
326220	Rubber and Plastics Hoses and Belting Manufacturing	104	**104**	$215	$195,530,785	$3,312,222	0.00%	0.01%
326291	Rubber Product Manufacturing for Mechanical Use	162	**162**	$334	$280,991,735	$4,759,900	0.00%	0.01%
326299	All Other Rubber Product Manufacturing	304	**304**	$628	$460,699,545	$7,804,086	0.00%	0.01%
327	**Nonmetallic Mineral Product Manufacturing**	**6,513**	**6,513**	**$13,604**	**$9,253,585,860**	**$160,254,290**	**0.00%**	**0.01%**
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	462	**462**	$954	$240,529,651	$3,783,551	0.00%	0.03%
327120	Clay Building Material and Refractories Manufacturing	199	**199**	$411	$392,927,143	$6,180,776	0.00%	0.01%
327211	Flat Glass Manufacturing	29	**29**	$60	$34,821,593	$985,903	0.00%	0.01%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	312	**312**	$646	$200,184,295	$5,667,816	0.00%	0.01%
327213	Glass Container Manufacturing	13	**13**	$27	$18,906,902	$535,311	0.00%	0.01%
327215	Glass Product Manufacturing Made of Purchased Glass	736	**736**	$1,522	$694,354,717	$19,659,259	0.00%	0.01%
327310	Cement Manufacturing	54	**54**	$116	$113,207,958	$1,664,546	0.00%	0.01%
327320	Ready-Mix Concrete Manufacturing	1,275	**1,275**	$2,736	$3,102,958,186	$45,624,145	0.00%	0.01%
327331	Concrete Block and Brick Manufacturing	241	**241**	$506	$448,924,550	$6,600,733	0.00%	0.01%
327332	Concrete Pipe Manufacturing	47	**47**	$97	$84,751,199	$1,246,134	0.00%	0.01%

Table VII-24: Screening Analysis for Very Small Entities (with Fewer than 20 Employees) Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2019 Dollars)

NAICS Code	Industry	<20 Firms	Affected <20 Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
327390	Other Concrete Product Manufacturing	1,018	**1,018**	$2,110	$1,265,924,521	$18,613,439	0.00%	0.01%
327410	Lime Manufacturing	17	**17**	$37	$38,643,412	$722,977	0.00%	0.01%
327420	Gypsum Product Manufacturing	98	**98**	$202	$168,446,629	$3,151,455	0.00%	0.01%
327910	Abrasive Product Manufacturing	159	**159**	$328	$307,171,245	$5,746,843	0.00%	0.01%
327991	Cut Stone and Stone Product Manufacturing	1,506	**1,506**	$3,130	$1,479,155,319	$27,673,400	0.00%	0.01%
327992	Ground or Treated Mineral and Earth Manufacturing	70	**70**	$147	$158,566,389	$2,966,606	0.00%	0.00%
327993	Mineral Wool Manufacturing	99	**99**	$204	$162,470,543	$3,039,649	0.00%	0.01%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	178	**178**	$372	$341,641,610	$6,391,746	0.00%	0.01%
331	**Primary Metal Manufacturing**	**1,802**	**1,802**	**$3,729**	**$3,862,267,143**	**$106,827,885**	**0.00%**	**0.00%**
331110	Iron and Steel Mills and Ferroalloy Manufacturing	197	**197**	$407	$556,014,680	$6,901,615	0.00%	0.01%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	50	**50**	$103	$74,174,756	$1,544,068	0.00%	0.01%
331221	Rolled Steel Shape Manufacturing	85	**85**	$175	$222,220,982	$4,625,890	0.00%	0.00%
331222	Steel Wire Drawing	113	**113**	$233	$175,334,657	$3,649,875	0.00%	0.01%
331313	Alumina Refining and Primary Aluminum Production	12	**12**	$25	$9,684,303	$239,106	0.00%	0.01%
331314	Secondary Smelting and Alloying of Aluminum	19	**19**	$39	$85,089,920	$2,100,876	0.00%	0.00%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	31	**31**	$64	$138,958,073	$3,364,350	0.00%	0.00%
331318	Other Aluminum Rolling, Drawing, and Extruding	98	**98**	$202	$179,057,465	$4,420,942	0.00%	0.00%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	76	**76**	$159	$334,535,758	$6,963,904	0.00%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	63	**63**	$130	$273,053,150	$5,684,044	0.00%	0.00%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	141	**141**	$293	$272,540,378	$5,673,370	0.00%	0.01%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	98	**98**	$206	$422,211,424	$8,789,015	0.00%	0.00%
331511	Iron Foundries	138	**138**	$285	$235,041,323	$11,101,414	0.00%	0.00%
331512	Steel Investment Foundries	26	**26**	$54	$59,008,379	$2,787,069	0.00%	0.00%
331513	Steel Foundries (except Investment)	89	**89**	$184	$158,529,911	$7,487,646	0.00%	0.00%
331523	Nonferrous Metal Die-Casting Foundries	180	**180**	$372	$264,021,276	$12,470,188	0.00%	0.00%
331524	Aluminum Foundries (except Die-Casting)	227	**227**	$469	$218,051,062	$10,298,934	0.00%	0.00%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	159	**159**	$328	$184,739,645	$8,725,578	0.00%	0.00%
339	**Miscellaneous Manufacturing**	**22,673**	**22,673**	**$223,907**	**$14,517,096,167**	**$741,894,194**	**0.00%**	**0.03%**
339112	Surgical and Medical Instrument Manufacturing	651	**651**	$6,414	$919,970,207	$67,455,729	0.00%	0.01%
339113	Surgical Appliance and Supplies Manufacturing	1,179	**1,179**	$11,823	$1,493,451,442	$109,505,563	0.00%	0.01%
339114	Dental Equipment and Supplies Manufacturing	468	**468**	$4,621	$281,217,897	$20,619,970	0.00%	0.02%
339115	Ophthalmic Goods Manufacturing	257	**257**	$2,532	$238,750,582	$17,506,104	0.00%	0.01%
339116	Dental Laboratories	5,294	**5,294**	$52,228	$1,804,762,383	$132,332,070	0.00%	0.04%
339910	Jewelry and Silverware Manufacturing	1,763	**1,763**	$17,390	$1,177,940,358	$47,517,171	0.00%	0.04%

Table VII-24: Screening Analysis for Very Small Entities (with Fewer than 20 Employees) Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2019 Dollars)

NAICS Code	Industry	<20 Firms	Affected <20 Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
339920	Sporting and Athletic Goods Manufacturing	1,289	**1,289**	$12,739	$970,497,005	$39,149,072	0.00%	0.03%
339930	Doll, Toy, and Game Manufacturing	434	**434**	$4,276	$357,636,551	$14,426,772	0.00%	0.03%
339940	Office Supplies (except Paper) Manufacturing	328	**328**	$3,281	$259,199,969	$10,455,919	0.00%	0.03%
339950	Sign Manufacturing	4,774	**4,774**	$47,134	$2,909,036,588	$117,348,207	0.00%	0.04%
339991	Gasket, Packing, and Sealing Device Manufacturing	293	**293**	$2,897	$439,494,549	$17,728,858	0.00%	0.02%
339992	Musical Instrument Manufacturing	504	**504**	$4,966	$255,684,563	$10,314,111	0.00%	0.05%
339993	Fastener, Button, Needle, and Pin Manufacturing	76	**76**	$749	$52,427,806	$2,114,896	0.00%	0.04%
339994	Broom, Brush, and Mop Manufacturing	96	**96**	$946	$122,499,344	$4,941,525	0.00%	0.02%
339995	Burial Casket Manufacturing	59	**59**	$591	$34,718,413	$1,400,513	0.00%	0.04%
339999	All Other Miscellaneous Manufacturing	5,208	**5,208**	$51,321	$3,199,808,510	$129,077,714	0.00%	0.04%
42	**Wholesale Trade**	**218,009**	**41,030**	**-$1,917,813**	**$662,069,497,910**	**$15,930,366,430**	**0.00%**	**-0.01%**
423	**Merchant Wholesalers, Durable Goods**	**137,679**	**11,469**	**$23,999**	**$358,307,048,518**	**$8,191,349,278**	**0.00%**	**0.00%**
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	6,893	**6,893**	$14,318	$12,491,750,129	$310,108,955	0.00%	0.00%
423840	Industrial Supplies Merchant Wholesalers	4,576	**4,576**	$9,681	$12,377,652,116	$381,888,523	0.00%	0.00%
424	**Merchant Wholesalers, Nondurable Goods**	**80,330**	**29,561**	**-$1,941,812**	**$303,762,449,392**	**$7,739,017,152**	**0.00%**	**-0.03%**
424210	Drugs and Druggists' Sundries Merchant Wholesalers	5,661	**5,661**	$11,785	$19,231,035,837	$667,361,198	0.00%	0.00%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	1,782	**1,782**	$3,787	$8,687,864,991	$265,341,794	0.00%	0.00%
424690	Other Chemical and Allied Products Merchant Wholesalers	4,967	**4,967**	$10,486	$20,817,877,435	$635,812,476	0.00%	0.00%
424710	Petroleum Bulk Stations and Terminals	1,334	**1,334**	$2,886	$19,778,343,816	$190,825,725	0.00%	0.00%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,301	**1,301**	$2,715	$21,107,021,411	$203,645,093	0.00%	0.00%
424910	Farm Supplies Merchant Wholesalers	3,985	**3,985**	-$1,640,179	$15,813,831,821	$429,029,596	-0.01%	-0.38%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	803	**803**	-$353,481	$1,831,250,389	$42,537,789	-0.02%	-0.83%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	9,728	**9,728**	$20,188	$15,541,966,801	$361,021,577	0.00%	0.01%
Total								
Total	**Total**	**5,305,646**	**88,174**	**-$1,673,340**	**$4,339,862,178,615**	**$165,526,269,969**	**0.00%**	**0.00%**

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0049).

Note: "Affected" firms, establishments, employees, labels, and SDSs are based on the maximum number affected by any one provision of the rule.

Table VII-25: Screening Analysis for SBA-Defined Small Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	Total Small Firms	Affected Small Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
21	**Mining, Quarrying, and Oil and Gas Extraction**	**13,480**	**5,111**	**$254,229**	**$126,641,777,686**	**$8,118,387,317**	**0.00%**	**0.00%**
211	**Oil and Gas Extraction**	**5,111**	**5,111**	**$254,229**	**$100,248,982,771**	**$6,247,086,913**	**0.00%**	**0.00%**
211120	Crude Petroleum Extraction	4,519	**4,519**	$180,109	$74,442,621,084	$4,638,945,066	0.00%	0.00%
211130	Natural Gas Extraction	592	**592**	$74,120	$25,806,361,687	$1,608,141,848	0.00%	0.00%
31-33	**Manufacturing**	**160,080**	**35,641**	**$971,639**	**$1,019,372,711,131**	**$46,934,620,433**	**0.00%**	**0.00%**
324	**Petroleum and Coal Products Manufacturing**	**488**	**488**	**$80,914**	**$36,291,381,929**	**$2,477,359,321**	**0.00%**	**0.00%**
324110	Petroleum Refineries	8	**8**	$6,300	$27,122,075,639	$1,847,343,982	0.00%	0.00%
324121	Asphalt Paving Mixture and Block Manufacturing	422	**422**	$35,347	$6,354,692,152	$438,285,045	0.00%	0.01%
324191	Petroleum Lubricating Oil and Grease Manufacturing	4	**4**	$34,585	$1,246,859,746	$84,935,545	0.00%	0.04%
324199	All Other Petroleum and Coal Products Manufacturing	54	**54**	$4,683	$1,567,754,391	$106,794,749	0.00%	0.00%
325	**Chemical Manufacturing**	**5,729**	**5,729**	**$609,316**	**$133,195,382,934**	**$11,287,569,408**	**0.00%**	**0.01%**
325110	Petrochemical Manufacturing	3	**3**	$1,893	$0	$0	0.00%	0.00%
325130	Synthetic Dye and Pigment Manufacturing	5	**5**	$446	$908,334,950	$30,994,367	0.00%	0.00%
325180	Other Basic Inorganic Chemical Manufacturing	24	**24**	$1,413	$2,244,838,764	$76,598,789	0.00%	0.00%
325193	Ethyl Alcohol Manufacturing	3	**3**	$227	$315,684,675	$10,771,849	0.00%	0.00%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	37	**37**	$2,391	$1,276,990,010	$43,573,681	0.00%	0.01%
325199	All Other Basic Organic Chemical Manufacturing	515	**515**	$40,159	$22,367,221,007	$763,218,305	0.00%	0.01%
325211	Plastics Material and Resin Manufacturing	771	**771**	$121,371	$23,872,209,387	$1,418,125,169	0.00%	0.01%
325311	Nitrogenous Fertilizer Manufacturing	3	**3**	$77	$0	$0	0.00%	0.00%
325312	Phosphatic Fertilizer Manufacturing	5	**5**	$88	$100,008,328	$9,715,657	0.00%	0.00%
325314	Fertilizer (Mixing Only) Manufacturing	340	**340**	$8,641	$3,500,940,093	$340,111,012	0.00%	0.00%
325411	Medicinal and Botanical Manufacturing	8	**8**	$447	$715,521,577	$99,247,824	0.00%	0.00%
325412	Pharmaceutical Preparation Manufacturing	930	**930**	$111,543	$30,020,579,790	$4,164,063,428	0.00%	0.00%
325413	In-Vitro Diagnostic Substance Manufacturing	167	**167**	$28,435	$2,572,663,655	$356,846,361	0.00%	0.01%
325414	Biological Product (except Diagnostic) Manufacturing	221	**221**	$7,969	$5,863,984,063	$813,375,416	0.00%	0.00%
325510	Paint and Coating Manufacturing	17	**17**	$14,636	$2,152,126,723	$89,777,490	0.00%	0.02%
325520	Adhesive Manufacturing	350	**350**	$58,659	$5,069,280,212	$211,468,614	0.00%	0.03%
325612	Polish and Other Sanitation Good Manufacturing	4	**4**	$714	$121,727,113	$15,025,819	0.00%	0.00%
325620	Toilet Preparation Manufacturing	896	**896**	$142,177	$16,735,776,539	$2,065,840,121	0.00%	0.01%
325910	Printing Ink Manufacturing	161	**161**	$16,517	$1,401,449,523	$71,070,871	0.00%	0.02%
325991	Custom Compounding of Purchased Resins	292	**292**	$5,705	$4,898,316,623	$248,405,400	0.00%	0.00%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	3	**3**	$274	$0	$0	0.00%	0.00%
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	974	**974**	$45,534	$9,057,729,902	$459,339,236	0.00%	0.01%
326	**Plastics and Rubber Products Manufacturing**	**1,543**	**1,543**	**$9,864**	**$29,139,202,553**	**$684,076,077**	**0.00%**	**0.00%**

Table VII-25: Screening Analysis for SBA-Defined Small Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	Total Small Firms	Affected Small Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
326111	Plastics Bag and Pouch Mfg.	5	**5**	$58	$784,503,219	$20,127,199	0.00%	0.00%
326112	Plastics Packaging Film and Sheet (including Laminated) Mfg.	8	**8**	$103	$1,208,634,905	$31,008,713	0.00%	0.00%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Mfg.	11	**11**	$127	$1,576,497,917	$40,446,600	0.00%	0.00%
326121	Unlaminated Plastics Profile Shape Mfg.	286	**286**	$1,694	$2,702,661,509	$69,339,431	0.00%	0.00%
326122	Plastics Pipe and Pipe Fitting Mfg.	3	**3**	$75	$225,529,681	$5,786,185	0.00%	0.00%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Mfg.	177	**177**	$920	$1,742,170,853	$44,697,101	0.00%	0.00%
326140	Polystyrene Foam Product Mfg.	8	**8**	$155	$1,052,864,685	$27,012,276	0.00%	0.00%
326150	Urethane and Other Foam Product (except Polystyrene) Mfg.	11	**11**	$112	$857,095,712	$21,989,631	0.00%	0.00%
326160	Plastics Bottle Mfg.	183	**183**	$1,657	$3,432,455,453	$88,063,010	0.00%	0.00%
326191	Plastics Plumbing Fixture Mfg.	5	**5**	$70	$550,566,149	$14,125,314	0.00%	0.00%
326199	All Other Plastics Product Mfg.	73	**73**	$764	$7,718,903,091	$198,036,027	0.00%	0.00%
326211	Tire Mfg. (except Retreading)	3	**3**	$45	$1,062,901,057	$18,005,165	0.00%	0.00%
326212	Tire Retreading	245	**245**	$1,054	$878,258,502	$14,877,386	0.00%	0.01%
326220	Rubber and Plastics Hoses and Belting Mfg.	7	**7**	$68	$469,067,062	$7,945,829	0.00%	0.00%
326291	Rubber Product Mfg. for Mechanical Use	7	**7**	$73	$666,269,920	$11,286,375	0.00%	0.00%
326299	All Other Rubber Product Mfg.	511	**511**	$2,889	$4,210,822,837	$71,329,836	0.00%	0.00%
327	**Nonmetallic Mineral Product Manufacturing**	**6,636**	**6,636**	**$31,859**	**$39,957,576,507**	**$648,610,549**	**0.00%**	**0.00%**
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	4	**4**	$20	$277,050,335	$4,358,024	0.00%	0.00%
327120	Clay Building Material and Refractories Manufacturing	7	**7**	$155	$706,797,682	$11,117,985	0.00%	0.00%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	372	**372**	$1,418	$1,168,942,607	$33,096,262	0.00%	0.00%
327213	Glass Container Manufacturing	21	**21**	$160	$333,956,284	$9,455,302	0.00%	0.00%
327215	Glass Product Manufacturing Made of Purchased Glass	7	**7**	$65	$686,676,277	$19,441,860	0.00%	0.00%
327310	Cement Manufacturing	4	**4**	$41	$527,929,122	$7,762,372	0.00%	0.00%
327320	Ready-Mix Concrete Manufacturing	2,038	**2,038**	$11,993	$17,735,436,381	$260,771,844	0.00%	0.00%
327331	Concrete Block and Brick Manufacturing	401	**401**	$2,291	$2,979,630,278	$43,810,801	0.00%	0.01%
327332	Concrete Pipe Manufacturing	3	**3**	$80	$157,861,666	$2,321,109	0.00%	0.00%
327390	Other Concrete Product Manufacturing	1,511	**1,511**	$7,194	$7,821,743,134	$115,006,495	0.00%	0.01%
327410	Lime Manufacturing	3	**3**	$66	$0	$0	0.00%	0.00%
327991	Cut Stone and Stone Product Manufacturing	1,886	**1,886**	$6,442	$4,360,344,846	$81,577,349	0.00%	0.01%
327992	Ground or Treated Mineral and Earth Manufacturing	125	**125**	$689	$1,326,716,138	$24,821,428	0.00%	0.00%
327993	Mineral Wool Manufacturing	4	**4**	$31	$246,343,878	$4,608,828	0.00%	0.00%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	250	**250**	$1,214	$1,628,147,880	$30,460,891	0.00%	0.00%
331	**Primary Metal Manufacturing**	**1,219**	**1,219**	**$6,983**	**$30,289,721,564**	**$751,879,539**	**0.00%**	**0.00%**
331110	Iron and Steel Mills and Ferroalloy Manufacturing	26	**26**	$425	$12,141,766,502	$150,711,488	0.00%	0.00%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	11	**11**	$197	$1,426,594,136	$29,696,869	0.00%	0.00%

Table VII-25: Screening Analysis for SBA-Defined Small Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	Total Small Firms	Affected Small Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
331221	Rolled Steel Shape Manufacturing	7	**7**	$35	$524,401,481	$10,916,267	0.00%	0.00%
331222	Steel Wire Drawing	9	**9**	$141	$1,092,743,284	$22,747,222	0.00%	0.00%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	49	**49**	$526	$1,812,679,081	$43,887,243	0.00%	0.00%
331318	Other Aluminum Rolling, Drawing, and Extruding	8	**8**	$87	$1,042,425,463	$25,737,563	0.00%	0.00%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	5	**5**	$40	$1,513,416,451	$31,504,216	0.00%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	7	**7**	$75	$2,483,469,095	$51,697,434	0.00%	0.00%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	3	**3**	$15	$181,179,708	$3,771,549	0.00%	0.00%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	3	**3**	$15	$0	$0	0.00%	0.00%
331511	Iron Foundries	3	**3**	$20	$86,096,560	$4,066,492	0.00%	0.00%
331512	Steel Investment Foundries	6	**6**	$71	$832,718,001	$39,330,733	0.00%	0.00%
331513	Steel Foundries (except Investment)	172	**172**	$933	$1,520,040,544	$71,794,183	0.00%	0.00%
331523	Nonferrous Metal Die-Casting Foundries	315	**315**	$1,733	$2,531,019,436	$119,544,491	0.00%	0.00%
331524	Aluminum Foundries (except Die-Casting)	359	**359**	$1,632	$1,831,306,669	$86,495,829	0.00%	0.00%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	236	**236**	$1,039	$1,269,865,153	$59,977,960	0.00%	0.00%
339	**Miscellaneous Manufacturing**	**20,026**	**20,026**	**$232,702**	**$39,530,013,204**	**$1,919,889,733**	**0.00%**	**0.01%**
339112	Surgical and Medical Instrument Manufacturing	26	**26**	$969	$4,254,912,087	$311,986,403	0.00%	0.00%
339113	Surgical Appliance and Supplies Manufacturing	10	**10**	$202	$977,823,332	$71,697,741	0.00%	0.00%
339114	Dental Equipment and Supplies Manufacturing	5	**5**	$127	$679,750,171	$49,841,878	0.00%	0.00%
339115	Ophthalmic Goods Manufacturing	4	**4**	$231	$197,531,165	$14,483,739	0.00%	0.00%
339116	Dental Laboratories	5,623	**5,623**	$57,004	$3,751,568,850	$275,079,354	0.00%	0.02%
339910	Jewelry and Silverware Manufacturing	1,954	**1,954**	$22,552	$3,925,308,912	$158,343,819	0.00%	0.01%
339920	Sporting and Athletic Goods Manufacturing	9	**9**	$283	$1,235,218,821	$49,827,738	0.00%	0.00%
339930	Doll, Toy, and Game Manufacturing	498	**498**	$6,090	$1,298,334,418	$52,373,771	0.00%	0.01%
339940	Office Supplies (except Paper) Manufacturing	6	**6**	$97	$460,233,465	$18,565,450	0.00%	0.00%
339950	Sign Manufacturing	5,571	**5,571**	$70,576	$10,768,055,741	$434,374,748	0.00%	0.02%
339991	Gasket, Packing, and Sealing Device Manufacturing	450	**450**	$6,975	$2,504,878,488	$101,044,793	0.00%	0.01%
339992	Musical Instrument Manufacturing	3	**3**	$129	$465,435,364	$18,775,290	0.00%	0.00%
339994	Broom, Brush, and Mop Manufacturing	153	**153**	$2,424	$1,160,531,125	$46,814,896	0.00%	0.01%
339999	All Other Miscellaneous Manufacturing	5,714	**5,714**	$65,044	$7,850,431,266	$316,680,112	0.00%	0.02%
42	**Wholesale Trade**	**255,199**	**47,541**	**$149,176**	**$2,029,694,592,065**	**$46,557,861,792**	**0.00%**	**0.00%**
423	**Merchant Wholesalers, Durable Goods**	**161,160**	**13,098**	**$41,544**	**$1,038,998,940,330**	**$22,996,072,728**	**0.00%**	**0.00%**
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	7,652	**7,652**	$24,512	$34,060,394,933	$845,552,734	0.00%	0.00%
423840	Industrial Supplies Merchant Wholesalers	5,446	**5,446**	$17,032	$26,894,452,293	$829,776,323	0.00%	0.00%

Table VII-25: Screening Analysis for SBA-Defined Small Entities Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	Total Small Firms	Affected Small Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
424	**Merchant Wholesalers, Nondurable Goods**	**94,039**	**34,443**	**$107,633**	**$990,695,651,735**	**$23,561,789,065**	**0.00%**	**0.00%**
424210	Drugs and Druggists' Sundries Merchant Wholesalers	6,663	**6,663**	$22,759	$75,561,309,955	$2,622,151,336	0.00%	0.00%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	2,090	**2,090**	$6,639	$19,151,107,910	$584,906,572	0.00%	0.00%
424690	Other Chemical and Allied Products Merchant Wholesalers	5,760	**5,760**	$18,937	$49,029,260,628	$1,497,434,869	0.00%	0.00%
424710	Petroleum Bulk Stations and Terminals	2,086	**2,086**	$8,705	$116,687,155,895	$1,125,822,836	0.00%	0.00%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,691	**1,691**	$5,361	$110,304,296,920	$1,064,239,637	0.00%	0.00%
424910	Farm Supplies Merchant Wholesalers	4,777	**4,777**	$16,020	$46,711,531,722	$1,267,284,855	0.00%	0.00%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	958	**958**	$3,025	$4,622,011,771	$107,363,888	0.00%	0.00%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,418	**10,418**	$26,187	$27,846,311,288	$646,837,002	0.00%	0.00%
Total								
Total	**Total**	**5,820,799**	**88,293**	**$1,375,044**	**$11,528,927,098,095**	**$1,258,949,490,569**	**0.00%**	**0.01%**

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0049).

Note: "Affected" firms, establishments, employees, labels, and SDSs are based on the maximum number affected by any one provision of the rule.

Table VII-26: Screening Analysis for Very Small Entities (with Fewer than 20 Employees) Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	<20 Firms	Affected <20 Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
21	**Mining, Quarrying, and Oil and Gas Extraction**	**13,018**	**4,573**	**$172,384**	**$17,191,968,980**	**$1,130,270,113**	**0.00%**	**0.02%**
211	**Oil and Gas Extraction**	**4,573**	**4,573**	**$172,384**	**$10,327,453,313**	**$643,562,624**	**0.00%**	**0.03%**
211120	Crude Petroleum Extraction	4,112	**4,112**	$135,467	$8,159,920,407	$508,491,264	0.00%	0.03%
211130	Natural Gas Extraction	461	**461**	$36,918	$2,167,532,907	$135,071,360	0.00%	0.03%
31-33	**Manufacturing**	**185,713**	**42,571**	**$729,431**	**$201,349,874,448**	**$8,599,149,973**	**0.00%**	**0.01%**
324	**Petroleum and Coal Products Manufacturing**	**482**	**482**	**$176,576**	**$2,264,038,256**	**$155,524,865**	**0.01%**	**0.11%**
324110	Petroleum Refineries	11	**11**	$1,595	$102,309,469	$6,968,522	0.00%	0.02%
324121	Asphalt Paving Mixture and Block Manufacturing	233	**233**	$14,604	$1,224,335,797	$84,442,811	0.00%	0.02%
324122	Asphalt Shingle and Coating Materials Manufacturing	67	**67**	$4,111	$304,121,711	$20,975,367	0.00%	0.02%
324191	Petroleum Lubricating Oil and Grease Manufacturing	134	**134**	$153,934	$515,936,132	$35,145,346	0.03%	0.44%
324199	All Other Petroleum and Coal Products Manufacturing	37	**37**	$2,332	$117,335,147	$7,992,819	0.00%	0.03%
325	**Chemical Manufacturing**	**6,028**	**6,028**	**$301,132**	**$15,398,580,338**	**$1,259,377,873**	**0.00%**	**0.02%**
325110	Petrochemical Manufacturing	7	**7**	$1,018	$54,148,510	$1,847,665	0.00%	0.06%
325120	Industrial Gas Manufacturing	39	**39**	$1,611	$113,739,490	$3,881,039	0.00%	0.04%
325130	Synthetic Dye and Pigment Manufacturing	58	**58**	$2,895	$153,296,928	$5,230,825	0.00%	0.06%
325180	Other Basic Inorganic Chemical Manufacturing	146	**146**	$3,945	$579,118,600	$19,760,788	0.00%	0.02%
325193	Ethyl Alcohol Manufacturing	18	**18**	$622	$237,677,096	$8,110,060	0.00%	0.01%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	20	**20**	$884	$80,989,829	$2,763,549	0.00%	0.03%
325199	All Other Basic Organic Chemical Manufacturing	260	**260**	$11,534	$1,118,327,492	$38,159,770	0.00%	0.03%
325211	Plastics Material and Resin Manufacturing	349	**349**	$11,428	$1,160,497,774	$68,939,204	0.00%	0.02%
325212	Synthetic Rubber Manufacturing	64	**64**	$997	$185,348,301	$11,010,589	0.00%	0.01%
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	40	**40**	$394	$109,443,461	$6,501,473	0.00%	0.01%
325311	Nitrogenous Fertilizer Manufacturing	101	**101**	$995	$339,914,652	$33,022,192	0.00%	0.00%
325312	Phosphatic Fertilizer Manufacturing	11	**11**	$108	$62,388,297	$6,060,928	0.00%	0.00%
325314	Fertilizer (Mixing Only) Manufacturing	235	**235**	$3,691	$585,272,906	$56,858,374	0.00%	0.01%
325320	Pesticide and Other Agricultural Chemical Manufacturing	116	**116**	$12,461	$375,076,009	$36,438,064	0.00%	0.03%
325411	Medicinal and Botanical Manufacturing	271	**271**	$8,874	$460,867,342	$63,925,509	0.00%	0.01%
325412	Pharmaceutical Preparation Manufacturing	579	**579**	$46,570	$1,865,009,961	$258,689,866	0.00%	0.02%
325413	In-Vitro Diagnostic Substance Manufacturing	91	**91**	$5,707	$151,862,834	$21,064,432	0.00%	0.03%
325414	Biological Product (except Diagnostic) Manufacturing	136	**136**	$2,897	$532,418,832	$73,850,199	0.00%	0.00%
325510	Paint and Coating Manufacturing	683	**683**	$54,980	$1,556,606,813	$64,934,956	0.00%	0.08%
325520	Adhesive Manufacturing	214	**214**	$17,172	$652,936,917	$27,237,726	0.00%	0.06%
325611	Soap and Other Detergent Manufacturing	454	**454**	$36,344	$649,681,023	$80,195,689	0.01%	0.05%

Table VII-26: Screening Analysis for Very Small Entities (with Fewer than 20 Employees) Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	<20 Firms	Affected <20 Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
325612	Polish and Other Sanitation Good Manufacturing	291	**291**	$11,998	$424,493,885	$52,398,913	0.00%	0.02%
325613	Surface Active Agent Manufacturing	59	**59**	$4,725	$153,105,159	$18,899,080	0.00%	0.02%
325620	Toilet Preparation Manufacturing	623	**623**	$25,667	$1,472,297,515	$181,738,282	0.00%	0.01%
325910	Printing Ink Manufacturing	111	**111**	$3,635	$268,942,637	$13,638,727	0.00%	0.03%
325920	Explosives Manufacturing	19	**19**	$790	$39,569,945	$2,006,687	0.00%	0.04%
325991	Custom Compounding of Purchased Resins	179	**179**	$2,788	$558,480,571	$28,321,891	0.00%	0.01%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	143	**143**	$3,088	$165,749,365	$8,405,548	0.00%	0.04%
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	711	**711**	$23,315	$1,291,318,197	$65,485,847	0.00%	0.04%
326	**Plastics and Rubber Products Manufacturing**	**5,073**	**5,073**	**$10,484**	**$8,440,100,253**	**$206,019,667**	**0.00%**	**0.01%**
326111	Plastics Bag and Pouch Manufacturing	112	**112**	$235	$289,529,597	$7,428,166	0.00%	0.00%
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	101	**101**	$211	$253,189,490	$6,495,825	0.00%	0.00%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	215	**215**	$444	$389,897,411	$10,003,200	0.00%	0.00%
326121	Unlaminated Plastics Profile Shape Manufacturing	148	**148**	$306	$212,873,316	$5,461,474	0.00%	0.01%
326122	Plastics Pipe and Pipe Fitting Manufacturing	115	**115**	$237	$319,401,690	$8,194,563	0.00%	0.00%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	113	**113**	$233	$175,678,590	$4,507,206	0.00%	0.01%
326140	Polystyrene Foam Product Manufacturing	145	**145**	$299	$369,023,841	$9,467,668	0.00%	0.00%
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	208	**208**	$429	$463,923,130	$11,902,403	0.00%	0.00%
326160	Plastics Bottle Manufacturing	66	**66**	$136	$153,118,708	$3,928,411	0.00%	0.00%
326191	Plastics Plumbing Fixture Manufacturing	182	**182**	$376	$246,216,000	$6,316,913	0.00%	0.01%
326199	All Other Plastics Product Manufacturing	2,904	**2,904**	$6,000	$4,360,390,703	$111,870,098	0.00%	0.01%
326211	Tire Manufacturing (except Retreading)	38	**38**	$78	$42,665,336	$722,736	0.00%	0.01%
326212	Tire Retreading	156	**156**	$322	$226,970,376	$3,844,797	0.00%	0.01%
326220	Rubber and Plastics Hoses and Belting Manufacturing	104	**104**	$215	$195,530,785	$3,312,222	0.00%	0.01%
326291	Rubber Product Manufacturing for Mechanical Use	162	**162**	$334	$280,991,735	$4,759,900	0.00%	0.01%
326299	All Other Rubber Product Manufacturing	304	**304**	$628	$460,699,545	$7,804,086	0.00%	0.01%
327	**Nonmetallic Mineral Product Manufacturing**	**6,513**	**6,513**	**$13,604**	**$9,253,585,860**	**$160,254,290**	**0.00%**	**0.01%**
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	462	**462**	$954	$240,529,651	$3,783,551	0.00%	0.03%
327120	Clay Building Material and Refractories Manufacturing	199	**199**	$411	$392,927,143	$6,180,776	0.00%	0.01%
327211	Flat Glass Manufacturing	29	**29**	$60	$34,821,593	$985,903	0.00%	0.01%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	312	**312**	$646	$200,184,295	$5,667,816	0.00%	0.01%

Table VII-26: Screening Analysis for Very Small Entities (with Fewer than 20 Employees) Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	<20 Firms	Affected <20 Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
327213	Glass Container Manufacturing	13	**13**	$27	$18,906,902	$535,311	0.00%	0.01%
327215	Glass Product Manufacturing Made of Purchased Glass	736	**736**	$1,522	$694,354,717	$19,659,259	0.00%	0.01%
327310	Cement Manufacturing	54	**54**	$116	$113,207,958	$1,664,546	0.00%	0.01%
327320	Ready-Mix Concrete Manufacturing	1,275	**1,275**	$2,736	$3,102,958,186	$45,624,145	0.00%	0.01%
327331	Concrete Block and Brick Manufacturing	241	**241**	$506	$448,924,550	$6,600,733	0.00%	0.01%
327332	Concrete Pipe Manufacturing	47	**47**	$97	$84,751,199	$1,246,134	0.00%	0.01%
327390	Other Concrete Product Manufacturing	1,018	**1,018**	$2,110	$1,265,924,521	$18,613,439	0.00%	0.01%
327410	Lime Manufacturing	17	**17**	$37	$38,643,412	$722,977	0.00%	0.01%
327420	Gypsum Product Manufacturing	98	**98**	$202	$168,446,629	$3,151,455	0.00%	0.01%
327910	Abrasive Product Manufacturing	159	**159**	$328	$307,171,245	$5,746,843	0.00%	0.01%
327991	Cut Stone and Stone Product Manufacturing	1,506	**1,506**	$3,130	$1,479,155,319	$27,673,400	0.00%	0.01%
327992	Ground or Treated Mineral and Earth Manufacturing	70	**70**	$147	$158,566,389	$2,966,606	0.00%	0.00%
327993	Mineral Wool Manufacturing	99	**99**	$204	$162,470,543	$3,039,649	0.00%	0.01%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	178	**178**	$372	$341,641,610	$6,391,746	0.00%	0.01%
331	**Primary Metal Manufacturing**	**1,802**	**1,802**	**$3,729**	**$3,862,267,143**	**$106,827,885**	**0.00%**	**0.00%**
331110	Iron and Steel Mills and Ferroalloy Manufacturing	197	**197**	$407	$556,014,680	$6,901,615	0.00%	0.01%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	50	**50**	$103	$74,174,756	$1,544,068	0.00%	0.01%
331221	Rolled Steel Shape Manufacturing	85	**85**	$175	$222,220,982	$4,625,890	0.00%	0.00%
331222	Steel Wire Drawing	113	**113**	$233	$175,334,657	$3,649,875	0.00%	0.01%
331313	Alumina Refining and Primary Aluminum Production	12	**12**	$25	$9,684,303	$239,106	0.00%	0.01%
331314	Secondary Smelting and Alloying of Aluminum	19	**19**	$39	$85,089,920	$2,100,876	0.00%	0.00%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	31	**31**	$64	$138,958,073	$3,364,350	0.00%	0.00%
331318	Other Aluminum Rolling, Drawing, and Extruding	98	**98**	$202	$179,057,465	$4,420,942	0.00%	0.00%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	76	**76**	$159	$334,535,758	$6,963,904	0.00%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	63	**63**	$130	$273,053,150	$5,684,044	0.00%	0.00%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	141	**141**	$293	$272,540,378	$5,673,370	0.00%	0.01%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	98	**98**	$206	$422,211,424	$8,789,015	0.00%	0.00%
331511	Iron Foundries	138	**138**	$285	$235,041,323	$11,101,414	0.00%	0.00%
331512	Steel Investment Foundries	26	**26**	$54	$59,008,379	$2,787,069	0.00%	0.00%
331513	Steel Foundries (except Investment)	89	**89**	$184	$158,529,911	$7,487,646	0.00%	0.00%
331523	Nonferrous Metal Die-Casting Foundries	180	**180**	$372	$264,021,276	$12,470,188	0.00%	0.00%
331524	Aluminum Foundries (except Die-Casting)	227	**227**	$469	$218,051,062	$10,298,934	0.00%	0.00%

Table VII-26: Screening Analysis for Very Small Entities (with Fewer than 20 Employees) Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	<20 Firms	Affected <20 Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
331529	Other Nonferrous Metal Foundries (except Die-Casting)	159	**159**	$328	$184,739,645	$8,725,578	0.00%	0.00%
339	**Miscellaneous Manufacturing**	**22,673**	**22,673**	**$223,907**	**$14,517,096,167**	**$741,894,194**	**0.00%**	**0.03%**
339112	Surgical and Medical Instrument Manufacturing	651	**651**	$6,414	$919,970,207	$67,455,729	0.00%	0.01%
339113	Surgical Appliance and Supplies Manufacturing	1,179	**1,179**	$11,823	$1,493,451,442	$109,505,563	0.00%	0.01%
339114	Dental Equipment and Supplies Manufacturing	468	**468**	$4,621	$281,217,897	$20,619,970	0.00%	0.02%
339115	Ophthalmic Goods Manufacturing	257	**257**	$2,532	$238,750,582	$17,506,104	0.00%	0.01%
339116	Dental Laboratories	5,294	**5,294**	$52,228	$1,804,762,383	$132,332,070	0.00%	0.04%
339910	Jewelry and Silverware Manufacturing	1,763	**1,763**	$17,390	$1,177,940,358	$47,517,171	0.00%	0.04%
339920	Sporting and Athletic Goods Manufacturing	1,289	**1,289**	$12,739	$970,497,005	$39,149,072	0.00%	0.03%
339930	Doll, Toy, and Game Manufacturing	434	**434**	$4,276	$357,636,551	$14,426,772	0.00%	0.03%
339940	Office Supplies (except Paper) Manufacturing	328	**328**	$3,281	$259,199,969	$10,455,919	0.00%	0.03%
339950	Sign Manufacturing	4,774	**4,774**	$47,134	$2,909,036,588	$117,348,207	0.00%	0.04%
339991	Gasket, Packing, and Sealing Device Manufacturing	293	**293**	$2,897	$439,494,549	$17,728,858	0.00%	0.02%
339992	Musical Instrument Manufacturing	504	**504**	$4,966	$255,684,563	$10,314,111	0.00%	0.05%
339993	Fastener, Button, Needle, and Pin Manufacturing	76	**76**	$749	$52,427,806	$2,114,896	0.00%	0.04%
339994	Broom, Brush, and Mop Manufacturing	96	**96**	$946	$122,499,344	$4,941,525	0.00%	0.02%
339995	Burial Casket Manufacturing	59	**59**	$591	$34,718,413	$1,400,513	0.00%	0.04%
339999	All Other Miscellaneous Manufacturing	5,208	**5,208**	$51,321	$3,199,808,510	$129,077,714	0.00%	0.04%
42	**Wholesale Trade**	**218,009**	**41,030**	**$86,042**	**$662,069,497,910**	**$15,930,366,430**	**0.00%**	**0.00%**
423	**Merchant Wholesalers, Durable Goods**	**137,679**	**11,469**	**$23,999**	**$358,307,048,518**	**$8,191,349,278**	**0.00%**	**0.00%**
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	6,893	**6,893**	$14,318	$12,491,750,129	$310,108,955	0.00%	0.00%
423840	Industrial Supplies Merchant Wholesalers	4,576	**4,576**	$9,681	$12,377,652,116	$381,888,523	0.00%	0.00%
424	**Merchant Wholesalers, Nondurable Goods**	**80,330**	**29,561**	**$62,042**	**$303,762,449,392**	**$7,739,017,152**	**0.00%**	**0.00%**
424210	Drugs and Druggists' Sundries Merchant Wholesalers	5,661	**5,661**	$11,785	$19,231,035,837	$667,361,198	0.00%	0.00%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	1,782	**1,782**	$3,787	$8,687,864,991	$265,341,794	0.00%	0.00%
424690	Other Chemical and Allied Products Merchant Wholesalers	4,967	**4,967**	$10,486	$20,817,877,435	$635,812,476	0.00%	0.00%
424710	Petroleum Bulk Stations and Terminals	1,334	**1,334**	$2,886	$19,778,343,816	$190,825,725	0.00%	0.00%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,301	**1,301**	$2,715	$21,107,021,411	$203,645,093	0.00%	0.00%
424910	Farm Supplies Merchant Wholesalers	3,985	**3,985**	$8,413	$15,813,831,821	$429,029,596	0.00%	0.00%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	803	**803**	$1,782	$1,831,250,389	$42,537,789	0.00%	0.00%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	9,728	**9,728**	$20,188	$15,541,966,801	$361,021,577	0.00%	0.01%
Total								

Table VII-26: Screening Analysis for Very Small Entities (with Fewer than 20 Employees) Affected by the Proposed Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2019 Dollars)

NAICS Code	Industry	<20 Firms	Affected <20 Firms	Total Annualized Costs	Revenues	Profits	Cost as a Percent of Revenues	Cost as a Percent of Profits
Total	**Total**	**5,305,646**	**88,174**	**$987,857**	**$4,339,862,178,615**	**$165,526,269,969**	**0.00%**	**0.02%**

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0049).

Note: "Affected" firms, establishments, employees, labels, and SDSs are based on the maximum number affected by any one provision of the rule.

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VIII. Federalism

OSHA reviewed the proposed updates to the HCS according to the most recent Executive order on federalism (E.O. 13132, 64 FR 43255), which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States before taking actions that would restrict States' policy options and take such actions only when clear constitutional and statutory authority exists and the problem is of national scope. The Executive order generally allows Federal agencies to preempt State law only with the expressed consent of Congress. Federal agencies must limit preemption of State law to the extent possible.

Under section 18 of the OSH Act, 29 U.S.C. 667, Congress expressly provides that States and U.S. territories may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to such States and territories as State Plan States. Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards and, when applicable to products that are distributed or used in interstate commerce, must be required by compelling local conditions and not unduly burden interstate commerce. 29 U.S.C. 667(c)(2). Subject to these requirements, State Plan States are free to develop and enforce their own requirements for safety and health standards.

In States without OSHA-approved State plans, Congress expressly provides for OSHA standards to preempt State occupational safety and health standards in areas addressed by the Federal standards. In these States, the proposed revisions to the HCS would limit State policy options in the same manner as every standard or amendment to a standard promulgated by OSHA. In States with OSHA-approved State plans, the proposed revisions to the HCS would not significantly limit State policy options to adopt stricter standards.

OSHA previously concluded that promulgation of the HCS complies with E.O. 13132 (77 FR 17687), and reaffirms that finding with respect to the proposed revisions to that standard.

VIX. State Plan States

When Federal OSHA promulgates a new standard or more stringent amendment to an existing standard, the 28 States and U.S. territories with their own OSHA-approved occupational safety and health plans (''State Plan States'') must amend their standards to reflect the new standard or amendment or show why such action is unnecessary, *e.g.,* because an existing State standard covering this area is ''at least as effective'' as the new Federal standard or amendment. 29 CFR 1953.5(a). The State standard must be at least as effective as the final Federal rule, and, when applicable to products that are distributed or used in interstate commerce, must be required by compelling local conditions and not unduly burden interstate commerce. 29 U.S.C. 667(c)(2). State Plans must adopt the Federal standard or complete their own standard within six months of the promulgation date of the final Federal rule. When OSHA promulgates a new rule or amendment that does not impose additional or more stringent requirements than existing standards, State Plan States are not required to amend their standards, although OSHA may encourage them to do so.

The 22 States and territories with OSHA-approved occupational safety and health plans that cover public and private-sector employees are Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Another six states and territories have OSHA-approved occupational safety and health plans that cover State and local government employees only: Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands.

X. Unfunded Mandates Reform Act

OSHA reviewed this proposal according to the Unfunded Mandates Reform Act of 1995 (UMRA), U.S.C. 1501 *et seq.,* and Executive Order 13132 (64 FR 43255). As discussed in the Preliminary Economic Analysis, OSHA has preliminarily concluded that the proposed revisions to the HCS will not impose a Federal mandate on the private sector in excess of $100 million (adjusted annually for inflation) in expenditures in any one year.

As noted previously, OSHA's standards do not apply to State and local governments except in States that have elected voluntarily to adopt a State Plan approved by the agency. Consequently, this proposal does not meet the definition of a ''Federal intergovernmental mandate.'' See 2 U.S.C. 658(5).

The OSH Act does not cover tribal governments in the performance of traditional governmental functions, though it generally does cover tribal governments when they engage in commercial activity. The proposed changes to the HCS would not require tribal governments to expend, in the aggregate, $100 million or more in any one year for their commercial activities.

For these reasons, for the purposes of the UMRA, OSHA certifies that this proposal would not mandate that State, local, or tribal governments adopt new, unfunded regulatory obligations of, or increase expenditures by the private sector by, more than $100 million in any year. In any event, the Preliminary Economic Analysis constitutes a written statement containing a qualitative and quantitative assessment of the anticipated costs and benefits. See 2 U.S.C. 1532.

XI. Protecting Children From Environmental Health and Safety Risks

Executive Order 13045 (62 FR 19885), requires that Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to E.O. 12866 provide OIRA with (1) an evaluation of the environmental health or safety effects that the planned regulation may have on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. E.O. 13045 defines ''covered regulatory actions'' as rules that are likely to (1) be economically significant under E.O. 12866 (*i.e.,* a rulemaking that has an annual effect on the economy of $100 million or more, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities), and (2) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. In this context, the term ''environmental health risks and safety risks'' means risks to health or safety that are attributable to products or substances that children are likely to come in contact with or ingest (*e.g.,* through air, food, water, soil, or product use).

OSHA has preliminarily determined that the proposed revisions to the HCS are not economically significant under E.O. 12866 (see Section VII of this preamble) and that the standard would not pose environmental health or safety

risks to children as set forth in E.O. 13045.

XII. Environmental Impacts

OSHA has reviewed the proposed revisions to the HCS according to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (40 CFR part 1500), and the Department of Labor's NEPA procedures (29 CFR part 11). As a result of that review, OSHA has made a preliminary determination that the proposed regulatory changes will have no impact on air, water, or soil quality; plant or animal life; or the use of land or aspects of the external environment. Therefore, OSHA preliminarily concludes that the proposed revisions to the HCS would have no significant environmental impacts.

XIII. Consultation and Coordination With Indian Tribal Governments

OSHA reviewed the proposed revisions to the HCS in accordance with E.O. 13175 on ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249), and determined that it does not have ''tribal implications'' as defined in that order. The amendments, if promulgated, would not 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.

XIV. Issues and Options Considered

OSHA is providing this issues and options section to solicit stakeholder input on various regulatory issues and to allow for some potential regulatory flexibility with respect to the content of any final rule resulting from this rulemaking. While OSHA invites stakeholders to comment on all aspects of this proposal, this section identifies specific areas of interest to the agency. OSHA is including certain issues and questions in this section to assist stakeholders as they review the proposal and consider the comments they plan to submit. However, to fully understand the questions, and to provide substantive input and feedback in response to them, the agency suggests commenters review the other sections of the preamble that address these issues in detail. Some issues and options that have cost implications are discussed more thoroughly in the Preliminary Economic Analysis (see Section VII. Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis).

A. Issues

In this section, OSHA solicits public feedback on specific issues associated with the proposed revisions to the HCS. It should be noted that the proposed regulatory text provided at the end of this document only includes those paragraphs that OSHA is proposing to change. Therefore, the agency is putting a marked-up version (redline strike out) of the text of the current rule on its web page and in the docket to help readers identify and understand the proposed changes in context (OSHA HCS Redline, 2020, Document ID 0222). The marked-up text will be found on www.osha.gov under Hazard Communication in the subject index.

OSHA has organized this issues section to follow the order of the preamble and requests that feedback be organized, to the extent possible, in similar order. Comments and feedback on particular provisions should contain the heading of the section (*e.g.,* Regulatory Text, Appendix A), the associated issue number, and, where appropriate, the paragraph in the standard that the comment is addressing. Comments addressing more than one section or paragraph should include all relevant references. Submitting comments in an organized manner with clear reference to the issue(s) raised will enable all participants to better understand the issues the commenter addressed and how they addressed them. Some commenters may confine their interest (and comments) to the issues that specifically affect them; correspondingly they will benefit from being able to quickly identify comments on these issues in others' submissions. While the agency welcomes relevant comments on any aspect of this proposal, OSHA is especially interested in responses, supported by evidence and explanations, to the following issues and questions:

Timeframe for Updates to the HCS

Since aligning the HCS with the GHS Rev. 3 in 2012, OSHA has intended for the HCS to stay current with more recent revisions of the GHS. The GHS is updated biennially through published revisions; most recently, revision 8 was published in July 2019 (UN GHS, Rev. 8, Document ID 0065). Regulatory authorities around the world have implemented the GHS at stages ranging from revision 1 through revision 5. Few regulatory authorities have put programs in place to update their regulations on a routine schedule. The European Union (EU) has made the most regular updates, and has most recently implemented the GHS Rev. 5 in August, 2016 (ECHA, 2016, Document ID 0177). In March 2019, the European Commission (EC) published the adaptation of technical progress (ATP) to EC regulation 1272/2008 (the Classification, Labelling, and Packaging (CLP) regulation) to align with both the sixth and seventh revised editions of the GHS (EC, 2019, Document ID 0176). These changes to the EC regulation become effective October 17, 2020. Other regulatory authorities, such as those in Canada, Australia, and New Zealand, have indicated that they will continue to update their regulations to align with the GHS and are in the process of aligning with Rev. 7; however, none of these countries have a mandate on how often they should do so (Canada, 2019, Document ID 0172; Australia, 2020, Document ID 0168; New Zealand, 2018, Document ID 0187). Similarly, to date, OSHA has not adopted a specific timeframe for regularly updating the HCS to implement GHS updates.

As stated previously, OSHA is proposing to align the HCS with the GHS Rev. 7, consistent with the actions of most of the countries listed above (EC, 2019, Document ID 0176; Canada, 2019, Document ID 0172; Australia, 2020, Document ID 0168; New Zealand, 2018, Document ID 0187). A more thorough explanation of OSHA's preliminary decision to align the HCS with the GHS Rev. 7 is detailed in the introduction to Section XV.

OSHA requests public comment on whether the agency should adopt a schedule for updates to the HCS standard (*e.g.,* every four years or every two revisions of the GHS) or wait until there are significant changes to the GHS before initiating rulemaking. More frequently updating the HCS to align with the GHS may provide greater protection for workers and reduce uncertainty for manufacturers, distributors, and employers. For example, in the GHS Rev. 7, several hazard classes have been updated to include additional hazard sub-categories and improved hazard information that will increase clarity and, therefore, protections for workers.

OSHA is interested in receiving public comment about the utility, costs, or other issues that might be associated with regular updates and about specific timeframes or criteria that OSHA should consider when determining when and whether to update the HCS. Specifically, would longer time periods between updates and realignment with the GHS and other standards be more or less burdensome for employers, especially those that operate

internationally? Would regular, shorter time periods provide more stability? How would longer or shorter periods between realignment affect worker protection?

Regulatory Text

(1) Under paragraph (f), *Labels and other forms of warning,* OSHA is proposing changes to paragraphs (f)(5) (bulk shipments) and (f)(11) (released-for-shipment) and is also proposing to add a new paragraph (f)(12) containing provisions specific to labelling on small containers.

(a) OSHA is requesting comments on the proposed additions to paragraph (f)(5), which would be newly titled *Transportation.* Proposed paragraph (f)(5)(ii) would provide that labels for bulk shipments may be placed on the immediate container or may be transmitted with the shipping papers or bills of lading or by other technological or electronic means as long as the label is immediately available to workers in printed form at the receiving end of the shipment. OSHA requests comments on the usefulness and effectiveness of allowing these alternate approaches for labeling bulk shipments.

(b) OSHA is proposing to update paragraph (f)(11) to provide that chemicals that have been released for shipment and are awaiting future distribution need not be relabeled to incorporate new significant information about hazards; however, the chemical manufacturer or importer would still have to provide the updated label for each individual container with each shipment. The purpose of this proposal is to account for the long distribution cycles of some products and the potential hazards workers could face in relabeling the immediate containers of hazardous chemicals (*e.g.,* chemical exposures, ergonomic issues). OSHA requests comments on whether it is appropriate to use ''released for shipment'' as the cutoff point for relabeling requirements, as opposed to, for example, the time of shipment. Would the proposed provision reduce worker protections, considering OSHA is also proposing to require that the updated label be sent with the shipment? Would the proposed change result in any cost savings?

(c) OSHA is proposing a new paragraph (f)(12) addressing labeling requirements for small containers. All of the provisions in this proposed paragraph would apply only where the chemical manufacturer, importer, or distributor can demonstrate that it is not feasible to use pull-out labels, fold-back labels, or tags containing the full label information required by paragraph (f)(1). Paragraph (f)(12)(ii), as proposed, would provide that labels for small containers less than or equal to 100 ml capacity must include just the product identifier, pictogram(s), signal word, chemical manufacturer's name and phone number, and a statement that the full label information for the hazardous chemical is provided on the immediate outer package. In addition, proposed (f)(12)(iii) would eliminate labeling requirements for small containers less than or equal to 3 ml capacity where the manufacturer, importer, or distributor can demonstrate that any label would interfere with the normal use of the container; in such cases, however, the proposed revisions to the standard would require the container to bear, at a minimum, the product identifier. For example, the product identifier could be etched on a small glass vial. This would ensure that each small container can be identified and linked with the full label information on the immediate outer package. OSHA is also proposing a provision at paragraph (f)(12)(iv), applicable to all small containers covered by paragraph (f)(12)(ii) or (iii), providing that the immediate outer package must include (1) the full label information for each hazardous chemical in the immediate outer package; and (2) a statement indicating that the small container(s) inside must be stored in the immediate outer package (bearing the complete label) when not in use. OSHA requests comments on the feasibility of, and any cost savings associated with, these proposed provisions for the labeling of small containers (both 100 ml and less and 3 ml and less). The agency also requests information on whether the proposed labeling requirements would be adequate to provide for safe handling and storage of chemicals in small containers. In addition, OSHA is interested in receiving comments on two specific alternatives to proposed paragraph (f)(12). First, instead of adopting proposed paragraph (f)(12), should OSHA simply allow for case-by-case exemptions if full labeling is not feasible? Second, should the agency require a showing that a full label would interfere with the normal use of the container before permitting the use of abbreviated labels on containers with a capacity of 100 ml and less (similar to the condition OSHA is proposing in paragraph (f)(12)(iii) for containers with a capacity of 3 ml and less)? Please provide reasons for your answers.

(2) Under paragraph (g) *Safety data sheets,* OSHA is proposing a change to paragraph (g)(10), which addresses the form and storage of safety data sheets, to allow SDSs to be stored, rather than designed, in a way that covers groups of hazardous chemicals in a work area. The original term ''design'' was used when OSHA did not require a specific format for material safety data sheets (MSDSs), but now that OSHA requires SDSs to be in a standard 16-section format, the agency is proposing to clarify that this paragraph refers to storage only. OSHA requests comments regarding whether this proposed revision would require significant changes to current practices.

(3) Under paragraph (i), *Trade secrets,* OSHA is proposing two significant changes.

(a) First, OSHA is proposing to allow manufacturers, importers, and employers to withhold a chemical's concentration range as a trade secret.

(b) Second, in proposed paragraphs (i)(1)(iv)(A) through (M), OSHA is proposing the use of prescriptive concentration ranges in lieu of the actual concentration or concentration range whenever the actual concentration or concentration range is claimed as a trade secret; the proposed ranges are the same as those required by Canada, a major trading partner of the United States (Canada, 2019, Document ID 0172).

OSHA currently does not permit manufacturers to claim concentration ranges as trade secrets (Colau, 2017, Document ID 0098; Nelson, 2017, Document ID 0099), and is requesting comments on its proposal to do so. Specifically, the agency is interested in any experience stakeholders have had with developing SDSs using the prescribed concentration ranges and any concerns stakeholders have about using concentration ranges on the SDS. The agency is also requesting comments addressing the adequacy of hazard information provided by these ranges. Do these ranges provide sufficient information for downstream manufacturers to conduct hazard classifications? Are the ranges prescribed too wide to provide sufficient information to protect workers (*i.e.,* should they be narrowed)? Notably, proposed paragraph (i)(1)(v) provides that the prescribed concentration range used must be the narrowest range possible. If the exact concentration range falls between 0.1% and 30% (proposed paragraphs (i)(1)(iv)(A) through (G)) and does not fit entirely into one of the prescribed concentration ranges, a single range created by the combination of two applicable consecutive ranges could be disclosed instead, provided that the combined concentration range does not include any range that falls entirely outside the

exact concentration range in which the ingredient is present. OSHA invites comments on whether it should allow combinations among all ranges (*i.e.,* all of the ranges (up to 100% concentration) listed in proposed paragraphs (i)(1)(iv)(A) through (M)) or whether the rule applicable to combining ranges should be even more restrictive (*e.g.,* only for the ranges (up to 10% concentration) listed in proposed paragraphs (i)(1)(iv)(A) through (E)). OSHA is also interested in receiving comments on whether there are any economic implications associated with including the prescribed concentration ranges.

Appendix B

OSHA is proposing several substantive updates to appendix B (as outlined in Section XV, Summary and Explanation). These include the addition of a new hazard class (desensitized explosives) and several new hazard categories (unstable gases and pyrophoric gases in the Flammable Gases class and nonflammable aerosols in the Aerosols class). OSHA has preliminarily determined that the addition of these specific hazard classes and categories would better differentiate between the hazards and better communicate hazards on labels for downstream users. OSHA is requesting comments on whether these changes provide improved safety through more targeted hazard statements, precautionary statements and pictograms.

Appendix C

OSHA has proposed numerous changes to appendix C, many of which are editorial, clarifying, or organizational in nature and are designed to clarify requirements for preparing labels. The agency is also proposing some substantive changes to correspond to proposed changes to appendix B or the regulatory text. In paragraph C.2.4.10, OSHA is proposing to require prioritization of certain precautionary statements related to medical response (see Section XV, Summary and Explanation, Appendix C, Proposed Revisions to Table C.2.4.). The agency requests comments on the particular system of prioritization specified in proposed C.2.4.10 and on whether the proposed prioritization provisions would improve clarity on labels.

Appendix D

Many of the issues related to changes proposed for appendix D are discussed in the summary and explanation of the regulatory text (see Section XV, Summary and Explanation, Regulatory Text), specifically in the discussion of OSHA's proposed changes to paragraphs (c), (g), and (i). OSHA requests comments on the following additional issues:

OSHA is proposing changes to section 2 of the SDS to emphasize that hazards identified under normal conditions of use that result from a chemical reaction must appear on the SDS, even though these hazards do not need to be listed on the label. This proposed change would simply reorganize the information presented in the SDS, as discussed in Section XV (Summary and Explanation, Appendix D). OSHA is requesting comments on whether the text OSHA is proposing for paragraph (c) in section 2 would clarify when it is appropriate to include information on the hazards associated with a change in the chemical's physical form or chemical reaction under normal conditions of use and the type of information that should be presented in section 2 of the SDS.

With some conditions, the HCS currently requires section 3 of the SDS to include the chemical name and concentration (exact percentage) or concentration ranges of all ingredients which are classified as ''health hazards'' in accordance with paragraph (d) of § 1910.1200. OSHA is not proposing to change this requirement, but is interested in comments on whether it should be expanded to include all classified chemicals (*i.e.,* also physical hazards and HNOCSs). Such a requirement would be similar to the EU REACh regulations, which require SDS preparers to list the classification of each hazardous ingredient (ECHA, 2016, Document ID 0177). Would expanding the requirements for section 3 in this way ensure that both users and manufacturers fully understand any potential hazard when handling the chemical? Would such a change result in the provision of additional information that would allow downstream manufacturers to more accurately classify their products where the mixture in question is one of their ingredients?

The use of newer electronic technology, such as quick response (QR) codes and radio-frequency identification (RFID), on package labels give responsible parties the ability to communicate information on chemical hazards in a variety of formats. In the December 2018 session of the UN Sub-committee, the members of an informal working group on labeling of small containers agreed to extend its scope beyond small containers and, accordingly, to change its name to ''Practical Labelling Issues.'' Among other activities proposed for the biennium 2019–2020, the working group planned to ''[r]eview the existing digital means of communication that can be used to convey the GHS hazard information to users (*e.g.,* electronic label, QR code etc.),'' ''consider the development of general principles and criteria on the provision of this information digitally,'' and ''develop guidance and examples wherever appropriate.'' (UN GHS, 2019, Document ID 0198; UN Secretariat, 2019, Document ID 0196).

As an example, a paper presented at the December 2018 session of the UN sub-committee noted that there are international efforts ''actively promoting the application of electronic labels for chemicals'' in such industrial processes as production; management of cylinders, laboratory samples, and warehouse operations; and the supervision of competent persons (UN GHS, 2019, Document ID 0198). The paper noted that common types of electronic labels include QR codes and RFID. The paper also discussed efforts to develop national standards on electronic labeling ''to establish a complete integrated information managing standard system based on chemical electronic labels and safety data'' in order to ''further ensure the effectiveness of chemical safety supervision, promote the implementation of the Globally Harmonized System of Classification and Labelling of Chemicals, and facilitate . . . trade.'' Among the benefits of practical labeling cited by the sub-committee expert are the convenience and efficiency derived from ''unified information collection,'' ''dynamic management,'' and ''real-time monitoring''; the ability to store a large capacity of information, reaching multiple mega-byte levels; and ''[improvement in] the level of safety management in complex scenarios.'' (UN GHS, 2018, Document ID 0082).

OSHA invites comments on the use of electronic labeling for chemical packaging. If a future revision to the HCS permitted some form of electronic labeling, what technological, economic, and security challenges would affected employers face? The agency also requests comments on the types of electronic chemical labeling already in existence or under development. For employers already implementing electronic labeling programs in the United States or in other countries, please provide information on the types of electronic coding systems utilized in the program and the costs incurred and benefits achieved from the program.

What back-up measures are in place to ensure immediate access to the hazard information? OSHA is interested in information about workers' experiences with the use of electronic labels. OSHA also requests comments on foreseeable challenges that OSHA should consider (*e.g.,* worker accessibility to electronic label information).

Preliminary Economic Analysis

(1) As explained in the preliminary economic analysis (see Section VII.F. Compliance Costs and Cost Savings), some chemical production and logistics employees who receive training under the provisions of the existing HCS would need to receive additional training to become familiar with the updates to SDSs and labels for impacted aerosols, desensitized explosives, and flammable gases. OSHA has preliminarily determined that the incremental training costs employers would incur for these employees will be relatively small (estimated annualized training costs of $120,158 for all affected employers). OSHA also believes that users of aerosols, desensitized explosives, and flammable gases in the workplace are already trained on the hazards of these chemicals and therefore would need to devote only a trivial amount of time, if any time at all, to additional training associated with the reclassification of these chemicals. Per the discussion of this issue in the preliminary economic analysis (see ''Costs Associated with Training Employees'' in Section VII.F. Compliance Costs and Cost Savings), OSHA acknowledges that some user training might be required for non-flammable aerosols not under pressure; the agency has preliminarily concluded, however, that such training time would be negligible given that, as discussed in Section XV.C (see Section XV, Summary and Explanation for Appendix B), most aerosols are currently classified as gases under pressure and therefore are already covered under the HCS. The agency requests comments on all of its preliminary conclusions regarding training time for users of reclassified chemicals.

(2) For purposes of estimating the costs associated with the proposed new hazard classification requirements, OSHA estimates that a Health & Safety Specialist would spend 1.75 hours per SDS for establishments with fewer than 100 employees; 1.25 hours per SDS for establishments with 100–499 employees; and 0.75 hours per SDS for establishments with 500 or more employees (see ''Costs Associated with Reclassifications and Revisions to Safety Data Sheets and Labels'' in Section VII.F, Compliance Costs and Cost Savings). At a loaded hourly wage of $56.87, this results in estimated unit costs of $101.51, $72.51, and $43.50 per SDS for small, medium, and large establishments, respectively. OSHA invites interested parties to comment on these estimates.

(3) For purposes of estimating the costs associated with revising labels and SDSs to conform to the revisions OSHA is proposing to mandatory language in the appendices, OSHA estimates that a Health & Safety Specialist would spend 0.7 hours per SDS for establishments with fewer than 100 employees; 0.5 hours per SDS for establishments with 100–499 employees; and 0.3 hours per SDS for establishments with 500 or more employees (see ''Revisions to SDSs and Labels Due to Revised Precautionary Statements,'' in Section VII.F. Compliance Costs and Cost Savings). At a loaded hourly wage of $56.39, this results in estimated unit costs of $40.60, $29.00, and $17.40 per SDS for small, medium, and large establishments, respectively. OSHA invites interested parties to comment on these estimates.

(4) To estimate the costs (cost savings) associated with the proposed released-for-shipment provisions in paragraph (f)(11), OSHA presented a cost methodology that required estimating four factors: (1) Cost savings (estimated relabeling costs) as a percentage of the value of the products needing relabeling; (2) the percentage of products in the affected NAICS industries that would be warehoused for more than six months; (3) the percentage of products warehoused for more than six months that would require relabeling in any particular year due to a manufacturer-initiated labeling change; [58] and (4) the percentage of all products in the NAICS industries that would be covered by the proposed revisions to the HCS. The estimated percentages are shown in Table VI–17: Calculation of the Percentage Loss Avoided Due to the Proposed Released-for-Shipment Provision. OSHA requests public comments on its estimates for each of the four factors described above and shown in Table VI–17.

(5) As described in the PEA (see ''Released for Shipment'' in Section VII.F. Compliance Costs and Cost Savings), OSHA anticipates that the proposed modifications to paragraph (f)(11) addressing chemicals that have been released for shipment would result in cost savings for manufacturers and distributors of certain products—those with large (and typically infrequent) production runs and lengthy shelf lives (often five years or longer) that, during production, are labeled, boxed, palletized, and shipped, and then go through the distribution chain usually without the chemical contents, packaging, or label being disturbed. OSHA identified six industries (NAICS 325311 Nitrogenous fertilizer manufacturing, NAICS 325312 Phosphatic fertilizer manufacturing, NAICS 325314 Fertilizer (mixing only) manufacturing, NAICS 325510 Paint and coating manufacturing, NAICS 424910 Farm supplies merchant wholesalers, and NAICS 424950 Paint, varnish, and supplies merchant wholesalers) that it expects would be impacted by the proposed modifications to paragraph (f)(11); see Table VI–17 in Section VII.D. Health and Safety Benefits and Unquantified Positive Economic Effects. OSHA invites comments on whether other industries would be affected by this proposed modification and whether there might be other cost or health effects resulting from this proposed modification that OSHA did not consider in this proposal.

(6) Also with respect to the estimate of cost savings associated with the proposed released-for-shipment provisions, OSHA assumes that if the relabeling costs associated with paragraph (f)(11) exceed the value of the product, manufacturers and wholesalers will discard the product rather than pay to relabel it. There may be some disposal costs for the discarded material, but there may also be some salvage value to the improperly-labeled product. In the preliminary economic analysis (see ''Released for Shipment'' in Section VII.F. Compliance Costs and Cost Savings), OSHA estimates, without further information on the distribution of the costs, that the average labeling cost is approximately 50 percent of the value of the products requiring relabeling. The agency invites comments on this assumption.

B. Options

In this section, OSHA presents a list of options that are under consideration for the proposed update to the HCS. The agency is requesting public comment on these options.

Regulatory Text

(1) OSHA is proposing, in paragraph (i), to mandate the use of prescriptive concentration ranges whenever an actual concentration or concentration range is being claimed as a trade secret. This change is being proposed, in part, to better align with Canada's Workplace

[58] That is, a labeling change resulting from new information obtained by the manufacturer and not from a new legal requirement.

Hazardous Materials Information System (WHMIS), allowing manufacturers, importers, and employers the ability to use the same SDS for both U.S. and Canadian workplaces. However, the agency is also considering a non-mandatory option for this provision. Under this scenario, OSHA would provide non-mandatory guidance on the use of concentration ranges, but would not require their use. This would allow manufacturers, importers, and employers flexibility to follow the current HCS requirements (which do not require the use of any concentration ranges when the actual concentration is claimed as a trade secret) or move to a system that aligns with WHMIS. OSHA is requesting comments on this option. Would this option provide beneficial flexibility to manufacturers, importers, and employers? Would this option be too confusing, and potentially weaken protective effects that would be associated with providing prescribed concentration ranges? How would this affect employee safety and comprehension?

(2) Under paragraph (i), OSHA is also considering allowing manufacturers and importers to provide their own ranges as long as the range is narrower than any prescribed range. This alternative could allow manufacturers and importers to provide downstream users with more precise information while still being able to claim a trade secret. This would be consistent with an approach Health Canada is considering (Canada, 2019, Document ID 0172). OSHA is seeking comments on the usefulness and viability of this option.

Revision 8 Changes

The GHS Rev. 8 was published in July 2019 and contains many changes from Rev. 7, including updates to certain hazard classification criteria, systematic updates to the definitions in the health hazard chapters, updates to hazard and precautionary statements, and updated labeling examples. An overview of the changes can be found in Document ID 0243. As discussed more thoroughly in the introduction to the Summary and Explanation (see Section XV), OSHA has preliminarily decided to use this proposed update to align the HCS with the GHS Rev. 7. However, OSHA has also identified specific updates found in the GHS Rev. 8 that are significant enough to warrant consideration in this rulemaking. Below, the agency highlights several updates from the GHS Rev. 8 and invites public comments on whether OSHA should consider adopting these updates.

1. Appendix A (Based on the GHS Rev. 8)

OSHA is proposing substantial revisions to appendix A.2 (skin corrosion/irritation) that reflect changes the UN subcommittee adopted through the GHS Rev. 7. However, the GHS Rev. 8, published in July 2019 (UN GHS, 2019, Document ID 0065), expanded the use of non-animal test methods in Chapter 3.2 (skin corrosion/irritation). These changes include recognition of specific *in vitro* test methods, reorganization of the chapter, reorganization of the tiered approach with an updated Figure 3.2.1 to reflect those changes, as well as descriptive text on use of new test methods, structure activity relationship (SAR) and read across methods, and an updated decision logic diagram. The expansion of non-animal test methods for use in hazard classification could potentially result in cost savings, as hazard testing for new chemicals could be done using potentially cheaper (non-animal) test methods. If OSHA were to adopt these changes, they would be reflected in appendix A.2 Skin Corrosion/Irritation.

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Table XIII.1 Tiered Approach to Classification of Chemicals for Skin Irritation/Corrosion

(from the GHS Rev. 8 Table 3.2.1)

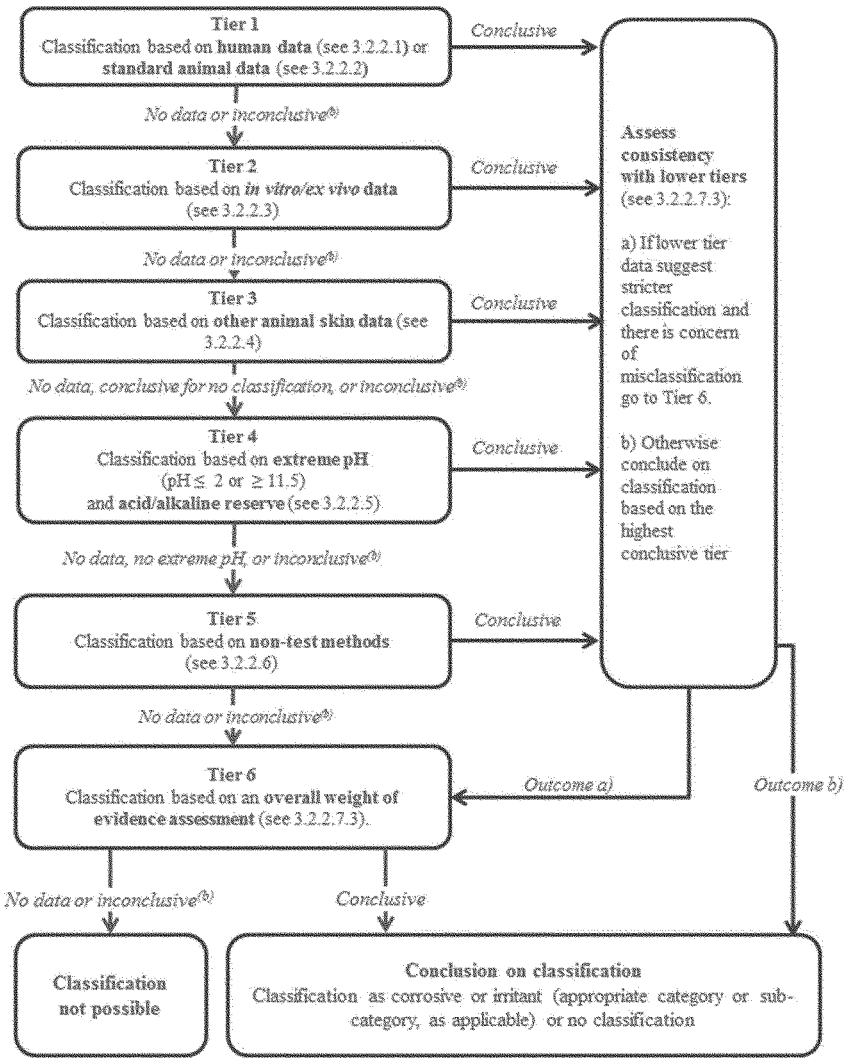

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Table 3.2.1 from the GHS Rev. 8 (shown above) provides an update to the tiered approach for classification. In recognition of the advancements made in non-animal test methods, the update includes an elevation in acceptance of *in vitro* data to tier 2 of the approach. The updated tiered approach also includes consideration of conflicting lower-tiered data when the lower tier suggests a higher classification level. In addition to the changes in the table, Rev. 8 updates the background information to provide additional guidance for how to use non-animal test data to classify chemicals. Adopting these updates in the HCS would not require a re-evaluation of chemicals already classified because the overall tiered approach for evaluating existing data has been retained. The agency believes the greatest benefit would be for new chemicals where no existing data currently exists. Although OSHA does not require testing, OSHA currently encourages chemical manufacturers wanting to develop hazard information for new chemicals to utilize non-animal testing strategies to develop hazard information. Should OSHA adopt Chapter 3.2 from the GHS Rev. 8 with all of the revisions to the classification scheme? Please explain your opinion and provide any relevant data or other information.

2. Appendix B (Based on the GHS Rev. 8)

In this NPRM, OSHA is proposing updates to the classification and labeling of aerosols that will align with the GHS Rev. 7. However, the GHS Rev. 8 contains several significant additional changes in the aerosol chapter. OSHA requests comments on whether the agency should adopt two specific changes that appear in the GHS Rev. 8. First, the GHS Rev. 8 lists classification criteria for aerosols as text in a table (see the GHS table 2.3.1, Criteria for aerosols), similar to other hazard chapters, rather than referring classifiers to the decision logics. When OSHA revised the HCS in 2012, the agency declined to adopt the GHS decision logics and used its own text for classification of flammable aerosols (§ 1910.1200, appendix B). OSHA has preliminarily determined that there are no substantive differences between OSHA's current text and the text

represented in the new Rev. 8 table (reproduced below), although they do not contain exactly the same language (UN GHS, Rev. 8, Document ID 0065).

TABLE XIV—REV. 8 CLASSIFICATION CRITERIA FOR AEROSOLS

[From the GHS Rev. 8 Table 2.3.1]

Category	Criteria
1	(1) Any aerosol that contains ≥85% flammable components (by mass) and has a heat of combustion of ≥30 kJ/g; (2) Any aerosol that dispenses a spray that, in the ignition distance test, has an ignition distance of ≥75 cm; or (3) Any aerosol that dispenses a foam that, in the foam flammability test, has: (a) a flame height of ≥20 cm and a flame duration of ≥2 s; or (b) a flame height of ≥4 cm and a flame duration of ≥7 s.
2	(1) Any aerosol that dispenses a spray that, based on the results of the ignition distance test, does not meet the criteria for Category 1, and which has: (a) A heat of combustion of ≥20 kJ/g; (b) a heat of combustion of <20 kJ/g along with an ignition distance of ≥15 cm; or (c) a heat of combustion of <20 kJ/g and an ignition distance of <15 cm along with either, in the enclosed space ignition test: A time equivalent of ≤300 s/m3; or a deflagration density of ≤300 g/m3; or (2) Any aerosol that dispenses a foam that, based on the results of the aerosol foam flammability test, does not meet the criteria for Category 1, and which has a flame height of ≥4 cm and a flame duration of ≥2 s.
3	(1) Any aerosol that contains ≤1% flammable components (by mass) and that has a heat of combustion <20 kJ/g; or (2) Any aerosol that contains >1% (by mass) flammable components or which has a heat of combustion of ≥20 kJ/g but which, based on the results of the ignition distance test, the enclosed space ignition test or the aerosol foam flammability test, does not meet the criteria for Category 1 or Category 2.

Should OSHA adopt the classification criteria for the aerosols hazard class as presented above? While the criteria themselves would not change as compared to OSHA's existing standard, adopting the precise language in the GHS text may minimize confusion.

Second, in Rev. 8, the GHS adopted a new hazard category within the aerosols class: Chemicals under pressure (UN GHS, 2019, Document ID 0065; UN GHS, 2018, Document ID 0247; UN GHS, 2018, Document ID 0248). These products function similarly to aerosol dispensers (UN 1950), but are packed in pressure receptacles (refillable and non-refillable) up to 450 liters ((UN GHS, 2019, Document ID 0065; UN TDG, 2020, Document ID 0195). Chemicals under pressure used for spray applications present hazards that are similar to those presented by aerosol dispensers. Therefore, the classification criteria and hazard information are the same as for aerosols. OSHA recognizes that adopting this hazard classification would bring some chemicals under the purview of the HCS that currently are not covered (*e.g.,* certain aerosols in refillable containers). Should OSHA consider adopting the new hazard category of chemicals under pressure in the aerosol chapter?

3. Appendix C (Based on the GHS Rev. 8)

In this NPRM, OSHA is proposing to update a number of precautionary statements to align with the GHS Rev. 7. However, the GHS Rev. 8 includes additional revisions to precautionary statements, most notably an overhaul of the medical response precautionary statements (UN GHS, 2019, Document ID 0065). These precautionary statements were revised for the GHS Rev. 8 because, among other reasons, manufacturers and suppliers had difficulty choosing the appropriate wording where options were given (*e.g.,* choosing between calling a poison center or doctor, or choosing between medical advice or attention) (UN GHS, 2019, Document ID 0065).

TABLE XV—REVISED MEDICAL RESPONSE STATEMENTS FROM THE GHS REV. 8

Code	Response precautionary statements	Hazard class	Hazard category	Conditions for use
P316	Get emergency medical help immediately.	Acute toxicity, oral (chapter 3.1)	1, 2, 3	Competent Authority or manufacturer/supplier may add, 'Call' followed by the appropriate emergency telephone number, or the appropriate emergency medical help provider, for example, a Poison Centre, Emergency Centre or Doctor.
		Acute toxicity, dermal (chapter 3.1)	1, 2, 3.	
		Acute toxicity, inhalation (chapter 3.1).	1, 2, 3.	
		Skin corrosion (chapter 3.2)	1, 1A, 1B, 1C.	
		Respiratory sensitization (chapter 3.4).	1, 1A, 1B.	
		Specific target organ toxicity, single exposure; (chapter 3.8).	1, 2.	
		Aspiration hazard (chapter 3.10)	1, 2.	
P317	Get medical help	Gases under pressure (chapter 2.5)	Refrigerated liquefied gas.	
		Acute toxicity, oral (chapter 3.1)	4, 5.	
		Acute toxicity, dermal (chapter 3.1)	4, 5.	
		Acute toxicity, inhalation (chapter 3.1).	4, 5.	
		Skin irritation (chapter 3.2)	2, 3.	
		Serious eye damage (chapter 3.3)	1.	
		Eye irritation (chapter 3.3)	2/2A, 2B.	
		Skin sensitization (chapter 3.4)	1, 1A, 1B.	
P318	If exposed or concerned, get medical advice.	Germ cell mutagenicity (chapter 3.5).	1, 1A, 1B, 2.	
		Carcinogenicity (chapter 3.6)	1, 1A, 1B, 2.	

TABLE XV—REVISED MEDICAL RESPONSE STATEMENTS FROM THE GHS REV. 8—Continued

Code	Response precautionary statements	Hazard class	Hazard category	Conditions for use
		Reproductive toxicity (chapter 3.7)	1, 1A, 1B, 2.	
		Reproductive toxicity, effects on or via lactation (chapter 3.7).	Additional category.	
P319	Get medical help if you feel unwell.	Specific target organ toxicity, single exposure; respiratory tract irritation (chapter 3.8).	3.	
		Specific target organ toxicity, single exposure; narcotic effects (chapter 3.8).	3.	
		Specific target organ toxicity, repeated exposure (chapter 3.9).	1, 2.	

As the new statements used in the GHS Rev. 8 provide standardized language and do not require manufacturers and suppliers to decide which statement is most appropriate, adopting these statements in the HCS as part of this rulemaking might save manufacturers or importers time and/or money compared to the existing statements. OSHA also believes that these statements could improve hazard communication and worker safety by more effectively conveying the type of medical action that is necessary. OSHA seeks comments on the potential benefits or drawbacks associated with adopting these revised medical response statements, or other precautionary statements that are part of the GHS Rev. 8, as a part of this rulemaking (see also Summary and Explanation, Section XV.D. Appendix C). OSHA's existing enforcement policy, as described in the OSHA hazard communication directive (OSHA, 2015, Document ID 0007), addresses situations in which employers may use precautionary statements from a more recent version of the GHS; does the policy described in the directive provide sufficient flexibility?

Incorporation by Reference

OSHA is proposing to revise the general incorporation by reference section, 29 CFR 1910.6, to include updated test methods referenced in the proposed revisions to the HCS. OSHA does not intend to require chemicals already classified using an earlier version of a consensus standard to be reclassified. OSHA believes that requiring the reclassification of chemicals based on updated test methods could result in unnecessary economic impacts and create unnecessary confusion for stakeholders. OSHA is considering ways to clarify this in the final regulatory text, *e.g.,* by including a provision in the Dates section of the rule stating that chemicals classified based on older test methods, prior to the effective date of the rule, do not need to be reclassified, and invites comments on this topic.

XV. Summary and Explanation of the Proposed Modifications to the Hazard Communication Standard

This section of the preamble explains OSHA's proposed changes to the HCS (29 CFR 1910.1200). OSHA is proposing to align this modification of the HCS with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). The agency has preliminarily decided to base most of the GHS alignment on Rev. 7 for several reasons, even though Rev. 8 of the GHS was issued in July 2019 (UN GHS, 2019, Document ID 0065). First, OSHA began its work to update the standard prior to the release of Rev. 8. While OSHA has always intended the HCS to be evergreen, preparation for amending any standard is a time-consuming process and changing course would have resulted in a significant delay to this rulemaking. Second, the U.S.'s major trading partners (Canada, Europe, Australia, and New Zealand) are all preparing to align with Rev. 7 (Canada, 2019, Document ID 0172; Australia, 2020, Document ID 0168; New Zealand, 2018, Document ID 0187; EC, 2019, Document ID 0176). Third, OSHA has discussed the potential for adopting some of the most consequential changes from Rev. 8 in the Issues and Options section (see Section XIV, Issues and Options Considered).

In general, OSHA has received broad support for this rulemaking. During OSHA's informal discussion with stakeholders in November 2016 about the potential changes to the HCS (Docket No. OSHA–2016–005), the agency received feedback supporting continued alignment of the HCS with the GHS and Health Canada, as well as support for addressing various implementation issues under the existing HCS (API, 2016, Document ID OSHA–2016–0005–0026; ACC, 2016, Document ID OSHA–2016–0005–0014; NGFA, 2016, Document ID OSHA–2016–0005–0018; AFIA, 2016, Document ID OSHA–2016–0005–0017). The proposed changes are intended to improve and enhance worker protection with regard to hazard communication by incorporating new hazard classes and categories, improving and streamlining precautionary statements, and providing additional clarification of existing regulatory requirements. The following is a discussion, by provision, of the proposed revisions to the standard.

In the discussion of the proposed modifications to the appendices, OSHA describes certain proposed changes that would affect multiple hazard classes. OSHA discusses some changes in general terms and indicates where those changes occur. However, to aid stakeholders, so they can see the proposed changes in context, OSHA is placing in the docket and on its website a redline strikeout version of all of the proposed revisions to the current HCS and appendices (OSHA HCS Redline, 2020, Document ID 0222; *https://www.osha.gov/dsg/hazcom/*).

A. Incorporation by Reference

OSHA is proposing to update the general incorporation by reference section, 29 CFR 1910.6, to include the national/international consensus standards listed below. OSHA does not intend to require chemicals already classified using an earlier version of a consensus standard to be reclassified. OSHA believes that requiring the reclassification of chemicals based on updated test methods could result in unnecessary economic impacts and create unnecessary confusion for stakeholders. OSHA is considering ways to clarify this in the final regulatory text, *e.g.,* by including a provision in the **DATES** section of the rule stating that chemicals classified based on older test methods, prior to the effective date of the rule, do not need to be reclassified, and invites comments on this topic.

In places where OSHA is proposing to cite to new or updated national/international consensus standards in the regulatory text and appendix B, OSHA

is proposing to include the title, edition/version, and year of the standard in the relevant reference for the benefit of stakeholders and for ease of compliance. OSHA is not currently proposing to add/update *all* existing references to consensus standards in the regulatory text and appendix B, but recognizes that in some places in the existing text consensus standards are cited without specific reference to the year, edition, or full title of the relevant standard. In such cases, stakeholders need to consult with § 1910.6 to find more details regarding the specific consensus standard that has been incorporated by reference in the HCS. For example, appendix B, Section B.6.3 (Flammable Liquids), incorporates by reference ASTM D1078, and § 1910.6 specifies that the version of that standard incorporated by reference is the one approved on May 15, 2005. Since there are many versions of ASTM D1078 available, OSHA realizes that the general reference to ASTM D1078 in appendix B could cause confusion to those classifying new chemicals. OSHA is requesting comments on whether additional information (year, edition/version, full title) should be added to all of the references to consensus standards that are already incorporated by reference in the HCS.

OSHA is proposing to incorporate by reference (in § 1910.6) the materials below. A brief description of each consensus standard is provided in the text below. A description of their use can be found in the Regulatory Text, Appendices, and Summary and Explanation for the Regulatory Text and Appendices (see Section XV.A and D) where the standard is referenced. Each standard is available for purchase through the publication agencies listed below:

- Regulatory Text—Paragraph c (Definitions)

○ ASTM D 4359–90 (2019)—Standard Test Method for Determining Whether a Material is a Liquid or a Solid, Re-approved 2019: This consensus standard provides specific details regarding the test methods used to determine whether a viscous material is a liquid or solid.

▪ ASTM, International: *https://astm.org/Standard/standards-and-publications.html.*

○ European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR): This consensus standard provides test methods for determining the specific physical characteristics of a liquid.

▪ *https://shop.un.org/series/european-agreement-concerning-international-carriage-dangerous-goods-road-adr.*

- Appendix B.1.3—Explosives

○ UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part I: This consensus standard provides test methods to determine if a substance has explosive properties, the degree of sensitivity of the explosive properties, and stability of explosive properties. The consensus standard also provides information on the procedures for classification of explosive materials.

▪ *https://www.unece.org/tans/danger/publi/manual/maual_e.html.*

- Appendix B.2.3—Flammable Gases

○ ISO 10156:2010, Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Third Edition, April, 2010: This consensus standard provides specific details of the methods used to determine flammability of a gas or gas mixture. The standard also provides methods for determining if a gas or gas mixture is more or less oxidizing than air under atmospheric conditions. The intention of the standard is for classifying gases and gas mixtures as flammable gases and can be used to select the appropriate gas cylinder valve outlet for the flammability classification.

▪ International Organization for Standards; *https://iso.org/store.html.*

○ ISO 817:2014 Refrigerants—Designation and safety classification: This consensus standard establishes a safety classification system based on the toxicity and flammability of the refrigerant. It also provides guidance on how to determine a refrigerant concentration limit.

▪ International Organization for Standards; *https://iso.org/store.html.*

○ IEC 60079–20–1 ed. 1.0 (2010–01) Explosive atmospheres—Part 20–1: Material characteristics for gas and vapor classification—Test methods and data: This consensus standard provides guidance for classification of gas-air mixtures and vapor-air mixtures under normal conditions of pressure/temperature while also providing guidance on the appropriate selection of equipment. In addition, the standard provides guidance for determining the auto-ignition temperature of gas-air mixtures and vapor-air mixtures with additional information provided to guide selection of appropriate equipment for use in hazardous areas.

▪ International Electrotechnical Commission: *https://iec.ch/index/htm#buy.*

○ DIN 51794 Determining the ignition temperature of petroleum products: This consensus standard provides detailed information on test methods used to determine the ignition temperature of petroleum products. The standard applies to flammable gases and liquids in a specific range of ignition temperature (75–650 °C) with particular emphasis on mineral oils hydrocarbons and their mixtures,

▪ German Institute of Standards: *https://din.de/en/about-standards/buy-standards.*

○ UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part III: This standard provides test methods for determining the flammability of aerosols and gases. The standard provides additional information on the criteria used in classifying gases with regards to their flammability.

▪ *https://www.unece.org/tans/danger/publi/manual/maual_e.html.*

- Appendix B.4—Oxidizing Gases

○ ISO 10156: 2010, Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Third Edition, April, 2010: This consensus standard provides specific details of the methods used to determine flammability of a gas or gas mixture. The standard also provides methods for determining if a gas or gas mixture is more or less oxidizing than air under atmospheric conditions. The standard provides information on criteria that may be used for classifying gases and gas mixtures as flammable gases and may be used to select the appropriate gas cylinder valve outlet for the flammability classification.

▪ *https://www.iso.org/store.html.*

- Appendix B.14.2—Oxidizing Solids

○ UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part III: This section of the standard provides detailed test methods for determining the potential of a solid substance to increase the burning potential or burning intensity of a combustible substance when the two are thoroughly mixed. The standard also provides schematic with criteria on classifying solid substances based on the oxidizing potential.

▪ *https://www.unece.org/tans/danger/publi/manual/maual_e.html.*

- Appendix B.17.2—Desensitized Explosives

○ UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of

Dangerous Goods, Manual of Tests and Criteria, Part V: This section of the Manual identifies criteria for classification of desensitized explosives, and addresses the proper storage of these substances. The standard provides testing criteria and guidance on classifying, storing, and properly transporting goods according to their physical hazards.

▪ *https://www.unece.org/tans/danger/publi/manual/maual_e.html.*

○ UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part II: This standard provides information on the definition of desensitized explosives, the test methods used to evaluate a substance's ability to suppress its explosive properties when thoroughly mixed as a homogenous liquid and provides the criteria used to classify these substances based on their desensitizing properties.

▪ *https://www.unece.org/tans/danger/publi/manual/maual_e.html.*

• Appendix B.17.3—Desensitized Explosives

○ UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part II: This standard provides information on the definition of desensitized explosives, the test methods used to evaluate a substance's ability to suppress its explosive properties when thoroughly mixed as a homogenous liquid and provides the criteria used to classify these substances based on their desensitizing properties.

▪ *https://www.unece.org/tans/danger/publi/manual/maual_e.html.*

The proposed inclusion of UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, in some sections of appendix B (B.1, B.2, B.3, B.4, B.14, and B.17) would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). However, an earlier version of UN ST/SG/AC.10 (Rev. 4) was incorporated by reference as part of the 2012 rulemaking and OSHA is not currently proposing to update all of the Rev. 4 references to Rev. 6 as part of this rulemaking. OSHA requests comments on whether it should, in the final rule, update all of the existing references to UN ST/SG/AC.10/30 to Rev.6 or add Rev. 6 references to the existing Rev. 4 references such that they would be alternative options for compliance.

UN ST/SG/AC.10/Rev.4 is included in the proposed regulatory text as part of the revision to the structure of § 1910.6(bb).

Copies of the standards are available for purchase from the issuing organizations at the addresses or through the other contact information listed in § 1910.6 for these private standards organizations. The UN documents are available at no cost through the contact information listed above. In addition, in accordance with § 1910.6(a)(4), these standards are available for inspection at any Regional Office of the Occupational Safety and Health Administration (OSHA), or at the OSHA Docket Office, U.S. Department of Labor, 200 Constitution Avenue NW, Room N–3508, Washington, DC 20210; telephone: 202–693–2350 (TTY number: 877–889–5627). Due to copyright issues, OSHA cannot post consensus standards on the OSHA website or through *regulations.gov*.

B. Regulatory Text

OSHA has proposed numerous revisions to the HCS regulatory text. The discussion of the proposed modifications is organized by paragraphs to the regulatory text with each modification/addition, and the reasons for and anticipated impact of each, described in detail below. Stakeholders can examine the redline strikeout version of the regulatory text at the OSHA HCS web page (*https://www.osha.gov/dsg/hazcom/*) or in the docket of this rulemaking (OSHA, 2020, Document ID 0222).

Paragraph (a) Purpose

Existing paragraph (a)(1) of the HCS states that the purpose of the standard is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees. This provision currently explains that the requirements of the standard are intended to be consistent with the GHS Rev. 3. As the changes in this proposal would align the HCS with the GHS Revision 7, OSHA proposes to change the reference from Rev. 3 to Rev. 7.

Paragraph (b) Scope and Application

The scope section of the HCS identifies the chemicals that are (and are not) covered by the standard. Existing paragraph (b)(6)(x) excludes nuisance particulates from the standard where the chemical manufacturer or importer can establish that they do not pose any physical or health hazard covered by the standard. OSHA proposes a slight revision to this provision to make clear that nuisance particulates are excluded if they do not pose any physical hazard, health hazard, or other hazards (*i.e.,* hazard not otherwise classified (HNOC)) covered by the standard. This proposal would clarify that all hazards covered by the standard must be considered when evaluating nuisance particulates.

Paragraph (c) Definitions

OSHA proposes to update three existing definitions and to add eight new terms and definitions to the HCS. In addition, the agency is proposing to eliminate one definition from the standard.

OSHA is proposing to add a definition of the term *Bulk Shipment* to the standard. The addition of this definition supports proposed paragraph (f)(5)(ii), which clarifies labeling requirements for bulk shipments of hazardous chemicals. The proposed definition would state that ''bulk shipment'' means any hazardous chemical transported where the mode of transportation (vehicle) comprises the immediate container (*e.g.,* contained in tanker truck, rail car, or intermodal container).

OSHA is proposing to add the term *Combustible Dust* to the standard. In updating the HCS in 2012, OSHA did not include a definition of combustible dust because the agency was considering a combustible dust rulemaking and the UNSCEGHS was also considering combustible dust classification and communication issues (see 77 FR at 17705). However, OSHA has not promulgated a combustible dust standard. Since 2012, the UNSCEGHS has adopted a definition; the GHS Rev. 7 defines combustible dust as ''finely divided solid particles of a substance or mixture that are liable to catch fire or explode on ignition when dispersed in air or other oxidizing media'' (definition adopted from ISO/IEC 80079–20–2 as referenced in UN GHS, 2017, Document ID 0060). OSHA has preliminarily determined that this definition is consistent with existing OSHA guidance on combustible dust hazards and proposes to adopt this definition (OSHA, 2020, Document ID 0190; OSHA, 2009, Document ID 0255). OSHA has several standards that use the term ''combustible dust,'' but do not define the term (*e.g.,* § 1910.272, Grain Handling Facilities). OSHA believes the proposed definition of the term for the HCS is consistent with the use of that term in those other standards.

OSHA is also proposing to revise the definition of *exposure or exposed.* The definition currently provides, in relevant part, that exposure or exposed means that an employee is subjected in the course of employment to a chemical that is a physical or health hazard. OSHA proposes to revise the definition to mean an employee is subjected in the course of employment to a ''hazardous chemical,'' rather than to ''a chemical

that is a physical or health hazard,'' to clarify that the HCS covers the hazards of all hazardous chemicals, including those considered to be HNOCs.

OSHA is proposing to include three new definitions for the terms *Gas, Liquid, and Solid.* The agency is proposing to include these terms to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). Although not included in the GHS, OSHA is proposing to add the temperature in equivalent degrees Fahrenheit and pressure in equivalent pounds per square inch (PSI) to the GHS definitions of gas and liquid because those measurements are more commonly used in the U.S.

Consistent with the GHS, OSHA proposes to define gas as a substance which (i) at 122 °F (50 °C) has a vapor pressure greater than 43.51 PSI (300 kPa) (absolute); or (ii) is completely gaseous at 68 °F (20 °C) at a standard pressure of 14.69 PSI (101.3 kPa). Also consistent with the GHS, OSHA proposes to adopt the definition of liquid as a substance or mixture which at 1220F (50 °C) has a vapor pressure of not more than 43.51 PSI (300 kPa (3 bar)), which is not completely gaseous at 680F (20 °C) and at a standard pressure of 101.3 kPa, and which has a melting point or initial melting point of 68 0F (20 °C) or less at a standard pressure of 14.69 PSI (101.3 kPa). Furthermore, in accordance with the GHS, OSHA is proposing to include the following as part of the definition of liquid: A viscous substance or mixture for which a specific melting point cannot be determined shall be subjected to ASTM D4359–90 (the Standard Test Method for Determining Whether a Material Is a Liquid or a Solid (2019)); or to the test for determining fluidity (penetrometer test) prescribed in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR, 2019). Finally, OSHA proposes to adopt the GHS definition of solid as a substance or mixture which does not meet the definitions of liquid or gas.

Although OSHA did not include these terms in the 2012 update to the HCS, the agency is now proposing to include these definitions in order to improve clarity and ensure consistency in hazard communication both domestically and internationally. The agency anticipates that including these terms in the standard will clarify provisions under appendices B and D for classification of hazardous chemicals and preparation of SDSs. OSHA does not anticipate that these new definitions will impact other existing standards for construction or general industry. OSHA is requesting comments on its preliminary decision to include these definitions in this update.

OSHA is proposing to update the definition of *hazardous chemical* to delete the reference to pyrophoric gas because OSHA is proposing to classify this hazard as a physical hazard in the flammable gas hazard class (see discussion of proposed revisions to appendix B.2) and it is no longer necessary to list it separately in the definition. Concomitantly, OSHA is proposing to delete the separate definition for *pyrophoric gas.*

OSHA proposes to add a definition for *immediate outer package* to mean the first packaging enclosing the container of hazardous chemical. While all containers of chemicals must be labeled, as discussed in the Summary and Explanation for paragraph (f), below, OSHA is proposing revised labeling requirements for small containers. Proposed paragraph (f)(12) would relax labeling requirements for small containers, but would require complete label information on the ''immediate outer package.'' For example, in the case of a kit, the container would be whatever surrounds the chemical itself (*e.g.,* a vial), and the immediate outer package would be the first box or package surrounding the container.

The agency is also proposing to update the definition of *physical hazard* to mean a chemical that is classified as posing one of the following hazardous effects: Explosive; flammable (gases, liquids, or solids); aerosols; oxidizer (liquid, solid or gas); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; in contact with water emits flammable gas; or desensitized explosive. The proposed definition also explicitly states that the criteria for determining whether a chemical is classified as a physical hazard are detailed in appendix B of the standard. The proposal would make two substantive changes to the current definition: (1) It would move the reference to aerosols out of the parenthetical following the word ''flammable''; and (2) it would add a reference to desensitized explosives. These proposed revisions are intended to reflect the proposed new hazard classes for aerosols and desensitized explosives in appendix B in accordance with the GHS Rev. 7. These changes are discussed in greater detail in the Summary and Explanation of appendix B.

OSHA is proposing to add a definition of *Physician or other licensed health care professional (PLHCP)* to the standard. OSHA proposes to define this term as an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows the individual to independently provide or be delegated the responsibility to provide some or all of the health care services referenced in paragraph (i) of the standard. The new definition is necessary in light of OSHA's proposal to replace the phrase ''physician and nurse'' in paragraph (i), trade secrets with the term ''PLHCP'' to be consistent with other OSHA standards that use the term PLHCP, and to better reflect current medical practices. That change is discussed in greater detail in the Summary and Explanation of paragraph (i). OSHA believes the proposed definition of ''PLHCP'' is consistent with the way the agency has defined that term in all health standards promulgated since the bloodborne pathogen standard, 29 CFR 1910.1030, in 1991.

OSHA is also proposing to add a new definition, *released-for-shipment,* to mean a chemical that has been packaged and labeled in the manner in which it will be distributed or sold. This is a new term OSHA is proposing to use in paragraphs (f)(1) and (11) related to updating labels when new hazard information becomes available. OSHA notes that this definition is similar, but not identical to, the definition used by the U.S. Environmental Protection Agency's (EPA's) Pesticide Registration and Classification Procedures regulation, 40 CFR 152.3. EPA defines a product as released for shipment when the producer has packaged and labeled it in the manner in which it will be distributed or sold, or if it is stored in an area where finished products are ordinarily held for shipment. OSHA is not proposing to include chemicals that are stored in an area where finished products are usually held (but not packaged and labeled) in the definition of ''released for shipment'' because there do not appear to be any feasibility issues with ensuring that such chemicals are labeled with the most updated information. The agency is requesting comments on whether the proposed definition is appropriate for application to the HCS. OSHA is also interested in understanding whether the slight differences between OSHA's and EPA's definitions will pose any compliance issues for entities dealing with both OSHA and EPA labeling requirements. See the discussion of the proposed revisions to paragraph (f) for additional details.

Paragraph (d) Hazard Classification

OSHA is proposing two changes to paragraph (d)(1). OSHA proposes to revise the second sentence of paragraph

(d)(1) to read that for each chemical, the chemical manufacturer or importer shall determine the hazard classes, and where appropriate, the category of each class that apply to the chemical being classified *under normal conditions of use and foreseeable emergencies.* The language OSHA is proposing to add at the end of that sentence (''under normal conditions of use and foreseeable emergencies'') simply reiterates the scope language currently in paragraph (b)(2) and OSHA's longstanding position that hazard classification must cover the normal conditions of use and foreseeable emergencies. As OSHA explained in its compliance directive for the HCS (OSHA, 2015, Document ID 0007), for example, known intermediates, by-products, and decomposition products that are produced during normal conditions of use or in foreseeable emergencies must be addressed in the hazard classification.

OSHA also proposes to add a new sentence to paragraph (d)(1) stating that the hazard classification shall include any hazards associated with a change in the chemical's physical form or resulting from a reaction with other chemicals under normal conditions of use. OSHA believes this language is necessary because there has been some confusion about whether chemical reactions that occur during normal conditions of use must be considered during classification. The agency's intent has always been to require information on SDSs that would identify all chemical hazards that workers could be exposed to under normal conditions of use and in foreseeable emergencies (see paragraph (b)(2)). This issue has been raised, for instance, when multiple chemicals are sold together with the intention that they be mixed together before use. For example, epoxy syringes contain two individual chemicals in separate sides of the syringe that are mixed under normal conditions of use. While OSHA intends for the hazards created by the mixing of these two chemicals to be considered in classification, those hazards need only appear on the SDS (see appendix D to § 1910.1200—Safety Data Sheets, section 3) and not on the label. For additional information, please see the Summary and Explanation for appendix D.

Paragraph (e) Written Hazard Communication Plan

OSHA is proposing a minor editorial correction in paragraph (e)(4). OSHA has found that an inadvertent misprint occurred in the print version of the CFR. Specifically, in the print version of the CFR, paragraph (e)(4) references § 1910.20 instead of § 1910.1020. Notably, this error is reflected only in the print version of the CFR; the eCFR (*www.ecfr.gov*) is correct. OSHA proposes to fix this error so that the print and electronic versions of the standard are the same.

Paragraph (f) Labels and Other Forms of Warning

Paragraph (f) of the HCS provides requirements for labeling. OSHA is proposing to modify paragraphs (f)(1), (5), and (11), and is also proposing a new paragraph (f)(12).

Paragraph (f)(1), *Labels on shipped containers,* currently specifies what information is required on shipped containers of hazardous chemicals and also provides that HNOCs do not have to be addressed on the containers. OSHA proposes to revise paragraph (f)(1) to provide that, in addition to HNOCs, hazards resulting from a reaction with other chemicals under normal conditions of use do not have to be addressed on shipped containers. OSHA believes this information is not appropriate on containers because it might confuse users about the immediate hazards associated with the chemical in the container. However, information on hazards resulting from a reaction with other chemicals under normal conditions of use is important for downstream users, and OSHA is not proposing to change the existing requirements for these hazards to be indicated on SDSs (under appendix D) and addressed in worker training where applicable (under paragraph (h)). OSHA also proposes to add the word ''distributor'' to the third sentence of paragraph (f)(1) to make it consistent with the first sentence.

In new paragraph (f)(1)(vii), OSHA is proposing to add a requirement that the label include the date a chemical is released for shipment. The agency is proposing this change in conjunction with changes in paragraph (f)(11) related to relabeling of containers that are released for shipment but have not yet been shipped. Providing the date a chemical is released for shipment on the label would allow manufacturers and distributors to more easily determine their obligations when new hazard information becomes available.

Paragraph (f)(5) specifies label requirements that apply to the transport of hazardous chemicals from workplace to workplace. OSHA proposes to add the heading ''Transportation'' to this paragraph and to add two new paragraphs to (f)(5) that specify requirements related to transportation of hazardous chemicals.

OSHA is proposing to add new paragraph (f)(5)(ii) to address the transport of bulk shipments of hazardous chemicals (*e.g.,*, in tanker trucks or rail cars). The proposed paragraph would specify that labels for bulk shipments of hazardous chemicals may either be on the immediate container or may be transmitted with shipping papers, bills of lading, or other technological or electronic means so that the information is immediately available in print to workers on the receiving end of the shipment. The proposed paragraph would codify policy from a 2016 guidance document that OSHA created jointly with DOT's Pipeline Hazardous Materials Safety Administration (PHMSA), with the intent of providing stakeholders with clarity for how to properly label bulk chemicals in transport (PHMSA, 2016, Document ID 0244). OSHA requests comments on whether it is appropriate to add proposed paragraph (f)(5)(ii) to the HCS and whether the addition of that paragraph would provide clarity regarding labeling of bulk chemical shipments.

Under the current HCS, appendix C, paragraph C.2.3.3 provides that where a pictogram required by the DOT appears on a shipped container, the HCS pictogram for the same hazard (specified in C.4) shall not appear. This provision was intended to prevent confusion associated with having two different representations of the same hazard on the container (77 FR 17728). However, after learning that DOT updated its regulations to indicate that it does not consider the HCS pictogram to conflict with the DOT pictogram, OSHA no longer believes that having both pictograms will create confusion for workers handling the chemical. Accordingly, OSHA proposes to: (1) Delete the language currently in paragraph C.2.3.3 from appendix C; and (2) adopt new paragraph (f)(5)(iii) to provide that where a DOT pictogram appears on a label for a shipped container, the appendix C pictogram for the same hazard is allowed, but is not required, on the HCS label.

For example, in the case where a chemical is shipped in only its immediate container, such as a 55-gallon drum containing a flammable liquid, both a DOT label and an OSHA-compliant label would be required. Under the current standard, the flame pictogram on the OSHA-compliant label would be prohibited because the DOT label would contain the equivalent pictogram. The proposed rule would allow, but not require, the flame pictogram to appear on the OSHA-compliant label. This means chemical

manufacturers could use the same labels for shipping containers and for containers that are solely used in the workplace; this would avoid information loss and eliminate the need to develop or print additional labels.

Paragraph (f)(11) currently requires that chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical revise the labels within six months of becoming aware of the new information and ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. OSHA recognizes that, on some occasions, a chemical manufacturer or importer may become aware of significant hazard information after a chemical has already been labeled but before it ships. Therefore, OSHA proposes to add a sentence to paragraph (f)(11) providing that chemicals that have been released for shipment and are awaiting future distribution need not be relabeled; however, the proposed sentence also states that the chemical manufacturer or importer must provide the updated label for each individual container with each shipment. The purpose of this proposal is to account for the long distribution cycles of some products and the potential hazards workers could face in relabeling the immediate containers of hazardous chemicals that have already been prepared for shipment.

Following publication of the 2012 updates to the HCS, OSHA received feedback related to difficulties some chemical manufacturers were having complying with paragraph (f)(11), particularly in the case of chemicals that travel through long distribution cycles (Kenyon, 2017, Document ID 0182). Many products have straightforward supply chains and are packaged, labeled, and promptly shipped downstream. Other products, for example in the agrochemical sector, are packaged and labeled when they leave the chemical manufacturer's facility, but they may reside at a warehouse or distribution facility for extended periods of time (*e.g.,*, several years) before being shipped downstream. There are also instances where products may be returned from the downstream users to the distribution facility and then shipped to other customers (NGFA, 2016, Document ID OSHA–2016–0005–0018; AFIA, 2016, Document ID OSHA–2016–0005–0017).

The act of relabeling these products in warehouses or distribution facilities has the potential to pose occupational safety and health risks to employees. Relabeling each individual container may require that employees open already secure packaging, a process that may result in potential chemical exposures. Furthermore, OSHA believes re-labeling of sealed hazardous chemical containers is not a common practice in warehouses and that warehouses may lack the equipment necessary to relabel products in a safe and effective manner.

OSHA has previously recognized the complexities involved with relabeling existing stock of hazardous chemicals. Following promulgation of the 2012 updates to the HCS, the HCS compliance directive (OSHA, 2015, Document ID 0007) provided enforcement guidance on the labeling of existing stock. Before June 1, 2015 (for manufacturers and importers), and before December 1, 2015 (for distributors), OSHA permitted chemical manufacturers, importers, and distributors with existing stock that was packaged (*e.g.,*, boxed, palletized, shrink wrapped, etc.) for shipment and labeled in accordance with the pre-2012 version of the HCS to ship those containers downstream without relabeling the containers with HCS 2012-compliant labels. However, the chemical manufacturer or importer generally had to provide an HCS 2012-compliant label for each individual container shipped and the appropriate HCS 2012-compliant SDS(s) with each shipment. After June 1, 2015, chemical manufacturers and importers of hazardous chemicals were required to ensure that each container was labeled with an HCS 2012-compliant label prior to shipping, and all distributors were generally required to ensure any chemicals shipped after December 1, 2015, were labeled in accordance with the 2012 updates to the HCS. OSHA used this enforcement policy as a basis for the proposed revisions to paragraph (f)(11).

OSHA has preliminarily determined that the proposed changes to paragraph (f)(11) would adequately address issues with long distribution cycles while still ensuring chemical users receive the most current hazard information. OSHA invites comments on the proposed revisions to this paragraph. In particular, OSHA requests comments on whether the proposed changes would adequately address issues associated with relabeling in cases of long distribution cycles, whether the proposed changes would provide sufficient flexibility, and whether the proposed revisions would alleviate safety concerns that would otherwise be associated with the relabeling of packaged stock.

OSHA is proposing a new paragraph, (f)(12), to address small container labeling. Currently, the HCS requires that all shipped containers be labeled with the information specified in paragraph (f)(1). The HCS, as updated in 2012, requires considerably more information on the label than the standard required previously; labels must include all hazards, as well as pictograms and precautionary statements. Many stakeholders have told OSHA that they have difficulties including all of the required information from paragraph (f)(1) on the labels they use for small containers. In some cases, the information becomes too small for a person to read it, and while it is sometimes possible to use alternate types of labels (such as pull-out labels or tags), it is not always feasible to do so (Watters, 2013, Document ID 0200; Collatz, 2015, Document ID 0174; Blankfield, 2017, Document ID 0170). In response to these concerns, through letters of interpretation and the HCS directive (OSHA, 2015, Document ID 0007; Watters, 2013, Document ID 0200; Collatz, 2015, Document ID 0174; Blankfield, 2017, Document ID 0170), OSHA provided a practical accommodation to address situations where it is infeasible to provide all HCS-required label information directly on small containers through the use of pull-out labels, fold-back labels, or tags. The practical accommodation allows limited information to be included on the small container label, but requires complete label information to be provided on the outside packaging. OSHA proposes to incorporate this practical accommodation into the standard in new paragraph (f)(12).

OSHA is proposing that all of the small container labeling provisions apply only where the chemical manufacturer, importer, or distributor can demonstrate that it is not feasible to use pull-out labels, fold-back labels, or tags containing the full label information required by paragraph (f)(1). Proposed paragraph (f)(12)(ii)(A) through (E) would provide that labels on small containers that are less than or equal to 100 milliliter (ml) capacity must include, at minimum: Product identifier; pictogram(s); signal word; chemical manufacturer's name and phone number; and a statement that the full label information for the hazardous chemical is provided on the immediate outer package. Additionally, proposed paragraph (f)(12)(iii) would provide that no labels are required for small containers of 3 ml capacity or less where the chemical manufacturer, importer, or distributor can demonstrate that any label would interfere with the normal use of the container; however,

that same proposed paragraph would state that if no label is required, the container must bear, at minimum, the product identifier. For example, the product identifier (*e.g.,* CAS number) could be etched on a 3 ml glass vial (container) to ensure that the identifier remains fixed to the vial. This type of identification would ensure that the chemical in the small container can be identified and matched with the chemical's full label information.

Proposed paragraph (f)(12)(iv) would provide that for any small container covered by paragraph (f)(12)(ii) or (iii), the immediate outer package must include the full label information required by paragraph (f)(1) for each hazardous chemical in the immediate outer package, along with a statement that the small container(s) inside must be stored in the immediate outer package bearing the complete label when not in use. This proposed paragraph would also state that labels affixed to the immediate outer package must not be removed or defaced, as required by existing paragraph (f)(9).

OSHA believes that proposed paragraph (f)(12) would provide chemical manufacturers, importers and distributors with flexibility in labeling small containers. The proposed paragraph is consistent with the small packaging examples provided in the GHS Annex 7: *Examples of Arrangements of the GHS Label Elements* (UN GHS, 2016, Document ID 0197), and would result in better alignment with Health Canada's *Hazardous Product Regulations (HPR)* small capacity container requirements (Health Canada, 2015, Document ID 0051). Specifically, the HPR, under 5.4(1), provides exemptions from certain labeling requirements (such as precautionary statements) for small capacity containers of 100 ml or less. In addition, under 5.4(2), the HPR provides labeling exemptions for containers of 3 ml or less if the label interferes with the normal use of the hazardous product. OSHA requests comments on the feasibility of the proposed small container labeling provisions. The agency also requests feedback about whether the proposed changes would improve safe handling and storage for chemicals in small containers.

Paragraph (g) Safety Data Sheets

SDSs provide important safety information to employers and employees on the use of hazardous chemicals in the workplace. Additionally, SDSs provide detailed technical information and serve as a reference source for exposed employees, industrial hygienists, safety professionals, emergency responders, health care professionals, and other interested parties. While OSHA believes that information in SDSs has greatly improved with the standardized, 16-section format prescribed in the 2012 updates to the HCS, the agency is proposing two minor changes to paragraph (g) to ensure consistency and accessibility of the SDSs.

The proposed revisions to paragraph (g) are confined to paragraphs (g)(2) and (10). The purpose of paragraph (g)(2) is to identify what information must be included on an SDS. The first part of existing paragraph (g)(2) states that the chemical manufacturer or importer preparing the SDS shall ensure that it is in English. However, as permitted by paragraph (g)(1), some chemical manufacturers and importers may obtain, rather than prepare, SDSs. To minimize any potential confusion between paragraphs (g)(1) and (2), OSHA is proposing to revise paragraph (g)(2) by removing the reference to preparing the SDS. The first part of the first sentence in paragraph (g)(2) would be revised to read simply that the chemical manufacturer or importer shall ensure that the SDS is in English. This is a technical clarification intended to ensure consistency with paragraph (g)(1).

Paragraph (g)(10) addresses the form and storage of SDSs. The original intent of paragraph (g)(10) was to allow employers alternatives to SDSs within a plant site (see 48 FR 53337). Alternatives to SDSs, such as written operating procedures and manuals, are generally permitted. Existing paragraph (g)(10) also permits employers to design SDSs to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual chemicals. In any case, paragraph (g)(10) requires the employer to ensure that the required information is provided for each hazardous chemical and is readily accessible to employees. However, with the update to the HCS in 2012, OSHA changed the requirements of the SDS from a performance-oriented format to a standardized format. Standardizing the SDS format improved hazard communication by ensuring users could quickly find relevant information (see 77 FR 17596–98). Because SDSs now have a standardized format and are specific to individual hazardous chemicals, they are not permitted to be designed to cover groups of hazards, as currently provided in paragraph (g)(10). Therefore, OSHA is proposing a change to paragraph (g)(10) that would allow SDSs to be stored, rather than designed, in a way to cover groups of hazardous chemicals in a work area. OSHA believes that this change would allow employers flexibility in how they keep SDSs in the workplace while also ensuring that the mandatory 16-section SDS is maintained. The agency is requesting comments regarding whether this proposed revision would require stakeholders to make any significant changes to their current practices.

Paragraph (i) Trade Secrets

This paragraph describes certain conditions under which a chemical manufacturer, importer, or employer may withhold the specific chemical identity (*e.g.,* chemical name), other specific identification of a hazardous chemical, or the exact percentage (concentration) of the substance in a mixture, from the SDS. OSHA is proposing three significant changes within paragraph (i)(1) and the paragraphs thereunder. First, OSHA is proposing to revise paragraph (i)(1) to allow for concentration ranges to be claimed as a trade secret and to specify that it is section 3 of the SDS from which trade secret information may be withheld.

Second, OSHA is proposing new paragraph (i)(1)(iv), which would require that when an ingredient's exact concentration or concentration range is claimed as a trade secret, the SDS must provide the ingredient's concentration as a concentration range selected from a prescribed list of ranges. These ranges are in proposed paragraphs (i)(1)(iv)(A) through (M) as follows: (1) From 0.1% to 1%; (2) from 0.5% to 1.5%; (3) from 1% to 5%; (4) from 3% to 7%; (5) from 5% to 10%; (6) from 7% to 13%; (7) from 10% to 30%; (8) from 15% to 40%; (9) from 30% to 60%; (10) from 45% to 70%; (11) from 60% to 80%; (12) from 65% to 85%; and (13) from 80% to 100%. These ranges are consistent with those used in Canada, first described under the WHMIS 1988 Controlled Products Regulation (CPR) and re-implemented in 2018 under the HPR (Canadian Gazette II, 2018, Document ID 0101). Using the same concentration ranges as Canada, one of the U.S.'s major trading partners, is part of the two countries' efforts through the Regulatory Cooperation Council to align hazard communication to the greatest extent possible.

OSHA has received numerous inquiries about the use of trade secrets for concentration ranges (Colau, 2017, Document ID 0098; Nelson, 2017, Document ID 0099). Although chemical manufacturers and importers are permitted to use concentration ranges rather than an exact percentage on the

SDS when there is batch-to-batch variability in the production of a mixture or for a group of substantially similar mixtures with similar chemical composition, OSHA does not currently allow trade secret status for a concentration range (see 77 FR 17731). However, in response to feedback from stakeholders who have indicated that there are instances where a concentration range is also a trade secret, OSHA has preliminarily determined it is appropriate to permit concentration ranges to be claimed as trade secrets as long as the ranges prescribed in proposed paragraphs (i)(1)(iv)(A) through (M) are used (Nelson, 2017, Document ID 0099; Colau, 2017, Document ID 0098).

Third, proposed new paragraph (i)(1)(v) would require that the concentration range used on the SDS be the narrowest range possible. This proposed paragraph would also provide that if the actual concentration range falls between 0.1% and 30% and does not fit entirely into one of the prescribed ranges in proposed paragraphs (i)(1)(iv)(A) through (G), a single range created by the combination of two applicable consecutive ranges between (i)(1)(v)(A) and (G) may be disclosed instead, provided that the combined concentration range does not include any range that falls entirely outside the exact range in which the ingredient is present. For example, a chemical manufacturer that wishes to claim the concentration of a specific ingredient (*e.g.,* 2.5%) as a trade secret would have to use the prescribed range in proposed paragraph (i)(1)(iv)(C) of 1% to 5%. If the ingredient is in the mixture at a concentration range of 0.9% to 2%, then the chemical manufacturer could combine the prescribed ranges in proposed paragraphs (i)(1)(iv)(B) and (C), resulting in a range of 0.5% to 5% on the SDS. If the ingredient is in the mixture at a concentration range of 5% to 7%, the chemical manufacturer would have to use the range in proposed paragraph (i)(1)(iv)(D) of 3% to 7%, because it is narrower than the range in proposed paragraph (i)(1)(iv)(E) of 5% to 10%.

OSHA is requesting comments on the proposed revisions to paragraph (i)(1). Specifically, the agency is interested in any experience stakeholders have had with developing SDSs using the prescribed concentration ranges and any concerns stakeholders have about using concentration ranges on SDSs. The agency is also requesting comments addressing the adequacy of hazard information provided by these ranges. Do these ranges provide sufficient information for downstream chemical manufacturers to conduct hazard classifications? Are the ranges listed in proposed paragraphs (i)(1)(iv)(A) through (M) too wide (should they be narrowed)? Should OSHA allow combinations among all ranges (*e.g.,* (i)(1)(v)(A) through (M)) or should the allowance for combining ranges be even more restrictive than proposed (*e.g.,* (i)(1)(v)(A) through (E))?

OSHA is also proposing other changes in paragraph (i) to reflect the proposal to permit concentration ranges to be claimed as trade secrets and to adopt the ''PLHCP'' terminology in lieu of references to ''physician or nurse.'' See discussion of proposed changes to paragraph (c), Definitions, where OSHA explains that it is proposing to replace the phrase ''physician and nurse'' with ''PLHCP'' to be consistent with other OSHA standards and to better reflect current medical practices. The specific changes OSHA is proposing are as follows:

- OSHA is proposing to revise paragraph (i)(1)(iii) to change ''percentage'' to ''concentration or concentration range.''
- OSHA is proposing to move existing paragraph (i)(1)(iv) to paragraph (i)(1)(vi) and to change ''percentage'' to ''exact concentration or concentration range.''
- In paragraph (i)(2), OSHA is proposing to change ''physician or nurse'' to ''PLHCP'' and to replace ''percentage of composition'' with ''concentration or concentration range.''
- OSHA is proposing to revise paragraph (i)(3) to change ''percentage composition'' to ''exact concentration or concentration range'' and to change the parenthetical from ''(*i.e.,* physician, industrial hygienist, toxicologist, epidemiologist, or occupational health nurse)'' to ''(*e.g.,* PLHCP, industrial hygienist, toxicologist, or epidemiologist).''

Paragraph (j) Dates

OSHA is proposing to implement the revised provisions over a two-year phase-in period. OSHA proposes that the revisions become effective 60 days after the publication date (paragraph (j)(1)) and that chemical manufacturers, importers, and distributors evaluating substances comply with all modified provisions of the HCS no later than one year after the effective date (paragraph (j)(2)). OSHA also proposes that chemical manufacturers, importers, and distributors evaluating mixtures comply with all modified provisions no later than two years after the effective date (paragraph (j)(3)).

Proposed paragraph (j) would replace the regulatory text currently in paragraph (j), as the dates specified in existing paragraph (j) have all passed. This proposed paragraph is based in part on stakeholder comments and the agency's experience implementing the 2012 updates to the HCS. In 2012, OSHA did not stagger the compliance dates for substances and mixtures; however, OSHA believes that such a tiered approach may ease the compliance burden for manufacturers of mixtures that may rely on the hazard information in the SDSs from their ingredient suppliers to update the labels and SDSs for the mixtures. The changes OSHA is proposing in this update are far less complicated than the 2012 revision and would result in no change in hazard classification for the vast majority of chemicals. Additionally, the proposed update to paragraph (f)(11) addressing relabeling requirements for chemicals that have been released for shipment would also reduce the need for a lengthier implementation period. OSHA is requesting comments regarding the adequacy and appropriateness of the proposed compliance dates and on the feasibility of implementing a tiered compliance approach for substances and mixtures.

C. Appendix A

OSHA is proposing to update appendix A in several respects. The proposed changes are discussed in order of revisions to specific health hazards in appendix A, followed by general changes to definitions and terminology, clarification of mandatory requirements, and corrections. OSHA preliminarily concludes that all of the proposed changes to appendix A will improve classification and communication of hazards and thus better protect workers. Many of the proposed changes would align the HCS with the GHS Rev. 7. Aligning the HCS with the GHS would ease compliance burdens for U.S. stakeholders who must also comply with international requirements for hazard classification and communication.

OSHA is providing a redline strikeout version of appendix A, which reflects all of OSHA's proposed revisions, in the docket and on the OSHA website (OSHA HCS Redline, 2020, Document ID 0222; *https://www.osha.gov/dsg/hazcom/*). This will allow interested parties to view all of the proposed changes in context. OSHA strongly encourages stakeholders to review that document in conjunction with the discussion of the proposed revisions below, as the discussion below does not fully describe all of the non-substantive or editorial changes OSHA is proposing.

Revisions to Health Hazards in Appendix A

General Classification Considerations

In Paragraph A.0.1, OSHA proposes to add a note from Paragraph 1.3.3.1.3 of the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), providing that where impurities, additives, or individual constituents of a substance or mixture have been identified and are themselves classified, they should be taken into account during classification if they exceed the cut-off value/concentration limit for a given hazard class. OSHA did not include this note in the HCS in 2012 because the definition of ''substance'' in paragraph (c) references additives and impurities, and therefore the classification of substances necessarily takes impurities and additives into account. Nonetheless, the agency now believes that this note is useful to align with the GHS and has added this note as proposed A.0.1.3. Including this provision would clarify that manufacturers and importers must consider the hazards of all classified components when classifying chemicals. This would help ensure accurate classification of chemicals and therefore improve protections for workers.

OSHA also proposes to modify the introduction of paragraph A.0.4.1 to include mandatory language. The current text indicates that the sequence in the process of classification of mixtures is recommended. OSHA proposes to revise A.0.4.1 to read ''Except as provided in A.0.4.2, the process of classification of mixtures is based on the following sequence'' to specify that this process is mandatory.

Acute Toxicity—(Appendix A.1)

In appendix A.1, OSHA proposes to revise the definition of acute toxicity to refer to serious adverse health effects (*i.e.,* lethality) occurring after a single or short-term oral, dermal, or inhalation exposure to a substance or mixture. (The current definition refers to adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours.) This change is being proposed to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2016, Document ID 0131).

OSHA also proposes to revise the classification criteria for substances in A.1.2.1 to note that while some *in vivo* methods determine LD_{50}/LC_{50} values directly, other newer *in vivo* methods (*e.g.,* using fewer animals) consider other indicators of acute toxicity, such as significant clinical signs of toxicity, which are used by reference to assign the hazard category. This change is being proposed to align with classification criteria in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2016, Document ID 0131).

OSHA is also proposing slight revisions to Table A.1.1, ''Acute toxicity hazard categories and acute toxicity estimate (ATE) values defining the respective categories'', to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2016, Document ID 0131). The GHS presents the ATE range in Table A.1.1 using the term ''ATE'' to express the range, while the HCS currently uses the term ''AND.'' Therefore, OSHA proposes to change the ''AND'' in the acute toxicity estimate (ATE) ranges to ''ATE'' to align with the GHS Rev. 7. This modification would not change the classification criteria itself, but would be more technically accurate and consistent with the way the table is expressed in the European Commission's (EC) Classification, Labelling, and Packaging of Substances and Mixtures (CLP) regulation (ECHA, 2017, Document ID 0256).

In paragraph A.1.2.3, OSHA proposes to include a new sentence at the end of the paragraph to clarify that both data from animal tests and human studies should be considered in evaluating acute toxicity. The new text states that in cases where data from human experience (*i.e.,* occupational data, data from accident databases, epidemiology studies, clinical reports) is also available, it should be considered in a weight of evidence approach consistent with the principles described in A.0.3. To ensure human data is considered in classifying chemicals for all acute toxicity hazard categories, the GHS added this clarifying text in paragraph 3.1.2.3 (UN GHS, 2016, Document ID 0131). OSHA is proposing these changes to paragraph A.1.2.3 to align with the GHS Rev. 7.

OSHA also proposes a new paragraph A.1.2.4, which is intended to correspond to Chapter 3.1, (paragraph 3.1.2.6.5) in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). This proposed paragraph would provide that in addition to classification for inhalation toxicity, if data are available that indicate that the mechanism of toxicity was corrosivity of the substance or mixture, the classifier must consider whether the chemical is corrosive to the respiratory tract. This proposed paragraph would clarify that the hazard *corrosive to the respiratory tract* is covered under the HCS. OSHA did not explicitly include the *corrosive to the respiratory tract* hazard in the HCS in 2012, but explained in OSHA 3844: *Hazard Communication: Hazard Classification Guidance for Manufacturers, Importers and Employers* (OSHA, 2016, Document 0008) that this hazard should be considered during classification. The Hazard Classification guidance explains that if the classifier has data indicating that there is acute inhalation toxicity with corrosion of the respiratory tract that leads to lethality, then the substance or mixture may be labeled with the additional hazard statement ''*corrosive to the respiratory tract.*'' However, if the classifier has data that indicates acute inhalation toxicity with corrosion of the respiratory tract and the effect does not lead to lethality, then the hazard may be addressed in the Specific Target Organ Toxicity hazard classes (see appendices A.8 and A.9). OSHA is including these clarifications in proposed A.1.2.4.1 and A.1.2.4.2, but is modifying the ''may'' language from the guidance to ''must'' language to ensure that *corrosive to the respiratory tract* is appropriately considered during the classification process.

In Figure A.1.1 and paragraph A.1.3.6.2.2, OSHA proposes to correct the cross-reference from A.1.3.6.2.3 to A.1.3.6.2.4. OSHA also proposes to amend paragraph A.1.3.6.2.3. If a mixture contains an ingredient of unknown acute toxicity at a concentration of at least 1 percent, paragraph A.1.3.6.2.3 currently requires a statement that ''X'' percent of a mixture consists of ingredient(s) of unknown toxicity on the label and SDS. OSHA proposes to revise this paragraph to require the statement to differentiate by route of exposure. For example, the statement(s) could read, ''x % of the mixture consists of ingredient(s) of unknown acute oral toxicity'' or ''x % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.'' Given that it is possible to have unknown ingredients for more than one relevant route of exposure (*e.g.,* oral, dermal, inhalation), differentiating the statement by route would be helpful to chemical users. This proposed change would align with paragraph 3.1.3.6.2.2 in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2010, Document 0089).

OSHA also proposes to delete the second paragraph in A.1.3.6.2.3 because it is duplicative of the first paragraph.

Skin Corrosion/Irritation and Serious Eye Damage/Eye Irritation—(Appendices A.2 and A.3)

OSHA is proposing more extensive revisions to the sections on skin corrosion/irritation and serious eye

damage/irritation (appendices A.2 and A.3) than it is proposing for the other health hazard sections in appendix A of the HCS. These two sections correspond to Chapters 3.2 and 3.3 in the GHS. The UNSCEGHS, in its 16th Session, assembled an informal working group to review the content of Chapters 3.2 and 3.3 in the GHS, and to propose editorial revisions in order to enhance clarity and user-friendliness in the application of the criteria (UN GHS, 2016, Document 0131). The group's primary focus was to change the order of the text to ensure that the classification strategy was clear, and to change the testing scheme to more of an evaluation scheme, since the GHS, like the HCS, is test method neutral. The work of the informal working group was not complete before OSHA published its updates to the HCS in 2012. The working group has since completed its efforts to clarify the skin corrosion/irritation and serious eye damage/irritation chapters. The work was approved by the UNSCEGHS in 2012 (UN GHS, 2012, Document ID 0212). Accordingly, OSHA is now proposing to revise appendices A.2 and A.3 to incorporate all of the modifications that were made to the GHS skin corrosion/irritation and serious eye damage/irritation chapters agreed to by the UNSCEGHS up to and including the GHS Rev. 7. This would ensure that OSHA remains aligned with the GHS. OSHA is not proposing any completely new provisions for the HCS; however, OSHA is proposing to revise the two appendices to align the language and format of the HCS with the GHS Rev. 7.

In appendix A.2, skin corrosion/irritation, OSHA proposes to modify paragraph A.2.1.2 to clarify the sequence in which data should be evaluated when classifying for skin corrosion/irritation using a tiered evaluation approach. The proposal would align the language in this paragraph with the tiered approach in Figure A.2.1. The first tier is existing human data, followed by existing animal data, followed by *in vitro* data, and then other sources of information.

The proposed changes to the skin corrosion/irritation criteria in paragraph A.2.2 are mainly editorial in nature. The classification criteria would remain the same, but the presentation of the information would be rearranged in a clearer, more logical fashion. In addition, OSHA is proposing new paragraph A.2.2.2.2, which is intended to provide classifiers with factors to be taken into consideration when evaluating irritant responses.

The proposed changes in paragraph A.2.3 are also mainly editorial in nature. The criteria would remain the same, but clarifying text would be introduced into the section and the criteria would be presented in a more logical sequence.

OSHA also proposes to include a new note to Table A.2.3, ''Concentration of ingredients of a mixture classified as skin Category 1 or 2 that would trigger classification of the mixture as hazardous to skin (Category 1 or 2),'' to indicate how to classify the mixture when data are available for sub-categorization of Category 1. The proposed note would align with the note to Table 3.2.3 in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0132), and OSHA believes that it provides useful information for classifiers.

Figure A.2.1, ''Tiered evaluation of skin corrosion and irritation potential'', would remain largely the same under OSHA's proposed revisions to the appendix. However, OSHA is proposing to revise the title to ''Tiered evaluation for skin corrosion and irritation.'' OSHA is also proposing to revise Steps 1a, 1b, and 1c of Figure A.2.1 to clarify that the parameter being evaluated is existing human or animal skin corrosion/irritation data. In addition, OSHA is proposing to modify the finding in Step 4 to clarify that high acid/alkaline reserve or no data for acid/alkaline reserve should be considered when the pH is ≤2 or ≥11.5. OSHA is also proposing some revisions to the footnotes of Figure A.2.1.

- In proposed footnote (1), OSHA is proposing to revise the current footnote to include an additional sentence indicating that although human data from accident or poison center databases can provide evidence for classification, absence of incidents is not itself evidence for a not classified determination. In addition, the reference to evidence from ethically-conducted human clinical studies would be removed. The text indicating that there is no internationally accepted test method for human skin irritation testing would also be removed.
- In proposed footnote (3), OSHA is proposing to revise the existing note to exclude the examples currently provided.
- In proposed footnote (6), OSHA is proposing to revise the current note to clarify that all available information on a substance *must* (instead of *should*) be considered in making a determination based on the total weight of evidence. OSHA is also proposing a new sentence at the end of the footnote to indicate that negative results from applicable validated skin corrosion/irritation *in vitro* tests are considered in the total weight of evidence evaluation.

In paragraph A.2.4, OSHA is proposing to include in A.2.4.1.1 language stating that the tiered approach must be taken into account when evaluating mixtures. In addition, a new paragraph A.2.4.1.2 is proposed to indicate that when considering testing of mixtures, classifiers must use the tiered approach to help ensure an accurate classification, as well as to avoid unnecessary animal testing. This proposed paragraph also indicates that if there are no other data on the mixture besides pH, and the pH is extreme (pH ≤2 or pH ≥11.5), that information is sufficient to classify the mixture as corrosive to the skin. However, if the acid/alkaline reserve suggests that the mixture may not be corrosive despite the extreme pH, then further evaluation may be necessary.

In Table A.2.4, ''Concentration of ingredients of a mixture for which the additivity approach does not apply, that would trigger classification of the mixture as hazardous to skin,'' OSHA proposes to delete the phrase ''for which additivity does not apply'' where it appears in the text of the table in order to reduce redundancy, as that language is already included in the title of the table. However, OSHA is proposing to modify the title of Table A.2.4 from ''for which additivity does not apply'' to ''when additivity does not apply'' to be consistent with the GHS Rev.7 (UN GHS, 2017, Document ID 0060).

In appendix A.3, serious eye damage/eye irritation, OSHA proposes to modify A.3.1.2 to clarify the sequence in which data should be evaluated when classifying for serious eye damage/eye irritation using a tiered evaluation approach. The proposal would align the language in this paragraph with the tiered approach in Figure A.3.1. The first tier is existing human data, followed by existing animal data, followed by *in vitro* data, and then other sources of information.

The changes OSHA is proposing in paragraphs A.3.2 and A.3.3, including Tables A.3.1 and A.3.2, are mainly editorial in nature. The classification criteria in these paragraphs would remain the same, but the presentation of the information would be rearranged and additional headings would be included to provide a clearer, more logical sequence. All of these proposed changes would conform with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document 0132).

Proposed paragraph A.3.2 provides a summary of the classification criteria for substances that is provided in Tables A.3.1 and A.3.2. In addition, proposed paragraph A.3.3.6 is a reorganization of existing paragraphs A.3.3.3 and A.3.3.4.

It would provide guidance on using the tiered approach and making weight of evidence decisions and also indicates a preference for not conducting new animal tests.

Under OSHA's proposed revisions, Figure A.3.1, ''Tiered Evaluation for serious eye damage and eye irritation'', currently titled ''Evaluation strategy for serious eye damage and eye irritation'', would remain largely the same. However, as in Figure A.2.1, OSHA is proposing to revise Steps 1a, 1b, and 1c to clarify that the parameter being evaluated is existing human or animal serious eye damage/eye irritation data. In addition, OSHA is proposing to modify the finding in Step 4 to clarify that high acid/alkaline reserve or no data for acid/alkaline reserve should be considered when the pH is ≤2 or ≥11.5. OSHA is also proposing modifications to the footnotes of Figure A.3.1 to reflect the most recent test methods.

- In proposed footnote (3), OSHA is proposing to include an additional sentence that emphasizes that expert judgement should be exercised when making determinations from existing animal data indicating serious eye damage/eye irritation, as not all skin irritants are eye irritants.
- In proposed footnote (4), OSHA is proposing to include OECD Test Guideline 460 (Fluorescein leakage (FL) as an additional example of an internationally accepted, scientifically validated test method for identifying eye corrosives and severe irritants. OSHA is also proposing an additional sentence for this footnote to indicate that there are presently no scientifically validated and internationally accepted *in vitro* test methods for identifying eye irritation.
- In proposed footnote (6), OSHA is proposing to revise existing language to make it clear that all available information on a substance *must* (instead of *should*) be considered in making a determination based on the total weight of evidence. In addition, OSHA is proposing to add two new sentences at the end of the footnote to indicate that the total weight of evidence, including information on skin irritation, may lead to classification for eye irritation and that negative results from applicable scientifically validated *in vitro* tests are considered in the total weight of evidence evaluation.

In paragraph A.3.4, OSHA is proposing several minor editorial changes to ensure consistency in the terminology used. For example, OSHA is proposing to use the term ''serious eye damage'' (rather than ''eye corrosion'') throughout the text to reflect the name of the hazard class.

Germ Cell Mutagenicity—(Appendix A.5)

OSHA is proposing to add a definition for germ cell mutagenicity in A.5.1.1 explaining that germ cell mutagenicity refers to heritable gene mutations, including heritable structural and numerical chromosome aberrations in germ cells occurring after exposure to a substance or mixture. OSHA is proposing this definition to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2016, Document ID 0131). Because of this new paragraph, the subsequent numbering of existing paragraphs in A.5.1 would be adjusted accordingly.

In A.5.4, *Examples of scientifically validated test methods*, paragraph A.5.4.2, OSHA proposes to delete the Mouse spot test (OECD 484) as an example of an *in vivo* somatic cell mutagenicity test, as it was deleted by the OECD on April 2, 2014. This change is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2014, Document 0087) and ensures that hazard classifications are being conducted with the most current scientific principles.

Reproductive Toxicity—(Appendix A.7)

In appendix A.7, Reproductive toxicity, OSHA proposes to revise the ''effects on or via lactation'' hazard category classification criteria to align with OSHA publication 3844 *Hazard Classification Guidance for Manufacturers, Importers and Employers* (OSHA 3844, 2016, Document 0008). During the development of the guidance document, it became apparent to OSHA that there were issues with regard to the classification criteria in existing Figure A.7.1(b). The hazard category for effects on or via lactation captures two separate effects:

i. Substances that can interfere with lactation; and

ii. substances and their metabolites that may be transmitted through breast milk to children in amounts sufficient to cause concern for the health of the breast feeding child.

However, the current criteria do not adequately distinguish between these two separate effects. The first issue has both grammatical and substantive aspects and is found in the second sentence of Figure A.7.1(b), which currently reads:

''Chemicals that are absorbed by women and have been shown to interfere with lactation or that may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child, shall be classified to indicate *this property hazardous to breastfed babies*.''

The italicized phrase is not grammatically correct and is also not correct as a matter of substance because it ignores the effects on lactation. As such, OSHA proposes to delete the text to indicate this property ''hazardous to breastfed babies.'' In addition, the categories of evidence currently listed in paragraphs (a) through (c) of Figure A.7.1(b) all provide evidence for effects *via* lactation rather than effects *on* lactation. To be more accurate, and to avoid confusion on how to apply the criteria for effects on lactation, OSHA proposes to modify the third sentence in the Figure to read: ''Classification for effects via lactation shall be assigned on the basis of:'' These proposed changes would not affect the classification of substances or mixtures as reproductive toxicants; however, they would be more accurate and provide more clarity for classifiers.

OSHA proposes to modify paragraph A.7.2.5.1 to include OECD Test Guideline 443, *Extended One Generation Reproductive Toxicity Study*, as an additional method for one or two generation toxicity testing. Additionally, in Table A.7.1 ''Cut-off values/concentration limits of ingredients of a mixture classified as reproductive toxicants or for effects on or via lactation that trigger classification of the mixture'', OSHA is proposing a correction to the top left heading from ''ingredients classified as'' to ''ingredient classified as.'' OSHA believes that the use of the word ''ingredients'' in this context may be confusing, as it may suggest that the additivity principle should be applied. Therefore, OSHA is proposing this change for clarity. These proposed modifications in appendix A.7 are consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2014, Document ID 0221).

Specific Target Organ Toxicity-Single Exposure—(Appendix A.8)

In appendix A.8, OSHA proposes to make a correction to paragraph A.8.1.6 to correctly name the hazard class as ''specific target organ toxicity—single exposure'' instead of ''specific organ systemic toxicity single exposure.'' Also, in paragraph A.8.2.1.7.3, OSHA proposes to delete the erroneous inclusion of the second use of the word ''evidence'' in the second sentence.

OSHA proposes to include the concept of ''relevant ingredient'' when classifying mixtures containing Category 3 ingredients using the additivity approach. Under the HCS, as updated in

2012, the additivity principle was introduced in paragraph A.8.3.4.5. However, a ''relevant ingredient'' for this procedure had not been established. Proposed new paragraph A.8.3.4.6 would provide that in cases where the additivity approach is used for Category 3 ingredients, the ''relevant ingredients'' of a mixture are those which are present in concentrations ≥1% (w/w for solids, liquids, dusts, mists, and vapors and v/v for gases), unless there is a reason to suspect that an ingredient present at a concentration <1% is still relevant when classifying the mixture for respiratory tract irritation or narcotic effects. This proposed paragraph would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2014, Document 0221).

Aspiration Hazard—(Appendix A.10)

The proposed changes to appendix A.10 would provide clarification on the classification criteria for mixtures when data are available for all ingredients or only for some ingredients. OSHA is proposing new paragraph A.10.3.3.1 to clarify that the concept of ''relevant ingredient'' applies and that relevant ingredients are those that are present in concentrations of at least 1%. In addition, a new heading, ''Category 1,'' is proposed as new paragraph A.10.3.3.2. Proposed A.10.3.3.2.1 and A.10.3.3.2.2 would clarify that the principle of additivity applies in appendix A.10, but OSHA is not proposing any substantive changes to the classification criteria. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2014, Document 0221).

Changes to Definitions and Terminology, Clarification of Mandatory Requirements, and Corrections

Definitions

OSHA proposes to update appendix A to include changes to the health hazard definitions to reflect those adopted by the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2016, Document ID 0131). Since OSHA revised the HCS in 2012, the UNSCEGHS has revised all of the health hazard definitions in the GHS. These modifications to the health hazard definitions were incorporated as a result of the work of the UNSCEGHS Practical Classification Issues working group. The scope of the working group is to clarify the GHS classification criteria, as appropriate, and to provide working examples to illustrate application of the criteria. The previous health hazard definitions were not consistent with respect to form or content, and many of the definitions were taken directly from the OECD test guidelines.

The UNSCEGHS determined that the definitions should be more general and neutral with respect to test guidelines and that test guideline criteria should not be part of a definition. The group also determined that the health hazard definitions should be clear and concise and that there should be a clear differentiation between ''definitions'' and ''general considerations'' text. OSHA is proposing to adopt all of the revised health hazard definitions from the GHS Rev. 7 in appendix A, as well as corresponding changes to text throughout the appendix. For example, in some cases OSHA is proposing to remove OECD test guidelines from definitions and to move them to paragraphs outlining classification criteria. The health hazard definitions that OSHA is proposing in appendix A are:

- Acute toxicity refers to serious adverse health effects (*i.e.,* lethality) occurring after a single or short-term oral, dermal, or inhalation exposure to a substance or mixture.
- Skin corrosion refers to the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis occurring after exposure to a substance or mixture.
- Skin irritation refers to the production of reversible damage to the skin occurring after exposure to a substance or mixture.
- Serious eye damage refers to the production of tissue damage in the eye, or serious physical decay of vision, which is not fully reversible, occurring after exposure of the eye to a substance or mixture.
- Eye irritation refers to the production of changes in the eye, which are fully reversible, occurring after exposure of the eye to a substance or mixture.
- Respiratory sensitization refers to hypersensitivity of the airways occurring after inhalation of a substance or mixture.
- Skin sensitization refers to an allergic response occurring after skin contact with a substance or mixture.
- Germ cell mutagenicity refers to heritable gene mutations, including heritable structural and numerical chromosome aberrations in germ cells occurring after exposure to a substance or mixture.
- Carcinogenicity refers to the induction of cancer or an increase in the incidence of cancer occurring after exposure to a substance or mixture.
- Reproductive toxicity refers to *adverse effects on sexual function and fertility* in adult males and females, as well as developmental toxicity in the offspring, occurring after exposure to a substance or mixture.
- Specific target organ toxicity-single exposure (STOT–SE) refers to specific, non-lethal toxic effects on target organs occurring after a single exposure to a substance or mixture.
- Specific target organ toxicity-repeated exposure (STOT–RE) refers to specific toxic effects on target organs occurring after repeated exposure to a substance or mixture.
- Aspiration hazard refers to severe acute effects such as chemical pneumonia, pulmonary injury or death occurring after aspiration of a substance or mixture.
- Aspiration means the entry of a liquid or solid chemical directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system.

Terminology Issues

The HCS is currently somewhat inconsistent in the way the terms ''hazard category'' and ''toxicity category'' are used throughout appendix A. In some cases the terms are used interchangeably, while in other instances the terms are intended to have different meanings. OSHA has reviewed appendix A and is proposing revisions to ensure that these terms are used appropriately and consistently. As such, OSHA proposes to delete the term ''toxicity category'' and replace it with ''hazard category'' in various places, including paragraphs A.0.5, A.1, A.8, A.9, and A.10. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document 0084).

Mandatory Language

OSHA is proposing to update a number of provisions in appendix A to make it clear that those provisions are mandatory. For example, OSHA proposes to change the term ''should'' to ''must'' in paragraph A.3.4.3.3. The change would clarify that the cut-off value/concentrations in Table A.3.3 are mandatory when determining if a mixture must be classified as seriously damaging to the eye or an eye irritant.

Corrections

OSHA proposes to correct a few errors that currently exist in the HCS. OSHA erroneously did not include appendix A.4, respiratory or skin sensitization, in the list of health hazards referenced in the ''concentration of mixtures'' paragraph at A.0.5.1.3. OSHA proposes

to add a reference to appendix A.4 in paragraph A.0.5.1.3 to clarify that the concentration of mixtures bridging principle applies to respiratory and skin sensitization. Similarly, appendix A.4 was also erroneously excluded from the list of health hazards referenced in the ''interpolation within one toxicity category'' paragraph at A.0.5.1.4. Thus, OSHA also proposes to add a reference to appendix A.4 in paragraph A.0.5.1.4 to clarify that the interpolation bridging principle applies to respiratory and skin sensitization. In addition, OSHA proposes to correct the cross-reference from A.1.3.6.2.3 to A.1.3.6.2.4 in Figure A.1.1 and paragraph A.1.3.6.2.2.

D. Appendix B

OSHA is proposing a number of changes to appendix B. First, since the HCS was aligned with the GHS in 2012, new physical hazard classes or hazard categories have been added to the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). OSHA proposes to adopt those additions. Second, the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) contains several updates to consensus standards and testing methods. Although the HCS does not require testing and permits classifiers to use data from literature or experience for classification purposes, OSHA is proposing to update consensus standards and testing methods referenced in appendix B in accordance with the GHS Rev. 7 to ensure that data considered for classification incorporate updated scientific principles. Third, OSHA is proposing certain corrections and clarifications to appendix B to address (1) previous inadvertent omissions from the GHS or the HCS; (2) changes made to the GHS to improve clarity or technical accuracy; and (3) how some hazard classes should be evaluated in light of the addition of new hazard classes in the GHS. These proposed changes are discussed below and would align the HCS with the GHS while improving the classification and communication of hazards [59] and maintaining or enhancing worker safety and health. Additionally, as noted elsewhere, aligning the HCS with the GHS would ease compliance burdens for U.S. stakeholders that must also comply with international requirements for hazard classification and communication.

OSHA is also proposing to make a limited number of changes to appendix B that arise out of its implementation of the HCS, as updated in 2012. These changes, explained below, would clarify compliance requirements. OSHA believes that all of these proposed changes maintain existing safety and health protections while easing or having no effect on the compliance burdens for regulated entities.

Finally, OSHA explains below that it is not proposing to incorporate one update reflected in the GHS Rev. 7 because that particular update is inconsistent with the scope of the HCS.

OSHA is providing a redline strike out version of appendix B, which reflects all of OSHA's proposed revisions, in the docket and on the OSHA website (OSHA, 2020, Document ID 0222; *https://www.osha.gov/dsg/hazcom*). This will allow interested parties to view all of the proposed changes in context. OSHA strongly encourages stakeholders to review that document in conjunction with the discussion of the proposed revisions below, as the discussion below does not fully describe all of the non-substantive or editorial changes OSHA is proposing.

Explosives—(Appendix B.1)

OSHA is proposing a few minor amendments to appendix B.1, Explosives. The first change that OSHA is proposing involves a clarification to the classification criteria for Division 1.6 explosives in B.1.2(f). Under the GHS Rev. 3, one of the criteria for classification of an article [OSHA uses the term ''item'' in the HCS] as a Division 1.6 explosive is that it contains ''only'' extremely insensitive detonating chemicals (UN GHS, 2009, Document ID 0085). The GHS Rev. 7 (UN GHS, 2017, Document ID 0060) states that the criteria is met if the article [''item'' in the HCS] ''predominantly'' contains extremely insensitive detonating chemicals. OSHA is proposing to make the same change to paragraph B.1.2(f) of appendix B in the HCS. Changing the criteria from containing ''only'' extremely insensitive detonating chemicals to ''predominantly'' containing extremely insensitive detonating chemicals is more technically accurate and better aligns with the guidance in test series 7 in the UN Manual of Tests and Criteria (UN TDG, 2016, Document ID 0151). OSHA believes that consistency in the use of terms will reduce confusion for chemical manufacturers or importers when classifying explosives.

OSHA is also proposing to add two notes from the GHS (UN GHS, 2017, Document ID 0060) to appendix B, paragraph B.1.3.1, that are related to the addition of the desensitized explosives hazards class (proposed appendix B.17), which is discussed later in this document. The first new note OSHA is proposing to add (Note 2) would provide that explosives for which explosive properties have been suppressed or reduced must be classified as desensitized explosives. The second new note OSHA proposes (Note 3) would provide that some chemicals that are exempt from classification as explosives under UN Recommendations on the Transport of Dangerous Goods guidelines still have explosive properties, which must be communicated in section 2 (Hazard identification) and section 9 (Physical and chemical properties) of the SDS, as appropriate. The notes would be incorporated in the HCS with edits to change these provisions from recommendations in the GHS to requirements in the HCS (*e.g.,* ''may be a candidate for classification as'' in the GHS would be revised to ''shall be classified as'' in the HCS) and to revise the GHS terminology to terminology more appropriate for the HCS (*e.g.,* ''substances and mixtures'' in the GHS would be revised to. ''chemicals'' in the HCS).

Flammable Gases—(Appendix B.2.)

OSHA is proposing several changes to the Flammable Gases hazard class (appendix B.2). Most significantly, OSHA is proposing to subdivide Category 1 of this class into two subcategories, 1A and 1B, and to specify that pyrophoric gases and chemically unstable gases are to be classified as Category 1A. These proposed changes would provide more detailed information about the flammable gas hazards and track changes made in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) since OSHA updated the HCS in 2012. These proposed changes would allow downstream users to have a better understanding of the severity of the hazards associated with flammable gases. Downstream users could then use this information to take appropriate precautions or determine if a substitute chemical is less hazardous.

The HCS currently lists two categories for flammable gases—Category 1 (Extremely flammable) and Category 2 (flammable)—that are based on the percentage of the gas in a mixture with air that is ignitable and on ranges of flammability in air. In practice, with the current criteria, almost all flammable gases (except ammonia and methyl bromide, which are treated separately) are classified as Category 1. This means that, for hazard identification and communication purposes, no distinctions are being drawn between gases that exhibit a wide spectrum of flammable properties. OSHA has preliminarily concluded that Category 1

[59] Specific changes to the hazard and precautionary statements are discussed below in the section on appendix C.

is too broad and can lead downstream users to choose a chemical without realizing that an alternative choice is actually less flammable. For example, 2,3,3,3-Tetrafluoropropene is a non-ozone depleting refrigerant which ignites less rapidly or violently than some other flammable gases. Many of these types of gases were developed as a result of the Montreal and Kyoto protocols, international treaties intended to phase out gases that are ozone depleting (UN GHS, 2016, Document ID 0138). However, with the current classification system, propane, which has a rapid, explosive ignition with a burn velocity of 46 cm/s, and 2,3,3,3-Tetrafluoropropene (R–1234yf), which has a slow, weak ignition, with a burn velocity of 1.5 cm/s, would both be classified as Category 1 gases, thus making it appear that the two gases are equally flammable when in fact 2,3,3,3-Tetrafluoropropene is considerably less flammable (UN GHS, 2016, Document ID 0138).

OSHA and DOT actively participated in the UN negotiations (joint informal working group) in 2015 to ensure that flammable gases are properly evaluated, classified and communicated. The joint informal working group activities included identifying, gathering, and reviewing data on ''less flammable'' gases, including the conduct of numerous burning velocity tests using approved test methods, as well as tests to demonstrate ignition behavior, flame propagation, and the speed of the flame front (UN GHS, 2016, Document ID 0254).

The revised classification criteria in Table 2.2.1 in Chapter 2.2 of the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) reflect recommendations made by the joint informal working group. The joint informal working group agreed that all flammable gases currently classified as Category 1 flammable gases should remain so. This decision allows the transport classification and communication scheme to remain the same. However, the joint informal working group agreed that Category 1 should be separated into two sub-categories, Category 1A and Category 1B, when data is available on burning velocity and lower flammability limit. This separation allows for more precise classification of chemicals and more appropriate communication of the hazards associated with flammable gases.

This proposed approach for classifying flammable gases is also consistent with the approach described in ANSI/ASHRAE Standard 34–2013—Designation and Safety Classification of Refrigerants (ANSI/ASHRAE, 2013, Document ID 0160). The ANSI/ASHRAE standard allows refrigerant gases (which can be category 1A or 1B) to be classified based on both the lower flammability limit and burning velocity (see Figure 6.1.4 and Section 6.1.3.2.1 (ANSI/ASHRAE, 2013, Document ID 0160). OSHA's proposed cut-off for the burning velocity for category 1A and 1B chemicals is the same as that in the ASHRAE standard. Therefore, the proposed approach is consistent with accepted scientific principles and industry norms.

OSHA has preliminary concluded that the classification scheme in Table 2.2.1 of the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) maintains safety for workers while allowing for more precise hazard classification and communication. Therefore, OSHA is proposing to replace Table B.2.1 of the HCS with the criteria from Table 2.2.1 in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). The only modification that OSHA proposes making to the GHS Table 2.2.1 is to add units of measurement used in the United States (*e.g.,* degrees Fahrenheit). Under the proposed new table, all flammable gases that are currently classified as Category 1 flammable gases would be classified as Category 1A, unless data on flammability limit or fundamental burning velocity indicates that the gas should be classified as Category 1B. For a gas to be classified in Category 1B, data would have to show that its lower flammability limit is more than 6% by volume in air or its fundamental burning velocity is less than 10 cm/s; in addition, the gas could not be either pyrophoric or chemically unstable. Since the HCS does not require testing, the data required to classify a gas as a Category 1B flammable gas could be obtained from literature. However, if data is lacking in the literature, then testing would be necessary to establish that a newly-developed flammable gas qualifies for classification as a Category 1B flammable gas. The joint informal working group compiled a list of data available on burning velocity and flammability limits for pure flammable gases (OSHA, 2017, Document ID 0164).

When OSHA revised the HCS in 2012, pyrophoric gases were not classified under the GHS, Rev. 3 (UN GHS, 2009, Document ID 0085). Therefore, to ensure that the hazards of pyrophoric gases would continue to be covered and communicated, OSHA maintained the approach taken in the HCS starting in 1994. This involved addressing pyrophoric gases under the definition of ''hazardous chemical'' and maintaining a definition for ''pyrophoric gas'' in paragraph (c) of the HCS (77 FR 17704). While OSHA retained the definition for ''pyrophoric gas'' when it updated the HCS in 2012, the agency explained it also intended to continue to work with the UNSCEGHS to add the pyrophoric gas hazard to the GHS, along with two other hazards that OSHA covered under the HCS but that were not classified under the GHS: Simple asphyxiants and combustible dust (77 FR 17704). Since OSHA revised the HCS in 2012, the UNSCEGHS updated the criteria for flammable gases to include pyrophoric gases (UN GHS, 2014, Document ID 0086; UN GHS, 2017, Document ID 0060). The UNSCEGHS agreed that pyrophoric gases, as well as chemically unstable gases, should always be classified as Category 1A flammable gases because of the nature of these two types of gases; pyrophoric gases ignite spontaneously in air at temperatures of 54 °C (130 °F) or below, and chemically unstable gases are able to react explosively even in the absence of air or oxygen. Under the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), pyrophoric gases and chemically unstable gases are both classified as Category 1A. OSHA preliminarily agrees with this decision and proposes incorporating it into appendix B.2.

If, as proposed, OSHA adds pyrophoric gases as a sub-category of flammable gases in appendix B.2, and, as proposed, includes a definition of pyrophoric gas in appendix B.2., it would no longer be necessary to include these gases as part of the definition of ''hazardous chemical'' or to include a definition for ''pyrophoric gas'' in § 1910.1200(c). Therefore, OSHA proposes to delete those terms in § 1910.1200(c). OSHA also proposes to incorporate the definition of ''pyrophoric gas'' found in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), in paragraph B.2.1. OSHA currently defines pyrophoric gas as a chemical in the gaseous state that ''will ignite'' spontaneously in air at a temperature of 130 °F (54.4 °C) or below. The GHS Rev. 7 defines a pyrophoric gas as a flammable gas that is ''liable to ignite'' spontaneously in air at a temperature of 54 °C (130 °F) or below (UN GHS, 2017, Document ID 0060). The change in the definition from a gas that ''will ignite'' to a gas that is ''liable to ignite'' was made because some pyrophoric gases may have a delayed ignition time (UN GHS, 2013, Document ID 0086). OSHA preliminarily finds the term ''liable to ignite'' to be more accurate, from a technical perspective. OSHA does not believe that these changes would have a significant impact on the scope of

gases considered pyrophoric gases, nor does OSHA expect that chemical manufacturers or importers would need to reclassify chemicals due to these changes.

As noted above, OSHA proposes adding a new sub-category for chemically unstable gases to the flammable gases hazard class to allow for more accurate communication of the hazards associated with those gases. OSHA proposes to adopt the GHS Rev. 7 definition of a chemically unstable gas, *i.e.,* a flammable gas that is able to react explosively even in the absence of air or oxygen (UN GHS, 2017, Document ID 0060), in paragraph B.2.1. Consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), under proposed Table B.2.1, a Category 1A chemically unstable gas would be further sub-characterized into one of two categories based on the temperature and pressure at which it becomes unstable. The proposed criteria for Category 1A/A chemically unstable gases are flammable gases which are chemically unstable at 20 °C (680 °F) and a standard pressure of 101.3 kPa (14.7 psi). The proposed criteria for Category 1A/B chemically unstable gases are flammable gases which are chemically unstable at a temperature greater than 20 °C (680 °F) and/or a pressure greater than 101.3 kPa (14.7 psi).

As chemically unstable gas is a subcategory of flammable gases, any chemical that meets the criteria for chemically unstable gas meets the current definition of flammable gas. While these hazards are currently classified in flammable gases under the HCS the UNSCEGHS noted that these gases exhibit slightly different behaviors and have the propensity to react dangerously even in the absence of any reaction partner (*e.g.,* air or oxygen) and should have different hazard communication elements (UN GHS, 2010, Document ID 0210). Types of flammable gases or gas mixtures that might be candidates for classification as chemically unstable are flammable gases with functional groups such as triple-bonds, adjacent or conjugated double-bonds, halogenated double-bonds, and strained rings (UN GHS, 2010, Document ID 0210). Because chemical manufacturers are currently classifying chemically unstable gases as flammable gases, OSHA does not consider these gases to be a new hazard. Instead, OSHA believes the addition of chemically unstable gases as a separate category in the appendix for flammable gases (appendix B.2) would improve the way the hazards of these gases are identified, evaluated, and communicated.

The GHS Rev. 7 (UN GHS, 2017, Document ID 0060) added three clarifying notes under Table 2.2.1 that were not included in the GHS Rev. 3 (UN GHS, 2009, Document ID 0085). The notes provide guidance on the classification of flammable gases under the new hazard categories. OSHA is proposing to add these notes to the HCS following Table B.2.1 (as new Note 2, Note 3, and Note 4) because they allow for better hazard classification.

The GHS Rev. 7, in Chapter 2.2.4.2, provides additional guidance on the classification of flammable gases, including the new hazard categories of pyrophoric gases, chemically unstable gases, and 1B flammable gases (UN GHS, 2017, Document ID 0060). It includes updated references to consensus standards and test methods (*i.e.,* ISO 10156:2010), and new references to consensus standards and test methods related to the new hazard categories (*i.e.,* ISO 817:2014, IEC 60079–20–1 ed1.0 (2010–01), or DIN 51794, and Part III of UN of the Manual of Tests and Criteria). OSHA proposes to adopt these changes in the HCS appendix B.2.3, with edits to make the GHS criteria mandatory (*i.e.,* changing ''should'' to ''shall''), to add U.S. units of measurement (*e.g.,* Fahrenheit), and to add statements that cited standards and test methods are incorporated by reference under 29 CFR 1910.6. This proposed modification would also align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). However, OSHA does not intend to require those already classified using an earlier version of ISO 10156, only those classifying new chemicals or chemicals not already classified. To incorporate this guidance from the GHS Chapter 2.2.4.2, OSHA is proposing edits to existing paragraph B.2.3. (B.2.3.1, as proposed) and new paragraphs B.2.3.2, B.2.3.3, and B.2.3.4.

Aerosols—(Appendix B.3)

OSHA is proposing to follow the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) by expanding the existing Flammable Aerosols hazard class (appendix B.3) to include non-flammable aerosols as well as flammable ones. Under the GHS Rev. 3 and the current HCS, Chapter 2.3 and appendix B.3, respectively, were titled ''Flammable Aerosols.'' Under the GHS Rev. 3, the hazards presented by non-flammable aerosols were either not classified at all or, more likely, were classified in another health hazard class or physical hazard class (*e.g.,* gases under pressure) (UN GHS, 2009, Document ID 0085). Flammable aerosols were likely to be classified as both flammable aerosols and gases under pressure.

OSHA believes that most aerosols are classified as gases under pressure under the GHS Rev. 3 (and accordingly under the existing HCS) because of the design criteria of the aerosols (ERG, 2015, Document ID 0163) under DOT regulations. Under DOT regulations, aerosols are non-refillable receptacles containing a gas compressed, liquefied, or dissolved under pressure, and the highest permissible pressure is 180 psig at 130 °F (see 49 CFR 171.8, 173.306). Accordingly, under DOT regulations, most aerosols meet the current HCS criteria for gases under pressure, which are gases contained in a receptacle at a pressure of 200 kPa (29 psi) or more, or which are liquefied or liquefied and refrigerated (see existing paragraph B.5.1 in appendix B.5). However, OSHA believes that classifying aerosols as gases under pressure may not accurately identify the hazards of aerosols because aerosol containers differ from pressurized gas cylinders in terms of container characteristics and failure mechanisms, as described further below.

Since the GHS Rev. 3 (UN GHS, 2009, Document ID 0085), the UNSCEGHS and the UN Sub-committee of Experts on the Transport of Dangerous Goods (UNSCETDG) agreed to rename Chapter 2.3 ''Aerosols'' and to add a new non-flammable aerosol hazard category, Category 3, to the aerosols hazard class (UN GHS, 2018, Document ID 0249). This hazard category captures aerosols that (1) contain 1% or less flammable components (by mass); and (2) have a heat of combustion that is less than 20 kJ/g.

Before proposing to adopt this category for non-flammable aerosols, OSHA reviewed the impact of this change to ensure that it would not compromise worker safety and health. OSHA assessed the hazards associated with aerosol containers and compressed gas cylinders. An ERG study evaluated how aerosol products and gases under pressure differ in terms of container characteristics, failure mechanisms, and previous incidents (ERG, 2015, Document ID 0009).

The ERG report concluded that sizes and pressures of compressed gas cylinders far exceed those of hand-held containers typically used for aerosol products (ERG, 2015, Document ID 0009). The report also noted differences in failure mechanisms for pressurized cylinders versus aerosols (ERG, 2015, Document ID 0009). As an example, increased temperatures can result in the release of container contents from the activation of pressure relief devices on

cylinders, whereas increased temperatures can result in the bursting of aerosol cans, which do not contain pressure relief devices. Also, hazards from falling cylinders include the release of contents following the valve breaking, the cylinder becoming a projectile or pinwheel, or the crushing of employees in the area; although aerosol containers can be damaged if they are dropped or punctured, they do not pose the same hazards as falling cylinders.

ERG reported that occupational incidents involving cylinders included explosions during high temperature activities (such as welding) and explosions resulting from mechanical deformation (*e.g.,* from falling cylinders), over-pressurization of cylinders (*e.g.,* from overfilling, which can result in a rupture of the cylinder), or leaks due to corrosion (ERG, 2015, Document ID 0009). Most incidents with aerosol cans involved explosions following heating or puncture of the can (ERG, 2015, Document ID 0009). The ERG report concluded that although non-flammable aerosol cans do not present a significant fire hazard, they can present a hazard from bursting resulting from thermal content expansion during heating. (ERG, 2015, Document ID 0009).

In addition to the ERG report, OSHA also considered data from the agency's Fatality and Catastrophe Information Summary (FatCat) database, located at *https://www.osha.gov/pls/imis/accidentsearch.html* (Document ID 0204), to evaluate the nature and severity of injuries and fatalities resulting from the use of aerosols and compressed gases. To determine if an incident was related to aerosols or compressed gas cylinders, OSHA searched for the keywords ''aerosol,'' ''spray,'' or ''foam'' (to identify aerosols), and the keywords ''compressed,'' ''cylinder,'' or ''CNG'' (to identify compressed gases). The data reviewed is available in the docket (OSHA, 2019, Document ID 0204).

From 1995 to 2014 there were more incidents related to the use of compressed gas cylinders than to the use of aerosol containers, but the percentage of the incidents that resulted in fatalities was similar (29% versus 28%, respectively). However, as explained below, fatalities are more likely to be associated with the container itself when compressed gas receptacles are in use as compared to situations involving aerosol containers. (OSHA, 2019, Document 0204).

Fatalities associated with use of compressed gas cylinders and aerosol containers primarily fall into three categories: (1) Incidents due to the contents of the container, such as flash fires or explosions; (2) incidents due to the container itself, such as incidents related to pressure, container failure, or ruptures; and (3) incidents unrelated to the use of the container, such as heart attacks or falls. A higher percentage of fatalities fell into the second category (incidents related to the container itself) for compressed gas cylinders (64% of the compressed gas cylinder fatalities) than for aerosol containers (17% of the aerosol fatalities). Conversely, a greater proportion of fatalities related to aerosols were attributed to reasons other than the container itself (83% for aerosol containers versus 36% for cylinders) (OSHA, 2019, Document ID 0204). This included fatalities related to the contents of the container and those in the third, ''miscellaneous,'' category (where the fatality could not be directly related to the use of the container, *e.g.,* situations such as heart attacks, falls, lack of training that occurred while employees were working with, or that generally related to, the use of aerosol or compressed gas cylinders) (OSHA, 2019, Document 0204). Thus, it appears that employees are at greater risk of a fatality due to the failure of the container if they are working with compressed gas cylinders than they are if they are working with aerosol cans.

Following a review of the data and the ERG report, OSHA preliminarily concludes that a new category for non-flammable aerosols is appropriate. OSHA believes this category would allow the hazards of non-flammable aerosols to be more appropriately classified and communicated, resulting in improved worker protection. The new hazard category would provide downstream users with more appropriate communication on the label by adding precautionary statements: *Keep away from heat, hot surfaces, sparks, open flames and other ignition sources; No smoking;* and *Do not pierce or burn, even after use* (see appendix C). Additionally, this new classification would ensure compressed gas pictograms are not included on aerosol labels, eliminating the risk of ''over warning'' about the hazards of aerosol containers (UN, 2010, Document ID 0095).

Specific changes OSHA is proposing include: Updating the aerosol hazard class to include non-flammable aerosols (hazard Category 3 in Table B.3.1), changing the name of appendix B.3 from ''Flammable Aerosols'' to ''Aerosols,'' replacing the phrase ''flammable aerosols'' with ''aerosols'' throughout appendix B.3, as appropriate, and adding clarifying information from the GHS Rev. 7 to paragraph B.3.2 (UN GHS, 2017, Document ID 0060). For example, OSHA is proposing to revise Note 2 to B.3.2.1 to explain that aerosols do not fall within the scope of gases under pressure, but may fall within the scope of other hazard classes. OSHA's preliminarily conclusion that aerosols (flammable and non-flammable) should not also be classified as gases under pressure would ensure that the appropriate hazard warnings are presented on aerosol containers.

OSHA is proposing to adopt the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) criteria for a non-flammable aerosol (*i.e.,* an aerosol that does not meet the criteria for Category 1 or 2, contains less than or equal to 1 percent flammable components (by mass), and has a heat of combustion less than 20 kJ/g), and to add those criteria as new Category 3 in Table B.3.1. This new category, Category 3, would update hazard communication requirements to better reflect the true hazards of non-flammable aerosols. This would result in changing the labeling for any such aerosols that are currently classified as compressed gases. In these situations, the ''gas cylinder'' pictogram would become unnecessary, as this hazard class would no longer be considered a compressed gas, the signal word ''danger'' would change to ''warning,'' due to the decreased hazard, and a hazard statement of ''contains gas under pressure; may explode if heated'' would change to ''pressurized container, may burst if heated'', which would more accurately reflect the hazards associated with this category (see proposed appendix C.4.16). As discussed above, OSHA believes that this approach would better differentiate between the hazards associated with compressed gases and the hazards associated with aerosols.

Oxidizing Gases—(Appendix B.4)

OSHA proposes to revise the note in B.4.1, and the text in the ''Additional classification considerations'' paragraph at B.4.3, to clarify that the provisions are referring to the most recent version of the ISO 10156 standard, (ISO, 10156, 2010). This proposed change would provide more clarity on the definition and classification of oxidizing gases and lead to more accurate classification and improved communication. This proposed modification would also align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). However, OSHA does not intend to require those already classified using an earlier version of ISO 10156, only those classifying new chemicals or chemicals not already classified.

Gases Under Pressure—(Appendix B.5)

OSHA is proposing to change the definition of gases under pressure in B.5.1 to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). OSHA proposes to add a temperature of 20 degrees Celsius (68 degrees Fahrenheit) to the definition so that the full definition would define gases under pressure as gases which are contained in a receptacle at a pressure of 200 kPa (29 psi) (gauge) or more at 20 °C (680 °F), or which are liquefied or liquefied and refrigerated. The change is intended to clarify that the pressure of the receptacle is measured at standard conditions. OSHA is also proposing to add a note to Table B.5.1 to clarify that aerosols should not be classified as gases under pressure. This proposed change is a consequence of OSHA's proposal to add a new hazard category for non-flammable aerosols, as discussed previously.

Flammable Liquids—(Appendix B.6)

OSHA is proposing to make three clarifying changes to the flammable liquid hazard class in appendix B.6. First, OSHA is proposing to add a reference to the Flammable Liquids standard, specifically 29 CFR 1910.106(a)(14), in paragraph B.6.3 in order to provide additional guidance about methods that can be used to determine flashpoint.

Second, after updating the HCS in 2012, OSHA realized there may be a concern with ensuring that information needed to determine the appropriate storage for flammable liquids is adequately documented on the SDS. Per 29 CFR 1910.106(a)(5), when an accurate boiling point is unavailable, or for mixtures which do not have a constant boiling point, the boiling point may be based on the 10% point of a distillation performed in accordance with the Standard Method of Test for Distillation of Petroleum Products, ASTM D–86–62. Together with an appropriately measured flash point, this boiling point can be used to categorize the mixture for use with Table H–12 in § 1910.106 to determine the maximum allowable container size and type. Use of a boiling point reported in section 9 of an SDS (physical properties), which is based on the ''first drop'' (or initial) distillation temperature in D–86, will likely be conservative, but may lead to more restrictive storage requirements than would be the case using the 10% distillation point (see appendix D, section 9(f)). OSHA is proposing to add a clarifying footnote to B.6.3 explaining that to determine the appropriate container size and container type for a flammable liquid, the boiling point must be determined by the methods specified under OSHA's Flammable Liquids standard (29 CFR 1910.106(a)(5)) and listed on the SDS. In addition, the proposed note would explain that the chemical manufacturer, importer, or distributor must clearly note on the SDS (in sections 7 and 9) if a calculation other than initial boiling point was used for storage purposes. OSHA did not intend for the updated HCS classification requirements for flammable liquids to impact the longstanding storage requirements under 29 CFR 1910.106 and views this proposed note as a method to ensure that the proper container size and type will be used for storing flammable liquids and that all necessary information is appropriately communicated on the SDS. OSHA is not proposing any changes to the classification criteria for flammable liquids under the HCS. OSHA is requesting comments on whether a footnote like the one proposed for B.6.3 should also be inserted in appendix D, section 9.

Finally, OSHA realized that a note regarding cross-classification of aerosols was inadvertently omitted from appendix B.6 (flammable liquids). In appendix B.3 (flammable aerosols), note 2 to the classification criteria currently indicates that ''[f]lammable aerosols do not fall additionally within the scope of flammable gases, flammable liquids, or flammable solids.'' The HCS currently contains a cross-referencing note in appendix B.2 (flammable gases), but OSHA inadvertently omitted the statement in appendix B.6 (flammable liquids). OSHA is therefore proposing to add a note stating that aerosols should not be classified as flammable liquids in appendix B.6, following Table B.6.1, for consistency and to minimize confusion. This would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060).

Flammable Solids—(Appendix B.7)

The only change proposed to appendix B. 7 (flammable solids) is a new note (Note 2) following Table B.7.1 stating that aerosols should not be classified as flammable solids. As with flammable liquids, the UNSCEGHS observed this omission in the flammable solids chapter, and the GHS Rev. 7 includes this note (UN GHS, 2017, Document ID 0060).

Self-Heating Chemicals—(Appendix B.11)

OSHA proposes adding a note to Table B.11.1. This proposed note would explain that classification of solid chemicals shall be based on tests performed on the chemical as presented. For example, if the chemical is presented for supply or transport in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form. Although this note was included in the GHS Rev. 3 (UN GHS, 2009, Document ID 0085), and incorporated into appendices B.1, B.7, B.10, B.12 and B.14 in the HCS in 2012, it was inadvertently omitted from appendix B.11. OSHA is proposing to add the note to be consistent with the GHS and the way the HCS treats other physical hazards.

Chemicals Which, in Contact With Water, Emit Flammable Gases—(Appendix B.12)

OSHA proposes to update the classification criteria for Category 3 of this hazard class in Table B.12.1. In the GHS Rev. 3 (UN GHS, 2009, Document ID 0085) and the existing HCS, one of the criteria for a Category 3 classification is that the maximum rate of evolution of the flammable gas is ''equal to or greater than 1 liter per kilogram of chemical per hour.'' However, this criteria does not accurately reflect the corresponding criteria in Test N.5 (test method for substances which, in contact with water, emit flammable gases) in Part III, sub-section 33.4.1.4.4.4 of the UN Manual of Tests and Criteria (UN TDG, 2016, Document ID 0151), which provides that the maximum rate of evolution of the flammable gas is *greater* than 1 liter per kilogram of chemical per hour. OSHA proposes to delete the words ''equal to or'' in the Category 3 criteria in Table B.12.1 to make the classification criteria consistent with the criteria in the test method. This will align the HCS with the GHS Rev.7 (UN GHS, 2017, Document ID 0060) and would not affect worker protections.

Oxidizing Solids—(Appendix B.14)

OSHA is proposing to add a second set of classification criteria to B.14.2 and to Table B.14.1.based on a new UN test method. Under the GHS Rev. 3 (UN GHS, 2009, Document, ID 0085), classification of oxidizing solids was based only on Test O.1 from Part III, sub-section 34.4.1 of the UN Manual of Tests and Criteria (UN TDG, 2016, Document ID 0151). This is reflected in the current HCS, appendix B.14. However, the test material used as the reference mixture in Test O.1 has been noted to pose a cancer hazard and is difficult to purchase. Therefore, a new test, Test O.3, Gravimetric tests for

oxidizing solids, has been added to Part III, sub-section 34.4.3 of the UN Manual of Tests and Criteria (UN TDG MTC, 2016, Document ID 0151). This new test underwent a thorough evaluation, including round robin testing, led by the UNSCETDG (UN SCETDG, 2016, Document ID 0150). Test O.3 uses a reference mixture of calcium peroxide and cellulose, whereas Test O.1 uses the reference substances potassium bromate and cellulose (UN TDG, 2016, Document ID 0165).

Consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), OSHA proposes to allow oxidizing solids to be classified using either Test O.1 or Test O.3. Since the proposed classification criteria would allow the use of data from either Test O.1 or O.3, data from existing classifications could be used and no new testing would be required for substances or mixtures that were previously classified based on Test O.1.

OSHA also proposes to update Note 1 to Table B.14.1 to reflect a 2017 revision to the International Maritime Solid Bulk Cargoes Code for testing of explosion hazards (IMSBC, 2017, Document ID 0141).

Corrosive to Metals—(Appendix B.16)

OSHA is not proposing to make any changes to appendix B.16, Corrosive to Metals. This is notable because OSHA has preliminarily decided not to adopt a note that was added in the GHS Rev. 7. Table 2.16.2 in Chapter 2.16 of the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) contains a note stating: ''Where a substance or mixture is classified as corrosive to metals but not corrosive to skin and/or eyes, some competent authorities may allow the labelling provisions described in 1.4.10.5.5.'' Chapter 1.4.10.5.5 contains labeling provisions that apply to ''substances or mixtures which are in the finished state as packaged for consumer use.'' OSHA has preliminarily concluded that the note in question, and the labeling provisions it refers to, are not applicable to the HCS because the HCS applies only to use of chemicals in the workplace, and not to consumer products (see 29 CFR 1910.1200(b)(5)(v)). Therefore, OSHA is not proposing to adopt the note found in Table 2.16.2 of Chapter 2.16 of the GHS Rev. 7.

Desensitized Explosives—(Appendix B.17)

OSHA is proposing to follow the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) by adding a new physical hazard class for desensitized explosives. Desensitized explosives are chemicals that are treated in such a way to stabilize the chemical or reduce or suppress its explosive properties. These types of chemicals can pose a hazard in the workplace when the stabilizer is removed, either as part of the normal work process or during storage of the chemical. Therefore, it is important that the hazards be identified and appropriately communicated.

In the HCS, as revised in 2012, OSHA acknowledged, consistent with the GHS Rev. 3 (UN GHS, 2009, Document ID 0085), that these chemicals are considered explosives if the wetting agent is removed, by including the precautionary statement ''keep wetted with'' and instructing the chemical manufacturer, importer, or distributor to specify appropriate material for wetting *if drying out increases the explosion hazard* (see existing appendix C at C.4.14). However, the hazard statement, signal word, pictogram and other precautionary statements required under existing C.4.14 are geared to more conventional explosives. This gap in communication was recognized as early as 2005, when the UNSCEGHS noted that desensitized explosives may become explosive under certain circumstances—especially after long term storage and during handling and use (UN GHS, 2005, Document ID 0206). The UNSCEGHS examined the issue of hazard classification for desensitized explosives and concluded a new hazard class was warranted to ensure the appropriate hazard statement, signal word and precautionary statements for desensitized explosives were incorporated into the GHS (UN GHS, Report, 2014, Document ID 0087). The GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2016, Document ID 0142) separately classified desensitized explosives with a full set of unique label elements (including the appropriate signal word, hazard statement, pictogram, and precautionary statements). As separately classified, desensitized explosives are labeled with a flame pictogram rather than the explosive bomb used for explosives, and the precautionary statements are tailored to the specific traits of desensitized explosives (*e.g., Avoid heating under confinement or reduction of the desensitizing agent.*).

OSHA reviewed the UNSCEGHS reports (UN GHS, 2014, Document ID 0087) on desensitized explosives and has preliminarily concluded that the hazard class should also be added to the HCS to improve communication about these hazards. While the chemicals captured by the desensitized explosives hazard class are currently covered under the scope of the HCS as explosives, OSHA believes there is a benefit to providing classification criteria and corresponding hazard communication specific to this hazard. Adding the proposed new hazard class to the HCS would ensure downstream users receive more accurate hazard information on labels and in SDSs for these chemicals.

For these reasons, and to align with the GHS, OSHA proposes to add the desensitized explosives hazard class to the HCS as appendix B.17. Proposed appendix B.17 provides relevant definitions and general considerations, specifies applicable classification criteria, and includes information about additional classification considerations for this hazard class. It also references several sections from the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria that will be incorporated by reference. As with all hazard classes, the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) does not require testing and allows classifiers to use data reported in the literature (UN TDG, 2016, Document ID 0151) that was generated using specified (or equivalent) test methods. Proposed appendix C.4.30, discussed later in this document, contains proposed communication elements for desensitized explosives.

Proposed appendix B.17 is based on Chapter 2.17 of the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). OSHA is proposing to adopt most of the classification language on desensitized explosives from Chapter 2.17 of the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) to minimize deviations from the GHS. However, OSHA has carefully reviewed each of the hazard classification criteria within the context of the HCS and is proposing to modify some of the language. These edits include changing some recommendations in the GHS to mandatory requirements in the HCS (*i.e.,* changing ''should'' to ''shall''); revising some terms in the GHS to more accurately reflect terminology in the HCS (*e.g.,* changing ''manufacturer/supplier'' to ''manufacturers, importers, and distributors''); revising text to make it clear that data for classification can be obtained from the literature; and removing references to classifications for transportation that do not apply under the HCS. Some of the GHS text stressing where a classification scheme is for scenarios other than transportation would also be removed (*e.g.,* terms referring to storage, supply, and use); this change is being proposed because the HCS does not cover transportation, and it is therefore not necessary to include such language in appendix B of the HCS. OSHA also proposes adding a definition for ''phlegmatized'' in a

footnote because many stakeholders may be unfamiliar with that term from the UN Recommendations (UN GHS, 2017, Document ID 0060).

OSHA is not proposing to include portions of the GHS Chapter 2.17 that do not relate specifically to the method of classification for desensitized explosives; this is the same approach OSHA took in the 2012 update. For example, similar to how OSHA has addressed the other hazard classes, OSHA is not proposing to adopt the decision logics from the GHS in appendix B.17; OSHA may, however, use them in guidance materials. Also, OSHA did not include text relating to hazard communication in proposed appendix B.17 because this information is contained in proposed appendix C.

E. Appendix C

OSHA is proposing a number of updates to appendix C of the HCS in an effort to improve communication of hazard information on labels. These proposed changes will: (1) Address labeling requirements for the new hazard classes and categories in appendix B (physical hazards); (2) align the HCS with the GHS Rev. 7; and (3) improve alignment of the HCS and Health Canada's labeling requirements in furtherance of the goals of the RCC.

Appendix C is the mandatory appendix that includes the requirements and instructions for the allocation of label elements. Paragraph (f)(2) of the HCS requires the chemical manufacturer, importer, or distributor to ensure that the information provided on the label is in accordance with appendix C. Appendix C provides hazard statements, signal words, pictograms, and precautionary statements for all four essential aspects of hazardous chemical management (prevention, response, storage and disposal), as well as general labeling instructions.

As discussed in the 2009 NPRM proposing to align the HCS with the GHS, the precautionary statements, unlike the hazard statements, were not harmonized (but were merely codified) under the GHS, meaning that numbers were assigned to them. This meant that the statements were not yet considered to be part of the harmonized text (like hazard statements); rather they were included in the GHS as suggested language (74 FR 50282–83). OSHA chose to add these statements in the final HCS rule in 2012 (77 FR 17574). However, since the promulgation of the updates to the HCS in 2012, the UNSCEGHS has continued work to improve the utility of precautionary statements by providing better guidance on the allocation of statements, updating the statements to provide better protection, and adding new statements for new hazard classes and categories. OSHA is proposing a number of changes based on new precautionary statements and instructions in the GHS Rev. 7. Additionally, since 2012, OSHA has continued to work with other Federal agencies on crosscutting labeling issues. The updates proposed in appendix C would ensure alignment with DOT labeling regulations and are expected to provide the same level of protection for workers as the current HCS. OSHA is also proposing updates to appendix C based on the agency's cooperation with Health Canada under the RCC. The RCC was reaffirmed through a memorandum of understanding that was signed in June 2018 (RCC, 2019, Document ID 0217), with the expectation of aligning efforts for international trade requirements between the two countries.

Overall, OSHA expects that the proposed changes to appendix C would provide improved safety information and greater detail and clarity for downstream users. They also would provide better consistency that bridges the jurisdictional differences between countries and Federal agencies. Aligning the HCS with the GHS and other Federal or international regulations would ease compliance burdens for U.S. stakeholders that must also comply with those requirements. The changes that OSHA is proposing would lead to improved communication of hazard information, which would maintain or enhance the safety and health of workers.

The changes OSHA is proposing to appendix Care extensive. OSHA addresses the substantive proposed changes in the discussion below, and a redline strike out version of appendix C, which reflects all of OSHA's proposed revisions, is available in the docket and on the OSHA website (OSHA HCS Redline Document, 2020, Document ID 0222; *https://www.osha.gov/dsg/hazcom/*). This will allow interested parties to view all of the proposed changes in context. OSHA strongly encourages stakeholders to review that document in conjunction with the discussion of the proposed revisions below, as the discussion below does not fully describe all of the non-substantive or editorial changes OSHA is proposing.

Proposed Changes to C.1–C.3

The instructions currently found in the beginning of appendix C (see C.1–C.3) provide directions and information about the signal words, pictograms, hazard statements and precautionary statements required per C.4. OSHA is proposing changes to C.1–C.3 to align with the GHS Rev. 7, better harmonize the HCS with DOT regulations, and better harmonize the HCS with Health Canada.

First, OSHA proposes to revise Figure C.1—Hazard Symbols and Classes to include ''HNOC (non-mandatory)'' as a hazard identified by the exclamation point pictogram. This proposed change reflects OSHA's agreement with Health Canada to permit the exclamation mark pictogram to be used for HNOCs. While OSHA does not require labelling for HNOC hazards, Health Canada requires a pictogram, signal word, hazard statements, and precautionary statements for HNOCs. In order to ensure that U.S. and Canadian requirements can simultaneously be met for HNOCs, OSHA and Health Canada have provided guidance allowing an exclamation mark pictogram to be used for HNOCs (OSHA, 2016, Document ID 0103). Use of the exclamation mark pictogram would not be mandatory under the HCS.

Relatedly, OSHA is proposing a number of additional changes. As discussed above, OSHA is proposing to move the current C.2.3.3 from appendix C to paragraph (f)(5) in the text of the standard, so that all of the instructions related to the transport of hazardous chemicals and DOT are in one section of the HCS. OSHA is also proposing to add a new paragraph C.2.3.3, which would allow the exclamation mark pictogram to be used for HNOCs if the words ''Hazard Not Otherwise Classified'' or the letters ''HNOC'' appear below the pictogram on the label. Health Canada and OSHA have agreed that the exclamation mark pictogram is an appropriate symbol for the HNOC, HHNOC (Health Hazards Not Otherwise Classified), and PHNOC (Physical Hazards Not Otherwise Classified) classifications. Additionally, because any pictogram may appear only once on a label, OSHA is also proposing to add a new paragraph at C.2.3.4 to specify that if multiple hazards require use of the same pictogram, it may not appear a second time on the label. This includes when the exclamation mark pictogram would be used, including as supplemental information for another hazard, such as HNOC. OSHA is requesting comments on these proposed changes, and is particularly interested in comments on whether the agency should require the exclamation mark pictogram to be used for HNOCs.

The remaining changes proposed for C.2 reflect updates to the GHS that are intended to provide additional flexibility to the label preparer while still communicating the required

information. OSHA is proposing to add new paragraph C.2.4.7 to note that precautionary statements may contain minor textual variations from the text prescribed elsewhere in appendix C (*e.g.,* spelling variations, synonyms or other equivalent terms), as long as those variations assist in the communication of safety information without diluting or compromising the safety advice. This proposed new paragraph would also provide that any variations must be used consistently throughout the label and SDS. Because of the proposed addition of new paragraph C.2.4.7, OSHA is also proposing to renumber existing paragraphs C.2.4.7 and C.2.4.8 to become C.2.4.8 and C.2.4.9, respectively.

OSHA is also proposing to add a new paragraph, C.2.4.10, to further address cases where substances or mixtures may trigger multiple precautionary statements for medical responses. Consistent with the GHS Rev. 7 (UN GHS, 2017, Documents ID 0060), OSHA is proposing principles for addressing situations where a substance or mixture is classified for a number of hazards and triggers multiple precautionary statements for medical responses (*e.g.,* calling a poison center/doctor/. . . . and getting medical advice/attention). Proposed paragraph C.2.4.10 would provide for a system of prioritization for precautionary statements. Under proposed C.2.4.10(a), labels would usually need only include one precautionary statement reflecting the response at the highest level with the greatest urgency, combined with at least one route of exposure or symptom ''IF'' statement. For example, the statement, ''Immediately call a poison center/doctor/. . .'' would be prioritized over the less urgent ''call a poison center/doctor.''

OSHA believes there is value in including more than one precautionary statement related to medical response to address both immediate (acute) and long-term (chronic) medical concerns; appropriate medical care may be different depending on whether there is a medical emergency (*e.g.,* chemical burns) or concerns about potential diseases (*e.g.,* cancer) due to prolonged exposures. However, OSHA also understands the difficulty involved in providing a long list of medical responses and that this could lead to confusion, particularly when immediate action is required. Therefore, proposed paragraph C.2.4.10(b) would allow for (but not require) combination of medical response statements. This means that if a chemical has, for example, inhalation and skin contact hazards that would require the same level of medical response, both of these routes of entry could be listed in a combined statement. Proposed paragraph C.2.4.10(c) would prohibit the combination of medical response statements where the statements ''Get medical advice/attention if you feel unwell'' and ''Get immediate medical/advice attention'' are both indicated. In those cases, both statements should appear without prioritization. OSHA is requesting comments on whether precautionary statements for medical responses should be prioritized and seeks input on the best method(s) to use for prioritization.

Proposed Revisions to C.4

OSHA is proposing to update the hazard label elements for specific hazard classes and categories. The following discussion on proposed revisions to C.4 is organized according to: (1) Labeling changes resulting from the addition of hazard classes and categories in appendix B (new subcategories for flammable gases (C.4.15), Aerosols category 3 (C.4.16), and desensitized explosives (C.4.30)); (2) revisions to hazard statements, hazard categories and notes; (3) revisions to precautionary statements; and (4) the GHS revisions that OSHA is not proposing to adopt. In the discussion of precautionary statements, OSHA will explain the proposed changes to the statements and indicate what hazard classes/categories trigger these statements. As noted previously, a redline strike out version of appendix C is available in the docket and on OSHA's website so interested parties can see all of the proposed changes in context (OSHA HCS Redline, 2020, Document ID 0222; *https://www.osha.gov/dsg/hazcom/*).

Proposed Revisions Based on Additions of Hazard Classes and Categories

OSHA is proposing a number of consequential revisions to appendix C based on the proposed additions of hazard classes and categories to appendix B. As discussed in the Summary and Explanation for appendix B, OSHA is proposing a number of changes to the flammable gas hazard class. The changes would include: (1) Subdividing category 1 flammable gases into categories 1A and 1B; (2) adding pyrophoric gases into category 1A; and (3) adding chemically unstable gases into category 1A (further subdivided into chemically unstable gas A and chemically unstable gas B). The proposed hazard and precautionary statements for those gases, consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) are in C.4.15. Each type of category 1A gas (including pyrophoric gases and chemically unstable gases) would require the hazard statement ''Extremely flammable gas,'' as is currently required for category 1 gases. On the other hand, the hazard statement for the new category 1B flammable gases would be ''Flammable gas.'' Additional hazard and precautionary statements would be added to communicate hazards specific to, and precautions that need to be taken for, pyrophoric and chemically unstable gases.

As also discussed in the Summary and Explanation for appendix B, OSHA is proposing to add non-flammable aerosols to the existing ''Flammable Aerosols'' hazard class and to rename the class ''Aerosols.'' Consequently, in appendix C, OSHA proposes to adopt the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) hazard and precautionary statements for non-flammable aerosols in C.4.16. OSHA believes that these communication requirements would better address the true hazards of aerosols. In cases where aerosols are currently labeled as gases under pressure, the proposal would require the label to be updated to include the flame pictogram for hazard categories 1 and 2 (no pictogram would be required for hazard category 3) and the signal word ''warning'' (if ''danger'' is not required due to flammability); the hazard statement ''pressurized container, may burst if heated'' would also be required. These changes would better differentiate the hazards of non-flammable aerosols from those of gases under pressure.

Finally, OSHA is also proposing to adopt the hazard class of desensitized explosives in appendix B, and consequently to adopt, in appendix C, the pictogram, signal word, hazard statements, and precautionary statements for desensitized explosives from the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). Under the proposal, the labeling information for desensitized explosives would be at C.4.30.

For flammable gases, aerosols, and desensitized explosives, OSHA is proposing to adopt the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) hazard communication information with only minor editorial revisions, such as the use of HCS instead of GHS terminology (*e.g.,* ''manufacturer, importer or distributor'' instead of ''manufacturer/supplier or the competent authority'' in conditional instructions). OSHA believes that the information called for by the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) effectively communicates the hazards of those substances and the precautions that need to be taken when handling them.

Therefore, requiring the information to appear on labels would improve hazard communication and enhance worker safety. In addition, because the changes would align the HCS with the GHS, adopting them would ease compliance burdens for U.S. stakeholders that must also comply with international requirements for hazard communication.

Proposed Revisions to Hazard and Precautionary Statements, Hazard Categories, and Notes

OSHA is proposing to revise a number of hazard and precautionary statements to align with the GHS Rev. 7. The hazard and precautionary statements in the current HCS were adopted from the GHS Rev. 3. Since the HCS was last updated in 2012, the UNSCEGHS has continued to discuss the utility and readability of the label elements, including hazard and precautionary statements, in order to improve the information presented. The specific goals of the UNSCEGHS are to make labeling information more comprehensible and useable by explaining and clarifying ambiguous or unhelpful instructions or statements and eliminating inconsistencies in statements (UN GHS, 2018, Document ID 0095; UN GHS, 2018, Document ID 0213). In addition, the UNSCEGHS is considering how precautionary statements could be consolidated or combined to save label space and make labels more readable and clear, all of which improve the safety message (UN GHS, 2018, Document ID 0095; UN GHS, 2018, Document ID 0213). OSHA shares these goals with the UNSCEGHS because they lead to better communication of hazards and therefore maintain or enhance protection of worker safety and health. Unless otherwise discussed below, OSHA is proposing to adopt the updated communication information presented in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) with only minor editorial revisions, such as using the HCS terminology instead of the GHS terminology (*e.g.,* ''manufacturer, importer or distributor'' instead of ''manufacturer/supplier or the competent authority'' in conditional instructions).

Proposed Revisions to Tables C.4.1, C.4.2, and C.4.3 (Acute Toxicity Tables)

OSHA is proposing to consolidate hazard category information for acute toxicity—oral, C.4.1. The change would involve deleting the table for acute toxicity—oral, category 3 and combining categories 1, 2, and 3 in one table, since all three categories have the same precautionary statements. None of the substantive communication information for categories 1, 2, or 3 would change, and the intent of the proposed modification is simply to make C.4.1 more concise.

Proposed Revisions to Precautionary Statements

The original GHS (UN GHS Rev. 1, 2005, Document ID 0215) precautionary statements were developed from existing classification systems, including the IPCS International Chemical Safety Card (ICSC) Compilers Guide (IPCS International, 2012, Document ID 0158), the American National Standards (ANSI Z129.1 2010, Document ID 0102), the EU classification and labelling directives, the Emergency Response Guidebook (UN TDG, 2016, Document ID 0218), and the Pesticide Label Review Manual of the United States Environmental Protection Agency (EPA, 2018, Document ID 0056). Since publication of the updates to the HCS in 2012, the UNSCEGHS has continued its ongoing review of the precautionary statements to ensure they are allocated to the correct hazard class and/or category, reduce redundancies, simplify and clarify the statements, and clarify and refine the conditions of use. This section discusses OSHA's proposed revisions to precautionary statements in appendix C.4. The intent or reasons provided below for the proposed changes reflect OSHA's preliminary agreement with explanations provided by the UNSCEGHS, unless otherwise specified. The changes are organized according to the column headings found in the C.4 tables (*i.e.,* prevention, response, storage, and disposal).

Proposed Changes in Prevention Column

Wear protective equipment (*e.g.,* gloves/protective clothing).

A precautionary statement for acute toxicity—dermal (categories 1–4) (Table C.4.2), skin corrosion/irritation (categories 1A–1C) (Table C.4.4), eye damage/irritation (categories 1 and 2A) (Table C.4.5), and sensitization—skin (Table C.4.7) specifies personal protective equipment, such as ''wear protective gloves'' or ''wear eye protection/face protection.'' Instructions for the statement currently indicate that the chemical manufacturer, importer, or distributer is ''to specify type of equipment.'' OSHA proposes to revise the instruction to state that the chemical manufacturer, importer, or distributor may further specify type of equipment where appropriate. The intent of this proposed revision is to clarify that label preparers may provide additional specification about the type of protective equipment, where appropriate, and to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060).

Because specific hazards may require specific protective equipment or instructions, current precautionary statements and instructions for certain health hazards (*e.g.,* germ cell mutagenicity, see Table C.4.8; carcinogenicity, see Table C.4.9; and reproductive toxicity, see Table C.4.10) and the majority of physical hazard classes specify one or more types of personal protective equipment and indicate that the chemical manufacturer, importer, or distributor is to specify the type of equipment. The types of equipment currently listed in the HCS were adopted from the GHS Rev. 3 and vary for the different hazard classes. In 2010, the UNSCEGHS recommended that the precautionary statement ''Wear protective gloves/protective clothing/eye protection/face protection'' be used for the hazard classes of germ cell mutagenicity (C.4.8), carcinogenicity (C.4.9), reproductive toxicity (C.4.10), explosives (C.4.14) and unstable explosives (C.4.30) (UN GHS, 2010, Document ID 0149), and this statement was included in the HCS in 2012. In 2015, the UNSCEGHS noted that hearing protection should often be worn when handling explosives and other physical hazards, such as desensitized explosives, because an explosion would result in a potentially hazardous noise level (UN GHS, 2015, Document ID 0219). Accordingly, the UNSCEGHS revised the precautionary statement to read, ''Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. . .'' (UN GHS, 2016, Document ID 0147). Adding the term ''/hearing protection. . .'' provides flexibility because hearing protection and other equipment can be selected when appropriate and not selected if not relevant. Adding the ellipsis at the end of the statement allows other types of personal protective equipment to be listed as necessary. The UNSCEGHS also revised the instruction for the precautionary statement to make it clear that it is referring to personal protective equipment. Consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) OSHA is proposing to adopt this revised precautionary statement and instruction for all relevant hazards: germ cell mutagenicity (C.4.8), categories 1A, 1B, and 2; carcinogenicity (C.4.9), categories 1A, 1B, and 2; reproductive toxicity (C.4.10), categories 1A, 1B, and 2; explosives (C.4.14),

unstable and division 1.1–1.5; flammable gases (C.4.15), category 1A, pyrophoric; flammable liquids (C.4.19), categories 1, 2, 3, and 4; flammable solids (C.4.20), categories 1 and 2; self-reactive substances and mixtures (C.4.21), categories Types A, B, C, D, E, and F; pyrophoric liquids (C.4.22), category 1; pyrophoric solids (C.4.23), category 1; self-heating substances and mixtures (C.4.24), categories 1, and 2; substances and mixtures which, in contact with water, emit flammable gases (C.4.25), categories 1, 2, and 3; oxidizing liquids (C.4.26), categories 1, 2, and 3; oxidizing solids (C.4.27), categories 1, 2, and 3; organic peroxides (C.4.28), categories Types A, B, C, D, E, and F; and desensitized explosives (proposed new C.4.30), categories 1, 2, 3, and 4.

Avoid Contact During Pregnancy/While Nursing

In Table C.4.10, for reproductive toxicity (effects on or via lactation), OSHA is proposing to revise a precautionary statement that currently says to avoid contact ''during pregnancy/while nursing'' so it reads ''during pregnancy and while nursing.'' This proposed revision would clarify that the chemical manufacturer, importer or distributor is not to choose between ''during pregnancy'' and ''while nursing'' but is to include both scenarios on the label. This proposed change would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0155).

Do Not Handle Until all Safety Precautions Have Been Read and Understood

For unstable explosives (Table C.4.14), OSHA is proposing to delete the precautionary statement about not handling until all safety precautions have been read and understood. A statement to obtain special instructions before use is already included and that statement is shorter and more relevant to safety. This proposed change would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0155).

Do Not Subject to Grinding/Shock/Friction

OSHA also proposes adding the precautionary statement ''Do not subject to grinding/shock/friction/. . .'' to the table for unstable explosives (Table C.4.14). That statement is already included for the other explosives categories, and is also relevant for unstable explosives. For each of the explosives categories that contain that statement, an explanatory conditional note clarifying that the statement applies only if the explosive is mechanically sensitive would also be added. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS 2012, Document ID 0153).

Keep Away From Heat/Sparks/Open Flames/Hot Surfaces

A number of the hazard classes that include flammable chemicals currently require precautionary statements and instructions about keeping away from ignition sources (heat/sparks/open flames/hot surfaces). Those statements generally require the chemical manufacturer, importer, or distributor to select one or more of the ignition sources listed, as applicable. OSHA is proposing to include more ignition sources in the statement and to require that they all be listed on the label. With that change, the statement would read, ''Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources.'' OSHA believes this change, which is consistent with the GHS Rev.7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152), would improve hazard communication by making users aware of additional ignition sources that should be avoided. The change would be made to precautionary statements for explosives (divisions 1.1–1.5 in Table C.4.14), flammable gases (Table C.4.15), aerosols (Table C.4.16), flammable liquids (Table C.4.19), flammable solids (Table C.4.20), self-reactive substances and mixtures (Table C.4.21), pyrophoric liquids (Table C.4.22), pyrophoric solids (Table C.4.23), oxidizing liquids (Table C.4.26), oxidizing solids (Table C.4.27), organic peroxides (Table C.4.28), and desensitized explosives (Table C.4.30).

Keep Wetted With

A conditional instruction used for division 1.1–1.3 and 1.5 explosives in Table C.4.14 currently states that the chemical manufacturer, importer, or distributer is to include the precautionary statement ''Keep wetted with. . .'' under conditions where drying would increase the explosion hazard, except as needed for manufacturing or operating processes. The GHS Rev. 7 changes the conditional instruction to clarify that the ''Keep wetted with. . .'' statement should be used for ''substances or mixtures which are wetted, diluted, dissolved or suspended with a phlegmatizer to reduce or suppress their explosive properties'' (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153). OSHA is proposing to make the same change in order to clarify when the ''Keep wetted with. . .'' statement is appropriate.

The ''Keep wetted with. . .'' precautionary statement also appears in proposed C.4.30, desensitized explosives. Consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), OSHA is not proposing to add the conditional statement that appears in C.4.14 because, by definition, desensitized explosives are phlegmatized to suppress their explosive properties, and therefore the ''Keep wetted with. . .'' statement is appropriate for all desensitized explosives. OSHA requests comment on these proposed changes.

Keep Only in Original Container

OSHA proposes to revise the statement ''Keep only in original container'' to ''Keep only in original packaging'' for self-reactive substances and mixtures (Table C.4.21), organic peroxides (Table C.4.28), and corrosive to metals (Table C.4.29). The revised statement would also be added to explosives in division 1.1–1.5 (Table C.4.14). OSHA believes that this proposed change is appropriate because the term ''packaging'' is more inclusive than ''container'' and would include the transport packaging as well as the immediate container. These proposed changes are consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152).

Ground/Bond Container and Receiving Equipment

Several hazard classes require the precautionary statement ''Ground/bond container and receiving equipment'' for chemicals that are electrostatically sensitive. OSHA proposes changing ''Ground/bond'' to ''Ground and bond'' to clarify that both of those precautions are to be included on the label. Appendix C.2.4.2, states that when a ''/'' is used the label preparer has a choice and should choose the most appropriate phrase. However, in this case, both ''ground and bond'' should be stated together to appropriately protect against electrostatically sensitive chemicals. These proposed changes would apply to explosives (division 1.1–1.5 in Table C.4.14), flammable liquids (categories 1–3 in Table C.4.19), and flammable solids (Table C.4.20). In addition, OSHA is proposing to revise existing conditional instructions to clarify that the need for grounding and bonding applies to flammable liquids only if they are volatile and may generate an explosive atmosphere (Table C.4.19) and to

explosives and flammable solids only if they are electrostatically sensitive (Tables C.4.14 and C.4.20). OSHA is also proposing to add the ''ground and bond'' precautionary statement and similar conditional notes (''if electrostatically sensitive and able to generate an explosive atmosphere'') to self-reactive substances and mixtures (Table C.4.21) and organic peroxides (Table C.4.28) because the precaution is also appropriate for those hazard classes. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152).

Keep/Store Away From Clothing, and Other Combustible Materials

OSHA is proposing to standardize precautionary statements regarding combustible materials for oxidizing chemicals. Currently, the tables for oxidizing gases (Table C.4.17), oxidizing liquids (Table C.4.26, hazard categories 2 and 3), and oxidizing solids (Table C.4.27, hazard categories 2 and 3) require the precautionary statement ''Keep/Store away from clothing/. . . /combustible materials,'' along with instructions for the chemical manufacturer, importer, or distributor to specify incompatible materials. OSHA proposes to change the statement to read: ''Keep away from clothing and other combustible materials,'' and to delete the instruction regarding incompatible materials, to make the statement more consistent with the statement currently applicable to hazard category 1 in both oxidizing liquids (Table C.4.26) and oxidizing solids (Table C.4.27). OSHA believes the proposed change is appropriate because the general term ''combustible materials'' encompasses any other materials that are incompatible with oxidizers. In addition, OSHA believes the term ''keep'' is adequate to encompass storage as well as use, and that eliminating the choice between ''keep'' and ''store'' would avoid confusion and improve consistency. Finally, OSHA is also proposing to remove the redundant statement ''Take any precaution to avoid mixing with combustibles/. . .'' under oxidizing liquids (Table C.4.26) and oxidizing solids (Table C.4.27), since this information is duplicative of the ''keep away from'' statement. These proposed changes are consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152).

OSHA is proposing to remove the ''keep/store away from clothing/. . . /combustible materials'' precautionary statement, along with its instruction, for self-reactive substances and mixtures (Table C.4.21) and organic peroxides (Table C.4.28). The wording of the precautionary statement is pertinent to oxidizing properties, which readily give oxygen or other oxidizing material, and therefore more readily support combustion. Neither self-reacting chemicals nor organic peroxides have oxidizing properties, so the statement is not appropriate for them. Both self-reacting chemicals and organic peroxides have alternate storage statements that are designed to more accurately address their particular chemical properties. These proposed changes would also align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Keep Valves and Fittings Free From Oil and Grease

For oxidizing gases (Table C.4.17), a precautionary statement currently allows the chemical manufacturer, importer, or distributor to specify that either ''reduction valves'' or ''valves and fittings'' be kept free from oil and grease. OSHA is proposing to revise the statement to ''Keep valves and fittings free from oil and grease.'' OSHA believes the change is appropriate because all valves and fittings must be kept free of oil and grease, not just the reduction valves attached to pressure receptacles. This proposed change is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2010, Document ID 0149).

Wear Cold Insulating Gloves/Face Shield/Eye Protection

OSHA is proposing to revise the precautionary statement for refrigerated liquefied gases (Table C.4.18), which currently provides that either cold insulated gloves, a face shield, or eye protection is to be used. The proposed change would clarify the intent of the precautionary statement, which is that cold-insulating gloves are to be used in addition to either a face shield or eye protection. This proposed change would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Keep Container Tightly Closed

The precautionary statement ''Keep container tightly closed'' is used for flammable liquids (categories 1–3 in Table C.4.19). The GHS Rev. 7 contains a conditional instruction indicating that the statement is to be used if the liquid is volatile and may generate an explosive atmosphere (UN GHS, 2017, Document ID 0060). OSHA is proposing to add this conditional instruction to the precautionary statement for flammable liquids (categories 1–3) because it clarifies the types of flammable liquids for which the statement applies.

OSHA also proposes to add the precautionary statement ''Keep container tightly closed'' to pyrophoric liquids (Table C.4.22) and pyrophoric solids (Table C.4.23). OSHA believes it is important to add that statement because for both pyrophoric liquids and pyrophoric solids it is necessary to avoid ignition via contact with air. Because the precaution applies to all chemicals in these hazard classes, OSHA does not believe a conditional note is necessary. These proposed changes would also align with the GHS, Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Take Precautionary Measures Against Static Discharge

For flammable liquids (Table C.4.19, hazard categories 1–3), OSHA proposes to revise the precautionary statement ''Take precautionary measures against static discharge'' to ''Take action to prevent static discharge.'' The revision would simply shorten the statement and clarify what action needs to be taken. OSHA also proposes to add a note that this precautionary statement is to be used if the liquid is volatile and may generate an explosive atmosphere. These proposed changes are consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Flammable Liquids/Solids Conditional Instructions

OSHA is proposing additional conditional instructions for flammable liquids (Table C.4.19) and flammable solids (Table C.4.20). Some categories of flammable liquids (categories 1–3) and flammable solids (categories 1 and 2) contain a precautionary statement specifying the use of ''explosion-proof [electrical/ventilating/lighting/. . .] equipment.'' OSHA believes that SDS and label creators are not actually properly and specifically identifying the prevention measures for the particular chemical, but rather are listing the entire line without the required details. For liquids, OSHA proposes a new conditional instruction to clarify that the statement is required if the chemical is volatile and may generate an explosive atmosphere. For both liquids and solids, a conditional instruction would be added to indicate that text in

square brackets may be used to specify specific electrical, ventilating, lighting or other equipment if necessary and as appropriate. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

OSHA is also proposing to add a conditional instruction to the precautionary statement to use non-sparking tools for flammable liquids (categories 1–3, Table C.4.19). The statement would clarify that the precautionary statement is only needed if the liquid is volatile and may generate an explosive atmosphere, and if the minimum ignition energy is very low (<0.1 mJ). The precautionary statement has very limited applicability for flammable liquids and therefore OSHA believes that the conditions need to be specified. This proposed change is also consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Keep Cool

For self-reactive substances and mixtures and organic peroxides (Tables C.4.21 and C.4.28), OSHA is proposing to move the precautionary statement ''Keep cool'' from the storage column to the prevention column. The precautionary statement is not needed in the storage column because that column includes a precautionary statement about storage temperatures not to be exceeded, and as discussed below, OSHA is proposing to add conditional instructions to that column to inform users of when a storage temperature would need to be listed. Under the prevention column, OSHA is proposing to include a conditional instruction indicating that the precautionary statement may be omitted if storage temperatures are included on the label. This proposed revision would not materially change the information that is presented on the label, and is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

For self-heating substances and mixtures (Table C.4.24), a combined precautionary statement currently instructs the user to keep cool and protect from sunlight. OSHA is proposing that a conditional instruction be added to indicate that ''Keep cool'' can be omitted where storage temperatures are listed on the label. Because ''Protect from sunlight'' still needs to be included if specific storage temperatures are listed on the label, OSHA is proposing to delete the combined statement under the prevention column, and to list only ''Keep cool'' (and the new conditional instruction) in that column. The statement: ''Protect from sunlight'' would be moved to the storage column, similar to the way this is handled for other hazard classes. OSHA believes that these proposed changes would provide the label preparer better instructions and would provide the appropriate level of information on the label without repetition. These proposed changes would also align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Do Not Allow Contact With

OSHA is proposing to add the conditional note ''if emphasis of the hazard statement is deemed necessary'' to precautionary statements indicating that contact is not to be allowed with air (for pyrophoric gases (proposed C.4.15, category 1A), pyrophoric liquids (C.4.22), and pyrophoric solids (C.4.23)) or water (for substances and mixtures that emit flammable gases in contact with water (C.4.25, categories 1 and 2). Because the hazard phrases, which are also included on labels for these categories, already warn about the hazards of these respective chemicals when they contact air or water, adding this precautionary statement as well could be repetitive. However, depending on the specific chemical, the label preparer may feel that added emphasis is warranted. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Handle Contents Under Inert Gas

For substances and mixtures which, in contact with water, emit flammable gases (Table C.4.25), OSHA proposes changing the precautionary statement ''Handle under inert gas. Protect from moisture'' to ''Handle and store contents under inert gas/. . . Protect from moisture.'' This would clarify that these substances should always be under inert atmospheres. In addition, conditional instructions would be added to indicate that if the substance or mixture reacts readily with moisture in air, then the chemical manufacturer, importer or distributer also has to specify the appropriate liquid or gas if inert gas is not appropriate. The new statement would provide greater clarity and is needed because inert gas is not appropriate in some cases (*e.g.,* white phosphorus should be handled and stored under water) (UN GHS, 2010, Document ID 0149). This proposed change is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

OSHA is also proposing to add the statement ''Handle and store contents under inert gas/. . .'' to pyrophoric liquids (C.4.22) and pyrophoric solids (C.4.23). A conditional statement would note that the manufacturer, importer, or distributor is to specify the appropriate liquid or gas if inert gas is not appropriate. Pyrophoric chemicals, by definition, are likely to ignite when in contact with air. Both Tables C.4.22 and C.4.23 currently contain the following statement in the storage column: ''Store contents under . . . Chemical manufacturer, importer, or distributor to specify appropriate liquid or inert gas.'' In light of the language OSHA is proposing to include in the prevention column, OSHA would delete this language from the storage column. OSHA believes that the language being proposed for the prevention column would emphasize that pyrophoric chemicals must be handled, as well as stored, under inert atmospheres. OSHA notes that the statements OSHA is proposing to add to the prevention column for Tables C.4.22 (pyrophoric liquids) and C.4.23 (pyrophoric solids) regarding handling and storing contents under inert gas were included in the GHS Rev. 5, but were inadvertently omitted from Rev. 7 (UN GHS, 2016, Document ID 0211; UN GHS, 2017, Document ID 0060). If OSHA finalizes the language as proposed, it will work with the UNSCEGHS to have this statement reinstated in future GHS revisions.

Wear Fire/Flame Resistant/Retardant Clothing

Category 1 oxidizing liquids (C.4.26) and category 1 oxidizing solids (C.4.27) currently have the precautionary statement ''Wear fire/flame resistant/retardant clothing.'' The intent of that statement is to alert the users of the chemical that they should wear either fire resistant or flame retardant clothing, not for the label preparer to choose between the terms ''fire'' and ''flame'' or ''resistant'' and ''retardant''. Therefore, OSHA proposes to replace the existing statement with ''Wear fire resistant or flame retardant clothing.'' This would clarify the intent of this statement and is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Proposed Changes in Response Column

For the response column, a number of the proposed revisions in appendix C are simply editorial and are made to improve clarity, correct simple omissions of a word or phrase, or more efficiently and concisely combine different precautionary statements. For example, OSHA is proposing to add the phrase ''If on skin'' to the statement ''Brush off loose particles from skin'' (see C.4.23 (pyrophoric solids) and hazard categories 1 and 2 in C.4.25 (substances and mixtures which, in contact with water, emit flammable gasses)) because those statements are always combined in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), and the additional phrase would add clarity. Another example is OSHA's proposal to add the phrase ''In case of fire'' at the beginning of the precautionary statements related to fire fighting for unstable explosives, as is already done for other explosives categories (see C.4.14). In a number of cases, OSHA is proposing to reorganize the precautionary statements and to remove redundant wording to improve clarity. For example, in C.4.14, instead of listing the individual statements and providing conditions of use, OSHA would now list the statements grouped together (except for materials for Division 1.4S, which have another set of statements as explained below).

The following discussion does not address proposed changes that are simply editorial in nature (although all proposed revisions can be found in the redlined version of appendix C that is available as part of the rulemaking record (OSHA HCS Redline, 2020, Document ID 0222) and on OSHA's website (*https://www.osha.gov/dsg/hazcom*). The discussion below highlights the substantive changes OSHA is proposing to make to the response column in appendix C.

Take Off Immediately All Contaminated Clothing. Rinse Skin With Water/Shower

The existing precautionary statements for skin corrosion/irritation (categories 1A to 1C in C.4.4) and flammable liquids (categories 1–3 in C.4.19) indicate that if the chemical is on hair or skin, the affected individual is to immediately take off all contaminated clothing and rinse skin with ''water/shower.'' OSHA proposes to revise the statement to instruct the affected individual to rinse skin with ''water [or shower],'' and to add a conditional note indicating that the text in square brackets is to be used where the chemical manufacturer, importer or distributor considers it appropriate for the specific chemical. The reason for the proposed change is that a deluge shower might be most appropriate for the chemical, and the use of the square brackets allows for selection of the most appropriate wording. The proposed change would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Get Medical Advice/Attention

A number of health hazards (*i.e.,* skin corrosion/irritation (category 2 in Table C.4.4), eye damage/irritation (categories 2A and 2B in Table C.4.5), sensitization—skin (Table C.4.7), germ cell mutagenicity (Table C.4.8), carcinogenicity (Table C.4.9), reproductive toxicity (Table C.4.10), specific target organ toxicity—repeated exposure (Table C.4.12), and refrigerated liquefied gases (Table C.4.18)) have combined precautionary statements that include the statement ''get medical advice/attention.'' OSHA is proposing to add an instruction indicating that the chemical manufacturer, importer, or distributer is to select medical advice or attention as appropriate. This is to alert label preparers that they should provide more specific instruction on the type of medical assistance needed based on the chemical hazard and to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060).

If Breathing Is Difficult, Remove Person to Fresh Air and Keep Comfortable for Breathing

A precautionary statement used for sensitization—respiratory (Table C.4.6) currently states ''If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.'' OSHA is proposing to remove the phrase ''if breathing is difficult.'' This is because including two conditions, ''if inhaled'' and ''if breathing is difficult,'' is confusing and unnecessary. Removal of the phrase would also make the precautionary statement consistent with the statement as it appears in other hazard classes in appendix C.4, such as acute toxicity—inhalation (Table C.4.3). This proposed change is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2010, Document ID 0149).

Take Off Contaminated Clothing and Wash it Before Reuse

A precautionary statement for skin sensitization (Table C.4.7) currently says to wash contaminated clothing before reuse. OSHA is proposing to add the phrase ''Take off contaminated clothing and'' to this precautionary statement. The UNSCEGHS previously recommended that this additional phrase be used for acute toxicity—dermal; skin irritation, category 2; and sensitization—skin (UN GHS, 2010, Document ID 0154). The phrase was inadvertently omitted for skin sensitization in the GHS Rev. 3 (UN GHS, 2009, Document ID 0085), and accordingly in the updates to the HCS in 2012, but it has since been added to the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2010, Document ID 0149; UN GHS, 2010, Document ID 0154).

If Exposed or Concerned

For specific target organ toxicity (single exposure) (Table C.4.11), OSHA is proposing to revise a precautionary statement indicating ''If exposed'' to ''If exposed or concerned.'' The revision, which would be consistent with language currently used for the germ cell mutagenicity (Table C.4.8), carcinogenicity (Table C.4.9), and reproductive toxicity (Table C.4.10) hazard classes, would maintain consistency throughout C.4 and with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). In 2010, a GHS subcommittee recommended that wherever ''If exposed'' is used, it be revised to ''If exposed or concerned,'' since the user of the chemical may not have evidence of exposure (UN GHS, 2010, Document ID 0154).

Division 1.4 Explosives (C.4.14) Precautionary Statements

For Division 1.4 explosives, the HCS currently provides fire-fighting precautionary statements and instructions on when to apply them (Table C.4.14). OSHA is proposing two changes to these statements. First, OSHA is proposing to change the instruction note from ''for explosives are 1.4S ammunition and components thereof'' to ''for explosives of division 1.4 (compatibility group S) in transport packaging.'' This revision would provide clarity about when the note applies and there is no intended change in meaning. Second, OSHA is proposing to revise the precautionary statement ''Fight fire with normal precautions from a reasonable distance'' to the statement ''Fight fire remotely due to the risk of explosion.'' OSHA believes the proposed new statement is more appropriate and protective because it specifies the explosion risk due to fire associated with 1.4 compatibility group S (1.4S) explosives. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Eliminate All Ignition Sources, if Safe To Do So

For category 1 and 2 flammable gases (C.4.15), a precautionary statement currently instructs the user to eliminate all ignition sources if safe to do so. OSHA proposes to revise the statement to ''In case of leakage, eliminate all ignition sources.'' The term ''in case of leakage'' would be added to stress that it is important to eliminate flammable gas leaks, even where the leaking gas is not burning, because the leak could create an explosive atmosphere. The term ''if safe to do so'' would be deleted because it could discourage quick action. Eliminating gas leaks would not be expected where a fire would hinder that action. OSHA is also proposing to add this statement to pyrophoric gases 1A and chemically unstable gases A and B. These proposed changes would be consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UNGHS, 2012, Document ID 0152).

In Case of Fire Use . . . To Extinguish

For self-reactive substances and mixtures (type A) (C.4.21), OSHA is proposing to delete the precautionary statements ''In case of fire use . . . to extinguish'' (along with its explanatory note) and ''Fight fire remotely due to the risk of explosion.'' In place of the language OSHA is proposing to delete, OSHA proposes to use language stating ''In case of fire: Explosion risk. Do NOT fight fire when fire reaches explosives.'' These changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) and are proposed because it is dangerous to fight a fire involving this type of material and individuals should always be advised against it (UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153). OSHA is not proposing to change the existing statement about evacuating the area.

For type B self-reactive substances and mixtures (C.4.21), OSHA is proposing to combine existing precautionary statements and to delete duplicate phrases that would occur with the new combination. OSHA does not intend these changes to alter the meaning of the statements. OSHA is proposing to use brackets around the statement ''Use . . . to extinguish'' with a conditional note to indicate that the text in square brackets is to be included if water increases risk. This is to preserve the conditions of use with the new combination of phrases. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0095).

Fire and Explosion Hazards for Organic Peroxides (C.4.28)

Precautionary statements and instructions related to fire and explosion hazards or fire-fighting procedures were not included in the GHS Rev. 3 (UN GHS, 2009, Document ID 0085), or in the current HCS, for organic peroxides (C.4.28). The UNSCEGHS has since adopted these precautionary statements (UN GHS, 2012, Document ID 0095). As in GHS Rev. 7 (UN GHS, 2017, Document ID 0060), OSHA is proposing to adopt the same precautionary statements in the response column for organic peroxides (C.4.28) as for self-reactive substances and mixtures (C.4.21). OSHA believes it is appropriate to include these statements for organic peroxides, as well as for self-reactive substances and mixtures, because the fire and explosion hazards of the two classes of compounds are equivalent (UN GHS, 2012, Document ID 0152; UN GHS, Document ID 0153; UN GHS, 2012, Document ID 0095).

Immerse in Cool Water/Wrap With Wet Bandages

For pyrophoric liquids (C.4.22), pyrophoric solids (C.4.23), and substances and mixtures which in contact with water emit flammable gases (C.4.25), a precautionary statement currently indicates that if the substance is on the skin, the user should ''immerse in cool water/wrap with wet bandages.'' For pyrophoric liquids (C.4.22) and solids (C.4.23), OSHA is proposing to change the forward slash to an ''or'' so that the statement would read ''Immerse in cool water or wrap in wet bandages.'' The change is proposed to make clear that the chemical manufacturer, importer, or distributer is not to choose one action or the other but is to include both actions on the label. In the case of substances and mixtures which, in contact with water, emit flammable gases, OSHA is proposing to delete ''wrap in wet bandages'' from the statement so that the complete statement reads ''Brush off loose particles from skin and immerse in cool water.'' This change is proposed because, for these chemicals, a large volume of water is needed and wrapping in wet bandages is not enough to address problems caused by the heat of the reaction (UN GHS, 2012, Document ID 0095). These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Proposed Changes in Storage Column

Store Away From Other Materials

For self-reactive substances and mixtures (C.4.21), self-heating substances and mixtures (C.4.24), and organic peroxides (C.4.28), OSHA proposes to revise the precautionary statement ''Store away from other materials'' to ''Store separately.'' OSHA believes that the revised statement is preferable because it is shorter and more appropriate. OSHA is also proposing to add the ''Store separately'' precautionary statement to category 1 oxidizing liquids (C.4.26) and category 1 oxidizing solids (C.4.27) because those chemicals are not compatible with other chemicals and thus must be stored separately. These proposed changes are consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Store Contents Under. . . .

For pyrophoric liquids (C.4.22) and solids (C.4.23), OSHA proposes to delete a precautionary statement that says ''Store contents under . . . ,'' along with the instructional note that the chemical manufacturer, importer, or distributer is to specify the appropriate liquid or inert gas. The UNSCEGHS recommended that the statement be deleted from the storage column because it adopted the statement ''Handle and store contents under inert gas/ . . . ,'' along with a similar instructional note, in the prevention column (UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153). OSHA believes placing the statement in the prevention column is more appropriate, as there it would warn the downstream user that pyrophoric chemicals must be under inert gas not only during storage but at all times, including during processing and use. This modification was inadvertently omitted from the text in the GHS Rev. 7, and the U.S. will work with the U.N. to submit a paper to add this statement to pyrophoric liquids (C.4.22) and solids (C.4.23) in a future revision of the GHS.

Maintain Air Gap Between Stacks/Pallets

For self-heating substances and mixtures (C.4.24), OSHA is proposing to revise the precautionary statement that currently says ''[m]aintain air gap between stacks/pallets'' so it reads instead ''[m]aintain air gap between stacks or pallets.'' The change would clarify that chemical manufacturers, importers or distributors are not to choose between ''stacks'' or ''pallets''

but are to include both words on the label. This proposed change would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Store in Corrosive Resistant/ . . . Container With a Resistant Inner Liner

A precautionary statement for the corrosive to metals (C.4.29) class currently says to store in a ''corrosive resistant/ . . . container with a resistant inner liner.'' OSHA is proposing to change the word ''corrosive'' to ''corrosion'' because it is the technically correct term. In addition, a new conditional instruction would be inserted to indicate that the precautionary statement may be omitted if the statement ''Keep only in original packaging'' is included on the label. This would eliminate the redundancy of including both statements. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Instructional Notes

For acute toxicity—inhalation (C.4.3) (category 1–3) and specific organ toxicity (single exposure, category 3) (C.4.11), OSHA is proposing minor, non-substantive edits to the conditional instruction for precautionary statements about keeping the container tightly closed and storing in a well-ventilated place. OSHA proposes to revise the note from ''if product is volatile so as to generate hazardous atmosphere'' to ''if the chemical is volatile and may generate a hazardous atmosphere.'' The intent of these edits is to improve clarity and make the instruction more consistent with a newly added instruction for flammable liquids (C.4.19). This proposed change is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

For flammable liquids (C.4.19), OSHA is proposing to add a clarifying instruction indicating that the precautionary statement ''Store in a well ventilated place. Keep cool'' applies to flammable liquids in category 1 and other flammable liquids that are volatile and may generate an explosive atmosphere. However, for category 4 flammable liquids, OSHA is proposing to delete ''Keep cool,'' because these liquids are less volatile and have a flashpoint above 60 °C and therefore are unlikely to generate a hazardous concentration of vapor during storage; OSHA believes the precautionary statement ''Store in a well ventilated place'' is the appropriate level of protection. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

For explosives (C.4.14), OSHA is proposing minor edits to precautionary statements and instructions for storing in accordance with local/regional/national/international regulations. The edits are intended to clarify that the chemical manufacturer, importer, or distributer is to specify the applicable regulations. These proposed changes are consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Aerosols (C.4.16), self-reactive substances (C.4.21), self-heating substances and mixtures (C.4.24), and organic peroxides (C.4.28) currently include precautionary statements addressing storage temperatures not to be exceeded, with temperatures listed in degrees Celsius/Fahrenheit. The GHS has added an instruction that the chemical manufacturer should use the applicable temperature scale for the region they are supplying (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153). In other OSHA standards, the primary temperature scale used is Fahrenheit. Therefore, OSHA is proposing to require only the Fahrenheit scale in the precautionary statements. However, the chemical manufacturer, importer or distributor would still be permitted to include the temperature in Celsius (as noted by parens ( )) in addition to Fahrenheit.

In addition, for self-reactive substances and mixtures (C.4.21) and organic peroxides (C.4.28), OSHA proposes to add conditional instructions to two precautionary statements. The first conditional instruction would clarify that the statement to store in a well-ventilated place should not be used for temperature-controlled substances and mixtures or organic peroxides because condensation and freezing may occur. The second would clarify that a storage temperature is only needed if temperature control is required or deemed necessary. OSHA also proposes moving the precautionary statement ''Keep cool'' to the prevention column, as discussed above under the section on proposed changes to the prevention column. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Proposed Changes in Disposal Column

For most of the health and physical hazards addressed by appendix C, the rule currently includes a precautionary statement to dispose of contents/container in accordance with local/regional/national/international regulations (to be specified). OSHA is proposing to add an instructional note in all relevant places in the appendix indicating that the chemical manufacturer, importer or distributor is to specify whether the disposal requirements apply to the contents, the container, or both. This proposed change would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

The tables for explosives (C.4.14), except for hazard category division 1.6, currently include the precautionary statement to dispose of contents/container in accordance with local/regional/national/international regulations (to be specified). However, this precautionary statement may not give users the information needed to safely dispose of explosives, particularly malfunctioning, expired, or non-used explosives where special care is needed. This is of particular concern for explosives such as fireworks, signal flares and ammunition. Ill-formulated advice on the label may lead to the disposal of such explosive waste in a way that poses a risk, *e.g.,* to the workers that handle the waste (UN GHS, 2015, Document ID 0156). Therefore, OSHA is proposing to change the precautionary note for explosives (C.4.14) to read: ''Refer to manufacturer, importer, or distributor . . . for information on disposal, recovery, or recycling.'' An instructional note would be added to indicate that the chemical manufacturer, importer, or distributor is to specify the appropriate source of information, in accordance with local/regional/national/international regulations as applicable. The change is proposed to address the recycling or recovery of unexploded fireworks or other unused explosive cartridges and signal flares, which can result in unsafe conditions and should only be performed by specialists. This proposed change is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2015, Document ID 0214; UN GHS, 2015, Document ID 0213).

Proposed Revisions to Label Elements for OSHA Defined Hazards (C.4.31)

OSHA is proposing a few changes to label elements for OSHA defined hazards (currently at C.4.30 and proposed to be renumbered as C.4.31).

This section of appendix C addresses the labeling of hazards that are not classified under the GHS, but that the HCS specifically defines as hazards that must be communicated on the label and SDS.

First, OSHA is proposing to delete the entry for ''Pyrophoric Gas.'' In the GHS Rev. 7, pyrophoric gases are now a category under the hazard class of flammable gases, and OSHA proposes to include them there as well.

OSHA is also proposing a change to the ''Combustible Dust'' hazard statement. When OSHA finalized the revisions to the HCS in 2012, the GHS did not address classification of combustible dust; however, it used combustible dust as an example of ''Other hazards which do not result in classification'' (UN GHS, 2009, Document ID 0085). In the GHS Rev. 5, the UN updated A.4.3.2.3 to include a statement ''May form explosible dust-air mixture if dispersed'' for dust explosion hazards to provide guidance on the type of statement that should be used in the case of dust explosion hazards (combustible dust) (UN GHS, 2012, Document ID 0251). Subsequently, OSHA initiated UNSCEGHS discussions regarding combustible dust hazards. The UNSCEGHS adopted an annex (Annex 11) that provides additional guidance on hazard identification, the factors that contribute to a dust explosion hazard, and the need for risk assessment, prevention, mitigation, and communication (UN GHS, 2017, Document ID 0157). OSHA is now proposing to allow either the previously required statement, ''may form combustible dust concentrations in air,'' or the statement suggested in the GHS Annex 4, ''[m]ay form explosible dust-air mixture.'' OSHA is proposing to add square brackets after both statements containing the following language: ''if small particles are generated during further processing, handling or by other means.'' This bracketed language is designed to indicate that this language should be added when the material can create a combustible dust hazard during the processing or handling of the chemical. OSHA is not proposing any changes to the signal word of ''warning'' or any pictogram requirements. These changes are the result of working papers presented to the UNSCEGHS meetings for discussion in December of 2017 (UN GHS, 2017, Document ID 0157).

GHS Revisions That OSHA Is Not Proposing To Adopt

There are a small number of revisions in the GHS Rev. 7 that OSHA is not proposing to adopt for the HCS. In general, OSHA does not propose to adopt any statements or conditional instructions that address consumer products because the HCS does not cover communication of hazards to consumers. This section discusses specific provisions in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) that OSHA is not proposing to adopt.

A number of tables for inhalation hazards in appendix C.4 (*i.e.,* acute toxicity—inhalation (C.4.3, categories 3 and 4), respiratory sensitization (C.4.6), skin sensitization (C.4.7), and specific target organ toxicity—single exposure (C.4.11, category 3)) contain a precautionary statement that says ''Avoid breathing dust/fume/gas/mist/vapors/spray.'' A conditional note in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) indicates that this precautionary statement is not needed where the precautionary statement ''Do not breathe dust/mist/fume/gas/vapors/spray'' is included on the label. Also, for skin corrosion/irritation (C.4.4, category 2), the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) contains a conditional note indicating that the statement ''If skin irritation occurs: Get medical advice/attention'' may be omitted if the statement ''If skin irritation or rash occurs: Get medical advice or treatment'' is used. OSHA is not proposing to adopt these conditional instructions because it believes that proposed appendix C.2.4.8 (currently C.2.4.7), which provides instructions for the precedence of precautionary statements, already provides the necessary flexibility.

In the GHS Rev. 7, the precautionary statements about explosion-proof equipment and taking action to prevent static discharge include a conditional instruction indicating that these precautionary statements can be omitted if national or local legislation contains provisions that are more specific (UN GHS, 2017, Document ID 0060). OSHA is not proposing to adopt this instruction because the agency believes these precautionary statements contain important information that should always be included on labels. Although some OSHA and consensus standards address the use of explosion-proof equipment and preventing static discharge for flammable liquids or solids, they do not address hazard communication. Therefore, OSHA does not believe they are specific enough to justify omitting the relevant precautionary statement from labels. Label preparers can add more specific supplementary information from standards as long as it complies with paragraph C.3. For example, they may reference OSHA's flammable liquids standard (29 CFR 1910.106), which addresses the requirements for electrical equipment in workplaces that store or handle flammable liquids. OSHA requests comments on its preliminary decision not to include the conditional instruction from the GHS.

Under the HCS, a precautionary statement for gases under pressure (C.4.18) currently says ''Protect from sunlight.'' The GHS Rev. 7 contains a conditional instruction indicating that this precautionary statement ''may be omitted for gases filled in transportable gas cylinders in accordance with packing instruction P200 of the UN Recommendations on the Transport of Dangerous Goods, Model Regulations, unless those gases are subject to (slow) decomposition or polymerization, or the competent authority provides otherwise'' (UN GHS, 2017, Document ID 0060). These special packaging instructions under P200 are not applicable to cylinders used in the U.S; therefore, OSHA is not proposing to add this conditional instruction to C.4.18 (UN GHS, 2017, Document ID 0060).

F. Appendix D

OSHA is proposing several changes to appendix D. These changes are being proposed to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) to clarify existing requirements where stakeholders have expressed confusion, and to ensure consistency with updated scientific principles. A redline strike out version of appendix D, which reflects all of OSHA's proposed revisions, is available in the docket and on the OSHA website (OSHA HCS Redline 2020, Document ID 0222); *https://www.osha.gov/dsg/hazcom/*). This will allow interested parties to view all of the proposed changes in context. OSHA strongly encourages stakeholders to review that document in conjunction with the discussion of the proposed revisions below.

In the introductory section of appendix D, OSHA proposes to add a sentence stating that while each section of the SDS must contain all of the specified information, preparers of SDSs are not required to present the information in any particular order within each section. OSHA proposes this change to help clarify that while all required information must be present on the SDS, there are no mandates about the order in which the information is presented within each section. Because the information within each section can be listed in any order, OSHA does not anticipate any increased burden on SDS preparers from this change.

In section 1, Identification, OSHA is proposing revisions to clarify that the address and telephone number provided

on the SDS must be domestic. Although OSHA explained in a 2016 letter of interpretation that a U.S. telephone number and U.S. address are required for the SDS and label (Lee, 2016, Document ID 0090), OSHA believes it is important to codify this requirement in the text of the HCS to minimize any future confusion.

In section 2, Hazard(s) identification, OSHA is proposing to clarify where and how chemical hazard information should be presented. First, OSHA proposes to clarify that paragrah (a) must include any hazards associated with a change in the chemical's physical form under normal conditions of use, an issue the agency has addressed in several LOIs (Cawthorn, 2014, Document ID 0238; McCarthy, 2015, Document ID 0185; Fox, 2008; Document ID 0239). For example, for a chemical that poses a combustible dust hazard when processed (but not in the form in which it is shipped), the combustible dust hazard must be included in section 2(a). OSHA is also proposing a new paragraph (c) covering hazards identified under normal conditions of use that result from a chemical reaction (changing the chemical structure of the original substance or mixture). One example of such a reaction under normal conditions of use is the chemical change and subsequent physical effects of adding water to ready-mix concrete or cement, which creates additional hazards besides those present before the water is added (MST; 1995, Document ID 0253). This information is already required on the SDS (Boros, 2014, Document ID 0171), but OSHA believes that adding this language in paragraph (c) of section 2 would provide a clear and separate location for chemical manufacturers, distributors and importers to place this information. To accommodate the new material being proposed for paragraph (c), OSHA is proposing to move existing paragraphs (c) and (d) to paragraphs (d) and (e). OSHA notes that if it adopts the proposed revisions to section 2, hazards associated with chemicals as shipped, as well as hazards associated with a change in the chemical's physical form under normal conditions of use, would be presented in paragraph (a), and new hazards created by a chemical reaction under normal conditions of use would be presented in paragraph (c). OSHA believes this would sufficiently differentiates the different types of hazards presented under normal conditions of use, but welcomes stakeholder comments on this issue.

In section 3, OSHA is proposing several changes. Under the subheading ''For Substances (d)'' OSHA is proposing to add ''(constituents)'' to clarify the term ''additives.'' OSHA intends that any individual part of an ''additive'' that contributes to the classification of that material needs to be listed in section 3 of the SDS. OSHA is also proposing to revise the information provided for mixtures. In addition to the information required for substances, section 3 requires the chemical name of all ingredients in a mixture that are classified as health hazards. OSHA proposes also requiring the CAS number or other unique identifier for these ingredients. CAS numbers are unique numerical identifiers assigned by the American Chemical Society (ACS) (CAS, 2020, Document ID 0173). CAS numbers are internationally recognized as being reliable and readily validated, are unique to only one compound, substance or chemical, and provide a common link between various nomenclature that may be used as descriptors for the substance or compound (UN, 2005, Document ID 0130; CAS, 2020, Document ID 0173). CAS numbers have been generated for all substances identified from the scientific literature from 1957 to the present, with some substances identified as far back as the early 1900s (CAS, 2020, Document ID 0173; UN, 2005, Document ID 0130). OSHA believes that this information provides the downstream user with important information, since it provides a unique descriptor of the chemical where the chemical identity may be ambiguous.

OSHA is proposing an additional change in section 3 to reflect the proposed revision to paragraph (i) (*Trade secrets*), which would allow for concentration ranges to be withheld as a trade secret. When the concentration or concentration range is withheld as a trade secret, the chemical composition range would have to be provided in accordance with the prescribed concentration ranges in paragraphs (i)(1)(iv)(A) through (M). As explained in the summary and explanation section for paragraph (i), this would create an alignment with the WHMIS under Health Canada (Canadian Gazette II, 2018, Document ID 0101).

Section 8 of the SDS includes information on exposure controls/personal protection. Section 8(a) currently requires the SDS to include the OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the SDS, when available. OSHA has received questions about whether this requirement applies to individual ingredients and constituents in the mixture, and has explained that it applies to any ingredient or constituent identified in section 3 of the SDS (McVeigh, 2013, Document ID 0088). To clarify this point, OSHA is proposing to revise section 8(a) to state that it applies to all ingredients or constituents listed in section 3. OSHA notes, however, that if the ingredient or constituent does not have an OSHA PEL, ACGIH TLV or any other exposure limit used or recommend by the SDS preparer, then the ingredient or constituent would not need to be listed in section 8.

In addition, OSHA is also proposing to revise section 8 to add language indicating that SDS preparers must also include a ''range'' of exposure limits whenever a range is used or recommended by the chemical manufacturer, importer, or employer preparing the SDS. This revision would acknowledge new tools, such as occupational exposure banding or hazard banding methods described by NIOSH and the United Kingdom Health and Safety Executive (NIOSH, 2017, Document ID 0106; HSE, 2013, Document ID 0104). Hazard banding and occupational exposure banding provide a concentration range (band) based on toxicity and hazard information associated with a known chemical with similar properties; this range can inform appropriate risk management decisions where a specific occupational exposure limit (OEL) or permissible exposure limit (PEL) is not available or out of date (NIOSH, 2017, Document ID 0106) This type of information has been developed and validated over the last few decades and these types of exposure ranges can provide hazard information on chemicals that can help reduce risk to workers, even if limited toxicological information is available (NIOSH, 2017, Document ID 0106). As noted by NIOSH and the U.S. EPA, more than 85,000 chemicals are in commerce, with only approximately one thousand having been assessed for hazard and toxicity (either through an authoritative entity or peer-reviewed process) (NIOSH, 2017, Document ID 0106; EPA, 2016, Document ID 0058).

OSHA is proposing several updates to section 9, Physical and chemical properties. OSHA proposes to revise section 9 to align with the GHS Rev. 7 by listing the required physical and chemical properties of the chemical in the same order that appears in the GHS (UN GHS, 2017, Document ID 0060). While OSHA does not require SDS

preparers to list the physical and chemical properties in any particular order, the agency is proposing this change in order to simplify preparation for those chemical manufacturers that may prepare SDSs for global distribution. Other proposed changes to section 9 include: Replacing ''appearance'' with ''physical state'' and ''color''; eliminating ''odor threshold'' and ''evaporation rate'' as separate required properties; adding the term ''kinematic'' to the property ''viscosity'' in order to better define the appropriate parameter to be characterized (*i.e.,* kinematic as opposed to dynamic viscosity); and adding ''particle characteristics'' as a new physical property. Particle characteristics apply to solids only and the description should include the particle size (median and range) and, if available and appropriate, further properties such as size distribution (range), shape and aspect ratio, and specific surface area. Particle characteristics can be an important indicator of the potential for a solid particle to pose a hazard as particles that are less than 100 microns increase the likelihood of exposure, especially through the route of inhalation (UN GHS, 2017, Document ID 0060; UN GHS, 2016; Document ID 0143, UN GHS, 2014, Document ID 0129).

OSHA is proposing one change to section 10 of the SDS, Stability and reactivity. Section 10(c) requires preparers to include the possibility of hazardous reactions, and OSHA is proposing to clarify that this includes hazardous reactions associated with foreseeable emergencies. The proposed language is consistent with the language OSHA is proposing for paragraph (d)(1) (*Hazard classification*).

In addition, OSHA is proposing to revise section 11, Toxicological information, to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) by adding interactive effects as paragraph (e). In light of that proposed change, OSHA is proposing to move existing paragraph (e) to paragraph (f). OSHA also proposes to add a new paragraph (g), providing that when specific chemical data or information is not available, SDS preparers must indicate if alternative information is used and the method used to derive the information (*e.g.,* where the preparer is using information from a class of chemicals rather than the exact chemical in question and using structure activity relationships (SAR) to derive the toxicological information). SAR and QSAR (quantitative SAR) are predictive tools that utilize the properties from known chemical structures and properties in relation to their biological activity to predict activities and properties of untested chemicals based on their structural similarity to tested chemicals (EPA, 2016, Document ID 0179). Read across is another predictive technique that uses information on an endpoint from a known (tested) substance to predict endpoint information from a similar (but unknown or untested) substance (ECHA, 2016, Document ID 0178). Specific, detailed examples of read across, SAR and QSAR are provided on the OECD's website for chemical safety—assessment of chemicals (OECD, 2019, Document ID 0091; EPA, 2016, Document ID 0179; ECHA, 2016, Document ID 0178). This proposed change reflects the advancement in the scientific application of computational toxicology to hazard assessment and identification and would align with the GHS Rev. 7 (Ballabio, 2018, Document ID 0128; Idakwo, 2020, Document ID 0123; OECD, Document ID 0091; Mangiatoridi, 2016, Document ID 0122; UN GHS, 2017, Document ID 0060).

Finally, OSHA is proposing to change non-mandatory section 14(f), Transport information, to read ''Transport in bulk according to IMO instructions'' [60] instead of ''Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)'' [61] to be consistent with text in the GHS Rev. 7 (IMSBC, 2017, Document ID 0141). This change is an update to the reference that previously only covered liquefied gases in bulk. The proposed change would provide guidance that the information in section 14 covers all bulk transport regardless of the physical form of the cargo, in accordance with IMO instruments: *e.g.,* Annex II or Annex V of MARPOL 73/789, the IBC code10, the IMSBC [62] code and the IGC [63] code. This change would also reflect standardization of conventions for the technology and safety upgrades in the IMO (a global standard-setting authority for the safety, security and environmental performance of international shipping under the United Nations).

XVI. Authority and Signature

This document was prepared under the direction of Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210. It is issued under the authority of sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); 5 U.S.C. 553; section 304, Clean Air Act Amendments of 1990 (Pub. L. 101–549, reprinted at 29 U.S.C.A. 655 Note); section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); section 107, Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); section 1031, Housing and Community Development Act of 1992 (42 U.S.C. 4853); section 126, Superfund Amendments and Reauthorization Act of 1986, as amended (reprinted at 29 U.S.C.A. 655 Note); Secretary of Labor's Order No. 8–2020 (85 FR 58383–94); and 29 CFR part 1911.

List of Subjects in 29 CFR Part 1910

Chemicals, Diseases, Explosives, Flammable materials, Gases, Hazardous substances, Incorporation by reference, Labeling, Occupational safety and health, Safety, Signs and symbols.

Signed at Washington, DC, on December 28, 2020.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

Proposed Amendments

For the reasons set forth in the preamble, chapter XVII of title 29, part 1910 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

■ 1. The authority citation for part 1910 continues to read as follows:

Authority: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754); 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), 1–2012 (77 FR 3912), or 08–2020 (85 FR 58393); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

■ 2. Amend § 1910.6 by:

■ a. Revising the last sentence of paragraph (a)(4);

■ b. Adding paragraphs (h)(29) and (r)(2)(vi);

■ c. Redesignating paragraphs (r)(4) and (5) as paragraphs (r)(6) and (7), redesignating paragraph (r)(3) as paragraph (r)(4), and adding new paragraphs (r)(3) and (r)(5);

■ d. Revising paragraph (bb); and

■ e. Adding paragraphs (cc) and (dd).

The revisions and additions read as follows:

[60] IMO Means the International Maritime Organization.

[61] MARPOL means the International Convention for prevention of Pollution from Ships.

[62] IMSBC Code means the International Maritime Solid Bulk Cargoes Code, as amended.

[63] IGC Code means The International Code of the Construction and Equipment of Ships Carrying Liquefied Gases in Bulk, as amended.

§ 1910.6 Incorporation by reference.

(a) * * *

(4) * * * For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

* * * * *

(h) * * *

(29) ASTM D 4359–90 (2019), Standard Test Method for Determining Whether a Material is a Liquid or a Solid, Re-approved 2019, IBR approved for § 1910.1200.

* * * * *

(r) * * *

(2) * * *

(vi) International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8 CP 401—1214 Vernier, Geneva, Switzerland; Telephone: +41 22 749 01 11; Fax: +41 22 733 34 30; Email: *central@iso.org;* website: *https://www.iso.org/store.html.*

(3) ISO 817:2014, Refrigerants—Designation and safety classification. Third Edition, June, 2014, IBR approved for appendix B to § 1910.1200.

* * * * *

(5) ISO 10156:2010, Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Third Edition, April, 2010, IBR approved for appendix B to § 1910.1200.

* * * * *

(bb) Except as noted, copies of the standards listed in this paragraph (bb) are available for purchase from United Nations Publications, P.O. Box 960 Herndon, VA 20172; telephone: 1–703–661–1571; fax: 1–703–996–1010; email: *order@un.org.*

(1) European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR), section 2.3.4 of Annex A, 2019, IBR approved for § 1910.1200. Website: *https://shop.un.org/series/european-agreement-concerning-international-carriage-dangerous-goods-road-adr.*

(2) UN ST/SG/AC.10/Rev.4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, IBR approved for appendix B to § 1910.1200. Copies available from:

(i) Bernan, 15200 NBN Way, Blue Ridge Summit, PA 17214; telephone: 1–800–865–3457; fax: 1–800–865–3450; email: customercare@bernan; website: *http://www.bernan.com;*

(ii) Renouf Publishing Co. Ltd., 812 Proctor Avenue, Ogdensburg, NY 13669–2205; telephone: 1–888–551–7470; Fax: 1–888–551–7471; email: *orders@renoufbooks.com;* website: *http://www.renoufbooks.com;* and

(iii) United Nations Publications, Customer Service, c/o National Book Network, 15200 NBN Way, P.O. Box 190, Blue Ridge Summit, PA 17214; telephone: 1–888–254–4286; fax: 1–800–338–4550; email: *unpublications@nbnbooks.com.*

(3) UN ST/SG/AC.10/30/Rev.6, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Sixth Revised Edition, 2015, IBR approved for appendix B to § 1910.1200. Website: *https://www.unece.org/trans/danger/publi/manual/manual_e.html.*

(cc) The following material is available for purchase from International Electrotechnical Commission through ANSI, 25 West 43rd Street, 4th Floor, New York, NY 10036; telephone: 1–212–642–4963; fax: 1–212–398–0023; website: *https://www.iec.ch.*

(1) IEC 60079–20–1 ed. 1.0 (2010–01) Explosive atmospheres—Part 20–1: Material characteristics for gas and vapor classification—Test methods and data, IBR approved for appendix B to § 1910.1200.

(2) [Reserved]

(dd) The following material is available for purchase from German Institute for Standardization (DIN) through ANSI, 25 West 43rd Street, 4th Floor, New York, NY 10036; telephone: 1–212–642–4963; fax: 1–212–398–0023; *https://din.de/en/about-standards/buy-standard.*

(1) DIN 51794—Determining the ignition temperature of petroleum products, 2003, IBR approved for appendix B to § 1910.1200.

(2) [Reserved]

■ 3. Amend § 1910.1200:

■ a. By revising paragraphs (a)(1) and (b)(6)(x);

■ b. In paragraph (c):

■ i. By removing the period following the subject heading and adding a colon in its place;

■ ii. By adding in alphabetical order definitions for ''Bulk shipment'' and ''Combustible dust'';

■ iii. By revising the definition of ''Exposure or exposed'';

■ iv. By adding in alphabetical order a definition for ''Gas'';

■ v. By revising the definition of ''Hazardous chemical'';

■ vi. By adding in alphabetical order definitions for ''Immediate outer package'' and ''Liquid'';

■ vii. By revising the definition of ''Physical hazard'';

■ viii. By adding in alphabetical order a definition for ''Physician or other licensed health are professional (PLHCP)'';

■ ix. By removing the definition of ''Pyrophoric gas''; and

■ x. By adding in alphabetical order definitions for ''Released for shipment'' and ''Solid'';

■ c. By revising paragraphs (d)(1), (e)(4), and (f)(1), (5), and (11);

■ d. By adding paragraph (f)(12);

■ e. By revising paragraphs (g)(2) introductory text, (g)(10), (i)(1) and (2), (i)(3) introductory text, and (j); and

■ f. By revising appendices A through D.

The revisions and additions read as follows:

§ 1910.1200 Hazard communication.

(a) * * *

(1) The purpose of this section is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees. The requirements of this section are intended to be consistent with the provisions of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Revision 7. The transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, safety data sheets and employee training.

* * * * *

(b) * * *

(6) * * *

(x) Nuisance particulates where the chemical manufacturer or importer can establish that they do not pose any physical hazard, health hazard, or other hazards covered under this section;

* * * * *

(c) * * *

Bulk shipment means any hazardous chemical transported where the mode of transportation (vehicle) comprises the immediate container (*i.e.,* contained in tanker truck, rail car, or intermodal container).

* * * * *

Combustible dust means finely divided solid particles of a substance or mixture that are liable to catch fire or explode on ignition when dispersed in air or other oxidizing media.

* * * * *

Exposure or exposed means that an employee is subjected in the course of employment to a hazardous chemical, and includes potential (*e.g.,* accidental or possible) exposure. ''Subjected'' in terms of health hazards includes any route of entry (*e.g.,* inhalation, ingestion, skin contact or absorption).

* * * * *

Gas means a substance which—at 122 °F (50 °C) has a vapor pressure greater than 43.51 PSI (300 kPa) (absolute); or

is completely gaseous at 68 °F (20 °C) at a standard pressure of 14.69 PSI (101.3 kPa).

* * * * *

Hazardous chemical means any chemical which is classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, or hazard not otherwise classified.

* * * * *

Immediate outer package means the first package enclosing the container of hazardous chemical.

* * * * *

Liquid means a substance or mixture which at 122 °F (50 °C) has a vapor pressure of not more than 43.51 PSI (300 kPa (3 bar)), which is not completely gaseous at 68 °F (20 °C) and at a standard pressure of 101.3 kPa, and which has a melting point or initial melting point of 68 °F (20 °C) or less at a standard pressure of 14.69 PSI (101.3 kPa). A viscous substance or mixture for which a specific melting point cannot be determined shall be subjected to ASTM D 4359–90 (2019) (Standard Test Method for Determining Whether a Material Is a Liquid or a Solid) (incorporated by reference; see § 1910.6); or to the test for determining fluidity (penetrometer test) prescribed in the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR), section 2.3.4 of Annex A (2019) (incorporated by reference; see § 1910.6).

* * * * *

Physical hazard means a chemical that is classified as posing one of the following hazardous effects: Explosive; flammable (gases, liquids, or solids); aerosols; oxidizer (liquid, solid or gas); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; in contact with water emits flammable gas; or desensitized explosive. The criteria for determining whether a chemical is classified as a physical hazard are detailed in appendix B to this section.

Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice (*i.e.,* license, registration, or certification) allows the individual to independently provide or be delegated the responsibility to provide some or all of the health care services referenced in paragraph (i) of this section.

* * * * *

Released for shipment means a chemical that has been packaged and labeled in the manner in which it will be distributed or sold.

* * * * *

Solid means a substance or mixture which does not meet the definitions of liquid or gas.

* * * * *

(d) * * *

(1) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to classify the chemicals in accordance with this section. For each chemical, the chemical manufacturer or importer shall determine the hazard classes, and where appropriate, the category of each class that apply to the chemical being classified under normal conditions of use and foreseeable emergencies. The hazard classification shall include any hazards associated with a change in the chemical's physical form or resulting from a reaction with other chemicals under normal conditions of use. Employers are not required to classify chemicals unless they choose not to rely on the classification performed by the chemical manufacturer or importer for the chemical to satisfy this paragraph (d)(1).

* * * * *

(e) * * *

(4) The employer shall make the written hazard communication program available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director, in accordance with the requirements of § 1910.1020(e).

* * * * *

(f) * * *

(1) *Labels on shipped containers.* The chemical manufacturer, importer, or distributor shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged or marked. Hazards not otherwise classified and hazards resulting from a reaction with other chemicals under normal conditions of use do not have to be addressed on the container. Where the chemical manufacturer, importer, or distributor is required to label, tag or mark the following shall be provided:

(i) Product identifier;

(ii) Signal word;

(iii) Hazard statement(s);

(iv) Pictogram(s);

(v) Precautionary statement(s);

(vi) Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party; and

(vii) Date chemical is released for shipment.

* * * * *

(5) *Transportation.* (i) Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 *et seq.*) and regulations issued under that Act by the Department of Transportation.

(ii) The label for bulk shipments of hazardous chemicals may be on the immediate container or may be transmitted with the shipping papers, bills of lading, or other technological or electronic means so that it is immediately available to workers in printed form on the receiving end of shipment.

(iii) Where a pictogram required by the Department of Transportation under title 49 of the Code of Federal Regulations appears on the label for a shipped container, the pictogram specified in appendix C.4 of this section for the same hazard is not required on the label.

* * * * *

(11) *Release for shipment.* Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. Chemicals that have been released for shipment and are awaiting future distribution need not be relabeled; however, the chemical manufacturer or importer must provide the updated label for each individual container with each shipment. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.

(12) *Small container labelling.* (i) This paragraph (f)(12) applies where the chemical manufacturer, importer, or distributor can demonstrate that it is not feasible to use pull-out labels, fold-back labels, or tags containing the full label information required by paragraph (f)(1) of this section.

(ii) For a container less than or equal to 100 ml capacity, the chemical manufacturer, importer, or distributor must include, at a minimum, the following information on the label of the container:

(A) Product identifier;

(B) Pictogram(s);

(C) Signal word;

(D) Chemical manufacturer's name and phone number; and

(E) A statement that the full label information for the hazardous chemical

is provided on the immediate outer package.

(iii) For a container less than or equal to 3 ml capacity, where the chemical manufacturer, importer, or distributor can demonstrate that any label interferes with the normal use of the container, no label is required, but the container must bear, at a minimum, the product identifier.

(iv) For all small containers covered by paragraph (f)(12)(ii) or (iii) of this section, the immediate outer package must include:

(A) The full label information required by paragraph (f)(1) of this section for each hazardous chemical in the immediate outer package. The label must not be removed or defaced, as required by paragraph (f)(9) of this section.

(B) A statement that the small container(s) inside must be stored in the immediate outer package bearing the complete label when not in use.

(g) * * *

(2) The chemical manufacturer or importer shall ensure that the safety data sheet is in English (although the employer may maintain copies in other languages as well), and includes at least the following section numbers and headings, and associated information under each heading, in the order listed (See appendix D to this section for the specific content of each section of the safety data sheet):

* * * * *

(10) Safety data sheets may be kept in any form, including as operating procedures, and may be stored in such a way to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual hazardous chemicals. However, the employer shall ensure that in all cases the required information is provided for each hazardous chemical, and is readily accessible during each work shift to employees when they are in their work area(s).

* * * * *

(i) * * *

(1) The chemical manufacturer, importer, or employer may withhold the specific chemical identity, including the chemical name, other specific identification of a hazardous chemical, or the exact percentage (concentration) or concentration range of the substance in a mixture, from section 3 of the safety data sheet, provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) Information contained in the safety data sheet concerning the properties and effects of the hazardous chemical is disclosed;

(iii) The safety data sheet indicates that the specific chemical identity and/or concentration or concentration range of composition is being withheld as a trade secret;

(iv) If the concentration or concentration range is being claimed as a trade secret then the safety data sheet provides the ingredient's concentration as one of the prescribed ranges in paragraphs (i)(1)(iv)(A) through (M) of this section.

(A) From 0.1% to 1%;
(B) From 0.5% to 1.5%;
(C) From 1% to 5%;
(D) From 3% to 7%;
(E) From 5% to 10%;
(F) From 7% to 13%;
(G) From 10% to 30%;
(H) From 15% to 40%;
(I) From 30% to 60%;
(J) From 45% to 70%;
(K) From 60% to 80%;
(L) From 65% to 85%; and
(M) From 80% to 100%.

(v) The prescribed concentration range used must be the narrowest range possible. If the exact concentration range falls between 0.1% and 30% and does not fit entirely into one of the prescribed concentration, a single range created by the combination of two applicable consecutive ranges (*e.g.,* between (i)(1)(iv)(A) and (G)) may be disclosed instead, provided that the combined concentration range does not include any range that falls entirely outside the exact concentration range in which the ingredient is present.

(vi) The specific chemical identity and exact concentration or concentration range is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of this paragraph (i).

(2) Where a treating PLHCP determines that a medical emergency exists and the specific chemical identity and/or specific concentration or concentration range of a hazardous chemical is necessary for emergency or first-aid treatment, the chemical manufacturer, importer, or employer shall immediately disclose the specific chemical identity or percentage composition of a trade secret chemical to that treating PLHCP, regardless of the existence of a written statement of need or a confidentiality agreement. The chemical manufacturer, importer, or employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (i)(3) and (4) of this section, as soon as circumstances permit.

(3) In non-emergency situations, a chemical manufacturer, importer, or employer shall, upon request, disclose a specific chemical identity or exact concentration or concentration range, otherwise permitted to be withheld under paragraph (i)(1) of this section, to a health professional (*e.g.,* PLHCP, industrial hygienist, toxicologist, or epidemiologist) providing medical or other occupational health services to exposed employee(s), and to employees or designated representatives, if:

* * * * *

(j) *Dates.* (1) This section is effective [DATE 60 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**].

(2) Chemical manufacturers, importers, and distributors evaluating substances shall be in compliance with all modified provisions of this section no later than [DATE ONE YEAR AFTER EFFECTIVE DATE OF FINAL RULE].

(3) Chemical manufacturers, importers, and distributors evaluating mixtures shall be in compliance with all modified provisions of this section no later than 24 months after [DATE TWO YEARS AFTER EFFECTIVE DATE OF FINAL RULE].

* * * * *

Appendix A to § 1910.1200—Health Hazard Criteria (Mandatory)

A.0 General Classification Considerations

A.0.1 Classification

A.0.1.1 The term ''hazard classification'' is used to indicate that only the intrinsic hazardous properties of chemicals are considered. Hazard classification incorporates three steps:

(a) Identification of relevant data regarding the hazards of a chemical;

(b) Subsequent review of those data to ascertain the hazards associated with the chemical;

(c) Determination of whether the chemical will be classified as hazardous and the degree of hazard.

A.0.1.2 For many hazard classes, the criteria are semi-quantitative or qualitative and expert judgment is required to interpret the data for classification purposes.

A.0.1.3 Where impurities, additives or individual constituents of a substance or mixture have been identified and are themselves classified, they should be taken into account during classification if they exceed the cut-off value/concentration limit for a given hazard class.

A.0.2 Available Data, Test Methods and Test Data Quality

A.0.2.1 There is no requirement for testing chemicals.

A.0.2.2 The criteria for determining health hazards are test method neutral, *i.e.,* they do not specify particular test methods, as long as the methods are scientifically validated.

A.0.2.3 The term ''scientifically validated'' refers to the process by which the reliability and the relevance of a procedure are established for a particular purpose. Any test that determines hazardous properties, which is conducted according to recognized scientific principles, can be used for purposes of a hazard determination for health hazards. Test conditions need to be standardized so that the results are reproducible with a given substance, and the standardized test yields ''valid'' data for defining the hazard class of concern.

A.0.2.4 Existing test data are acceptable for classifying chemicals, although expert judgment also may be needed for classification purposes.

A.0.2.5 The effect of a chemical on biological systems is influenced, by the physico-chemical properties of the substance and/or ingredients of the mixture and the way in which ingredient substances are biologically available. A chemical need not be classified when it can be shown by conclusive experimental data from scientifically validated test methods that the chemical is not biologically available.

A.0.2.6 For classification purposes, epidemiological data and experience on the effects of chemicals on humans (*e.g.,* occupational data, data from accident databases) shall be taken into account in the evaluation of human health hazards of a chemical.

A.0.3 Classification Based on Weight of Evidence

A.0.3.1 For some hazard classes, classification results directly when the data satisfy the criteria. For others, classification of a chemical shall be determined on the basis of the total weight of evidence using expert judgment. This means that all available information bearing on the classification of hazard shall be considered together, including the results of valid *in vitro* tests, relevant animal data, and human experience such as epidemiological and clinical studies and well-documented case reports and observations.

A.0.3.2 The quality and consistency of the data shall be considered. Information on chemicals related to the material being classified shall be considered as appropriate, as well as site of action and mechanism or mode of action study results. Both positive and negative results shall be considered together in a single weight-of-evidence determination.

A.0.3.3 Positive effects which are consistent with the criteria for classification, whether seen in humans or animals, shall normally justify classification. Where evidence is available from both humans and animals and there is a conflict between the findings, the quality and reliability of the evidence from both sources shall be evaluated in order to resolve the question of classification. Reliable, good quality human data shall generally have precedence over other data. However, even well-designed and conducted epidemiological studies may lack a sufficient number of subjects to detect relatively rare but still significant effects, or to assess potentially confounding factors. Therefore, positive results from well-conducted animal studies are not necessarily negated by the lack of positive human experience but require an assessment of the robustness, quality and statistical power of both the human and animal data.

A.0.3.4 Route of exposure, mechanistic information, and metabolism studies are pertinent to determining the relevance of an effect in humans. When such information raises doubt about relevance in humans, a lower classification may be warranted. When there is scientific evidence demonstrating that the mechanism or mode of action is not relevant to humans, the chemical should not be classified.

A.0.3.5 Both positive and negative results are considered together in the weight of evidence determination. However, a single positive study performed according to good scientific principles and with statistically and biologically significant positive results may justify classification.

A.0.4 Considerations for the Classification of Mixtures

A.0.4.1 Except as provided in A.0.4.2, the process of classification of mixtures is based on the following sequence:

(a) Where test data are available for the complete mixture, the classification of the mixture will always be based on those data;

(b) Where test data are not available for the mixture itself, the bridging principles designated in each health hazard chapter of this appendix shall be considered for classification of the mixture;

(c) If test data are not available for the mixture itself, and the available information is not sufficient to allow application of the above-mentioned bridging principles, then the method(s) described in each chapter for estimating the hazards based on the information known will be applied to classify the mixture (*e.g.,* application of cut-off values/concentration limits).

A.0.4.2 An exception to the above order or precedence is made for Carcinogenicity, Germ Cell Mutagenicity, and Reproductive Toxicity. For these three hazard classes, mixtures shall be classified based upon information on the ingredient substances, unless on a case-by-case basis, justification can be provided for classifying based upon the mixture as a whole. See chapters A.5, A.6, and A.7 for further information on case-by-case bases.

A.0.4.3 Use of cut-off values/concentration limits

A.0.4.3.1 When classifying an untested mixture based on the hazards of its ingredients, cut-off values/concentration limits for the classified ingredients of the mixture are used for several hazard classes. While the adopted cut-off values/concentration limits adequately identify the hazard for most mixtures, there may be some that contain hazardous ingredients at lower concentrations than the specified cut-off values/concentration limits that still pose an identifiable hazard. There may also be cases where the cut-off value/concentration limit is considerably lower than the established non-hazardous level for an ingredient.

A.0.4.3.2 If the classifier has information that the hazard of an ingredient will be evident (*i.e.,* it presents a health risk) below the specified cut-off value/concentration limit, the mixture containing that ingredient shall be classified accordingly.

A.0.4.3.3 In exceptional cases, conclusive data may demonstrate that the hazard of an ingredient will not be evident (*i.e.,* it does not present a health risk) when present at a level above the specified cut-off value/concentration limit(s). In these cases the mixture may be classified according to those data. The data must exclude the possibility that the ingredient will behave in the mixture in a manner that would increase the hazard over that of the pure substance. Furthermore, the mixture must not contain ingredients that would affect that determination.

A.0.4.4 Synergistic or antagonistic effects

When performing an assessment in accordance with these requirements, the evaluator must take into account all available information about the potential occurrence of synergistic effects among the ingredients of the mixture. Lowering classification of a mixture to a less hazardous category on the basis of antagonistic effects may be done only if the determination is supported by sufficient data.

A.0.5 Bridging principles for the classification of mixtures where test data are not available for the complete mixture

A.0.5.1 Where the mixture itself has not been tested to determine its toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles, subject to any specific provisions for mixtures for each hazard class. These principles ensure that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture.

A.0.5.1.1 Dilution

For mixtures classified in accordance with A.1 through A.10 of this appendix, if a tested mixture is diluted with a diluent that has an equivalent or lower toxicity classification than the least toxic original ingredient, and which is not expected to affect the toxicity of other ingredients, then:

(a) The new diluted mixture shall be classified as equivalent to the original tested mixture; or

(b) For classification of acute toxicity in accordance with A.1 of this appendix, paragraph A.1.3.6 (the additivity formula) shall be applied.

A.0.5.1.2 Batching

For mixtures classified in accordance with A.1 through A.10 of this appendix, the toxicity of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same mixture, when produced by or under the control of the same *chemical manufacturer*, unless there is reason to believe there is significant variation such that the toxicity of the untested batch has changed. If the latter occurs, a new classification is necessary.

A.0.5.1.3 Concentration of mixtures

For mixtures classified in accordance with A.1, A.2, A.3, A.4, A.8, A.9, or A.10 of this appendix, if a tested mixture is classified in Category 1, and the concentration of the

ingredients of the tested mixture that are in Category 1 is increased, the resulting untested mixture shall be classified in Category 1.

A.0.5.1.4 Interpolation within one hazard category

For mixtures classified in accordance with A.1, A.2, A.3, A.4, A.8, A.9, or A.10 of this appendix, for three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same hazard category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same hazard category as A and B.

A.0.5.1.5 Substantially similar mixtures

For mixtures classified in accordance with A.1 through A.10 of this appendix, given the following set of conditions:

(a) Where there are two mixtures: (i) A + B; (ii) C + B;

(b) The concentration of ingredient B is essentially the same in both mixtures;

(c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);

(d) And data on toxicity for A and C are available and substantially equivalent; *i.e.,* they are in the same hazard category and are not expected to affect the toxicity of B; then

If mixture (i) or (ii) is already classified based on test data, the other mixture can be assigned the same hazard category.

A.0.5.1.6 Aerosols

For mixtures classified in accordance with A.1, A.2, A.3, A.4, A.8, or A.9 of this appendix, an aerosol form of a mixture shall be classified in the same hazard category as the tested, non-aerosolized form of the mixture, provided the added propellant does not affect the toxicity of the mixture when spraying.

A.1 Acute Toxicity

A.1.1 Definition

Acute toxicity refers to serious adverse health effects (*i.e.,* lethality) occurring after a single or short-term oral, dermal, or inhalation exposure to a substance or mixture.

A.1.2 Classification Criteria for Substances

A.1.2.1 Substances can be allocated to one of four hazard categories based on acute toxicity by the oral, dermal or inhalation route according to the numeric cut-off criteria as shown in Table A.1.1. Acute toxicity values are expressed as (approximate) LD50 (oral, dermal) or LC50 (inhalation) values or as acute toxicity estimates (ATE). While some *in vivo* methods determine LD_{50}/LC_{50} values directly, other newer *in vivo* methods (*e.g.,* using fewer animals) consider other indicators of acute toxicity, such as significant clinical signs of toxicity, which are used by reference to assign the hazard category. See the footnotes following Table A.1.1 for further explanation on the application of these values.

Table A.1.1: Acute toxicity hazard categories and acute toxicity estimate (ATE) values defining the respective categories

Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) see: *Note (a)* *Note (b)*	ATE ≤ 5	>5 ATE ≤ 50	>50 ATE ≤ 300	>300 ATE ≤ 2000
Dermal (mg/kg bodyweight) see: *Note (a)* *Note (b)*	ATE ≤ 5	>50 ATE ≤ 200	>200 ATE ≤ 1000	>1000 ATE ≤ 2000
Inhalation - Gases (ppmV) see: *Note (a)* *Note (b)* *Note (c)*	ATE ≤ 100	>100 ATE ≤ 500	>500 ATE ≤ 2500	>2500 ATE ≤ 20000
Inhalation - Vapors (mg/l) see: *Note (a)* *Note (b)* *Note (c)* *Note (d)*	ATE ≤ 0.5	>0.5 ATE ≤ 2.0	>2.0 ATE ≤ 10.0	>10.0 ATE ≤ 20.0
Inhalation – **Dusts and Mists** (mg/l) see: *Note (a)* *Note (b)* *Note (c)*	ATE ≤ 0.05	>0.05 ATE ≤ 0.5	>0.5 ATE ≤ 1.0	>1.0 ATE ≤ 5.0

Note: Gas concentrations are expressed in parts per million per volume (ppmV).

Notes to Table A.1.1:

(a) The acute toxicity estimate (ATE) for the classification of a substance is derived using the LD_{50}/LC_{50} where available;

(b) The acute toxicity estimate (ATE) for the classification of a substance or ingredient in a mixture is derived using:

(i) the LD_{50}/LC_{50} where available. Otherwise,

(ii) the appropriate conversion value from Table 1.2 that relates to the results of a range test, or

(iii) the appropriate conversion value from Table 1.2 that relates to a classification category;

(c) Inhalation cut-off values in the table are based on 4 hour testing exposures. Conversion of existing inhalation toxicity data which has been generated according to 1 hour exposure is achieved by dividing by a factor of 2 for gases and vapors and 4 for dusts and mists;

(d) For some substances the test atmosphere will be a vapor which consists of a combination of liquid and gaseous phases. For other substances the test atmosphere may consist of a vapor which is nearly all the gaseous phase. In these latter cases, classification is based on ppmV as follows: Category 1 (100 ppmV), Category 2 (500 ppmV), Category 3 (2500 ppmV), Category 4 (20000 ppmV).

The terms "dust", "mist" and "vapor" are defined as follows:

(i) Dust: solid particles of a substance or mixture suspended in a gas (usually air);

(ii) Mist: liquid droplets of a substance or mixture suspended in a gas (usually air);

(iii) Vapor: the gaseous form of a substance or mixture released from its liquid or solid state.

A.1.2.3 The preferred test species for evaluation of acute toxicity by the oral and inhalation routes is the rat, while the rat or rabbit are preferred for evaluation of acute dermal toxicity. Test data already generated for the classification of chemicals under

existing systems should be accepted when reclassifying these chemicals under the harmonized system. When experimental data for acute toxicity are available in several animal species, scientific judgment should be used in selecting the most appropriate LD_{50} value from among scientifically validated tests. In cases where data from human experience (*i.e.,* occupational data, data from accident databases, epidemiology studies, clinical reports) is also available, it should be considered in a weight of evidence approach consistent with the principles described in A.0.3.

A.1.2.4 In addition to classification for inhalation toxicity, if data are available that indicates that the mechanism of toxicity was corrosivity of the substance or mixture, the classifier must consider if the chemical is *corrosive to the respiratory tract.* Corrosion of the respiratory tract is defined as destruction of the respiratory tract tissue after a single, limited period of exposure analogous to skin corrosion; this includes destruction of the mucosa. The corrosivity evaluation could be based on expert judgment using such evidence as: Human and animal experience, existing (*in vitro*) data, pH values, information from similar substances or any other pertinent data.

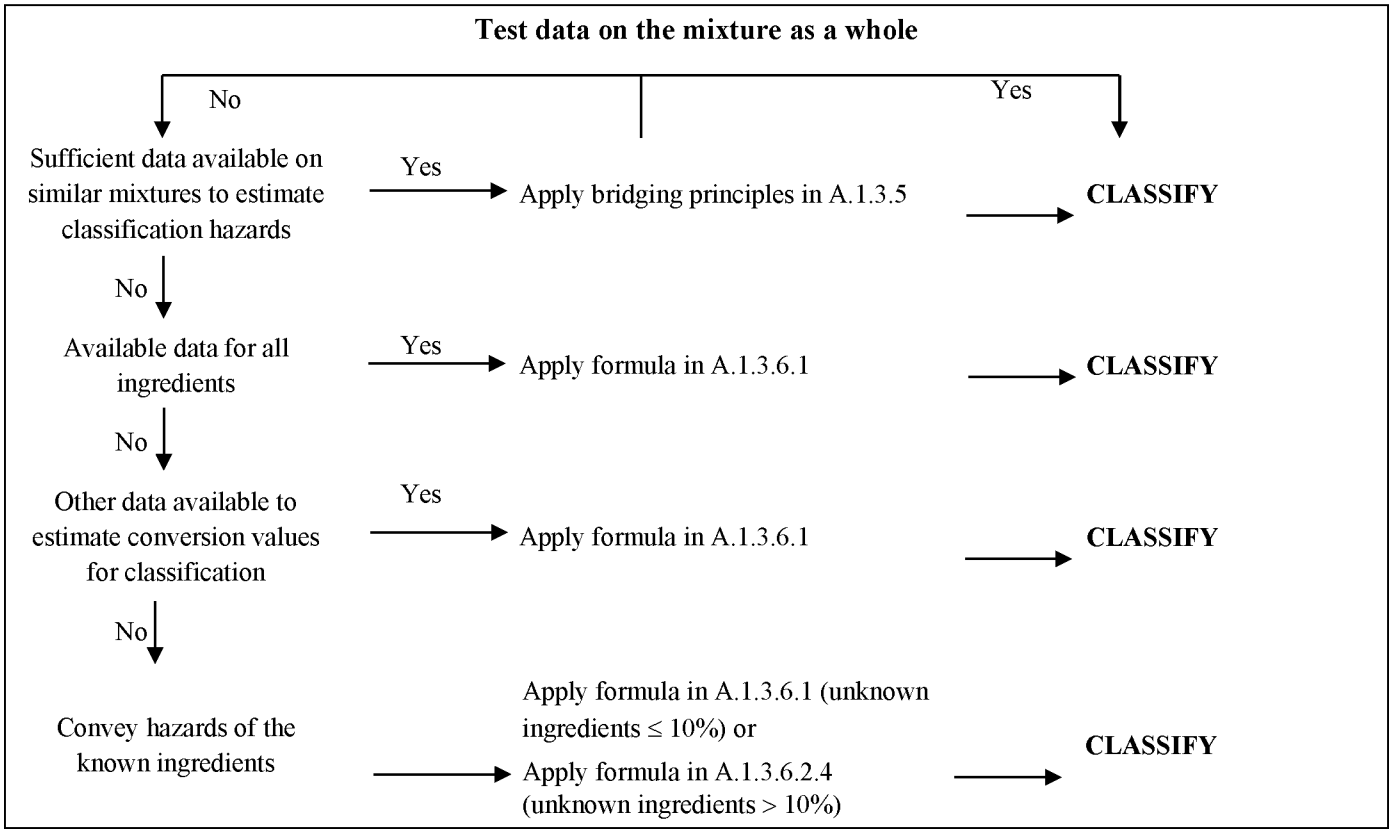
A.1.2.4.1 If the classifier determines the chemical is corrosive to the respiratory tract and data are available that indicate that the effect leads to lethality, then the chemical must be labelled with the hazard statement ''corrosive to the respiratory tract.''

A.1.2.4.2 If the classifier determines the chemical is corrosive to the respiratory tract and the effect does not lead to lethality, then the chemical must be addressed in the Specific Target Organ Toxicity hazard classes (see A.8 and A.9).

A.1.3 Classification Criteria for Mixtures

A.1.3.1 The approach to classification of mixtures for acute toxicity is tiered, and is dependent upon the amount of information available for the mixture itself and for its ingredients. The flow chart of Figure A.1.1 indicates the process that must be followed:

Figure A.1.1: Tiered approach to classification of mixtures for acute toxicity



A.1.3.2 Classification of mixtures for acute toxicity may be carried out for each route of exposure, but is only required for one route of exposure as long as this route is followed (estimated or tested) for all ingredients and there is no relevant evidence to suggest acute toxicity by multiple routes. When there is relevant evidence of acute toxicity by multiple routes of exposure, classification is to be conducted for all appropriate routes of exposure. All available information shall be considered. The pictogram and signal word used shall reflect the most severe hazard category; and all relevant hazard statements shall be used.

A.1.3.3 For purposes of classifying the hazards of mixtures in the tiered approach:

(a) The ''relevant ingredients'' of a mixture are those which are present in concentrations ≥1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases). If there is reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for acute toxicity, that ingredient shall also be considered relevant. Consideration of ingredients present at a concentration <1% is particularly important when classifying untested mixtures which contain ingredients that are classified in Category 1 and Category 2;

(b) Where a classified mixture is used as an ingredient of another mixture, the actual or derived acute toxicity estimate (ATE) for that mixture is used when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.

(c) If the converted acute toxicity point estimates for all ingredients of a mixture are within the same category, then the mixture should be classified in that category.

(d) When only range data (or acute toxicity hazard category information) are available for ingredients in a mixture, they may be converted to point estimates in accordance with Table A.1.2 when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.

A.1.3.4 Classification of Mixtures Where Acute Toxicity Test Data Are Available for the Complete Mixture

Where the mixture itself has been tested to determine its acute toxicity, it is classified according to the same criteria as those used for substances, presented in Table A.1.1. If test data for the mixture are not available, the procedures presented below must be followed.

A.1.3.5 Classification of Mixtures Where Acute Toxicity Test Data Are Not Available for the Complete Mixture: Bridging Principles

A.1.3.5.1 Where the mixture itself has not been tested to determine its acute toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one hazard category, Substantially similar mixtures, and Aerosols.

A.1.3.6 Classification of Mixtures Based on Ingredients of the Mixture (Additivity Formula)

A.1.3.6.1 Data available for all ingredients.

The acute toxicity estimate (ATE) of ingredients is considered as follows:

(a) *Include ingredients with a known acute toxicity, which fall into any of the acute toxicity hazard categories, or have an oral or dermal LD_{50} greater than 2,000 but less than or equal to 5,000 mg/kg body weight (or the equivalent dose for inhalation);

(b) Ignore ingredients that are presumed not acutely toxic (*e.g.,* water, sugar);

(c) Ignore ingredients if the data available are from a limit dose test (at the upper threshold for Category 4 for the appropriate route of exposure as provided in Table A.1.1) and do not show acute toxicity.

Ingredients that fall within the scope of this paragraph are considered to be ingredients with a known acute toxicity estimate (ATE). See note (b) to Table A.1.1 and paragraph A.1.3.3 for appropriate application of available data to the equation below, and paragraph A.1.3.6.2.4.

The ATE of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula below for oral, dermal or inhalation toxicity:

$$\frac{100}{\mathrm{ATEmix}} = \sum_{n} \frac{\mathrm{Ci}}{\mathrm{ATE}_{i}}$$

where:

Ci = concentration of ingredient i

n ingredients and i is running from 1 to n

ATEi = acute toxicity estimate of ingredient i.

A.1.3.6.2 Data are not available for one or more ingredients of the mixture

A.1.3.6.2.1 Where an ATE is not available for an individual ingredient of the mixture, but available information provides a derived conversion value, the formula in A.1.3.6.1 may be applied. This information may include evaluation of:

(a) Extrapolation between oral, dermal and inhalation acute toxicity estimates. Such an evaluation requires appropriate pharmacodynamic and pharmacokinetic data;

(b) Evidence from human exposure that indicates toxic effects but does not provide lethal dose data;

(c) Evidence from any other toxicity tests/assays available on the substance that indicates toxic acute effects but does not necessarily provide lethal dose data; or

(d) Data from closely analogous substances using structure/activity relationships.

A.1.3.6.2.2 This approach requires substantial supplemental technical information, and a highly trained and experienced expert, to reliably estimate acute toxicity. If sufficient information is not available to reliably estimate acute toxicity, proceed to the provisions of A.1.3.6.2.4.

A.1.3.6.2.3 In the event that an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥1%, and the mixture has not been classified based on testing of the mixture as a whole, the mixture cannot be attributed a definitive acute toxicity estimate. In this situation the mixture is classified based on the known ingredients only. *Note:* A statement that × percent of the mixture consists of ingredient(s) of unknown acute (oral/dermal/inhalation) toxicity is required on the label and safety data sheet in such cases; see appendix C to this section, Allocation of Label Elements and appendix D to this section, Safety Data Sheets.)

A.1.3.6.2.4 If the total concentration of the relevant ingredient(s) with unknown acute toxicity is ≤10% then the formula presented in A.1.3.6.1 must be used. If the total concentration of the relevant ingredient(s) with unknown acute toxicity is >10%, the formula presented in A.1.3.6.1 is corrected to adjust for the percentage of the unknown ingredient(s) as follows:

$$\frac{100-\left(\sum \mathrm{C}_{\mathrm{unknown}}\mathrm{if} > 10\%\right)}{\mathrm{ATE}_{\mathrm{mix}}} = \sum_{n} \frac{\mathrm{Ci}}{\mathrm{ATE}_{i}}$$

A.2 Skin Corrosion/Irritation

A.2.1 Definitions and General Considerations

A.2.1.1 *Skin corrosion* refers to the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis occurring after exposure to a substance or mixture.

Skin irritation refers to the production of reversible damage to the skin occurring after exposure to a substance or mixture.

A.2.1.2 Skin corrosion/irritation shall be classified using a tiered approach as detailed in figure A.2.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by existing animal data, followed by *in vitro* data and then other sources of information. Classification results directly when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means that all available information bearing on the determination of skin corrosion/irritation is considered together, including the results of appropriate scientifically validated *in-vitro* tests, relevant animal data, and human data

such as epidemiological and clinical studies and well-documented case reports and observations.

A.2.2 Classification Criteria for Substances

Substances shall be allocated to one of the following categories within this hazard class:

(a) Category 1 (skin corrosion)

This category may be further divided into up to three sub-categories (1A, 1B and 1C)

(b) Category 2 (skin irritation)

A.2.2.1 Classification Based on Standard Animal Test Data

A.2.2.1.1 Skin Corrosion

A.2.2.1.2 A substance is corrosive to the skin when it produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure up to a 4-hour duration.

A.2.2.1.3 Three sub-categories of Category 1 are provided in Table A.2.1, all of which shall be regulated as Category 1.

TABLE A.2.1—SKIN CORROSION CATEGORY AND SUB-CATEGORIES [a]

	Criteria
Category 1	Destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure ≤4 h.
Sub-category 1A	Corrosive responses in at least one animal following exposure ≤3 min during an observation period ≤1 h.
Sub-category 1B	Corrosive responses in at least one animal following exposure >3 min and ≤1 h and observations ≤14 days.
Sub-category 1C	Corrosive responses in at least one animal after exposures >1 h and ≤4 h and observations ≤14 days.

[a] The use of human data is discussed in A.2.3.

A.2.2.2 Skin Irritation

A.2.2.2.1 A single irritant category (Category 2) is presented in the Table A.2.2. A substance is irritant to skin when it produces reversible damage to the skin following its application for up to 4 hours.

The major criterion for the irritant category is that at least 2 tested animals have a mean score of ≥2.3 ≤4.0.

A.2.2.2.2 An irritation category (Category 2) is provided that:

(a) Recognizes that some test substances may lead to effects which persist throughout the length of the test; and

(b) acknowledges that animal responses in a test may be variable.

A.2.2.2.3 Reversibility of skin lesions is another consideration in evaluating irritant responses. When inflammation persists to the end of the observation period in two or more test animals, taking into consideration alopecia (limited area), hyperkeratosis, hyperplasia and scaling, then a chemical should be considered to be an irritant.

A.2.2.2.4 Animal irritant responses within a test can be quite variable, as they are with corrosion. A separate irritant criterion accommodates cases when there is a significant irritant response but less than the mean score criterion for a positive test. For example, a substance might be designated as an irritant if at least 1 of 3 tested animals shows a very elevated mean score throughout the study, including lesions persisting at the end of an observation period of normally 14 days. Other responses could also fulfill this criterion. However, it should be ascertained that the responses are the result of chemical exposure. Addition of this criterion increases the sensitivity of the classification system.

TABLE A.2.2—SKIN IRRITATION CATEGORY [a b]

	Criteria
Irritant (Category 2)	(1) Mean score of ≥2.3 ≤4.0 for erythema/eschar or for edema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or (2) Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or (3) In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above.

[a] Grading criteria are understood as described in OECD Test Guideline 404.

A.2.3 Classification in a Tiered Approach

A.2.3.1 A *tiered approach* to the evaluation of initial information shall be used (Figure A.2.1) recognizing that not all elements may be relevant.

A.2.3.2 Existing human and animal data including information from single or repeated exposure should be the first line of evaluation, as they give information directly relevant to effects on the skin.

A.2.3.3 Acute dermal toxicity data may be used for classification. If a substance is highly toxic by the dermal route, a skin corrosion/irritation study may not be practicable since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. When observations are made of skin corrosion/irritation in acute toxicity studies and are observed up through the limit dose, these data may be used for classification provided that the dilutions used and species tested are equivalent. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes.

A.2.3.4 In *vitro* alternatives that have been scientifically validated shall be used to make classification decisions.

A.2.3.5 Likewise, pH extremes like ≤2 and ≥11.5 may indicate skin effects, especially when associated with significant acid/alkaline reserve (buffering capacity). Generally, such substances are expected to produce significant effects on the skin. In the absence of any other information, a substance is considered corrosive (Skin Category 1) if it has a pH ≤2 or a pH ≥11.5. However, if consideration of acid/alkaline reserve suggests the substance or mixture may not be corrosive despite the low or high pH value, this needs to be confirmed by other data, preferably data from an appropriate validated *in vitro* test.

A.2.3.6 In some cases sufficient information may be available from structurally related substances to make classification decisions.

A.2.3.7 The tiered approach explains how to organize existing information on a substance and to make a weight of evidence decision about hazard assessment and hazard classification (ideally without conducting new animal tests). Although information might be gained from the evaluation of single parameters within a tier, consideration should be given to the totality of existing information and making an overall weight of evidence determination. This is especially true when there is conflict in information available on some parameters.

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Figure A.2.1: Tiered evaluation for skin corrosion and irritation

Step	Parameter	Finding	Conclusion
1a:	Existing human or animal skin corrosion/irritation data [a] → ↓ Not corrosive/No data ↓	Skin corrosive →	**Category 1**[b]
1b:	Existing human or animal skin corrosion/irritation data [a] → ↓ Not irritant/No data ↓	Skin irritant →	**Category 2**[b]
1c:	Existing human or animal skin corrosion/irritation data [a] → ↓ No/Insufficient data ↓	Not a skin corrosive or skin irritant →	**Not classified**
2:	Other, existing skin data in animals [c] → ↓ No/Insufficient data ↓	Yes; other existing data showing that substance may cause skin corrosion or skin irritation →	**Category 1**[b] or **Category 2**[b]
3:	Existing *ex vivo/in vitro* data [d] → ↓ ↘ No/Insufficient data/Negative response ↓	Positive: Skin corrosive → Positive: Skin irritant →	**Category 1**[b] **Category 2**[b]
4:	pH-based assessment (with consideration of acid/alkaline reserve of the chemical) [e] → ↓	pH ≤ 2 or ≥ 11.5 with high acid/alkaline reserve or no data for acid/alkaline reserve →	**Category 1**

	Not pH extreme, no pH data or extreme pH with data showing low/no acid/alkaline reserve ↓		
5:	Validated Structure Activity Relationship (SAR) methods → ↓ ↘ No/Insufficient data ↓	Skin corrosive → Skin irritant →	**Category 1**[b] **Category 2**[b]
6:	Consideration of the total weight of evidence [f] → ↓ ↘	Skin corrosive → Skin irritant →	**Category1**[b] **Category 2**[b]
	No concern based on consideration of the sum of available data ↓		
7:	**Not classified**		

[a] *Existing human or animal data could be derived from single or repeated exposure(s), for example in occupational, consumer, transport or emergency response scenarios; or from purposely-generated data from animal studies conducted according to validated and internationally accepted test methods. Although human data from accident or poison center databases can provide evidence for classification, absence of incidents is not itself evidence for no classification as exposures are generally unknown or uncertain;*

[b] *Classify in the appropriate category/sub-category, as applicable;*

[c] *All existing animal data should be carefully reviewed to determine if sufficient skin corrosion/irritation evidence is available. In evaluating such data, however, the reviewer should bear in mind that the reporting of dermal lesions may be incomplete, testing and observations may be made on a species other than the rabbit, and species may differ in sensitivity in their responses;*

[d] *Evidence from studies using validated protocols with isolated human/animal tissues or other, non-tissue-based, though validated, protocols should be assessed. Examples of internationally accepted validated test methods for skin corrosion include OECD Test Guidelines 430 (Transcutaneous Electrical Resistance Test (TER)), 431(Human Skin Model Test), and 435 (Membrane Barrier Test Method). An example of a validated internationally accepted in vitro test method for skin irritation is OECD Test Guideline 439 (Reconstructed Human Epidermis Test Method);*

[e] *Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable. Presently there is no validated and internationally accepted method for assessing this parameter;*

[f] *All information that is available must be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. Expert judgment should be exercised prior to making such a determination. Negative results from applicable validated skin corrosion/irritation in vitro tests are considered in the total weight of evidence evaluation.*

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A.2.4 Classification Criteria for Mixtures

A.2.4.1 Classification of Mixtures When Data Are Available for the Complete Mixture

A.2.4.1.1 The mixture shall be classified using the criteria for substances, taking into account the tiered approach to evaluate data for this hazard class (as illustrated in Figure A.2.1).

A.2.4.1.2 When considering testing of the mixture, classifiers must use a tiered approach as included in the criteria for classification of substances for skin corrosion and irritation to help ensure an accurate classification, as well as to avoid unnecessary animal testing. In the absence of any other information, a mixture is considered corrosive (Skin Category 1) if it has a pH ≤2 or a pH ≥11.5. However, if consideration of acid/alkaline reserve suggests the mixture may not be corrosive despite the low or high pH value, then further evaluation may be necessary.

A.2.4.2 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.2.4.2.1 Where the mixture itself has not been tested to determine its skin corrosion/irritation potential, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one hazard category, Substantially similar mixtures, and Aerosols.

A.2.4.3 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.2.4.3.1 In order to make use of all available data for purposes of classifying the skin corrosion/irritation hazards of mixtures, the following assumption has been made and is applied where appropriate in the tiered approach:

The ''relevant ingredients'' of a mixture are those which are present in concentrations ≥1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases). If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for skin corrosion/irritation, that ingredient shall also be considered relevant.

A.2.4.3.2 In general, the approach to classification of mixtures as corrosive or irritant to the skin when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant ingredient contributes to the overall corrosive or irritant properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as corrosive or irritant when the sum of the concentrations of such ingredients exceeds a cut-off value/concentration limit.

A.2.4.3.3 Table A.2.3 below provides the cut-off value/concentration limits to be used to determine if the mixture is considered to be corrosive or irritant to the skin.

A.2.4.3.4 Particular care shall be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.2.4.3.1 and A.2.4.3.2 might not work given that many of such substances are corrosive or irritant at concentrations <1%. For mixtures containing strong acids or bases the pH should be used as classification criteria since pH will be a better indicator of corrosion than the concentration limits in Table A.2.3. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach shown in Table A.2.3, due to chemical characteristics that make this approach unworkable, should be classified as skin corrosion Category 1 if it contains ≥1% of a corrosive ingredient and as skin irritation Category 2 when it contains ≥3% of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.2.3 does not apply is summarized in Table A.2.4 below.

A.2.4.3.5 On occasion, reliable data may show that the skin corrosion/irritation of an ingredient will not be evident when present at a level above the generic cut-off values/concentration limits mentioned in Tables A.2.3 and A.2.4. In these cases the mixture could be classified according to those data (See *Use of cut-off values/concentration limits*, paragraph A.0.4.3 of this appendix).

A.2.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant to skin at a concentration of <1% (corrosive) or <3% (irritant), the mixture shall be classified accordingly (See *Use of cut-off values/concentration limits*, paragraph A.0.4.3 of this appendix).

TABLE A.2.3—CONCENTRATION OF INGREDIENTS OF A MIXTURE CLASSIFIED AS SKIN CATEGORY 1 OR 2 THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE AS HAZARDOUS TO SKIN

[Category 1 or 2]

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin corrosive	Skin irritant
	Category 1	Category 2
Skin Category 1	≥5%	≥1% but <5%
Skin Category 2		≥10%
(10 × Skin Category 1) + Skin Category 2		≥10%

Note: Where data are available and the sub-categories of skin Category 1 (corrosive) are used, the sum of all ingredients of a mixture classified as sub-category 1A, 1B or 1C respectively, must each be ≥5% in order to classify the mixture as either skin sub-category 1A, 1B or 1C. Where the sum of 1A ingredients is <5% but the sum of 1A + 1B ingredients is ≥5%, the mixturemust be classified as sub-category 1B. Similarly, where the sum of 1A + 1B ingredients is <5% but the sum of 1A + 1B + 1C ingredients is ≥5% the mixture must be classified as sub-category 1C. Where at least one relevant ingredient in a mixture is classified as Category 1 without sub-categorization, the mixture must be classified as Category 1 without sub-categorization if the sum of all ingredients corrosive to skin is ≥5%.

TABLE A.2.4—CONCENTRATION OF INGREDIENTS OF A MIXTURE WHEN THE ADDITIVITY APPROACH DOES NOT APPLY, THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE AS HAZARDOUS TO SKIN

Ingredient:	Concentration:	Mixture classified as: Skin
Acid with pH ≤2	≥1%	Category 1.
Base with pH ≥11.5	≥1%	Category 1.
Other corrosive (Category 1) ingredient	≥1%	Category 1.
Other irritant (Category 2) ingredient, including acids and bases	≥3%	Category 2.

A.3 Serious Eye Damage/Eye Irritation

A.3.1 Definitions and General Considerations

A.3.1.1 *Serious eye damage* refers to the production of tissue damage in the eye, or serious physical decay of vision, which is not fully reversible, occurring after exposure of the eye to a substance or mixture.

Eye irritation refers to the production of changes in the eye, which are fully reversible, occurring after exposure of the eye to a substance or mixture.

A.3.1.2 Serious eye damage/eye irritation shall be classified using a tiered approach as detailed in Figure A.3.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by existing animal data, followed by *in vitro* data and then other sources of information. Classification results directly when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means that all available information bearing on the determination of serious eye damage/eye irritation is considered together, including the results of appropriate scientifically validated *in vitro* tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.

A.3.2 Classification Criteria for Substances

Substances are allocated to one of the categories within this hazard class, Category 1 (serious eye damage) or Category 2 (eye irritation), as follows:

(a) Category 1 (serious eye damage/irreversible effects on the eye): Substances that have the potential to seriously damage the eyes (see Table A.3.1).

(b) Category 2 (eye irritation/reversible effects on the eye): Substances that have the potential to induce reversible eye irritation (see Table A.3.2).

A.3.2.1 *Classification based on standard animal test data.*

A.3.2.1.1 Serious eye damage (Category 1)/Irreversible effects on the eye.

A single hazard category is provided in Table A.3.1, for substances that have the potential to seriously damage the eyes. Category 1, irreversible effects on the eye, includes the criteria listed below. These observations include animals with grade 4 cornea lesions and other severe reactions (*e.g.,* destruction of cornea) observed at any time during the test, as well as persistent corneal opacity, discoloration of the cornea by a dye substance, adhesion, pannus, and interference with the function of the iris or other effects that impair sight. In this context, persistent lesions are considered those which are not fully reversible within an observation period of normally 21 days. Category 1 also contains substances fulfilling the criteria of corneal opacity ≥3 and/or iritis >1.5 observed in at least 2 of 3 tested animals detected in a Draize eye test with rabbits, because severe lesions like these usually do not reverse within a 21-day observation period.

TABLE A.3.1—SERIOUS EYE DAMAGE/IRREVERSIBLE EFFECTS ON THE EYE CATEGORY [a]

	Criteria
Category 1: Serious eye damage/Irreversible effects on the eye.	A substance that produces: (a) In at least one animal effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or (b) in at least 2 of 3 tested animals, a positive response of: (i) Corneal opacity ≥3; and/or (ii) iritis >1.5; calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the test material.

[a] Grading criteria are understood as described in OECD Test Guideline 405.

A.3.2.2 Eye irritation (Category 2)/Reversible effects on the eye.

A.3.2.2.1 A single Category 2 is provided in Table A.3.2 for substances that have the potential to induce reversible eye irritation.

When data are available, substances may be classified into Category 2A and Category 2B:

(a) For substances inducing eye irritant effects reversing within an observation time of normally 21 days, Category 2A applies.

(b) For substances inducing eye irritant effects reversing within an observation time of 7 days, Category 2B applies.

When a substance is classified as Category 2, without further categorization, the classification criteria are the same as those for 2A.

A.3.2.3 For those substances where there is pronounced variability among animal responses, this information may be taken into account in determining the classification.

TABLE A.3.2—REVERSIBLE EFFECTS ON THE EYE CATEGORIES [a]

	Criteria
	Substances that have the potential to induce reversible eye irritation.
Category 2/2A	Substances that produce in at least 2 of 3 tested animals a positive response of: (a) corneal opacity ≥1; and/or (b) iritis ≥1; and/or (c) conjunctival redness ≥2; and/or (d) conjunctival edema (chemosis) ≥2 calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the test material, and which fully reverses within an observation period of normally 21 days.
Category 2B	Within Category 2A an eye irritant is considered mildly irritating to eyes (Category 2B) when the effects listed above are fully reversible within 7 days of observation.

[a] Grading criteria are understood as described in OECD Test Guideline 405.

A.3.3 Classification in a Tiered Approach

A.3.3.1 A tiered approach to the evaluation of initial information shall be used where applicable, recognizing that all elements may not be relevant in certain cases (Figure A.3.1).

A.3.3.2 Existing human and animal data should be the first line of analysis, as they give information directly relevant to effects on the eye. Possible skin corrosion shall be evaluated prior to consideration of any testing for serious eye damage/eye irritation in order to avoid testing for local effects on eyes with skin corrosive substances.

A.3.3.3 *In vitro* alternatives that have been scientifically validated and accepted shall be used to make classification decisions.

A.3.3.4 Likewise, pH extremes like ≤2 and ≥11.5, may indicate serious eye damage, especially when associated with significant acid/alkaline reserve (buffering capacity). Generally, such substances are expected to produce significant effects on the eyes. In the absence of any other information, a substance is considered to cause serious eye damage (Category 1) if it has a pH ≤2 or ≥11.5.

However, if consideration of acid/alkaline reserve suggests the substance may not cause serious eye damage despite the low or high pH value, this needs needs to be confirmed by other data, preferably by data from an appropriate validated *in vitro* test.

A.3.3.5 In some cases sufficient information may be available from structurally related substances to make classification decisions.

A.3.3.6 The tiered approach explains how to organize existing information and to make a weight-of-evidence decision about hazard assessment and hazard classification (ideally without conducting new animal tests). Animal testing with corrosive substances should be avoided wherever possible. Although information might be gained from the evaluation of single parameters within a tier, consideration should be given to the totality of existing information and making an overall weight of evidence determination. This is especially true when there is conflict in information available on some parameters.

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Figure A.3.1 Tiered Evaluation for serious eye damage and eye irritation (See also Figure A.2.1)

Step	Parameter	Finding	Conclusion
1a:	Existing human or animal serious eye damage/eye irritation data [a] →	Serious eye damage →	**Category 1**
	↘	Eye irritant →	**Category 2**[b]
	↓ Negative data/Insufficient data/No data ↓		
1b:	Existing human or animal data, skin corrosion →	Skin corrosion →	**Category 1**
	↓ Negative data/Insufficient data/No data ↓		
1c:	Existing human or animal serious eye damage/eye irritation data [a] →	Existing data showing that substance does not cause serious eye damage or eye irritation →	**Not classified**
	↓ No/Insufficient data ↓		
2:	Other, existing skin/eye data in animals [c] →	Yes, other existing data showing that substance may cause serious eye damage →	**Category 1** [b]
	↘	Yes, other existing data showing that substance may cause eye irritation →	**Category 2**[b]
	↓ No/Insufficient data ↓		
3:	Existing *ex vivo/in vitro eye* data[d] →	Positive: serious eye damage →	**Category 1**

Step	Parameter	Finding	Conclusion
	↓ ↘ No/Insufficient data/Negative response ↓	Positive: eye irritant →	**Category 2**[b]
4:	pH-based assessment (with consideration of acid/alkaline reserve of the chemical) [e] → ↓ Not pH extreme, no pH data or extreme pH with data showing low/no acid/alkaline reserve ↓	pH ≤ 2 or ≥ 11.5 with high acid/alkaline reserve or no data for acid/alkaline reserve →	**Category 1**
5:	Validated Structure Activity Relationship (SAR) methods → ↗ ↓ ↘ No/Insufficient data ↓	Severe damage to eyes → Eye irritant → Skin corrosive →	**Category 1** **Category 2**[b] **Category 1**
6:	Consideration of the total weight of evidence [f] → ↓ ↘	Serious eye damage → Eye irritant →	**Category 1** **Category 2**[b]
	No concern based on consideration of the sum of available data ↓		
7:	**Not classified**		

[a] *Existing human or animal data could be derived from single or repeated exposure(s), for example in occupational, consumer, transport, or emergency response scenarios; or from purposely-generated data from animal studies conducted according to validated and internationally accepted test methods. Although human data from accident or poison center databases can provide evidence for classification, absence of incidents is not itself evidence for no classification as exposures are generally unknown or uncertain;*

[b] *Classify in the appropriate category as applicable;*

[c] *Existing animal data should be carefully reviewed to determine if sufficient serious eye damage/eye irritation evidence is available through other, similar information. It is recognized that not all skin irritants are eye irritants. Expert judgment should be exercised prior to making such a determination;*

[d] *Evidence from studies using validated protocols with isolated human/animal tissues or other non-tissue-based, validated protocols should be assessed. Examples of internationally accepted, validated test methods for identifying eye corrosives and severe irritants (*i.e.*, Serious Eye Damage) include OECD Test Guidelines 437 (Bovine Corneal Opacity and Permeability (BCOP)), 438 (Isolated Chicken Eye (ICE) and 460 (Fluorescein leakage (FL)). Presently there are no validated and internationally accepted in vitro test methods for identifying eye irritation. A positive test result from a validated in vitro test on skin corrosion would lead to the conclusion to classify as causing serious eye damage;*

[e] *Measurement of pH alone may be adequate, but assessment of acid/alkaline reserve (buffering capacity) would be preferable. Presently, there is no validated and internationally accepted method for assessing this parameter;*

[f] *All information that is available on a substance must be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. The weight of evidence including information on skin irritation may lead to classification for eye irritation. Negative results from applicable validated in vitro tests are considered in the total weight of evidence evaluation.*

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A.3.4 Classification Criteria for Mixtures

A.3.4.1 Classification of Mixtures When Data Are Available for the Complete Mixture

A.3.4.1.1 The mixture will be classified using the criteria for substances, and taking into account the tiered approach to evaluate data for this hazard class (as illustrated in Figure A.3.1).

A.3.4.1.2 When considering testing of the mixture, chemical manufacturers shall use a tiered approach as included in the criteria for classification of substances for skin corrosion and serious eye damage and eye irritation to help ensure an accurate classification, as well as to avoid unnecessary animal testing. In the absence of any other information, a mixture is considered to cause serious eye damage (Category 1) if it has a pH ≤2 or ≥11.5. However, if consideration of acid/alkaline reserve suggests the mixture may not have the potential to cause serious eye damage despite the low or high pH value, then further evaluation may be necessary.

A.3.4.2 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.3.4.2.1 Where the mixture itself has not been tested to determine its skin corrosivity or potential to cause serious eye damage or eye irritation, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one hazard category, Substantially similar mixtures, and Aerosols.

A.3.4.3 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.3.4.3.1 For purposes of classifying the serious eye damage/eye irritation hazards of mixtures in the tiered approach:

The ''relevant ingredients'' of a mixture are those which are present in concentrations ≥1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases). If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for serious eye damage/eye irritation, that ingredient shall also be considered relevant.

A.3.4.3.2 In general, the approach to classification of mixtures as seriously damaging to the eye or eye irritant when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each skin corrosive or serious eye damage/eye irritant ingredient contributes to the overall serious eye damage/eye irritation properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for skin corrosive and serious eye damaging ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as serious eye damaging/eye irritant. The mixture is classified as seriously damaging to the eye or eye irritant when the sum of the concentrations of such ingredients exceeds a threshold cut-off value/concentration limit.

A.3.4.3.3 Table A.3.3 provides the cut-off value/concentration limits to be used to determine if the mixture must be classified as seriously damaging to the eye or an eye irritant.

A.3.4.3.4 Particular care must be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.3.4.3.1 and A.3.4.3.2 might not work given that many of such substances are seriously damaging to the eye/eye irritating at concentrations <1%. For mixtures containing strong acids or bases, the pH should be used as classification criteria (See A.3.4.1) since pH will be a better indicator of serious eye damage (subject to consideration of acid/alkali reserve) than the concentration limits of Table A.3.3. A mixture containing skin corrosive or serious eye damaging/eye irritating ingredients that cannot be classified based on the additivity approach applied in Table A.3.3 due to chemical characteristics that make this approach unworkable, should be classified as serious eye damage (Category 1) if it contains ≥1% of a skin corrosive or serious eye damaging ingredient and as Eye Irritation (Category 2) when it contains ≥3% of an eye irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.3.3 does not apply is summarized in Table A.3.4.

A.3.4.3.5 On occasion, reliable data may show that the irreversible/reversible eye effects of an ingredient will not be evident when present at a level above the generic cut-off values/concentration limits mentioned in Tables A.3.3 and A.3.4. In these cases the mixture could be classified according to those data (See also A.0.4.3 Use of cut-off values/concentration limits''). On occasion, when it is expected that the skin corrosion/irritation or the reversible/irreversible eye effects of an ingredient will not be evident when present at a level above the generic concentration/cut-off levels mentioned in Tables A.3.3 and A.3.4, testing of the mixture may be considered. In those cases, the tiered weight of evidence approach should be applied as referred to in section A.3.3, Figure A.3.1 and explained in detail in this chapter.

A.3.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive to the skin or seriously damaging to the eye/eye irritating at a concentration of <1% (corrosive to the skin or seriously damaging to the eye) or <3% (eye irritant), the mixture shall be classified accordingly (See also paragraph A.0.4.3, Use of cut-off values/concentration limits).

TABLE A.3.3—CONCENTRATION OF INGREDIENTS OF A MIXTURE CLASSIFIED AS SKIN CATEGORY 1 AND/OR EYE CATEGORY 1 OR 2 THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURES AS HAZARDOUS TO THE EYE

Sum of ingredients classified as	Concentration triggering classification of a mixture as	
	Serious eye damage	Eye irritation
	Category 1	Category 2/2A
Skin corrosion (Category 1) + Serious eye damage (Category 1) [a]	≥3%	≥1% but <3%.
Eye irritation (Category 2)		[b] ≥10%.
10 × (Skin corrosion (Category 1) + Serious eye damage (Category 1)) [a] + Eye irritation (Category 2)		≥10%.

Notes:
[a] If an ingredient is classified as both skin Category 1 and eye Category 1 its concentration is considered only once in the calculation.
[b] A mixture may be classified as Eye Irritation Category 2B in cases when all relevant ingredients are classified as Eye Irritation Category 2B.

TABLE A.3.4—CONCENTRATION OF INGREDIENTS OF A MIXTURE FOR WHICH THE ADDITIVITY APPROACH DOES NOT APPLY, THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE AS HAZARDOUS TO THE EYE

Ingredient	Concentration (%)	Mixture classified as:
Acid with pH ≤2	≥1	Serious eye damage (Category 1).
Base with pH ≥11.5	≥1	Serious eye damage (Category 1).
Other skin corrosive or serious eye damage (Category 1) ingredients.	≥1	Serious eye damage (Category 1).
Other eye irritant (Category 2) ingredients	≥3	Eye irritation (Category 2).

A.4 Respiratory or Skin Sensitization

A.4.1 Definitions and General Considerations

A.4.1.1 Respiratory sensitization refers to hypersensitivity of the airways occurring after inhalation of a substance or mixture.

Skin sensitization refers to an allergic response occurring after skin contact with a substance or mixture.

A.4.1.2 For the purpose of this chapter, sensitization includes two phases: The first phase is induction of specialized immunological memory in an individual by exposure to an allergen. The second phase is elicitation, *i.e.,* production of a cell-mediated or antibody-mediated allergic response by exposure of a sensitized individual to an allergen.

A.4.1.3 For respiratory sensitization, the pattern of induction followed by elicitation phases is shared in common with skin sensitization. For skin sensitization, an induction phase is required in which the immune system learns to react; clinical symptoms can then arise when subsequent exposure is sufficient to elicit a visible skin reaction (elicitation phase). As a consequence, predictive tests usually follow this pattern in which there is an induction phase, the response to which is measured by a standardized elicitation phase, typically involving a patch test. The local lymph node assay is the exception, directly measuring the induction response. Evidence of skin sensitization in humans normally is assessed by a diagnostic patch test.

A.4.1.4 Usually, for both skin and respiratory sensitization, lower levels are necessary for elicitation than are required for induction.

A.4.1.5 The hazard class ''respiratory or skin sensitization'' is differentiated into:

(a) Respiratory sensitization; and
(b) Skin sensitization.

A.4.2 Classification Criteria for Substances

A.4.2.1 Respiratory Sensitizers

A.4.2.1.1 Hazard categories

A.4.2.1.1.1 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for respiratory sensitizers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table A.4.1 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals.

A.4.2.1.1.2 Where data are not sufficient for sub-categorization, respiratory sensitizers shall be classified in Category 1.

TABLE A.4.1—HAZARD CATEGORY AND SUB-CATEGORIES FOR RESPIRATORY SENSITIZERS

Category 1:	Respiratory sensitizer
	A substance is classified as a respiratory sensitizer: (a) If there is evidence in humans that the substance can lead to specific respiratory hypersensitivity and/or (b) if there are positive results from an appropriate animal test.[1]
Sub-category 1A:	Substances showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitization rate in humans based on animal or other tests.1 Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitization rate in humans based on animal or other tests.[1] Severity of reaction may also be considered.

A.4.2.1.2 Human evidence

A.4.2.1.2.1 Evidence that a substance can lead to specific respiratory hypersensitivity will normally be based on human experience. In this context, hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms do not have to be demonstrated.

[1] *At this writing, recognized and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.*

A.4.2.1.2.2 When considering the human evidence, it is necessary that in addition to the evidence from the cases, the following be taken into account:

(a) The size of the population exposed;

(b) The extent of exposure.

A.4.2.1.2.3 The evidence referred to above could be:

(a) Clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include:

(i) *In vivo* immunological test (*e.g.,* skin prick test);

(ii) *In vitro* immunological test (*e.g.,* serological analysis);

(iii) Studies that may indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven, *e.g.,* repeated low-level irritation, pharmacologically mediated effects;

(iv) A chemical structure related to substances known to cause respiratory hypersensitivity;

(b) Data from positive bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.

A.4.2.1.2.4 Clinical history should include both medical and occupational history to determine a relationship between exposure to a specific substance and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history should also include a note of other allergic or airway disorders from childhood and smoking history.

A.4.2.1.2.5 The results of positive bronchial challenge tests are considered to provide sufficient evidence for classification on their own. It is, however, recognized that in practice many of the examinations listed above will already have been carried out.

A.4.2.1.3 Animal studies

A.4.2.1.3.1 Data from appropriate animal studies [2] which may be indicative of the potential of a substance to cause sensitization by inhalation in humans [3] may include:

(a) Measurements of Immunoglobulin E (IgE) and other specific immunological parameters, for example in mice.

(b) Specific pulmonary responses in guinea pigs.

A.4.2.2 Skin Sensitizers

A.4.2.2.1 Hazard categories

A.4.2.2.1.1 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for skin sensitizers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table A.4.2 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals according to the guidance values provided in A.4.2.2.2.1 and A.4.2.2.3.2 for sub-category 1A and in A.4.2.2.2.2 and A.4.2.2.3.3 for sub-category 1B.

A.4.2.2.1.2 Where data are not sufficient for sub-categorization, skin sensitizers shall be classified in Category 1.

TABLE A.4.2—HAZARD CATEGORY AND SUB-CATEGORIES FOR SKIN SENSITIZERS

Category 1:	Skin sensitizer
	A substance is classified as a skin sensitizer: (a) If there is evidence in humans that the substance can lead to sensitization by skin contact in a substantial number of persons, or (b) if there are positive results from an appropriate animal test.
Sub-category 1A:	Substances showing a high frequency of occurrence in humans and/or a high potency in animals can be presumed to have the potential to produce significant sensitization in humans. Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce sensitization in humans. Severity of reaction may also be considered.

A.4.2.2.2 Human evidence

A.4.2.2.2.1 Human evidence for sub-category 1A may include:

(a) Positive responses at ≤500 μg/cm2 (Human Repeat Insult Patch Test (HRIPT), Human Maximization Test (HMT)—induction threshold);

(b) Diagnostic patch test data where there is a relatively high and substantial incidence of reactions in a defined population in relation to relatively low exposure;

(c) Other epidemiological evidence where there is a relatively high and substantial incidence of allergic contact dermatitis in relation to relatively low exposure.

A.4.2.2.2.2 Human evidence for sub-category 1B may include:

(a) Positive responses at >500 μg/cm^2 (HRIPT, HMT—induction threshold);

(b) Diagnostic patch test data where there is a relatively low but substantial incidence of reactions in a defined population in relation to relatively high exposure;

(c) Other epidemiological evidence where there is a relatively low but substantial incidence of allergic contact dermatitis in relation to relatively high exposure.

A.4.2.2.3 Animal studies

A.4.2.2.3.1 For Category 1, when an adjuvant type test method for skin sensitization is used, a response of at least 30% of the animals is considered as positive. For a non-adjuvant Guinea pig test method a response of at least 15% of the animals is considered positive. For Category 1, a stimulation index of three or more is considered a positive response in the local lymph node assay.[4]

A.4.2.2.3.2 Animal test results for sub-category 1A can include data with values indicated in Table A.4.3 below:

TABLE A.4.3—ANIMAL TEST RESULTS FOR SUB-CATEGORY 1A

Assay	Criteria
Local lymph node assay	EC3 value ≤2%.
Guinea pig maximization test.	≥30% responding at ≤0.1% intradermal induction dose *or* ≥60% responding at >0.1% to ≤1% intradermal induction dose.

[2] *At this writing, recognized and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.*

[3] *The mechanisms by which substances induce symptoms of asthma are not yet fully known. For preventive measures, these substances are considered respiratory sensitizers. However, if on the basis of the evidence, it can be demonstrated that these substances induce symptoms of asthma by irritation only in people with bronchial hyperactivity, they should not be considered as respiratory sensitizers.*

[4] *Test methods for skin sensitization are described in OECD Guideline 406 (the Guinea Pig Maximization test and the Buehler guinea pig test) and Guideline 429 (Local Lymph Node Assay). Other methods may be used provided that they are scientifically validated. The Mouse Ear Swelling Test (MEST), appears to be a reliable screening test to detect moderate to strong sensitizers, and can be used, in accordance with professional judgment, as a first stage in the assessment of skin sensitization potential.*

TABLE A.4.3—ANIMAL TEST RESULTS FOR SUB-CATEGORY 1A—Continued

Assay	Criteria
Buehler assay	≥15% responding at ≤0.2% topical induction dose *or* ≥60% responding at >0.2% to ≤20% topical induction dose.

Note: EC3 refers to the estimated concentration of test chemical required to induce a stimulation index of 3 in the local lymph node assay.

A.4.2.2.3.3 Animal test results for sub-category 1B can include data with values indicated in the following Table A.4.4:

TABLE A.4.4—ANIMAL TEST RESULTS FOR SUB-CATEGORY 1B

Assay	Criteria
Local lymph node assay	EC3 value >2%.
Guinea pig maximization test.	≥30% to <60% responding at >0.1% to ≤1% intradermal induction dose *or* ≥30% responding at >1% intradermal induction dose.
Buehler assay	≥15% to <60% responding at >0.2% to ≤20% topical induction dose *or* ≥15% responding at >20% topical induction dose.

Note: EC3 refers to the estimated concentration of test chemical required to induce a stimulation index of 3 in the local lymph node assay.

A.4.2.2.4 Specific considerations

A.4.2.2.4.1 For classification of a substance, evidence shall include one or more of the following using a weight of evidence approach:

(a) Positive data from patch testing, normally obtained in more than one dermatology clinic;

(b) Epidemiological studies showing allergic contact dermatitis caused by the substance. Situations in which a high proportion of those exposed exhibit characteristic symptoms are to be looked at with special concern, even if the number of cases is small;

(c) Positive data from appropriate animal studies;

(d) Positive data from experimental studies in humans (See paragraph A.0.2.6 of this appendix);

(e) Well documented episodes of allergic contact dermatitis, normally obtained in more than one dermatology clinic;

(f) Severity of reaction.

A.4.2.2.4.2 Evidence from animal studies is usually much more reliable than evidence from human exposure. However, in cases where evidence is available from both sources, and there is conflict between the results, the quality and reliability of the evidence from both sources must be assessed in order to resolve the question of classification on a case-by-case basis. Normally, human data are not generated in controlled experiments with volunteers for the purpose of hazard classification but rather as part of risk assessment to confirm lack of effects seen in animal tests. Consequently, positive human data on skin sensitization are usually derived from case-control or other, less defined studies. Evaluation of human data must, therefore, be carried out with caution as the frequency of cases reflect, in addition to the inherent properties of the substances, factors such as the exposure situation, bioavailability, individual predisposition and preventive measures taken. Negative human data should not normally be used to negate positive results from animal studies. For both animal and human data, consideration should be given to the impact of vehicle.

A.4.2.2.4.3 If none of the above-mentioned conditions are met, the substance need not be classified as a skin sensitizer. However, a combination of two or more indicators of skin sensitization, as listed below, may alter the decision. This shall be considered on a case-by-case basis.

(a) Isolated episodes of allergic contact dermatitis;

(b) Epidemiological studies of limited power, *e.g.,* where chance, bias or confounders have not been ruled out fully with reasonable confidence;

(c) Data from animal tests, performed according to existing guidelines, which do not meet the criteria for a positive result described in A.4.2.2.3, but which are sufficiently close to the limit to be considered significant;

(d) Positive data from non-standard methods;

(e) Positive results from close structural analogues.

A.4.2.2.4.4 Immunological contact urticaria

A.4.2.2.4.4.1 Substances meeting the criteria for classification as respiratory sensitizers may, in addition, cause immunological contact urticaria. Consideration shall be given to classifying these substances as skin sensitizers.

A.4.2.2.4.4.2 Substances which cause immunological contact urticaria without meeting the criteria for respiratory sensitizers shall be considered for classification as skin sensitizers.

A.4.2.2.4.4.3 There is no recognized animal model available to identify substances which cause immunological contact urticaria. Therefore, classification will normally be based on human evidence, similar to that for skin sensitization.

A.4.3 Classification Criteria for Mixtures

A.4.3.1 Classification of Mixtures When Data Are Available for the Complete Mixture

When reliable and good quality evidence, as described in the criteria for substances, from human experience or appropriate studies in experimental animals, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of these data. Care must be exercised in evaluating data on mixtures that the dose used does not render the results inconclusive.

A.4.3.2 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.4.3.2.1 Where the mixture itself has not been tested to determine its sensitizing properties, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles as found in paragraph A.0.5 of this appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one hazard category/subcategory, Substantially similar mixtures, and Aerosols.

A.4.3.3 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

The mixture shall be classified as a respiratory or skin sensitizer when at least one ingredient has been classified as a respiratory or skin sensitizer and is present at or above the appropriate cut-off value/concentration limit for the specific endpoint as shown in Table A.4.5.

TABLE A.4.5—CUT-OFF VALUES/CONCENTRATION LIMITS OF INGREDIENTS OF A MIXTURE CLASSIFIED AS EITHER RESPIRATORY SENSITIZERS OR SKIN SENSITIZERS THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:		
	Respiratory sensitizer Category 1		Skin sensitizer Category 1
	Solid/Liquid (%)	Gas	All physical states (%)
Respiratory Sensitizer: Category 1	≥0.1	≥0.1	.....
Respiratory Sensitizer: Sub-category 1A	≥0.1	≥0.1	.....
Respiratory Sensitizer: Sub-category 1B	≥1.0	≥0.2	.....
Skin Sensitizer: Category 1	.....	.....	≥0.1
Skin Sensitizer: Sub-category 1A	.....	.....	≥0.1
Skin Sensitizer: Sub-category 1B	.....	.....	≥1.0

A.5 Germ Cell Mutagenicity

A.5.1 Definitions and General Considerations

A.5.1.1 Germ cell mutagenicity refers to heritable gene mutations, including heritable structural and numerical chromosome aberrations in germ cells occurring after exposure to a substance or mixture.

A.5.1.2 A mutation is defined as a permanent change in the amount or structure of the genetic material in a cell. The term mutation applies both to heritable genetic changes that may be manifested at the phenotypic level and to the underlying DNA modifications when known (including, for example, specific base pair changes and chromosomal translocations). The term mutagenic and mutagen will be used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms.

A.5.1.3 The more general terms genotoxic and genotoxicity apply to agents or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non-physiological manner (temporarily) alter its replication. Genotoxicity test results are usually taken as indicators for mutagenic effects.

A.5.1.4 This hazard class is primarily concerned with chemicals that may cause mutations in the germ cells of humans that can be transmitted to the progeny. However, mutagenicity/genotoxicity tests in vitro and in mammalian somatic cells in vivo are also considered in classifying substances and mixtures within this hazard class.

A.5.2 Classification Criteria for Substances

A.5.2.1 The classification system provides for two different categories of germ cell mutagens to accommodate the weight of evidence available. The two-category system is described in the Figure A.5.1.

FIGURE A.5.1—HAZARD CATEGORIES FOR GERM CELL MUTAGENS

CATEGORY 1: Substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans.

Category 1A: Substances known to induce heritable mutations in germ cells of humans. Positive evidence from human epidemiological studies.

Category 1B: Substances which should be regarded as if they induce heritable mutations in the germ cells of humans:

(a) Positive result(s) from *in vivo* heritable germ cell mutagenicity tests in mammals; or

(b) Positive result(s) from *in vivo* somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. This supporting evidence may, for example, be derived from mutagenicity/genotoxicity tests in germ cells *in vivo*, or by demonstrating the ability of the substance or its metabolite(s) to interact with the genetic material of germ cells; or

(c) Positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny; for example, an increase in the frequency of aneuploidy in sperm cells of exposed people.

CATEGORY 2: Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans.

Positive evidence obtained from experiments in mammals and/or in some cases from in vitro experiments, obtained from:

(a) Somatic cell mutagenicity tests *in vivo*, in mammals; or

(b) Other *in vivo* somatic cell genotoxicity tests which are supported by positive results from *in vitro* mutagenicity assays.

Note: *Substances which are positive in in vitro mammalian mutagenicity assays, and which also show chemical structure activity relationship to known germ cell mutagens, should be considered for classification as Category 2 mutagens.*

A.5.2.2 Specific considerations for classification of substances as germ cell mutagens:

A.5.2.2.1 To arrive at a classification, test results are considered from experiments determining mutagenic and/or genotoxic effects in germ and/or somatic cells of exposed animals. Mutagenic and/or genotoxic effects determined in in vitro tests shall also be considered.

A.5.2.2.2 The system is hazard based, classifying chemicals on the basis of their intrinsic ability to induce mutations in germ cells. The scheme is, therefore, not meant for the (quantitative) risk assessment of chemical substances.

A.5.2.2.3 Classification for heritable effects in human germ cells is made on the basis of scientifically validated tests. Evaluation of the test results shall be done using expert judgment and all the available evidence shall be weighed for classification.

A.5.2.2.4 The classification of substances shall be based on the total weight of evidence available, using expert judgment. In those instances where a single well-conducted test is used for classification, it shall provide clear and unambiguously positive results. The relevance of the route of exposure used in the study of the substance compared to the route of human exposure should also be taken into account.

A.5.3 Classification Criteria for Mixtures[5]

A.5.3.1 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.5.3.1.1 Classification of mixtures shall be based on the available test data for the

[5] *It should be noted that the classification criteria for health hazards usually include a tiered scheme in which test data available on the complete mixture are considered as the first tier in the*

individual ingredients of the mixture using cut-off values/concentration limits for the ingredients classified as germ cell mutagens.

A.5.3.1.2 The mixture will be classified as a mutagen when at least one ingredient has been classified as a Category 1A, Category 1B or Category 2 mutagen and is present at or above the appropriate cut-off value/concentration limit as shown in Table A.5.1 below for Category 1 and 2 respectively.

TABLE A.5.1—CUT-OFF VALUES/CONCENTRATION LIMITS OF INGREDIENTS OF A MIXTURE CLASSIFIED AS GERM CELL MUTAGENS THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE

Ingredient classified as:	Cut-off/concentration limits triggering classification of a mixture as:	
	Category 1 mutagen	Category 2 mutagen
Category 1A/B mutagen	≥0.1%	
Category 2 mutagen		≥1.0%

Note: *The cut-off values/concentration limits in the table above apply to solids and liquids (w/w units) as well as gases (v/v units).*

A.5.3.2 Classification of Mixtures When Data Are Available for the Mixture Itself

The classification may be modified on a case-by-case basis based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (*e.g.,* statistical analysis, test sensitivity) of germ cell mutagenicity test systems.

A.5.3.3 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.5.3.3.1 Where the mixture itself has not been tested to determine its germ cell mutagenicity hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this appendix: Dilution, Batching, and Substantially similar mixtures.

A.5.4 Examples of Scientifically Validated Test Methods

A.5.4.1 Examples of *in vivo* heritable germ cell mutagenicity tests are:

(a) Rodent dominant lethal mutation test (OECD 478)

(b) Mouse heritable translocation assay (OECD 485)

(c) Mouse specific locus test

A.5.4.2 Examples of *in vivo* somatic cell mutagenicity tests are:

(a) Mammalian bone marrow chromosome aberration test (OECD 475)

(b) Mammalian erythrocyte micronucleus test (OECD 474)

A.5.4.3 Examples of mutagenicity/genotoxicity tests in germ cells are:

(a) Mutagenicity tests:

(i) Mammalian spermatogonial chromosome aberration test (OECD 483)

(ii) Spermatid micronucleus assay

(b) Genotoxicity tests:

(i) Sister chromatid exchange analysis in spermatogonia

(ii) Unscheduled DNA synthesis test (UDS) in testicular cells

A.5.4.4 Examples of genotoxicity tests in somatic cells are:

(a) Liver Unscheduled DNA Synthesis (UDS) *in vivo* (OECD 486)

(b) Mammalian bone marrow Sister Chromatid Exchanges (SCE)

A.5.4.5 Examples of *in vitro* mutagenicity tests are:

(a) *In vitro* mammalian chromosome aberration test (OECD 473)

(b) *In vitro* mammalian cell gene mutation test (OECD 476)

(c) Bacterial reverse mutation tests (OECD 471)

A.5.4.6 As new, scientifically validated tests arise, these may also be used in the total weight of evidence to be considered.

A.6 Carcinogenicity

A.6.1 Definitions

Carcinogenicity refers to the induction of cancer or an increase in the incidence of cancer occurring after exposure to a substance or mixture. Substances and mixtures which have induced benign and malignant tumors in well-performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumor formation is not relevant for humans.

Classification of a substance or mixture as posing a carcinogenic hazard is based on its inherent properties and does not provide information on the level of the human cancer risk which the use of the substance or mixture may represent.

A.6.2 Classification Criteria for Substances[6]

A.6.2.1 For the purpose of classification for carcinogenicity, substances are allocated to one of two categories based on strength of evidence and additional weight of evidence considerations. In certain instances, route-specific classification may be warranted.

FIGURE A.6.1—HAZARD CATEGORIES FOR CARCINOGENS

CATEGORY 1: Known or presumed human carcinogens. The classification of a substance as a Category 1 carcinogen is done on the basis of epidemiological and/or animal data. This classification is further distinguished on the basis of whether the evidence for classification is largely from human data (Category 1A) or from animal data (Category 1B):

Category 1A: Known to have carcinogenic potential for humans. Classification in this category is largely based on human evidence.

Category 1B: Presumed to have carcinogenic potential for humans. Classification in this category is largely based on animal evidence. The classification of a substance in Category 1A and 1B is based on strength of evidence together with weight of evidence considerations (See paragraph A.6.2.5). Such evidence may be derived from:

—human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen); or

—animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen).

In addition, on a case by case basis, scientific judgment may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals.

evaluation, followed by the applicable bridging principles, and lastly, cut-off values/concentration limits or additivity. However, this approach is not used for Germ Cell Mutagenicity. These criteria for Germ Cell Mutagenicity consider the cut-off values/concentration limits as the primary tier and allow the classification to be modified only on a case-by-case evaluation based on available test data for the mixture as a whole.

[6] See *Non-mandatory appendix F of this section, part A for further guidance regarding hazard classification for carcinogenicity. This appendix is consistent with the GHS and is provided as guidance excerpted from the International Agency for Research on Cancer (IARC) ''Monographs on the Evaluation of Carcinogenic Risks to Humans'' (2006).*

FIGURE A.6.1—HAZARD CATEGORIES FOR CARCINOGENS—Continued

CATEGORY 2: Suspected human carcinogens. The classification of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or B. This classification is based on strength of evidence together with weight of evidence considerations (See paragraph A.6.2.5). Such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.

Other considerations: Where the weight of evidence for the carcinogenicity of a substance does not meet the above criteria, any positive study conducted in accordance with established scientific principles, and which reports statistically significant findings regarding the carcinogenic potential of the substance, must be noted on the safety data sheet.

A.6.2.2 Classification as a carcinogen is made on the basis of evidence from reliable and acceptable methods, and is intended to be used for substances which have an intrinsic property to produce such toxic effects. The evaluations are to be based on all existing data, peer-reviewed published studies and additional data accepted by regulatory agencies.

A.6.2.3 *Carcinogen classification* is a one-step, criterion-based process that involves two interrelated determinations: Evaluations of strength of evidence and consideration of all other relevant information to place substances with human cancer potential into hazard categories.

A.6.2.4 *Strength of evidence* involves the enumeration of tumors in human and animal studies and determination of their level of statistical significance. Sufficient human evidence demonstrates causality between human exposure and the development of cancer, whereas sufficient evidence in animals shows a causal relationship between the agent and an increased incidence of tumors. Limited evidence in humans is demonstrated by a positive association between exposure and cancer, but a causal relationship cannot be stated. Limited evidence in animals is provided when data suggest a carcinogenic effect, but are less than sufficient. (Guidance on consideration of important factors in the classification of carcinogenicity and a more detailed description of the terms ''limited'' and ''sufficient'' have been developed by the International Agency for Research on Cancer (IARC) and are provided in non-mandatory appendix F of this section.)

A.6.2.5 *Weight of evidence:* Beyond the determination of the strength of evidence for carcinogenicity, a number of other factors should be considered that influence the overall likelihood that an agent may pose a carcinogenic hazard in humans. The full list of factors that influence this determination is very lengthy, but some of the important ones are considered here.

A.6.2.5.1 These factors can be viewed as either increasing or decreasing the level of concern for human carcinogenicity. The relative emphasis accorded to each factor depends upon the amount and coherence of evidence bearing on each. Generally, there is a requirement for more complete information to decrease than to increase the level of concern. Additional considerations should be used in evaluating the tumor findings and the other factors in a case-by-case manner.

A.6.2.5.2 Some important factors which may be taken into consideration, when assessing the overall level of concern are:

(a) Tumor type and background incidence;

(b) Multisite responses;

(c) Progression of lesions to malignancy;

(d) Reduced tumor latency;

Additional factors which may increase or decrease the level of concern include:

(e) Whether responses are in single or both sexes;

(f) Whether responses are in a single species or several species;

(g) Structural similarity or not to a substance(s) for which there is good evidence of carcinogenicity;

(h) Routes of exposure;

(i) Comparison of absorption, distribution, metabolism and excretion between test animals and humans;

(j) The possibility of a confounding effect of excessive toxicity at test doses; and,

(k) Mode of action and its relevance for humans, such as mutagenicity, cytotoxicity with growth stimulation, mitogenesis, immunosuppression.

Mutagenicity: It is recognized that genetic events are central in the overall process of cancer development. Therefore, evidence of mutagenic activity *in vivo* may indicate that a substance has a potential for carcinogenic effects.

A.6.2.5.3 A substance that has not been tested for carcinogenicity may in certain instances be classified in Category 1A, Category 1B, or Category 2 based on tumor data from a structural analogue together with substantial support from consideration of other important factors such as formation of common significant metabolites, *e.g.,* for benzidine congener dyes.

A.6.2.5.4 The classification should also take into consideration whether or not the substance is absorbed by a given route(s); or whether there are only local tumors at the site of administration for the tested route(s), and adequate testing by other major route(s) show lack of carcinogenicity.

A.6.2.5.5 It is important that whatever is known of the physico-chemical, toxicokinetic and toxicodynamic properties of the substances, as well as any available relevant information on chemical analogues, *i.e.,* structure activity relationship, is taken into consideration when undertaking classification.

A.6.3 Classification Criteria for Mixtures[7]

A.6.3.1 The mixture shall be classified as a carcinogen when at least one ingredient has been classified as a Category 1 or Category 2 carcinogen and is present at or above the appropriate cut-off value/concentration limit as shown in Table A.6.1.

TABLE A.6.1—CUT-OFF VALUES/CONCENTRATION LIMITS OF INGREDIENTS OF A MIXTURE CLASSIFIED AS CARCINOGEN THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE

Ingredient classified as:	Category 1 carcinogen	Category 2 carcinogen
Category 1 carcinogen	≥0.1%	
Category 2 carcinogen		≥0.1% (note 1)

Note: *If a Category 2 carcinogen ingredient is present in the mixture at a concentration between 0.1% and 1%, information is required on the SDS for a product. However, a label warning is optional. If a Category 2 carcinogen ingredient is present in the mixture at a concentration of ≥1%, both an SDS and a label is required and the information must be included on each.*

[7] *It should be noted that the classification criteria for health hazards usually include a tiered scheme in which test data available on the complete mixture are considered as the first tier in the evaluation, followed by the applicable bridging principles, and lastly, cut-off values/concentration limit or additivity. However, this approach is not used for Carcinogenicity. These criteria for Carcinogenicity consider the cut-off values/concentration limits as the primary tier and allow the classification to be modified only on a case-by-case evaluation based on available test data for the mixture as a whole.*

A.6.3.2 Classification of Mixtures When Data Are Available for the Complete Mixture

A mixture may be classified based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (*e.g.,* statistical analysis, test sensitivity) of carcinogenicity test systems.

A.6.3.3 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

Where the mixture itself has not been tested to determine its carcinogenic hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this appendix: Dilution; Batching; and Substantially similar mixtures.

A.6.4 Classification of Carcinogenicity[8]

A.6.4.1 Chemical manufacturers, importers and employers evaluating chemicals may treat the following sources as establishing that a substance is a carcinogen or potential carcinogen for hazard communication purposes in lieu of applying the criteria described herein:

A.6.4.1.1 National Toxicology Program (NTP), ''Report on Carcinogens'' (latest edition);

A.6.4.1.2 International Agency for Research on Cancer (IARC) ''Monographs on the Evaluation of Carcinogenic Risks to Humans'' (latest editions)

A.6.4.2 Where OSHA has included cancer as a health hazard to be considered by classifiers for a chemical covered by this section subpart, chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen.

A.7 Reproductive Toxicity

A.7.1 Definitions and General Considerations

A.7.1.1 *Reproductive toxicity* refers to *adverse effects on sexual function and fertility* in adult males and females, as well as developmental toxicity in the offspring, occurring after exposure to a substance or mixture. Some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, substances and mixtures with these effects shall be classified as reproductive toxicants.

For classification purposes, the known induction of genetically based inheritable effects in the offspring is addressed in *Germ cell mutagenicity* (See A.5).

A.7.1.2 *Adverse effects on sexual function and fertility* means any effect of chemicals that interferes with reproductive ability or sexual capacity. This includes, but is not limited to, alterations to the female and male reproductive system, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behaviour, fertility, parturition, pregnancy outcomes, premature reproductive senescence, or modifications in other functions that are dependent on the integrity of the reproductive systems.

A.7.1.3 *Adverse effects on development of the offspring* means any effect of chemicals which interferes with normal development of the conceptus either before or after birth, which is induced during pregnancy or results from parental exposure. These effects can be manifested at any point in the life span of the organism. The major manifestations of developmental toxicity include death of the developing organism, structural abnormality, altered growth and functional deficiency.

A.7.1.4 Adverse effects on or via lactation are also included in reproductive toxicity, but for classification purposes, such effects are treated separately (See A.7.2.1).

A.7.2 Classification Criteria for Substances

A.7.2.1 For the purpose of classification for reproductive toxicity, substances shall be classified in one of two categories in accordance with Figure A.7.1(a). Effects on sexual function and fertility, and on development, shall be considered. In addition, effects on or via lactation shall be classified in a separate hazard category in accordance with Figure A.7.1(b).

FIGURE A.7.1(a)—HAZARD CATEGORIES FOR REPRODUCTIVE TOXICANTS

CATEGORY 1: Known or presumed human reproductive toxicant. Substance shall be classified in Category 1 for reproductive toxicity when they are known to have produced an adverse effect on sexual function and fertility or on development in humans or when there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans. The classification of a substance is further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).

Category 1A: Known human reproductive toxicant. The classification of a substance in this category is largely based on evidence from humans.

Category 1B: Presumed human reproductive toxicant. The classification of a substance in this category is largely based on evidence from experimental animals. Data from animal studies shall provide sufficient evidence of an adverse effect on sexual function and fertility or on development in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects. However, when there is mechanistic information that raises doubt about the relevance of the effect for humans, classification in Category 2 may be more appropriate.

CATEGORY 2: Suspected human reproductive toxicant. Substances shall be classified in Category 2 for reproductive toxicity when there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development, in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects, and where the evidence is not sufficiently convincing to place the substance in Category 1. For instance, deficiencies in the study may make the quality of evidence less convincing, and in view of this, Category 2 would be the more appropriate classification.

FIGURE A.7.1(b)—HAZARD CATEGORY FOR EFFECTS ON OR VIA LACTATION

Effects on or Via Lactation

Effects on or via lactation shall be classified in a separate single category. Chemicals that are absorbed by women and have been shown to interfere with lactation or that may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child, shall be classified to indicate this property. Classification for effects via lactation shall be assigned on the basis of:

(a) Absorption, metabolism, distribution and excretion studies that indicate the likelihood the substance would be present in potentially toxic levels in breast milk; and/or

(b) results of one or two generation studies in animals which provide clear evidence of adverse effect in the offspring due to transfer in the milk or adverse effect on the quality of the milk; and/or

(c) human evidence indicating a hazard to babies during the lactation period.

[8] See *Non-mandatory appendix F of this section for further guidance regarding hazard classification for carcinogenicity and how to relate carcinogenicity classification information from IARC and NTP to GHS.*

A.7.2.2 Basis of Classification

A.7.2.2.1 Classification is made on the basis of the criteria, outlined above, an assessment of the total weight of evidence, and the use of expert judgment. Classification as a reproductive toxicant is intended to be used for substances which have an intrinsic, specific property to produce an adverse effect on reproduction and substances should not be so classified if such an effect is produced solely as a non-specific secondary consequence of other toxic effects.

A.7.2.2.2 In the evaluation of toxic effects on the developing offspring, it is important to consider the possible influence of maternal toxicity.

A.7.2.2.3 For human evidence to provide the primary basis for a Category 1A classification there must be reliable evidence of an adverse effect on reproduction in humans. Evidence used for classification shall be from well conducted epidemiological studies, if available, which include the use of appropriate controls, balanced assessment, and due consideration of bias or confounding factors. Less rigorous data from studies in humans may be sufficient for a Category 1A classification if supplemented with adequate data from studies in experimental animals, but classification in Category 1B may also be considered.

A.7.2.3 Weight of Evidence

A.7.2.3.1 Classification as a reproductive toxicant is made on the basis of an assessment of the total weight of evidence using expert judgment. This means that all available information that bears on the determination of reproductive toxicity is considered together. Included is information such as epidemiological studies and case reports in humans and specific reproduction studies along with sub-chronic, chronic and special study results in animals that provide relevant information regarding toxicity to reproductive and related endocrine organs. Evaluation of substances chemically related to the material under study may also be included, particularly when information on the material is scarce. The weight given to the available evidence will be influenced by factors such as the quality of the studies, consistency of results, nature and severity of effects, level of statistical significance for intergroup differences, number of endpoints affected, relevance of route of administration to humans and freedom from bias. Both positive and negative results are considered together in a weight of evidence determination. However, a single, positive study performed according to good scientific principles and with statistically or biologically significant positive results may justify classification (See also A.7.2.2.3).

A.7.2.3.2 Toxicokinetic studies in animals and humans, site of action and mechanism or mode of action study results may provide relevant information, which could reduce or increase concerns about the hazard to human health. If it is conclusively demonstrated that the clearly identified mechanism or mode of action has no relevance for humans or when the toxicokinetic differences are so marked that it is certain that the hazardous property will not be expressed in humans then a chemical which produces an adverse effect on reproduction in experimental animals should not be classified.

A.7.2.3.3 In some reproductive toxicity studies in experimental animals the only effects recorded may be considered of low or minimal toxicological significance and classification may not necessarily be the outcome. These effects include, for example, small changes in semen parameters or in the incidence of spontaneous defects in the fetus, small changes in the proportions of common fetal variants such as are observed in skeletal examinations, or in fetal weights, or small differences in postnatal developmental assessments.

A.7.2.3.4 Data from animal studies shall provide sufficient evidence of specific reproductive toxicity in the absence of other systemic toxic effects. However, if developmental toxicity occurs together with other toxic effects in the dam (mother), the potential influence of the generalized adverse effects should be assessed to the extent possible. The preferred approach is to consider adverse effects in the embryo/fetus first, and then evaluate maternal toxicity, along with any other factors which are likely to have influenced these effects, as part of the weight of evidence. In general, developmental effects that are observed at maternally toxic doses should not be automatically discounted. Discounting developmental effects that are observed at maternally toxic doses can only be done on a case-by-case basis when a causal relationship is established or refuted.

A.7.2.3.5 If appropriate information is available it is important to try to determine whether developmental toxicity is due to a specific maternally mediated mechanism or to a non-specific secondary mechanism, like maternal stress and the disruption of homeostasis. Generally, the presence of maternal toxicity should not be used to negate findings of embryo/fetal effects, unless it can be clearly demonstrated that the effects are secondary non-specific effects. This is especially the case when the effects in the offspring are significant, *e.g.,* irreversible effects such as structural malformations. In some situations it is reasonable to assume that reproductive toxicity is due to a secondary consequence of maternal toxicity and discount the effects, for example if the chemical is so toxic that dams fail to thrive and there is severe inanition; they are incapable of nursing pups; or they are prostrate or dying.

A.7.2.4 Maternal Toxicity

A.7.2.4.1 Development of the offspring throughout gestation and during the early postnatal stages can be influenced by toxic effects in the mother either through non-specific mechanisms related to stress and the disruption of maternal homeostasis, or by specific maternally-mediated mechanisms. So, in the interpretation of the developmental outcome to decide classification for developmental effects it is important to consider the possible influence of maternal toxicity. This is a complex issue because of uncertainties surrounding the relationship between maternal toxicity and developmental outcome. Expert judgment and a weight of evidence approach, using all available studies, shall be used to determine the degree of influence to be attributed to maternal toxicity when interpreting the criteria for classification for developmental effects. The adverse effects in the embryo/fetus shall be first considered, and then maternal toxicity, along with any other factors which are likely to have influenced these effects, as weight of evidence, to help reach a conclusion about classification.

A.7.2.4.2 Based on pragmatic observation, it is believed that maternal toxicity may, depending on severity, influence development via non-specific secondary mechanisms, producing effects such as depressed fetal weight, retarded ossification, and possibly resorptions and certain malformations in some strains of certain species. However, the limited numbers of studies which have investigated the relationship between developmental effects and general maternal toxicity have failed to demonstrate a consistent, reproducible relationship across species. Developmental effects which occur even in the presence of maternal toxicity are considered to be evidence of developmental toxicity, unless it can be unequivocally demonstrated on a case by case basis that the developmental effects are secondary to maternal toxicity. Moreover, classification shall be considered where there is a significant toxic effect in the offspring, *e.g.,* irreversible effects such as structural malformations, embryo/fetal lethality, or significant post-natal functional deficiencies.

A.7.2.4.3 Classification shall not automatically be discounted for chemicals that produce developmental toxicity only in association with maternal toxicity, even if a specific maternally-mediated mechanism has been demonstrated. In such a case, classification in Category 2 may be considered more appropriate than Category 1. However, when a chemical is so toxic that maternal death or severe inanition results, or the dams (mothers) are prostrate and incapable of nursing the pups, it is reasonable to assume that developmental toxicity is produced solely as a secondary consequence of maternal toxicity and discount the developmental effects. Classification is not necessarily the outcome in the case of minor developmental changes, *e.g.,* a small reduction in fetal/pup body weight or retardation of ossification when seen in association with maternal toxicity.

A.7.2.4.4 Some of the endpoints used to assess maternal toxicity are provided below. Data on these endpoints, if available, shall be evaluated in light of their statistical or biological significance and dose-response relationship.

(a) Maternal mortality: An increased incidence of mortality among the treated dams over the controls shall be considered evidence of maternal toxicity if the increase occurs in a dose-related manner and can be attributed to the systemic toxicity of the test material. Maternal mortality greater than 10% is considered excessive and the data for that dose level shall not normally be considered to need further evaluation.

(b) Mating index (Number of animals with seminal plugs or sperm/Number of mated × 100).

(c) Fertility index (Number of animals with implants/Number of matings × 100).

(d) Gestation length (If allowed to deliver).

(e) Body weight and body weight change: Consideration of the maternal body weight change and/or adjusted (corrected) maternal body weight shall be included in the evaluation of maternal toxicity whenever such data are available. The calculation of an adjusted (corrected) mean maternal body weight change, which is the difference between the initial and terminal body weight minus the gravid uterine weight (or alternatively, the sum of the weights of the fetuses), may indicate whether the effect is maternal or intrauterine. In rabbits, the body weight gain may not be a useful indicator of maternal toxicity because of normal fluctuations in body weight during pregnancy.

(f) Food and water consumption (if relevant): The observation of a significant decrease in the average food or water consumption in treated dams (mothers) compared to the control group may be useful in evaluating maternal toxicity, particularly when the test material is administered in the diet or drinking water. Changes in food or water consumption must be evaluated in conjunction with maternal body weights when determining if the effects noted are reflective of maternal toxicity or more simply, unpalatability of the test material in feed or water.

(g) Clinical evaluations (including clinical signs, markers, and hematology and clinical chemistry studies): The observation of increased incidence of significant clinical signs of toxicity in treated dams (mothers) relative to the control group is useful in evaluating maternal toxicity. If this is to be used as the basis for the assessment of maternal toxicity, the types, incidence, degree and duration of clinical signs shall be reported in the study. Clinical signs of maternal intoxication include, but are not limited to: Coma, prostration, hyperactivity, loss of righting reflex, ataxia, or labored breathing.

(h) Post-mortem data: Increased incidence and/or severity of post-mortem findings may be indicative of maternal toxicity. This can include gross or microscopic pathological findings or organ weight data, including absolute organ weight, organ-to-body weight ratio, or organ-to-brain weight ratio. When supported by findings of adverse histopathological effects in the affected organ(s), the observation of a significant change in the average weight of suspected target organ(s) of treated dams (mothers), compared to those in the control group, may be considered evidence of maternal toxicity.

A.7.2.5 Animal and Experimental Data

A.7.2.5.1 A number of scientifically validated test methods are available, including methods for developmental toxicity testing (*e.g.,* OECD Test Guideline 414, ICH Guideline S5A, 1993), methods for peri- and post-natal toxicity testing (*e.g.,* ICH S5B, 1995), and methods for one or two-generation toxicity testing (*e.g.,* OECD Test Guidelines 415, 416, 443).

A.7.2.5.2 Results obtained from screening tests (*e.g.,* OECD Guidelines 421—Reproduction/Developmental Toxicity Screening Test, and 422—Combined Repeated Dose Toxicity Study with Reproduction/Development Toxicity Screening Test) can also be used to justify classification, although the quality of this evidence is less reliable than that obtained through full studies.

A.7.2.5.3 Adverse effects or changes, seen in short- or long-term repeated dose toxicity studies, which are judged likely to impair reproductive function and which occur in the absence of significant generalized toxicity, may be used as a basis for classification, *e.g.,* histopathological changes in the gonads.

A.7.2.5.4 Evidence from *in vitro* assays, or non-mammalian tests, and from analogous substances using structure-activity relationship (SAR), can contribute to the procedure for classification. In all cases of this nature, expert judgment must be used to assess the adequacy of the data. Inadequate data shall not be used as a primary support for classification.

A.7.2.5.5 It is preferable that animal studies are conducted using appropriate routes of administration which relate to the potential route of human exposure. However, in practice, reproductive toxicity studies are commonly conducted using the oral route, and such studies will normally be suitable for evaluating the hazardous properties of the substance with respect to reproductive toxicity. However, if it can be conclusively demonstrated that the clearly identified mechanism or mode of action has no relevance for humans or when the toxicokinetic differences are so marked that it is certain that the hazardous property will not be expressed in humans then a substance which produces an adverse effect on reproduction in experimental animals should not be classified.

A.7.2.5.6 Studies involving routes of administration such as intravenous or intraperitoneal injection, which may result in exposure of the reproductive organs to unrealistically high levels of the test substance, or elicit local damage to the reproductive organs, *e.g.,* by irritation, must be interpreted with extreme caution and on their own are not normally the basis for classification.

A.7.2.5.7 There is general agreement about the concept of a limit dose, above which the production of an adverse effect may be considered to be outside the criteria which lead to classification. Some test guidelines specify a limit dose, other test guidelines qualify the limit dose with a statement that higher doses may be necessary if anticipated human exposure is sufficiently high that an adequate margin of exposure would not be achieved. Also, due to species differences in toxicokinetics, establishing a specific limit dose may not be adequate for situations where humans are more sensitive than the animal model.

A.7.2.5.8 In principle, adverse effects on reproduction seen only at very high dose levels in animal studies (for example doses that induce prostration, severe inappetence, excessive mortality) do not normally lead to classification, unless other information is available, for example, toxicokinetics information indicating that humans may be more susceptible than animals, to suggest that classification is appropriate.

A.7.2.5.9 However, specification of the actual ''limit dose'' will depend upon the test method that has been employed to provide the test results.

A.7.3 Classification Criteria for Mixtures[9]

A.7.3.1 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.7.3.1.1 The mixture shall be classified as a reproductive toxicant when at least one ingredient has been classified as a Category 1 or Category 2 reproductive toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.7.1 for Category 1 and 2, respectively.

A.7.3.1.2 The mixture shall be classified for effects on or via lactation when at least one ingredient has been classified for effects on or via lactation and is present at or above the appropriate cut-off value/concentration limit specified in Table A.7.1 for the additional category for effects on or via lactation.

[9] *It should be noted that the classification criteria for health hazards usually include a tiered scheme in which test data available on the complete mixture are considered as the first tier in the evaluation, followed by the applicable bridging principles, and lastly, cut-off values/concentration limits or additivity. However, this approach is not used for Reproductive Toxicity. These criteria for Reproductive Toxicity consider the cut-off values/concentration limits as the primary tier and allow the classification to be modified only on a case-by-case evaluation based on available test data for the mixture as a whole.*

TABLE A.7.1—CUT-OFF VALUES/CONCENTRATION LIMITS OF INGREDIENTS OF A MIXTURE CLASSIFIED AS REPRODUCTIVE TOXICANTS OR FOR EFFECTS ON OR VIA LACTATION THAT TRIGGER CLASSIFICATION OF THE MIXTURE

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:		
	Category 1 reproductive toxicant	Category 2 reproductive toxicant	Additional category for effects on or via lactation
Category 1 reproductive toxicant	≥0.1%		
Category 2 reproductive toxicant		≥0.1%	
Additional category for effects on or via lactation			≥0.1%

A.7.3.2 Classification of Mixtures When Data Are Available for the Complete Mixture

Available test data for the mixture as a whole may be used for classification on a case-by-case basis. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (*e.g.,* statistical analysis, test sensitivity) of reproduction test systems.

A.7.3.3 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.7.3.3.1 Where the mixture itself has not been tested to determine its reproductive toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this appendix: Dilution, Batching, and Substantially similar mixtures.

A.8 Specific Target Organ Toxicity Single Exposure

A.8.1 Definitions and General Considerations

A.8.1.1 *Specific target organ toxicity—single exposure, (STOT–SE)* refers to specific, non-lethal toxic effects on target organs occurring after a single exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in A.1 to A.7 and A.10 of this appendix are included. Specific target organ toxicity following repeated exposure is classified in accordance with *SPECIFIC TARGET ORGAN TOXICITY—REPEATED EXPOSURE* (A.9 of this appendix) and is therefore not included here.

A.8.1.2 Classification identifies the chemical as being a specific target organ toxicant and, as such, it presents a potential for adverse health effects in people who are exposed to it.

A.8.1.3 The adverse health effects produced by a single exposure include consistent and identifiable toxic effects in humans; or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or have produced serious changes to the biochemistry or hematology of the organism, and these changes are relevant for human health. Human data is the primary source of evidence for this hazard class.

A.8.1.4 Assessment shall take into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

A.8.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, *i.e.,* principally oral, dermal or inhalation.

A.8.1.6 The classification criteria for specific target organ toxicity—single exposure are organized as criteria for substances Categories 1 and 2 (See A.8.2.1), criteria for substances Category 3 (See A.8.2.2) and criteria for mixtures (See A.8.3). See also Figure A.8.1.

A.8.2 Classification Criteria for Substances

A.8.2.1 Substances of Category 1 and Category 2

A.8.2.1.1 Substances shall be classified for immediate or delayed effects separately, by the use of expert judgment on the basis of the weight of all evidence available, including the use of recommended guidance values (See A.8.2.1.9). Substances shall then be classified in Category 1 or 2, depending upon the nature and severity of the effect(s) observed, in accordance with Figure A.8.1.

FIGURE A.8.1—HAZARD CATEGORIES FOR SPECIFIC TARGET ORGAN TOXICITY FOLLOWING SINGLE EXPOSURE

CATEGORY 1: Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following single exposure: Substances are classified in Category 1 for STOT–SE on the basis of:

(a) Reliable and good quality evidence from human cases or epidemiological studies; or

(b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects of relevance to human health were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (See A.8.2.1.9) to be used as part of weight-of-evidence evaluation.

CATEGORY 2: Substances that, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to be harmful to human health following single exposure: Substances are classified in Category 2 for STOT–SE on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (See A.8.2.1.9) in order to help in classification. In exceptional cases, human evidence can also be used to place a substance in Category 2 (See A.8.2.1.6).

CATEGORY 3: Transient target organ effects: There are target organ effects for which a substance does not meet the criteria to be classified in Categories 1 or 2 indicated above. These are effects which adversely alter human function for a short duration after exposure and from which humans may recover in a reasonable period without leaving significant alteration of structure or function. This category only includes narcotic effects and respiratory tract irritation. Substances are classified specifically for these effects as discussed in A.8.2.2.

Note: *The primary target organ/system shall be identified where possible, and where this is not possible, the substance shall be identified as a general toxicant. The data shall be evaluated and, where possible, shall not include secondary effects (e.g., a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems).*

A.8.2.1.2 The relevant route(s) of exposure by which the classified substance produces damage shall be identified.

A.8.2.1.3 Classification is determined by expert judgment, on the basis of the weight of all evidence available including the guidance presented below.

A.8.2.1.4 Weight of evidence of all available data, including human incidents, epidemiology, and studies conducted in experimental animals is used to substantiate specific target organ toxic effects that merit classification.

A.8.2.1.5 The information required to evaluate specific target organ toxicity comes either from single exposure in humans (*e.g.,* exposure at home, in the workplace or environmentally), or from studies conducted in experimental animals. The standard animal studies in rats or mice that provide this information are acute toxicity studies which can include clinical observations and detailed macroscopic and microscopic examination to enable the toxic effects on target tissues/organs to be identified. Results of acute toxicity studies conducted in other species may also provide relevant information.

A.8.2.1.6 In exceptional cases, based on expert judgment, it may be appropriate to place certain substances with human evidence of target organ toxicity in Category 2: (a) When the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. Dose/concentration levels in humans shall not be considered in the classification and any available evidence from animal studies shall be consistent with the Category 2 classification. In other words, if there are also animal data available on the substance that warrant Category 1 classification, the chemical shall be classified as Category 1.

A.8.2.1.7 Effects considered to support classification for Category 1 and 2.

A.8.2.1.7.1 Classification is supported by evidence associating single exposure to the substance with a consistent and identifiable toxic effect.

A.8.2.1.7.2 Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and may not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.

A.8.2.1.7.3 Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, and macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently, all available evidence, and relevance to human health, must be taken into consideration in the classification process. Relevant toxic effects in humans and/or animals include, but are not limited to:

(a) Morbidity resulting from single exposure;

(b) Significant functional changes, more than transient in nature, in the respiratory system, central or peripheral nervous systems, other organs or other organ systems, including signs of central nervous system depression and effects on special senses (*e.g.,* sight, hearing and sense of smell);

(c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;

(d) Significant organ damage that may be noted at necropsy and/or subsequently seen or confirmed at microscopic examination;

(e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;

(f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction; and,

(g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

A.8.2.1.8 Effects considered not to support classification for Category 1 and 2.

Effects may be seen in humans and/or animals that do not justify classification. Such effects include, but are not limited to:

(a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate ''significant'' toxicity;

(b) Small changes in clinical biochemistry, hematology or urinalysis parameters and/or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;

(c) Changes in organ weights with no evidence of organ dysfunction;

(d) Adaptive responses that are not considered toxicologically relevant; and,

(e) Substance-induced species-specific mechanisms of toxicity, *i.e.,* demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.

A.8.2.1.9 Guidance values to assist with classification based on the results obtained from studies conducted in experimental animals for Category 1 and 2.

A.8.2.1.9.1 In order to help reach a decision about whether a substance shall be classified or not, and to what degree it shall be classified (Category 1 vs. Category 2), dose/concentration ''guidance values'' are provided for consideration of the dose/concentration which has been shown to produce significant health effects. The principal argument for proposing such guidance values is that all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged.

A.8.2.1.9.2 Thus, in animal studies, when significant toxic effects are observed that indicate classification, consideration of the dose/concentration at which these effects were seen, in relation to the suggested guidance values, provides useful information to help assess the need to classify (since the toxic effects are a consequence of the hazardous property(ies) and also the dose/concentration).

A.8.2.1.9.3 The guidance value (C) ranges for single-dose exposure which has produced a significant non-lethal toxic effect are those applicable to acute toxicity testing, as indicated in Table A.8.1.

TABLE A.8.1—GUIDANCE VALUE RANGES FOR SINGLE-DOSE EXPOSURES

		Guidance value ranges for:		
Route of exposure	Units	Category 1	Category 2	Category 3
Oral (rat)	mg/kg body weight	C ≤ 300	2,000 ≥ C > 300	Guidance values do not apply.
Dermal (rat or rabbit)	mg/kg body weight	C ≤ 1,000	2,000 ≥ C > 1,000.	
Inhalation (rat) gas	ppmV/4h	C ≤ 2,500	20,000 ≥ C > 2,500.	
Inhalation (rat) vapor	mg/1/4h	C ≤ 10	20 ≥ C > 10.	
Inhalation (rat) dust/mist/fume.	mg/l/4h	C ≤ 1.0	5.0 ≥ C > 1.0.	

A.8.2.1.9.4 The guidance values and ranges mentioned in Table A.8.1 are intended only for guidance purposes, *i.e.,* to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values. Guidance values are not provided for Category 3 since this classification is primarily based on human data; animal data may be included in the weight of evidence evaluation.

A.8.2.1.9.5 Thus, it is feasible that a specific profile of toxicity occurs at a dose/concentration below the guidance value, *e.g.,* <2,000 mg/kg body weight by the oral route, however the nature of the effect may result in the decision not to classify. Conversely, a specific profile of toxicity may be seen in animal studies occurring at above a guidance value, *e.g.,* ≥2,000 mg/kg body weight by the oral route, and in addition there is supplementary information from other sources, *e.g.,* other single dose studies, or human case experience, which supports a conclusion that, in view of the weight of evidence, classification is the prudent action to take.

A.8.2.1.10 Other considerations.

A.8.2.1.10.1 When a substance is characterized only by use of animal data the classification process includes reference to dose/concentration guidance values as one of

the elements that contribute to the weight of evidence approach.

A.8.2.1.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to single exposure to a substance, the substance shall be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a substance is unclassified because specific target organ toxicity observed was considered not relevant or significant to humans, if subsequent human incident data become available showing a specific target organ toxic effect, the substance shall be classified.

A.8.2.1.10.3 A substance that has not been tested for specific target organ toxicity shall, where appropriate, be classified on the basis of data from a scientifically validated structure activity relationship and expert judgment-based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important factors such as formation of common significant metabolites.

A.8.2.2 Substances of Category 3

A.8.2.2.1 Criteria for respiratory tract irritation.

The criteria for classifying substances as Category 3 for respiratory tract irritation are:

(a) Respiratory irritant effects (characterized by localized redness, edema, pruritis and/or pain) that impair function with symptoms such as cough, pain, choking, and breathing difficulties are included. It is recognized that this evaluation is based primarily on human data;

(b) Subjective human observations supported by objective measurements of clear respiratory tract irritation (RTI) (*e.g.,* electrophysiological responses, biomarkers of inflammation in nasal or bronchoalveolar lavage fluids);

(c) The symptoms observed in humans shall also be typical of those that would be produced in the exposed population rather than being an isolated idiosyncratic reaction or response triggered only in individuals with hypersensitive airways. Ambiguous reports simply of ''irritation'' should be excluded as this term is commonly used to describe a wide range of sensations including those such as smell, unpleasant taste, a tickling sensation, and dryness, which are outside the scope of classification for respiratory tract irritation;

(d) There are currently no scientifically validated animal tests that deal specifically with RTI; however, useful information may be obtained from the single and repeated inhalation toxicity tests. For example, animal studies may provide useful information in terms of clinical signs of toxicity (dyspnoea, rhinitis etc.) and histopathology (*e.g.,* hyperemia, edema, minimal inflammation, thickened mucous layer) which are reversible and may be reflective of the characteristic clinical symptoms described above. Such animal studies can be used as part of weight of evidence evaluation; and,

(e) This special classification will occur only when more severe organ effects including the respiratory system are not observed as those effects would require a higher classification.

A.8.2.2.2 Criteria for narcotic effects.

The criteria for classifying substances in Category 3 for narcotic effects are:

(a) Central nervous system depression including narcotic effects in humans such as drowsiness, narcosis, reduced alertness, loss of reflexes, lack of coordination, and vertigo are included. These effects can also be manifested as severe headache or nausea, and can lead to reduced judgment, dizziness, irritability, fatigue, impaired memory function, deficits in perception and coordination, reaction time, or sleepiness; and,

(b) Narcotic effects observed in animal studies may include lethargy, lack of coordination righting reflex, narcosis, and ataxia. If these effects are not transient in nature, then they shall be considered for classification as Category 1 or 2.

A.8.3 Classification Criteria for Mixtures

A.8.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.

A.8.3.2 Classification of Mixtures When Data Are Available for the Complete Mixture

When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of this data. Care shall be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

A.8.3.3 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.8.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one hazard category, Substantially similar mixtures, or Aerosols.

A.8.3.4 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.8.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.8.2 for Categories 1 and 2, respectively.

TABLE A.8.2—CUT-OFF VALUES/CONCENTRATION LIMITS OF INGREDIENTS OF A MIXTURE CLASSIFIED AS A SPECIFIC TARGET ORGAN TOXICANT THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE AS CATEGORY 1 OR 2

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:	
	Category 1	Category 2
Category 1: Target organ toxicant	≥1.0%	
Category 2: Target organ toxicant		≥1.0%

A.8.3.4.2 These cut-off values and consequent classifications shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

A.8.3.4.3 Mixtures shall be classified for either or both single and repeated dose toxicity independently.

A.8.3.4.4 Care shall be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause target organ toxicity at <1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

A.8.3.4.5 Care shall be exercised when extrapolating the toxicity of a mixture that contains Category 3 ingredient(s). A cut-off value/concentration limit of 20%, considered as an additive of all Category 3 ingredients for each hazard endpoint, is appropriate; however, this cut-off value/concentration limit may be higher or lower depending on the Category 3 ingredient(s) involved and the fact that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20% value. Expert judgment shall be exercised. Respiratory tract irritation and narcotic

effects are to be evaluated separately in accordance with the criteria given in A.8.2.2. When conducting classifications for these hazards, the contribution of each ingredient should be considered additive, unless there is evidence that the effects are not additive.

A.8.3.4.6 In cases where the additivity approach is used for Category 3 ingredients, the ''relevant ingredients'' of a mixture are those which are present in concentrations ≥1% (w/w for solids, liquids, dusts, mists, and vapours and v/v for gases), unless there is a reason to suspect that an ingredient present at a concentration <1% is still relevant when classifying the mixture for respiratory tract irritation or narcotic effects.

A.9 Specific Target Organ Toxicity Repeated or Prolonged Exposure

A.9.1 Definitions and General Considerations

A.9.1.1 *Specific target organ toxicity—repeated exposure (STOT–RE)* refers to specific toxic effects on target organs occurring after repeated exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in A.1 to A.7 and A.10 of this appendix are included. Specific target organ toxicity following a single-event exposure is classified in accordance with *SPECIFIC TARGET ORGAN TOXICITY–SINGLE EXPOSURE* (A.8 of this appendix) and is therefore not included here.

A.9.1.2 Classification identifies the substance or mixture as being a specific target organ toxicant and, as such, it may present a potential for adverse health effects in people who are exposed to it.

A.9.1.3 These adverse health effects produced by repeated exposure include consistent and identifiable toxic effects in humans, or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or have produced serious changes to the biochemistry or hematology of the organism and these changes are relevant for human health. Human data will be the primary source of evidence for this hazard class.

A.9.1.4 Assessment shall take into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

A.9.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, *e.g.,* principally oral, dermal or inhalation.

A.9.2 Classification Criteria for Substances

A.9.2.1 Substances shall be classified as STOT–RE by expert judgment on the basis of the weight of all evidence available, including the use of recommended guidance values which take into account the duration of exposure and the dose/concentration which produced the effect(s), (See A.9.2.9). Substances shall be placed in one of two categories, depending upon the nature and severity of the effect(s) observed, in accordance with Figure A.9.1.

FIGURE A.9.1—HAZARD CATEGORIES FOR SPECIFIC TARGET ORGAN TOXICITY FOLLOWING REPEATED EXPOSURE

CATEGORY 1: Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following repeated or prolonged exposure. Substances are classified in Category 1 for specific target organ toxicity (repeated exposure) on the basis of:

(a) Reliable and good quality evidence from human cases or epidemiological studies; or,

(b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects, of relevance to human health, were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (See A.9.2.9) to be used as part of weight-of-evidence evaluation.

CATEGORY 2: Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following repeated or prolonged exposure. Substances are classified in Category 2 for specific target organ toxicity (repeated exposure) on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (See A.9.2.9) in order to help in classification. In exceptional cases human evidence can also be used to place a substance in Category 2 (See A.9.2.6).

Note: *The primary target organ/system shall be identified where possible, or the substance shall be identified as a general toxicant. The data shall be carefully evaluated and, where possible, shall not include secondary effects (e.g., a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems).*

A.9.2.2 The relevant route of exposure by which the classified substance produces damage shall be identified.

A.9.2.3 Classification is determined by expert judgment, on the basis of the weight of all evidence available including the guidance presented below.

A.9.2.4 Weight of evidence of all data, including human incidents, epidemiology, and studies conducted in experimental animals, is used to substantiate specific target organ toxic effects that merit classification.

A.9.2.5 The information required to evaluate specific target organ toxicity comes either from repeated exposure in humans, *e.g.,* exposure at home, in the workplace or environmentally, or from studies conducted in experimental animals. The standard animal studies in rats or mice that provide this information are 28 day, 90 day or lifetime studies (up to 2 years) that include hematological, clinico-chemical and detailed macroscopic and microscopic examination to enable the toxic effects on target tissues/organs to be identified. Data from repeat dose studies performed in other species may also be used. Other long-term exposure studies, *e.g.,* for carcinogenicity, neurotoxicity or reproductive toxicity, may also provide evidence of specific target organ toxicity that could be used in the assessment of classification.

A.9.2.6 In exceptional cases, based on expert judgment, it may be appropriate to place certain substances with human evidence of specific target organ toxicity in Category 2: (a) When the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. Dose/concentration levels in humans shall not be considered in the classification and any available evidence from animal studies shall be consistent with the Category 2 classification. In other words, if there are also animal data available on the substance that warrant Category 1 classification, the substance shall be classified as Category 1.

A.9.2.7 Effects Considered To Support Classification

A.9.2.7.1 Classification is supported by reliable evidence associating repeated exposure to the substance with a consistent and identifiable toxic effect.

A.9.2.7.2 Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and may not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.

A.9.2.7.3 Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, hematology, clinical chemistry, macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently, all available evidence, and relevance to human health, must be taken into consideration in the classification process. Relevant toxic effects in humans and/or animals include, but are not limited to:

(a) Morbidity or death resulting from repeated or long-term exposure. Morbidity or death may result from repeated exposure, even to relatively low doses/concentrations, due to bioaccumulation of the substance or its metabolites, or due to the overwhelming of the de-toxification process by repeated exposure;

(b) Significant functional changes in the central or peripheral nervous systems or other organ systems, including signs of

central nervous system depression and effects on special senses (*e.g.,* sight, hearing and sense of smell);

(c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;

(d) Significant organ damage that may be noted at necropsy and/or subsequently seen or confirmed at microscopic examination;

(e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;

(f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction (*e.g.,* severe fatty change in the liver); and,

(g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

A.9.2.8 Effects Considered Not To Support Classification

Effects may be seen in humans and/or animals that do not justify classification. Such effects include, but are not limited to:

(a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate ''significant'' toxicity;

(b) Small changes in clinical biochemistry, hematology or urinalysis parameters and/or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;

(c) Changes in organ weights with no evidence of organ dysfunction;

(d) Adaptive responses that are not considered toxicologically relevant;

(e) Substance-induced species-specific mechanisms of toxicity, *i.e.,* demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.

A.9.2.9 Guidance Values To Assist With Classification Based on the Results Obtained From Studies Conducted in Experimental Animals

A.9.2.9.1 In studies conducted in experimental animals, reliance on observation of effects alone, without reference to the duration of experimental exposure and dose/concentration, omits a fundamental concept of toxicology, *i.e.,* all substances are potentially toxic, and what determines the toxicity is a function of the dose/concentration and the duration of exposure. In most studies conducted in experimental animals the test guidelines use an upper limit dose value.

A.9.2.9.2 In order to help reach a decision about whether a substance shall be classified or not, and to what degree it shall be classified (Category 1 vs. Category 2), dose/concentration ''guidance values'' are provided in Table A.9.1 for consideration of the dose/concentration which has been shown to produce significant health effects. The principal argument for proposing such guidance values is that all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged. Also, repeated-dose studies conducted in experimental animals are designed to produce toxicity at the highest dose used in order to optimize the test objective and so most studies will reveal some toxic effect at least at this highest dose. What is therefore to be decided is not only what effects have been produced, but also at what dose/concentration they were produced and how relevant is that for humans.

A.9.2.9.3 Thus, in animal studies, when significant toxic effects are observed that indicate classification, consideration of the duration of experimental exposure and the dose/concentration at which these effects were seen, in relation to the suggested guidance values, provides useful information to help assess the need to classify (since the toxic effects are a consequence of the hazardous property(ies) and also the duration of exposure and the dose/concentration).

A.9.2.9.4 The decision to classify at all can be influenced by reference to the dose/concentration guidance values at or below which a significant toxic effect has been observed.

A.9.2.9.5 The guidance values refer to effects seen in a standard 90-day toxicity study conducted in rats. They can be used as a basis to extrapolate equivalent guidance values for toxicity studies of greater or lesser duration, using dose/exposure time extrapolation similar to Haber's rule for inhalation, which states essentially that the effective dose is directly proportional to the exposure concentration and the duration of exposure. The assessment should be done on a case-by-case basis; for example, for a 28-day study the guidance values below would be increased by a factor of three.

A.9.2.9.6 Thus for Category 1 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur at or below the (suggested) guidance values (C) as indicated in Table A.9.1 would justify classification:

TABLE A.9.1—GUIDANCE VALUES TO ASSIST IN CATEGORY 1 CLASSIFICATION

[Applicable to a 90-day study]

Route of exposure	Units	Guidance values (dose/concentration)
Oral (rat)	mg/kg body weight/day	C ≤10
Dermal (rat or rabbit)	mg/kg body weight/day	C ≤20
Inhalation (rat) gas	ppmV/6h/day	C ≤50
Inhalation (rat) vapor	mg/liter/6h/day	C ≤0.2
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	C ≤0.02

A.9.2.9.7 For Category 2 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur within the (suggested) guidance value ranges as indicated in Table A.9.2 would justify classification:

TABLE A.9.2—GUIDANCE VALUES TO ASSIST IN CATEGORY 2 CLASSIFICATION

[Applicable to a 90-day study]

Route of exposure	Units	Guidance value range (dose/concentration)
Oral (rat)	mg/kg body weight/day	10 <C ≤100
Dermal (rat or rabbit)	mg/kg body weight/day	20 <C ≤200
Inhalation (rat) gas	ppmV/6h/day	50 <C ≤250
Inhalation (rat) vapor	mg/liter/6h/day	0.2 <C ≤1.0
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	0.02 <C ≤0.2

A.9.2.9.8 The guidance values and ranges mentioned in A.2.9.9.6 and A.2.9.9.7 are intended only for guidance purposes, *i.e.,* to be used as part of the weight of evidence approach, and to assist with decisions about

classification. They are not intended as strict demarcation values.

A.9.2.9.9 Thus, it is possible that a specific profile of toxicity occurs in repeat-dose animal studies at a dose/concentration below the guidance value, *e.g.,* <100 mg/kg body weight/day by the oral route, however the nature of the effect, *e.g.,* nephrotoxicity seen only in male rats of a particular strain known to be susceptible to this effect, may result in the decision not to classify. Conversely, a specific profile of toxicity may be seen in animal studies occurring at above a guidance value, *e.g.,* ≥100 mg/kg body weight/day by the oral route, and in addition there is supplementary information from other sources, *e.g.,* other long-term administration studies, or human case experience, which supports a conclusion that, in view of the weight of evidence, classification is prudent.

A.9.2.10 Other Considerations

A.9.2.10.1 When a substance is characterized only by use of animal data the classification process includes reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

A.9.2.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to repeated or prolonged exposure to a substance, the substance shall be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a substance is unclassified because no specific target organ toxicity was seen at or below the dose/concentration guidance value for animal testing, if subsequent human incident data become available showing a specific target organ toxic effect, the substance shall be classified.

A.9.2.10.3 A substance that has not been tested for specific target organ toxicity may in certain instances, where appropriate, be classified on the basis of data from a scientifically validated structure activity relationship and expert judgment-based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important factors such as formation of common significant metabolites.

A.9.3 Classification Criteria for Mixtures

A.9.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.

A.9.3.2 Classification of Mixtures When Data Are Available for the Complete Mixture

When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of these data. Care shall be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

A.9.3.3 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.9.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this appendix: Dilution; Batching; Concentration of mixtures; Interpolation within one hazard category; Substantially similar mixtures; and Aerosols.

A.9.3.4 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.9.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.9.3 for Category 1 and 2 respectively.

TABLE A.9.3—CUT-OFF VALUE/CONCENTRATION LIMITS OF INGREDIENTS OF A MIXTURE CLASSIFIED AS A SPECIFIC TARGET ORGAN TOXICANT THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE AS CATEGORY 1 OR 2

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:	
	Category 1	Category 2
Category 1: Target organ toxicant	≥1.0%	
Category 2: Target organ toxicant		≥1.0%

A.9.3.4.2 These cut-off values and consequent classifications shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

A.9.3.4.3 Mixtures shall be classified for either or both single- and repeated-dose toxicity independently.

A.9.3.4.4 Care shall be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause specific target organ toxicity at <1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

A.10 Aspiration Hazard

A.10.1 Definitions and General Considerations

A.10.1.1 Aspiration hazard refers to severe acute effects such as chemical pneumonia, pulmonary injury or death occurring after aspiration of a substance or mixture.

A.10.1.2 Aspiration means the entry of a liquid or solid chemical directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system.

A.10.1.3 Aspiration is initiated at the moment of inspiration, in the time required to take one breath, as the causative material lodges at the crossroad of the upper respiratory and digestive tracts in the laryngopharyngeal region.

A.10.1.4 Aspiration of a substance or mixture can occur as it is vomited following ingestion. This may have consequences for labelling, particularly where, due to acute toxicity, a recommendation may be considered to induce vomiting after ingestion. However, if the substance/mixture also presents an aspiration toxicity hazard, the recommendation to induce vomiting may need to be modified.

A.10.1.5 Specific Considerations

A.10.1.5.1 The classification criteria refer to kinematic viscosity. The following provides the conversion between dynamic and kinematic viscosity:

$$\frac{\text{Dynamic viscosity}(\text{mPa}\cdot\text{s})}{\text{Density}(\text{g/cm}^3)} = \text{Kinematic viscosity}(\text{mm}^2/\text{s})$$

A.10.1.5.2 Although the definition of aspiration in A.10.1.1 includes the entry of solids into the respiratory system, classification according to (b) in table A.10.1 for Category 1 is intended to apply to liquid substances and mixtures only.

A.10.1.5.3 Classification of aerosol/mist products

Aerosol and mist products are usually dispensed in containers such as self-pressurized containers, trigger and pump sprayers. Classification for these products shall be considered if their use may form a pool of product in the mouth, which then may be aspirated. If the mist or aerosol from a pressurized container is fine, a pool may not be formed. On the other hand, if a pressurized container dispenses product in a stream, a pool may be formed that may then be aspirated. Usually, the mist produced by trigger and pump sprayers is coarse and therefore, a pool may be formed that then may be aspirated. When the pump mechanism may be removed and contents are available to be swallowed then the classification of the products should be considered.

A.10.2 Classification Criteria for Substances

TABLE A.10.1—CRITERIA FOR ASPIRATION TOXICITY

Category	Criteria
Category 1: Chemicals known to cause human aspiration toxicity hazards or to be regarded as if they cause human aspiration toxicity hazard.	A substance shall be classified in Category 1: (a) If reliable and good quality human evidence indicates that it causes aspiration toxicity (See note); or (b) If it is a hydrocarbon and has a kinematic viscosity ≤20.5 mm2/s, measured at 40 °C.

Note: *Examples of substances included in Category 1 are certain hydrocarbons, turpentine and pine oil.*

A.10.3 Classification Criteria for Mixtures

A.10.3.1 Classification When Data Are Available for the Complete Mixture

A mixture shall be classified in Category 1 based on reliable and good quality human evidence.

A.10.3.2 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.10.3.2.1 Where the mixture itself has not been tested to determine its aspiration toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazard of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this appendix: Dilution; Batching; Concentration of mixtures; Interpolation within one hazard category; and Substantially similar mixtures. For application of the dilution bridging principle, the concentration of aspiration toxicants shall not be less than 10%.

A.10.3.3 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.10.3.3.1 The ''relevant ingredients'' of a mixture are those which are present in concentrations ≥1%.

A.10.3.3.2 *Category 1*

A.10.3.3.2.1 A mixture is classified as Category 1 when the sum of the concentrations of Category 1 ingredients is ≥10%, and the mixture has a kinematic viscosity of ≤20.5 mm2/s, measured at 40 °C.

A.10.3.3.2.2 In the case of a mixture which separates into two or more distinct layers, the entire mixture is classified as Category 1 if in any distinct layer the sum of the concentrations of Category 1 ingredients is ≥10%, and it has a kinematic viscosity of ≤20.5 mm2/s, measured at 40 °C.

Appendix B to § 1910.1200—Physical Hazard Criteria (Mandatory)

B.1 Explosives

B.1.1 Definitions and General Considerations

B.1.1.1 An *explosive chemical* is a solid or liquid chemical which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic chemicals are included even when they do not evolve gases.

A *pyrotechnic chemical* is a chemical designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self-sustaining exothermic chemical reactions.

An *explosive item* is an item containing one or more explosive chemicals.

A *pyrotechnic item* is an item containing one or more pyrotechnic chemicals.

An *unstable explosive* is an explosive which is thermally unstable and/or too sensitive for normal handling, transport, or use.

An *intentional explosive* is a chemical or item which is manufactured with a view to produce a practical explosive or pyrotechnic effect.

B.1.1.2 The class of explosives comprises:

(a) Explosive chemicals;

(b) Explosive items, except devices containing explosive chemicals in such quantity or of such a character that their inadvertent or accidental ignition or initiation shall not cause any effect external to the device either by projection, fire, smoke, heat or loud noise; and

(c) Chemicals and items not included under (a) and (b) of this section which are manufactured with the view to producing a practical explosive or pyrotechnic effect.

B.1.2 Classification Criteria

Chemicals and items of this class shall be classified as unstable explosives or shall be assigned to one of the following six divisions depending on the type of hazard they present:

(a) Division 1.1—Chemicals and items which have a mass explosion hazard (a mass explosion is one which affects almost the entire quantity present virtually instantaneously);

(b) Division 1.2—Chemicals and items which have a projection hazard but not a mass explosion hazard;

(c) Division 1.3—Chemicals and items which have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but not a mass explosion hazard:

(i) Combustion of which gives rise to considerable radiant heat; or

(ii) Which burn one after another, producing minor blast or projection effects or both;

(d) Division 1.4—Chemicals and items which present no significant hazard: Chemicals and items which present only a small hazard in the event of ignition or initiation. The effects are largely confined to the package and no projection of fragments of appreciable size or range is to be expected. An external fire shall not cause virtually instantaneous explosion of almost the entire contents of the package;

(e) Division 1.5—Very insensitive chemicals which have a mass explosion hazard: Chemicals which have a mass explosion hazard but are so insensitive that there is very little probability of initiation or of transition from burning to detonation under normal conditions;

(f) Division 1.6—Extremely insensitive items which do not have a mass explosion hazard: Items which predominantly contain extremely insensitive detonating chemicals and which demonstrate a negligible probability of accidental initiation or propagation.

B.1.3 Additional Classification Considerations

B.1.3.1 Explosives shall be classified as unstable explosives or shall be assigned to one of the six divisions identified in B.1.2 in accordance with the three-step procedure in Part I of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6). The first step is to ascertain whether the substance or mixture has explosive effects (Test Series 1). The second step is the acceptance procedure (Test Series 2 to 4) and the third step is the assignment to a hazard division (Test Series

5 to 7). The assessment whether a candidate for ''ammonium nitrate emulsion or suspension or gel, intermediate for blasting explosives (ANE)'' is insensitive enough for inclusion as an oxidizing liquid (See B.13) or an oxidizing solid (See B.14) is determined by Test Series 8 tests.

Note 1: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

Note 2: Some explosive chemicals are wetted with water or alcohols, diluted with other substances or dissolved or suspended in water or other liquid substances to suppress or reduce their explosive properties. These chemicals shall be classified as desensitized explosives (see Chapter B.17).

Note 3: Chemicals with a positive result in Test Series 2 in Part I, Section 12, of UN ST/SG/AC.10/30/Rev.6 (UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria) (incorporated by reference; see § 1910.6) UN ST/SG/AC.10/30/Rev.6 (UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria) (incorporated by reference; see § 1910.6)), still have explosive properties. The explosive properties of the chemical shall be communicated in Section 2 (Hazard identification) and Section 9 (Physical and chemical properties) of the Safety Data Sheet, as appropriate.

B.1.3.2 Explosive properties are associated with the presence of certain chemical groups in a molecule which can react to produce very rapid increases in temperature or pressure. The screening procedure in B.1.3.1 is aimed at identifying the presence of such reactive groups and the potential for rapid energy release. If the screening procedure identifies the chemical as a potential explosive, the acceptance procedure (See section 10.3 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6)) is necessary for classification.

Note: Neither a Series 1 type (a) propagation of detonation test nor a Series 2 type (a) test of sensitivity to detonative shock is necessary if the exothermic decomposition energy of organic materials is less than 800 J/g.

B.1.3.3 If a mixture contains any known explosives, the acceptance procedure is necessary for classification.

B.1.3.4 A chemical is not classified as explosive if:

(a) There are no chemical groups associated with explosive properties present in the molecule. Examples of groups which may indicate explosive properties are given in Table A6.1 in Appendix 6 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6); or

(b) The substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than −200.

The oxygen balance is calculated for the chemical reaction:

$$C_xH_yO_z + [x + (y/4) - (z/2)]\ O2 \rightarrow x.\ CO_2 + (y/2)\ H_2O$$

using the formula:

$$\text{oxygen balance} = -1600\ [2x + (y/2) - z]/\text{molecular weight}$$; or

(c) The organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500 °C (932 °F). The exothermic decomposition energy may be determined using a suitable calorimetric technique; or

(d) For mixtures of inorganic oxidizing substances with organic material(s), the concentration of the inorganic oxidizing substance is:

(i) Less than 15%, by mass, if the oxidizing substance is assigned to Category 1 or 2;

(ii) less than 30%, by mass, if the oxidizing substance is assigned to Category 3.

B.2 Flammable Gases

B.2.1 Definition

Flammable gas means a gas having a flammable range with air at 20 °C (68 °F) and a standard pressure of 101.3 kPa (14.7 psi).

A *pyrophoric gas* means a flammable gas that is liable to ignite spontaneously in air at a temperature of 54 °C (130 °F) or below.

A *chemically unstable gas* means a flammable gas that is able to react explosively even in the absence of air or oxygen.

B.2.2 Classification Criteria

B.2.2.1 A flammable gas shall be classified in Category 1A, 1B, or 2 in accordance with Table B.2.1:

Table B.2.1: Criteria for flammable gases

Category			Criteria
1A	Flammable gas		Gases, which at 20 °C (68 ºF) and a standard pressure of 101.3 kPa (14.7 psi): (a) are ignitable when in a mixture of 13% or less by volume in air; or (b) have a flammable range with air of at least 12 percentage points regardless of the lower flammability limit, unless data show they meet the criteria for Category 1B.
	Pyrophoric gas		Flammable gases that ignite spontaneously in air at a temperature of 54 °C (130 ºF) or below.
	Chemically unstable gas	A	Flammable gases which are chemically unstable at 20 °C (68 ºF) and a standard pressure of 101.3 kPa (14.7 psi).
		B	Flammable gases which are chemically unstable at a temperature greater than 20 °C (68 ºF) and/or a pressure greater than 101.3 kPa (14.7 psi).
1B	Flammable gas		Gases which meet the flammability criteria for Category 1A, but which are not pyrophoric, nor chemically unstable, and which have at least either: (a) a lower flammability limit of more than 6% by volume in air; or (b) a fundamental burning velocity of less than 10 cm/s.
2	Flammable gas		Gases, other than those of Category 1A or 1B, which, at 20 °C (68 ºF) and a standard pressure of 101.3 kPa (14.7 psi), have a flammable range while mixed in air.

NOTE 1: Aerosols should not be classified as flammable gases. *See* B.3.

NOTE 2: In the absence of data allowing classification into Category 1B, a flammable gas that meets the criteria for Category 1A shall be classified by default in Category 1A.

NOTE 3: Spontaneous ignition for pyrophoric gases is not always immediate, and there may be a delay.

NOTE 4: In the absence of data on its pyrophoricity, a flammable gas mixture should be classified as a pyrophoric gas if it contains more than 1% (by volume) of pyrophoric component(s).

B.2.3 Additional Classification Considerations

B.2.3.1 Flammability shall be determined by tests or by calculation in accordance with ISO 10156 (Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets; 1996, first edition or 2010, third edition) (incorporated by reference; see § 1910.6) and, if using fundamental burning velocity for Category 1B, use ISO 817:2014 (third edition) (Refrigerants—Designation and safety classification, Annex C: Method of test for burning velocity measurement of flammable gases) (incorporated by reference; see § 1910.6). Where insufficient data are available to use this method, equivalent validated methods may be used.

B.2.3.2 Pyrophoricity shall be determined at 130 °F (54 °C) in accordance with either IEC 60079–20–1, edition 1.0 (2010–01) (Explosive atmospheres—Part 20–1: Material characteristics for gas and vapor classification—Test methods and data) (incorporated by reference; see § 1910.6) or DIN 51794 (2003) (Determining the ignition temperature of petroleum products) (incorporated by reference; see § 1910.6).

B.2.3.3 The classification procedure for pyrophoric gases need not be applied when experience in production or handling shows that the substance does not ignite spontaneously on coming into contact with air at a temperature of 130 °F (54 °C) or below. Flammable gas mixtures which have not been tested for pyrophoricity and which contain more than one percent pyrophoric components shall be classified as a pyrophoric gas. Expert judgement on the properties and physical hazards of pyrophoric gases and their mixtures should be used in assessing the need for classification of flammable gas mixtures containing one percent or less pyrophoric components. In this case, testing need only be considered if expert judgement indicates a need for additional data to support the classification process.

B.2.3.4 Chemical instability shall be determined in accordance with the method described in Part III of the UN ST/SG/AC.10/30/Rev.6 (UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria) (incorporated by reference; see § 1910.6)]. If the calculations performed in accordance with ISO 10156 (Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets; 1996, first edition or 2010, third edition) (incorporated by reference; see § 1910.6) show that a gas mixture is not flammable, no additional testing is required for determining chemical instability for classification purposes.

B.3 Aerosols

B.3.1 Definition

Aerosol means any non-refillable receptacle containing a gas compressed, liquefied or dissolved under pressure, and fitted with a release device allowing the contents to be ejected as particles in suspension in a gas, or as a foam, paste, powder, liquid or gas.

B.3.2 Classification Criteria

B.3.2.1 Aerosols are classified in one of three categories, depending on their flammable properties and their heat of combustion. Aerosols shall be considered for classification in Categories 1 or 2 if they contain more than 1% components (by mass) which are classified as flammable in accordance with this appendix, *i.e.*:

Flammable gases (See B.2);
Flammable liquids (See B.6);
Flammable solids (See B.7);
or if their heat of combustion is at least 20 kJ/g.

Note 1: Flammable components do not include pyrophoric, self-heating or water-reactive chemicals.

Note 2: Aerosols do not fall additionally within the scope of flammable gases, gases under pressure, flammable liquids, or flammable solids. However, depending on their contents, aerosols may fall within the scope of other hazard classes.

B.3.2.2 An aerosol shall be classified in one of the three categories for this class in accordance with Table B.3.1.

TABLE B.3.1—CRITERIA FOR AEROSOLS

Category	Criteria
1	Contains ≥85% flammable components and the chemical heat of combustion is ≥30 kJ/g; or (a) For spray aerosols, in the ignition distance test, ignition occurs at a distance ≥75 cm (29.5 in), or (b) For foam aerosols, in the aerosol foam flammability test (i) The flame height is ≥20 cm (7.87 in) and the flame duration ≥2 s; or (ii) The flame height is ≥4 cm (1.57 in) and the flame duration ≥7 s.
2	Contains >1% flammable components, or the heat of combustion is ≥20 kJ/g; and (a) for spray aerosols, in the ignition distance test, ignition occurs at a distance ≥15 cm (5.9 in), or in the enclosed space ignition test, the (i) Time equivalent is ≤300 s/m3; or (ii) Deflagration density is ≤300 g/m3 (b) For foam aerosols, in the aerosol foam flammability test, the flame height is ≥4 cm and the flame duration is ≥2 s and it does not meet the criteria for Category 1.
3	The chemical does not meet the criteria for Categories 1 and 2. The chemical contains ≤1% flammable components (by mass) *and* has a heat of combustion <20 kJ/g.

Note: Aerosols containing more than 1% flammable components or with a heat of combustion of at least 20 kJ/g, which are not submitted to the flammability classification procedures in this appendix shall be classified as Category 1.

B.3.3 Additional Classification Considerations

B.3.3.1 To classify an aerosol, data on its flammable components, on its chemical heat of combustion and, if applicable, the results of the aerosol foam flammability test (for foam aerosols) and of the ignition distance test and enclosed space test (for spray aerosols) are necessary.

B.3.3.2 The chemical heat of combustion (ΔHc), in kilojoules per gram (kJ/g), is the product of the theoretical heat of combustion (ΔHcomb), and a combustion efficiency, usually less than 1.0 (a typical combustion efficiency is 0.95 or 95%).

For a composite aerosol formulation, the chemical heat of combustion is the summation of the weighted heats of combustion for the individual components, as follows:

$$\Delta Hc\ (\text{product}) = \sum_{i}^{n} [\ wi\% \times \Delta Hc(i)]$$

where:

ΔHc = chemical heat of combustion (kJ/g);
wi% = mass fraction of component i in the product;
ΔHc(i) = specific heat of combustion (kJ/g) of component i in the product;

The chemical heats of combustion shall be found in literature, calculated or determined by tests (See ASTM D240–02; ISO 13943, Sections 86.1 to 86.3; and NFPA 30B (incorporated by reference; See § 1910.6)).

B.3.3.3 The Ignition Distance Test, Enclosed Space Ignition Test and Aerosol Foam Flammability Test shall be performed in accordance with sub-sections 31.4, 31.5 and 31.6 of the of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6).

B.4 Oxidizing Gases

B.4.1 Definition

Oxidizing gas means any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

Note: ''Gases which cause or contribute to the combustion of other material more than air does'' means pure gases or gas mixtures with an oxidizing power greater than 23.5% (as determined by a method specified in ISO 10156 (Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets; 1996, first edition or 2010, third edition) (incorporated by reference; see § 1910.6) or 10156–2:2005 (E) (Gas cylinders—Gases and Gas Mixtures—Part 2: Determination of Oxidizing Ability of Toxic and Corrosive Gases and Gas Mixtures, First Edition) (incorporated by reference; see § 1910.6) or an equivalent testing method).

B.4.2 Classification Criteria

An oxidizing gas shall be classified in a single category for this class in accordance with Table B.4.1:

TABLE B.4.1—CRITERIA FOR OXIDIZING GASES

Category	Criteria
1	Any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

B.4.3 Additional Classification Considerations

Classification shall be in accordance with tests or calculation methods as described in ISO 10156 (Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets; 1996, first edition or 2010, third edition) (incorporated by reference; see § 1910.6) and ISO 10156–2:2005 (E) (Gas cylinders—Gases and Gas Mixtures—Part 2: Determination of Oxidizing Ability of Toxic and Corrosive Gases and Gas Mixtures, First Edition) (incorporated by reference; see § 1910.6).

B.5 Gases Under Pressure

B.5.1 Definition

Gases under pressure are gases which are contained in a receptacle at a pressure of 200 kPa (29 psi) (gauge) or more at 20 °C (68 °F), or which are liquefied or liquefied and refrigerated.

They comprise compressed gases, liquefied gases, dissolved gases and refrigerated liquefied gases.

B.5.2 Classification Criteria

Gases under pressure shall be classified in one of four groups in accordance with Table B.5.1:

TABLE B.5.1—CRITERIA FOR GASES UNDER PRESSURE

Group	Criteria
Compressed gas	A gas which when under pressure is entirely gaseous at −50 °C (−58 °F), including all gases with a critical temperature [1] ≤ −50 °C (−58 °F).
Liquefied gas	A gas which when under pressure, is partially liquid at temperatures above −50 °C (−58 °F). A distinction is made between: (a) High pressure liquefied gas: A gas with a critical temperature1 between −50 °C (−58 °F) and +65 °C (149 °F); and (b) Low pressure liquefied gas: A gas with a critical temperature [1] above +65 °C (149 °F).
Refrigerated liquefied gas	A gas which is made partially liquid because of its low temperature.
Dissolved gas	A gas which when under pressure is dissolved in a liquid phase solvent.

[1] *The critical temperature is the temperature above which a pure gas cannot be liquefied, regardless of the degree of compression.*
Note: *Aerosols should not be classified as gases under pressure. See appendix B.3 of this section.*

B.6 Flammable Liquids

B.6.1 Definition

Flammable liquid means a liquid having a flash point of not more than 93 °C (199.4 °F).

Flash point means the minimum temperature at which a liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid, as determined by a method identified in Section B.6.3.

B.6.2 Classification Criteria

A flammable liquid shall be classified in one of four categories in accordance with Table B.6.1:

TABLE B.6.1—CRITERIA FOR FLAMMABLE LIQUIDS

Category	Criteria
1	Flash point <23 °C (73.4 °F) and initial boiling point ≤35 °C (95 °F).
2	Flash point <23 °C (73.4 °F) and initial boiling point >35 °C (95 °F).
3	Flash point ≥23 °C (73.4 °F) and ≤60 °C (140 °F).
4	Flash point >60 °C (140 °F) and ≤93 °C (199.4 °F).

Note: Aerosols should not be classified as flammable liquids. See appendix B.3 of this section.

B.6.3 Additional Classification Considerations

The flash point shall be determined in accordance with ASTM D56–05, ASTM D3278, ASTM D3828, ASTM D93–08 (incorporated by reference; See § 1910.6), any method specified in 29 CFR 1910.106(a)(14), or any other method specified in GHS Revision 7, Chapter 2.6.

The initial boiling point shall be determined in accordance with ASTM D86–07a or ASTM D1078 (incorporated by reference; see § 1910.6).[9]

B.7 Flammable Solids

B.7.1 Definitions

Flammable solid means a solid which is a readily combustible solid, or which may cause or contribute to fire through friction.

Readily combustible solids are powdered, granular, or pasty chemicals which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly.

B.7.2 Classification Criteria

B.7.2.1 Powdered, granular or pasty chemicals shall be classified as flammable solids when the time of burning of one or more of the test runs, performed in accordance with the test method described in the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), Part III, sub-section 33.2.1, is less than 45 s or the rate of burning is more than 2.2 mm/s (0.0866 in/s).

B.7.2.2 Powders of metals or metal alloys shall be classified as flammable solids when they can be ignited and the reaction spreads over the whole length of the sample in 10 min or less.

B.7.2.3 Solids which may cause fire through friction shall be classified in this class by analogy with existing entries (*e.g.,* matches) until definitive criteria are established.

B.7.2.4 A flammable solid shall be classified in one of the two categories for this class using Method N.1 as described in Part III, sub-section 33.2.1 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.7.1:

TABLE B.7.1—CRITERIA FOR FLAMMABLE SOLIDS

Category	Criteria
1	Burning rate test: Chemicals other than metal powders: (a) Wetted zone does not stop fire; and (b) Burning time <45 s or burning rate >2.2 mm/s. Metal powders: Burning time ≤5 min.
2	Burning rate test:

[9] To determine the appropriate flammable liquid storage container size and type, the boiling point shall be determined by methods specified under § 1910.106(a)(5) and then listed on the SDS. In addition, the manufacturer, importer, and distributor shall clearly note in sections 7 and 9 of the SDS if an alternate calculation was used for storage purposes.

TABLE B.7.1—CRITERIA FOR FLAMMABLE SOLIDS—Continued

Category	Criteria
	Chemicals other than metal powders: (a) Wetted zone stops the fire for at least 4 min; and (b) Burning time <45 s or burning rate >2.2 mm/s. Metal powders: Burning time >5 min and ≤10 min.

Note 1: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

Note 2: Aerosols should not be classified as flammable solids. See appendix B.3 of this section.

B.8 Self-Reactive Chemicals

B.8.1 Definitions

Self-reactive chemicals are thermally unstable liquid or solid chemicals liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes chemicals classified under this section as explosives, organic peroxides, oxidizing liquids or oxidizing solids.

A self-reactive chemical is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

B.8.2 Classification Criteria

B.8.2.1 A self-reactive chemical shall be considered for classification in this class unless:

(a) It is classified as an explosive according to B.1 of this appendix;

(b) It is classified as an oxidizing liquid or an oxidizing solid according to B.13 or B.14 of this appendix, except that a mixture of oxidizing substances which contains 5% or more of combustible organic substances shall be classified as a self-reactive chemical according to the procedure defined in B.8.2.2;

(c) It is classified as an organic peroxide according to B.15 of this appendix;

(d) Its heat of decomposition is less than 300 J/g; or

(e) Its self-accelerating decomposition temperature (SADT) is greater than 75 °C (167 °F) for a 50 kg (110 lb) package.

B.8.2.2 Mixtures of oxidizing substances, meeting the criteria for classification as oxidizing liquids or oxidizing solids, which contain 5% or more of combustible organic substances and which do not meet the criteria mentioned in B.8.2.1(a), (c), (d) or (e), shall be subjected to the self-reactive chemicals classification procedure in B.8.2.3. Such a mixture showing the properties of a self-reactive chemical type B to F shall be classified as a self-reactive chemical.

B.8.2.3 Self-reactive chemicals shall be classified in one of the seven categories of ''types A to G'' for this class, according to the following principles:

(a) Any self-reactive chemical which can detonate or deflagrate rapidly, as packaged, will be defined as self-reactive chemical TYPE A;

(b) Any self-reactive chemical possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package will be defined as self-reactive chemical TYPE B;

(c) Any self-reactive chemical possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion will be defined as self-reactive chemical TYPE C;

(d) Any self-reactive chemical which in laboratory testing meets the criteria in (d)(i), (ii), or (iii) will be defined as self-reactive chemical TYPE D:

(i) Detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or

(ii) Does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or

(iii) Does not detonate or deflagrate at all and shows a medium effect when heated under confinement;

(e) Any self-reactive chemical which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement will be defined as self-reactive chemical TYPE E;

(f) Any self-reactive chemical which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power will be defined as self-reactive chemical TYPE F;

(g) Any self-reactive chemical which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60 °C (140 °F) to 75 °C (167 °F) for a 50 kg (110 lb) package), and, for liquid mixtures, a diluent having a boiling point greater than or equal to 150 °C (302 °F) is used for desensitization will be defined as self-reactive chemical TYPE G. If the mixture is not thermally stable or a diluent having a boiling point less than 150 °C (302 °F) is used for desensitization, the mixture shall be defined as self-reactive chemical TYPE F.

B.8.3 Additional Classification Considerations

B.8.3.1 For purposes of classification, the properties of self-reactive chemicals shall be determined in accordance with test series A to H as described in Part II of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6).

B.8.3.2 Self-accelerating decomposition temperature (SADT) shall be determined in accordance with the UN ST/SG/AC.10, Part II, section 28 (incorporated by reference; See § 1910.6).

B.8.3.3 The classification procedures for self-reactive substances and mixtures need not be applied if:

(a) There are no chemical groups present in the molecule associated with explosive or self-reactive properties; examples of such groups are given in Tables A6.1 and A6.2 in the Appendix 6 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6); or

(b) For a single organic substance or a homogeneous mixture of organic substances, the estimated SADT is greater than 75 °C (167 °F) or the exothermic decomposition energy is less than 300 J/g. The onset temperature and decomposition energy may be estimated using a suitable calorimetric technique (See 20.3.3.3 in Part II of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6)).

B.9 Pyrophoric Liquids

B.9.1 Definition

Pyrophoric liquid means a liquid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

B.9.2 Classification Criteria

A pyrophoric liquid shall be classified in a single category for this class using test N.3 in Part III, sub-section 33.3.1.5 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.9.1:

TABLE B.9.1—CRITERIA FOR PYROPHORIC LIQUIDS

Category	Criteria
1	The liquid ignites within 5 min when added to an inert carrier and exposed to air, or it ignites or chars a filter paper on contact with air within 5 min.

B.9.3 Additional Classification Considerations

The classification procedure for pyrophoric liquids need not be applied when experience in production or handling shows that the chemical does not ignite spontaneously on coming into contact with air at normal temperatures (*i.e.,* the substance is known to be stable at room temperature for prolonged periods of time (days)).

B.10 Pyrophoric Solids

B.10.1 Definition

Pyrophoric solid means a solid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

B.10.2 Classification Criteria

A pyrophoric solid shall be classified in a single category for this class using test N.2 in Part III, sub-section 33.3.1.4 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.10.1:

TABLE B.10.1—CRITERIA FOR PYROPHORIC SOLIDS

Category	Criteria
1	The solid ignites within 5 min of coming into contact with air.

Note: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.10.3 Additional Classification Considerations

The classification procedure for pyrophoric solids need not be applied when experience in production or handling shows that the chemical does not ignite spontaneously on coming into contact with air at normal temperatures (*i.e.,* the chemical is known to be stable at room temperature for prolonged periods of time (days)).

B.11 SELF–Heating Chemicals

B.11.1 Definition

A self-heating chemical is a solid or liquid chemical, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this chemical differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days).

Note: Self-heating of a substance or mixture is a process where the gradual reaction of that substance or mixture with oxygen (in air) generates heat. If the rate of heat production exceeds the rate of heat loss, then the temperature of the substance or mixture will rise which, after an induction time, may lead to self-ignition and combustion.

B.11.2 Classification Criteria

B.11.2.1 A self-heating chemical shall be classified in one of the two categories for this class if, in tests performed in accordance with test method N.4 in Part III, sub-section 33.3.1.6 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), the result meets the criteria shown in Table B.11.1.

TABLE B.11.1—CRITERIA FOR SELF-HEATING CHEMICALS

Category	Criteria
1	A positive result is obtained in a test using a 25 mm sample cube at 140 °C (284 °F).
2	A negative result is obtained in a test using a 25 mm cube sample at 140 °C (284 °F), a positive result is obtained in a test using a 100 mm sample cube at 140 °C (284 °F), and: (a) The unit volume of the chemical is more than 3 m^3; or (b) A positive result is obtained in a test using a 100 mm cube sample at 120 °C (248 °F) and the unit volume of the chemical is more than 450 liters; or (c) A positive result is obtained in a test using a 100 mm cube sample at 100 °C (212 °F).

Note: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.11.2.2 Chemicals with a temperature of spontaneous combustion higher than 50°C (122 °F) for a volume of 27 m3 shall not be classified as self-heating chemicals.

B.11.2.3 Chemicals with a spontaneous ignition temperature higher than 50 °C (122 °F) for a volume of 450 liters shall not be classified in Category 1 of this class.

B.11.3 Additional Classification Considerations

B.11.3.1 The classification procedure for self-heating chemicals need not be applied if the results of a screening test can be adequately correlated with the classification test and an appropriate safety margin is applied.

B.11.3.2 Examples of screening tests are:

(a) The Grewer Oven test (VDI guideline 2263, part 1, 1990, Test methods for the Determination of the Safety Characteristics of Dusts) with an onset temperature 80 °K above the reference temperature for a volume of 1 *l*;

(b) The Bulk Powder Screening Test (Gibson, N. Harper, D.J. Rogers, R. Evaluation of the fire and explosion risks in drying powders, Plant Operations Progress, 4 (3), 181–189, 1985) with an onset temperature 60 °K above the reference temperature for a volume of 1 *l*.

B.12 Chemicals Which, in Contact With Water, Emit Flammable Gases

B.12.1 Definition

Chemicals which, in contact with water, emit flammable gases are solid or liquid chemicals which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.

B.12.2 Classification Criteria

B.12.2.1 A chemical which, in contact with water, emits flammable gases shall be classified in one of the three categories for this class, using test N.5 in Part III, sub-section 33.4.1.4 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.12.1:

TABLE B.12.1—CRITERIA FOR CHEMICALS WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES

Category	Criteria
1	Any chemical which reacts vigorously with water at ambient temperatures and demonstrates generally a tendency for the gas produced to ignite spontaneously, or which reacts readily with water at ambient temperatures such that the rate of evolution of flammable gas is equal to or greater than 10 liters per kilogram of chemical over any one minute.
2	Any chemical which reacts readily with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 20 liters per kilogram of chemical per hour, and which does not meet the criteria for Category 1.
3	Any chemical which reacts slowly with water at ambient temperatures such that the maximum rate of evolution of flammable gas is greater than 1 liter per kilogram of chemical per hour, and which does not meet the criteria for Categories 1 and 2.

Note: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.12.2.2 A chemical is classified as a chemical which, in contact with water, emits flammable gases if spontaneous ignition takes place in any step of the test procedure.

B.12.3 Additional Classification Considerations

The classification procedure for this class need not be applied if:

(a) The chemical structure of the chemical does not contain metals or metalloids;

(b) Experience in production or handling shows that the chemical does not react with water, (*e.g.,* the chemical is manufactured with water or washed with water); or

(c) The chemical is known to be soluble in water to form a stable mixture.

B.13 Oxidizing Liquids

B.13.1 Definition

Oxidizing liquid means a liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

B.13.2 Classification Criteria

An oxidizing liquid shall be classified in one of the three categories for this class using test O.2 in Part III, sub-section 34.4.2 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.13.1:

TABLE B.13.1—CRITERIA FOR OXIDIZING LIQUIDS

Category	Criteria
1	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, spontaneously ignites; or the mean pressure rise time of a 1:1 mixture, by mass, of chemical and cellulose is less than that of a 1:1 mixture, by mass, of 50% perchloric acid and cellulose;
2	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 40% aqueous sodium chlorate solution and cellulose; and the criteria for Category 1 are not met;
3	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 65% aqueous nitric acid and cellulose; and the criteria for Categories 1 and 2 are not met.

B.13.3 Additional Classification Considerations

B.13.3.1 For organic chemicals, the classification procedure for this class shall not be applied if:

(a) The chemical does not contain oxygen, fluorine or chlorine; or

(b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

B.13.3.2 For inorganic chemicals, the classification procedure for this class shall not be applied if the chemical does not contain oxygen or halogen atoms.

B.13.3.3 In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgments based on known experience shall take precedence over test results.

B.13.3.4 In cases where chemicals generate a pressure rise (too high or too low), caused by chemical reactions not characterizing the oxidizing properties of the chemical, the test described in Part III, sub-section 34.4.2 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6) shall be repeated with an inert substance (*e.g.,* diatomite (kieselguhr)) in place of the cellulose in order to clarify the nature of the reaction.

B.14 Oxidizing Solids

B.14.1 Definition

Oxidizing solid means a solid which, while in itself is not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

B.14.2 Classification Criteria

An oxidizing solid shall be classified in one of the three categories for this class using test O.1 in Part III, sub-section 34.4.1 or test O.3 in Part III, sub-section 34.4.3, of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.14.1:

TABLE B.14.1—CRITERIA FOR OXIDIZING SOLIDS

Category	Criteria using test O.1	Criteria using test O.3
1	Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time less than the mean burning time of a 3:2 mixture, (by mass), of potassium bromate and cellulose.	Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning rate greater than the mean burning rate of a 3:1 mixture (by mass) of calcium peroxide and cellulose.

TABLE B.14.1—CRITERIA FOR OXIDIZING SOLIDS—Continued

Category	Criteria using test O.1	Criteria using test O.3
2	Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 2:3 mixture (by mass) of potassium bromate and cellulose and the criteria for Category 1 are not met.	Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning rate equal to or greater than the mean burning rate of a 1:1 mixture (by mass) of calcium peroxide and cellulose and the criteria for Category 1 are not met.
3	Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 3:7 mixture (by mass) of potassium bromate and cellulose and the criteria for Categories 1 and 2 are not met.	Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning rate equal to or greater than the mean burning rate of a 1:2 mixture (by mass) of calcium peroxide and cellulose and the criteria for Categories 1 and 2 are not met.

Note 1: Some oxidizing solids may present explosion hazards under certain conditions (*e.g.,* when stored in large quantities). For example, some types of ammonium nitrate may give rise to an explosion hazard under extreme conditions and the ''Resistance to detonation test'' (International Maritime Solid Bulk Cargoes Code, IMO (IMSBC), Appendix 2, Section 5) may be used to assess this hazard. When information indicates that an oxidizing solid may present an explosion hazard, it shall be indicated on the Safety Data Sheet.

Note 2: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.14.3 Additional Classification Considerations

B.14.3.1 For organic chemicals, the classification procedure for this class shall not be applied if:

(a) The chemical does not contain oxygen, fluorine or chlorine; or

(b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

B.14.3.2 For inorganic chemicals, the classification procedure for this class shall not be applied if the chemical does not contain oxygen or halogen atoms.

B.14.3.3 In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgements based on known experience shall take precedence over test results.

B.15 Organic Peroxides

B.15.1 Definition

B.15.1.1 Organic peroxide means a liquid or solid organic chemical which contains the bivalent -0–0- structure and as such is considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes organic peroxide mixtures containing at least one organic peroxide. Organic peroxides are thermally unstable chemicals, which may undergo exothermic self-accelerating decomposition. In addition, they may have one or more of the following properties:

(a) Be liable to explosive decomposition;

(b) Burn rapidly;

(c) Be sensitive to impact or friction;

(d) React dangerously with other substances.

B.15.1.2 An organic peroxide is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

B.15.2 Classification Criteria

B.15.2.1 Any organic peroxide shall be considered for classification in this class, unless it contains:

(a) Not more than 1.0% available oxygen from the organic peroxides when containing not more than 1.0% hydrogen peroxide; or

(b) Not more than 0.5% available oxygen from the organic peroxides when containing more than 1.0% but not more than 7.0% hydrogen peroxide.

Note: The available oxygen content (%) of an organic peroxide mixture is given by the formula:

$$16 \times \sum_{i}^{n} \left(\frac{n_i \times c_i}{m_i} \right)$$

where:

n_i = number of peroxygen groups per molecule of organic peroxide i;

c_i = concentration (mass %) of organic peroxide i;

m_i = molecular mass of organic peroxide i.

B.15.2.2 Organic peroxides shall be classified in one of the seven categories of ''Types A to G'' for this class, according to the following principles:

(a) Any organic peroxide which, as packaged, can detonate or deflagrate rapidly shall be defined as organic peroxide TYPE A;

(b) Any organic peroxide possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package shall be defined as organic peroxide TYPE B;

(c) Any organic peroxide possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion shall be defined as organic peroxide TYPE C;

(d) Any organic peroxide which in laboratory testing meets the criteria in (d)(i), (ii), or (iii) shall be defined as organic peroxide TYPE D:

(i) Detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or

(ii) Does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or

(iii) Does not detonate or deflagrate at all and shows a medium effect when heated under confinement;

(e) Any organic peroxide which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement shall be defined as organic peroxide TYPE E;

(f) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power shall be defined as organic peroxide TYPE F;

(g) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60 °C (140 °F) or higher for a 50 kg (110 lb) package), and, for liquid mixtures, a diluent having a boiling point of not less than 150 °C (302 °F) is used for desensitization, shall be defined as organic peroxide TYPE G. If the organic peroxide is not thermally stable or a diluent having a boiling point less than 150 °C (302 °F) is used for desensitization, it shall be defined as organic peroxide TYPE F.

B.15.3 Additional Classification Considerations

B.15.3.1 For purposes of classification, the properties of organic peroxides shall be determined in accordance with test series A to H as described in Part II of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6).

B.15.3.2 Self-accelerating decomposition temperature (SADT) shall be determined in accordance with the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), Part II, section 28.

B.15.3.3 Mixtures of organic peroxides may be classified as the same type of organic peroxide as that of the most dangerous ingredient. However, as two stable ingredients can form a thermally less stable mixture, the SADT of the mixture shall be determined.

B.16 Corrosive to Metals

B.16.1 Definition

A chemical which is corrosive to metals means a chemical which by chemical action will materially damage, or even destroy, metals.

B.16.2 Classification criteria

A chemical which is corrosive to metals shall be classified in a single category for this class, using the test in Part III, sub-section 37.4 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.16.1:

TABLE B.16.1—CRITERIA FOR CHEMICALS CORROSIVE TO METAL

Category	Criteria
1	Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm per year at a test temperature of 55 °C (131 °F) when tested on both materials.

Note: Where an initial test on either steel or aluminium indicates the chemical being tested is corrosive the follow-up test on the other metal is not necessary.

B.16.3 Additional Classification Considerations

The specimen to be used for the test shall be made of the following materials:

(a) For the purposes of testing steel, steel types S235JR+CR (1.0037 resp.St 37–2), S275J2G3+CR (1.0144 resp.St 44–3), ISO 3574, Unified Numbering System (UNS) G 10200, or SAE 1020;

(b) For the purposes of testing aluminium: non-clad types 7075–T6 or AZ5GU–T6.

Chapter B.17

Desensitized Explosives

B.17.1 Definitions and General Considerations

Desensitized explosives are solid or liquid explosive chemicals which are phlegmatized [10] to suppress their explosive properties in such a manner that they do not mass explode and do not burn too rapidly and therefore may be exempted from the hazard class ''Explosives'' (Chapter B.1; see also Note 2 of paragraph B.1.3).[11]

B.17.1.2 The class of desensitized explosives comprises:

(a) *Solid desensitized explosives:* Explosive substances or mixtures which are wetted with water or alcohols or are diluted with other substances, to form a homogeneous solid mixture to suppress their explosive properties.

Note: This includes desensitization achieved by formation of hydrates of the substances.

(b) *Liquid desensitized explosives:* Explosive substances or mixtures which are dissolved or suspended in water or other liquid substances, to form a homogeneous liquid mixture to suppress their explosive properties.

B.17.2 Classification Criteria

B.2.17.2.1 Any explosive which is desensitized shall be considered in this class, unless:

(a) It is intended to produce a practical, explosive or pyrotechnic effect; or

(b) It has a mass explosion hazard according to test series 6(a) or 6(b) or its corrected burning rate according to the burning rate test described in part V, subsection 51.4 of UN ST/SG/AC.10/30/Rev.6 (UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria) (incorporated by reference; see § 1910.6) is greater than 1200 kg/min; or

(c) Its exothermic decomposition energy is less than 300 J/g.

Note 1: Substances or mixtures which meet the criterion (a) or (b) shall be classified as explosives (see Chapter B.1). Substances or mixtures which meet the criterion (c) may fall within the scope of other physical hazard classes.

Note 2: The exothermic decomposition energy may be estimated using a suitable calorimetric technique (see section 20, sub-section 20.3.3.3 in Part II of UN ST/SG/AC.10/30/Rev.6 (UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria) (incorporated by reference; see § 1910.6).

B.17.2.2 Desensitized explosives shall be classified in one of the four categories of this class depending on the corrected burning rate (Ac) using the test ''burning rate test (external fire)'' described in Part V, sub-section 51.4 of UN ST/SG/AC.10/30/Rev.6 (UN Recommendations of the Transport of Dangerous Goods, Manual of Tests and Criteria) (incorporated by reference; see § 1910.6), according to Table B.17.1:

TABLE B.17.1 CRITERIA FOR DESENSITIZED EXPLOSIVES

Category	Criteria
1	Desensitized explosives with a corrected burning rate (A_C) equal to or greater than 300 kg/min but not more than 1200 kg/min.
2	Desensitized explosives with a corrected burning rate (A_C) equal to or greater than 140 kg/min but less than 300 kg/min.
3	Desensitized explosives with a corrected burning rate (A_C) equal to or greater than 60 kg/min but less than 140 kg/min.
4	Desensitized explosives with a corrected burning rate (A_C) less than 60 kg/min.

Note 1: Desensitized explosives shall be prepared so that they remain homogeneous and do not separate during normal storage and handling, particularly if desensitized by wetting. The manufacturer, importer, or distributor shall provide information in Section 10 of the safety data sheet about the shelf-life and instructions on verifying desensitization. Under certain conditions the content of desensitizing agent (*e.g.,* phlegmatizer, wetting agent or treatment) may decrease during supply and use, and thus, the hazard potential of the desensitized explosive may increase. In addition, Sections 5 and/or 8 of the safety data sheet shall include advice on avoiding increased fire, blast or protection hazards when the chemical is not sufficiently desensitized.

Note 2: Explosive properties of desensitized explosives shall be determined using data from Test Series 2 of UN ST/SG/

[10] *Phlegmatized* means that a substance (or ''phlegmatizer'') has been added to an explosive to enhance its safety in handling and transport. The phlegmatizer renders the explosive insensitive, or less sensitive, to the following actions: Heat, shock, impact, percussion or friction. Typical phlegmatizing agents include, but are not limited to: Wax, paper, water, polymers (such as chlorofluoropolymers), alcohol and oils (such as petroleum jelly and paraffin). (As defined in Chapter 2.1 of UN ST/SG/AC.10/30/Rev.6 (UN Recommendations on the Transport of Dangerous Goods, Manual of Test Criteria) (incorporated by reference; see § 1910.6)).

[11] Unstable explosives as defined in Chapter B.1 can also be stabilized by desensitization and consequently may be re-classified as desensitized explosives, provided all criteria of Chapter B.17 are met. In this case, the desensitized explosive should be tested according to Test Series 3 (Part I of UN ST/SG/AC.10/30/Rev. 6 (UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria) (incorporated by reference; see § 1910.6)) because information about its sensitiveness to mechanical stimuli is likely to be important for determining conditions for safe handling and use. The results shall be communicated on the safety data sheet.

AC.10/30/Rev.6 (UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria) (incorporated by reference; see § 1910.6) and shall be communicated in the safety data sheet. For testing of liquid desensitized explosives, refer to section 32, sub-section 32.3.2 of UN ST/SG/AC.10/30/Rev.6 (UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria) (incorporated by reference; see § 1910.6). Testing of solid desensitized explosives is addressed in section 33, sub-section 33.2.3 of UN ST/SG/AC.10/30/Rev.6 (UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria) (incorporated by reference; see § 1910.6).

Note 3: Desensitized explosives do not fall additionally within the scope of chapters B.1 (explosives), B.6 (flammable liquids) and B.7 (flammable solids).

B.17.3 Additional Classification Considerations

B.17.3.1 The classification procedure for desensitized explosives does not apply if:

(a) The substances or mixtures contain no explosives according to the criteria in Chapter B.1; or

(b) The exothermic decomposition energy is less than 300 J/g.

B.17.3.2 The exothermic decomposition energy shall be determined using the explosive already desensitized (*i.e.,* the homogenous solid or liquids mixture formed by the explosive and the substance(s) used to suppress its explosive properties). The exothermic decomposition energy may be estimated using a suitable calorimetric technique (see Section 20, sub-section 20.3.3.3 in Part II of UN ST/SG/AC.10/30/Rev. 6 (UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria) (incorporated by reference; see § 1910.6).

Appendix C to § 1910.1200—Allocation of Label Elements (Mandatory)

C.1 The label for each hazardous chemical shall include the product identifier used on the safety data sheet.

C.1.1 The labels on shipped containers shall also include the name, address, and telephone number of the chemical manufacturer, importer, or responsible party.

C.2 The label for each hazardous chemical that is classified shall include the signal word, hazard statement(s), pictogram(s), and precautionary statement(s) specified in C.4 for each hazard class and associated hazard category, except as provided for in C.2.1 through C.2.4.

C.2.1 Precedence of hazard information

C.2.1.1 If the signal word ''Danger'' is included, the signal word ''Warning'' shall not appear;

C.2.1.2 If the skull and crossbones pictogram is included, the exclamation mark pictogram shall not appear where it is used for acute toxicity;

C.2.1.3 If the corrosive pictogram is included, the exclamation mark pictogram shall not appear where it is used for skin or eye irritation;

C.2.1.4 If the health hazard pictogram is included for respiratory sensitization, the exclamation mark pictogram shall not appear where it is used for skin sensitization or for skin or eye irritation.

C.2.2 Hazard statement text

C.2.2.1 The text of all applicable hazard statements shall appear on the label, except as otherwise specified. The information in italics shall be included as part of the hazard statement as provided. For example: ''Causes damage to organs (state all organs affected) through prolonged or repeated exposure (state route of exposure if no other routes of exposure cause the hazard)''. Hazard statements may be combined where appropriate to reduce the information on the label and improve readability, as long as all of the hazards are conveyed as required.

C.2.2.2 If the chemical manufacturer, importer, or responsible party can demonstrate that all or part of the hazard statement is inappropriate to a specific substance or mixture, the corresponding statement may be omitted from the label.

C.2.3 Pictograms

C.2.3.1 Pictograms shall be in the shape of a square set at a point and shall include a black hazard symbol on a white background with a red frame sufficiently wide to be clearly visible. A square red frame set at a point without a hazard symbol is not a pictogram and is not permitted on the label.

C.2.3.2 One of eight standard hazard symbols shall be used in each pictogram. The eight hazard symbols are depicted in Figure C.1. A pictogram using the exclamation mark symbol is presented in Figure C.2, for the purpose of illustration.

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Figure C.1 – Hazard Symbols and Classes

Flame	Flame Over Circle	Exclamation Mark	Exploding Bomb
Flammables Self Reactives Pyrophorics Self-heating Emits Flammable Gas Organic Peroxides Desensitized Explosives	Oxidizers	Irritant Dermal Sensitizer Acute Toxicity (harmful) Narcotic Effects Respiratory Tract Irritation HNOC (non-mandatory)	Explosives Self Reactives Organic Peroxides
Corrosion	**Gas Cylinder**	**Health Hazard**	**Skull and Crossbones**
Corrosives	Gases Under Pressure	Carcinogen Respiratory Sensitizer Reproductive Toxicity Target Organ Toxicity Mutagenicity Aspiration Toxicity	Acute Toxicity (severe)

Figure C.2 – Exclamation Mark Pictogram

C.2.3.3 The exclamation mark pictogram is permitted (but not required) for HNOCs as long as the words ''Hazard Not Otherwise Classified'' or the letters ''HNOC'' appear below the pictogram.

C.2.3.4 Pictograms may only appear once on a label. If multiple hazards require the use of the same pictogram, it may not appear a second time on the label.

C.2.4 Precautionary statement text

C.2.4.1 There are four types of precautionary statements presented, ''prevention,'' ''response,'' ''storage,'' and ''disposal.'' The core part of the precautionary statement is presented in bold print. This is the text, except as otherwise specified, that shall appear on the label. Where additional information is required, it is indicated in plain text.

C.2.4.2 When a backslash or diagonal mark (/) appears in the precautionary

statement text, it indicates that a choice has to be made between the separated phrases. In such cases, the chemical manufacturer, importer, or responsible party can choose the most appropriate phrase(s). For example, ''Wear protective gloves/protective clothing/eye protection/face protection'' could read ''wear eye protection''.

C.2.4.3 When three full stops (. . .) appear in the precautionary statement text, they indicate that all applicable conditions are not listed. For example, in ''Use explosion-proof electrical/ventilating/lighting/. . ./equipment'', the use of ''. . .'' indicates that other equipment may need to be specified. In such cases, the chemical manufacturer, importer, or responsible party can choose the other conditions to be specified.

C.2.4.4 When text *in italics* is used in a precautionary statement, this indicates specific conditions applying to the use or allocation of the precautionary statement. For example, ''Use explosion-proof electrical/ventilating/lighting/. . ./equipment'' is only required for flammable solids ''*if dust clouds can occur*''. Text in italics is intended to be an explanatory, conditional note and is not intended to appear on the label.

C.2.4.5 Where square brackets ([ ]) appear around text in a precautionary statement, this indicates that the text in square brackets is not appropriate in every case and should be used only in certain circumstances. In these cases, conditions for use explaining when the text should be used are provided. For example, one precautionary statement states: ''[In case of inadequate ventilation] wear respiratory protection.'' This statement is given with the condition for use ''—text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use''. This means that, if additional information is provided with the chemical explaining what type of ventilation would be adequate for safe use, the text in square brackets should be used and the statement would read: ''In case of inadequate ventilation wear respiratory protection.'' However, if the chemical is supplied without such ventilation information, the text in square brackets should not be used, and the precautionary statement should read: ''Wear respiratory protection.''

C.2.4.6 Precautionary statements may be combined or consolidated to save label space and improve readability. For example, ''Keep away from heat, sparks and open flame,'' ''Store in a well-ventilated place'' and ''Keep cool'' can be combined to read ''Keep away from heat, sparks and open flame and store in a cool, well-ventilated place.''

C.2.4.7 Precautionary statements may incorporate minor textual variations from the text prescribed in this appendix if these variations assist in communicating safety information (*e.g.,* spelling variations, synonyms or other equivalent terms) and the safety advice is not diluted or compromised. Any variations must be used consistently on the label and the safety data sheet.

C.2.4.8 In most cases, the precautionary statements are independent (*e.g.,* the phrases for explosive hazards do not modify those related to certain health hazards, and products that are classified for both hazard classes shall bear appropriate precautionary statements for both). Where a chemical is classified for a number of hazards, and the precautionary statements are similar, the most stringent shall be included on the label (this will be applicable mainly to preventive measures).

C.2.4.9 If the chemical manufacturer, importer, or responsible party can demonstrate that a precautionary statement is inappropriate to a specific substance or mixture, the precautionary statement may be omitted from the label.

C.2.4.10 Where a substance or mixture is classified for a number of health hazards, this may trigger multiple precautionary statements relating to medical response, *e.g.,* calling a poison center/doctor/. . . and getting medical advice/attention.

In general, the following principles should be applied:

(a) Where the classification of a substance or mixture triggers several different precautionary statements, a system of prioritization should be applied. Usually, the label need only include one precautionary statement reflecting the response at the highest level with the greatest urgency, which should always be combined with at least one route of exposure or symptom ''IF'' statement.

(b) Routes of exposure, including ''IF exposed or concerned,'' may be combined when triggered with a medical response statement. If the response statement is triggered with three or more routes of exposure, ''IF exposed or concerned'' may be used. However, relevant ''IF'' statements describing symptoms must be included in full. If a route of exposure is triggered multiple times, it need only be included once.

(c) This does not apply to ''Get medical advice/attention if you feel unwell'' or ''Get immediate medical advice/attention'' when they are combined with an ''If'' statement and should appear without prioritization.

C.3 Supplementary hazard information

C.3.1 To ensure that non-standardized information does not lead to unnecessarily wide variation or undermine the required information, supplementary information on the label is limited to when it provides further detail and does not contradict or cast doubt on the validity of the standardized hazard information.

C.3.2 Where the chemical manufacturer, importer, or distributor chooses to add supplementary information on the label, the placement of supplemental information shall not impede identification of information required by this section.

C.3.3 Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥1%, and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity (oral/dermal/inhalation) is required on the label and safety data sheet.

C.4 REQUIREMENTS FOR SIGNAL WORDS, HAZARD STATEMENTS, PICTOGRAMS, AND PRECAUTIONARY STATEMENTS

C.4.1 ACUTE TOXICITY – ORAL
(Classified in Accordance with Appendix A.1 of this Section)

Pictogram
Skull and crossbones

Hazard category	Signal word	Hazard statement
1	Danger	Fatal if swallowed
2	Danger	Fatal if swallowed
3	Danger	Toxic if swallowed

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash …thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If swallowed: Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see … on this label)** … Reference to supplemental first aid instruction. *- if immediate administration of antidote is required.* **Rinse mouth.**	**Store locked up.**	**Dispose of contents/container to…** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.1 ACUTE TOXICITY – ORAL (CONTINUED)
(Classified in Accordance with Appendix A.1 of this Section)

Hazard category	Signal word	Hazard statement
4	Warning	Harmful if swallowed

Pictogram
Exclamation mark

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If swallowed: Call a poison center/doctor/…/ if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Rinse mouth.**		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.2 ACUTE TOXICITY - DERMAL
(Classified in Accordance with Appendix A.1 of this section)

Pictogram
Skull and crossbones

Hazard category	Signal word	Hazard statement
1	Danger	Fatal in contact with skin
2	Danger	Fatal in contact with skin

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not get in eyes, on skin, or on clothing. **Wash … thoroughly after handling.** … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.** **Wear protective gloves/protective clothing.** Chemical manufacturer, importer, or distributor may further specify type of equipment where appropriate.	**If on skin: Wash with plenty of water/...** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *if immediate measures such as specific cleansing agent is advised.* **Take off immediately all contaminated clothing and wash it before reuse.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/ international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.2 ACUTE TOXICITY - DERMAL (CONTINUED)
(Classified in Accordance with Appendix A.1 of this Section)

Hazard category	Signal word	Hazard statement
3	Danger	Toxic in contact with skin

Pictogram
Skull and crossbones

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear protective gloves/protective clothing. Chemical manufacturer, importer, or distributor may further specify type of equipment where appropriate.	**If on skin: Wash with plenty of water/…** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. *- if immediate measures such as specific cleansing agent is advised.* **Take off immediately all contaminated clothing and wash it before reuse.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.2 ACUTE TOXICITY – DERMAL (CONTINUED)
(Classified in Accordance with Appendix A.1 of this Section)

Pictogram
Exclamation mark

Hazard category	Signal word	Hazard statement
4	Warning	Harmful in contact with skin

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear protective gloves/protective clothing. Chemical manufacturer, importer, or distributor may further specify type of equipment where appropriate.	**If on skin: Wash with plenty of water/...** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Call a poison center/doctor/…/if you feel unwell**. … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *if measures such as specific cleansing agent is advised.* **Take off contaminated clothing and wash it before reuse.**		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.3 ACUTE TOXICITY - INHALATION
(Classified in Accordance with Appendix A.1 of this Section)

Pictogram
Skull and crossbones

Hazard category	Signal word	Hazard statement
1	Danger	Fatal if inhaled
2	Danger	Fatal if inhaled

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.** **[In case of inadequate ventilation] wear respiratory protection.** Chemical manufacturer, importer, or distributor to specify equipment. - *Text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use.*	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment is urgent (see ... on this label)** ... Reference to supplemental first aid instruction. - *if immediate administration of antidote is required.*	**Store in a well-ventilated place. Keep container tightly closed.** - *if the chemical is volatile and may generate a hazardous atmosphere.* **Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.3 ACUTE TOXICITY – INHALATION (CONTINUED)
(Classified in Accordance with Appendix A.1 of this Section)

Hazard category	Signal word	Hazard statement	Pictogram
3	Danger	Toxic if inhaled	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Call a poison center/doctor/...** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *if immediate specific measures are required.*	**Store in a well-ventilated place. Keep container tightly closed.** - *if the chemical is volatile and may generate a hazardous atmosphere.* **Store locked up.**	**Dispose of content/container to…** … in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

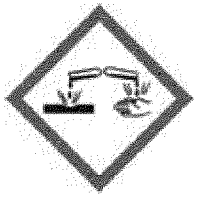
C.4.3 ACUTE TOXICITY – INHALATION (CONTINUED)
(Classified in Accordance with Appendix A.1 of this Section)

Hazard category	Signal word	Hazard statement	Pictogram Exclamation mark
4	Warning	Harmful if inhaled	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		

C.4.4 SKIN CORROSION/IRRITATION
(Classified in Accordance with Appendix A.2 of this Section)

Pictogram
Corrosion



Hazard category	Signal word	Hazard statement
1A to 1C	Danger	Causes severe skin burns and eye damage

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dusts or mists. - *if inhalable particles of dusts or mists may occur during use.* **Wash …thoroughly after handling.** …Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear protective gloves/protective clothing/eye protection/face protection.** Chemical manufacturer, importer, or distributor may further specify type of equipment where appropriate.	**If swallowed: Rinse mouth. Do NOT induce vomiting.** **If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].** - *text in square brackets to be included where the chemical manufacturer, importer or distributor considers it appropriate for the specific chemical.* **Wash contaminated clothing before reuse.** **If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate. **If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/ international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.4 SKIN CORROSION/IRRITATION (CONTINUED)
(Classified in Accordance with Appendix A.2 of this Section)

Pictogram
Exclamation mark

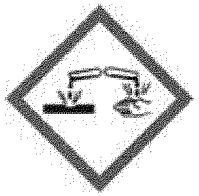
Hazard category	Signal word	Hazard statement
2	Warning	Causes skin irritation

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear protective gloves.** Chemical manufacturer, importer, or distributor may further specify type of equipment where appropriate.	**If on skin: Wash with plenty of water/...** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate. **If skin irritation occurs: Get medical advice/attention.** - Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate. **Take off contaminated clothing and wash it before reuse.**		

C.4.5 EYE DAMAGE/IRRITATION
(Classified in Accordance with Appendix A.3 of this Section)

Pictogram
Corrosion

Hazard category	Signal word	Hazard statement
1	Danger	Causes serious eye damage



Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear eye protection/face protection. Chemical manufacturer, importer, or distributor may further specify type of equipment where appropriate.	**If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** **Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		

C.4.5 EYE DAMAGE/IRRITATION (CONTINUED)
(Classified in Accordance with Appendix A.3 of this Section)

Pictogram
Exclamation mark

Hazard category	Signal word	Hazard statement
2A	Warning	Causes serious eye irritation

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear eye protection/face protection.** Chemical manufacturer, importer, or distributor may further specify type of equipment where appropriate.	**If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** **If eye irritation persists: Get medical advice/attention.** Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.		

C.4.5 EYE DAMAGE/IRRITATION (CONTINUED)
(Classified in Accordance with Appendix A.3 of this Section)

Pictogram
No Pictogram

Hazard category	Signal word	Hazard statement
2B	Warning	Causes eye irritation

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.	**If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** **If eye irritation persists: Get medical advice/attention.** Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.		

C.4.6 SENSITIZATION - RESPIRATORY
(Classified in Accordance with Appendix A.4 of this Section)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1 (including both sub-categories 1A and 1B)	Danger	May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **[In case of inadequate ventilation] wear respiratory protection.** Chemical manufacturer, importer, or distributor to specify equipment. - *text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use.*	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **If experiencing respiratory symptoms: Call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.7 SENSITIZATION - SKIN
(Classified in Accordance with Appendix A.4 of this Section)

Pictogram
Exclamation mark

Hazard category	Signal word	Hazard statement
1 (including both sub-categories 1A and 1B)	Warning	May cause an allergic skin reaction

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Contaminated work clothing must not be allowed out of the workplace.** **Wear protective gloves.** Chemical manufacturer, importer, or distributor may further specify type of equipment where appropriate.	**If on skin: Wash with plenty of water/...** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **If skin irritation or rash occurs: Get medical advice/attention.** Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate. **Take off contaminated clothing and wash it before reuse.**		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.8 GERM CELL MUTAGENICITY
(Classified in Accordance with Appendix A.5 of this Section)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1A and 1B	Danger	May cause genetic defects <...>
2	Warning	Suspected of causing genetic defects <...>

< > *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**If exposed or concerned: Get medical advice/attention.** Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.9 CARCINOGENICITY
(Classified in Accordance with Appendix A.6 of this Section)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1A and 1B	Danger	May cause cancer <...>
2	Warning	Suspected of causing cancer <...>

< > *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**If exposed or concerned: Get medical advice/attention.** Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

Note: If a Category 2 carcinogen ingredient is present in the mixture at a concentration between 0.1% and 1%, information is required on the SDS for a product; however, a label warning is optional. If a Category 2 carcinogen ingredient is present in the mixture at a concentration of > 1%, both an SDS and a label is required and the information must be included on each.

C.4.10 REPRODUCTIVE TOXICITY
(Classified in Accordance with Appendix A.7 of this Section)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1A and 1B	Danger	May damage fertility or the unborn child <...> <<...>>
2	Warning	Suspected of damaging fertility or the unborn child <...> <<...>>
		< > *(state specific effect if known)*
		<<... >>*(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**If exposed or concerned: Get medical advice/attention.** Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.10 REPRODUCTIVE TOXICITY (CONTINUED)
(Classified in Accordance with Appendix A.7 of this Section)
(EFFECTS ON OR VIA LACTATION)

Pictogram
No Pictogram

Hazard category	Signal word	Hazard statement
No designated number	*No signal word*	May cause harm to breast-fed children

(See Table A.7.1 in appendix A.7 of this section)

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not breathe dusts or mists.** - *if inhalable particles of dusts or mists may occur during use.* **Avoid contact during pregnancy and while nursing.** **Wash … thoroughly after handling.** …Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If exposed or concerned: Get medical advice/attention.** Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.		

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure)
(Classified in Accordance with Appendix A.8 of this section)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1	Danger	Causes damage to organs <...> <<...>> <...> *(or state all organs affected if known)* <<...>> *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Wash …thoroughly after handling.** … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If exposed or concerned: Call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *if immediate measures are required.*	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (CONTINUED)
(Classified in Accordance with Appendix A.8 of this Section)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
2	Warning	May cause damage to organs <...> <<...>> <...> *(or state all organs affected, if known)* <<...>> *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Wash … thoroughly after handling.** … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If exposed or concerned: Call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (CONTINUED)
(Classified in Accordance with Appendix A.8 of this Section)

Pictogram
Exclamation mark

Hazard category	Signal word	Hazard statement
3	Warning	May cause respiratory irritation; or May cause drowsiness or dizziness

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.	**Store in a well-ventilated place. Keep container tightly closed.** *- if the chemical is volatile and may generate a hazardous atmosphere.* **Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.12 SPECIFIC TARGET ORGAN TOXICITY (Repeated Exposure)
(Classified in Accordance with Appendix A.9 of this Section)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1	Danger	Causes damage to organs <...> through prolonged or repeated exposure <<...>> <...> *(state all organs affected, if known)* <<...>> *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Wash … thoroughly after handling.** …Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**Get medical advice/attention if you feel unwell.** Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.12 SPECIFIC TARGET ORGAN TOXICITY (Repeated Exposure) (CONTINUED)
(Classified in Accordance with Appendix A.9 of this Section)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
2	Warning	May cause damage to organs <...> through prolonged or repeated exposure <<...>> <...> *(state all organs affected, if known)* <<...>> *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions.	**Get medical advice/attention if you feel unwell.** Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

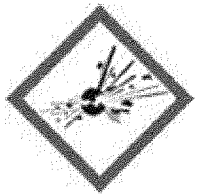
C.4.13 ASPIRATION HAZARD
(Classified in Accordance with Appendix A.10 of this Section)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1	Danger	May be fatal if swallowed and enters airways

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
	If swallowed: Immediately call a poison center/doctor/… … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Do NOT induce vomiting.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

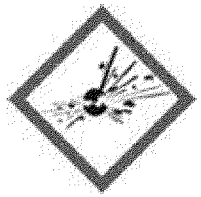
C.4.14 EXPLOSIVES
(Classified in Accordance with Appendix B.1 of this Section)

Hazard category	Signal word	Hazard statement	Pictogram
Unstable explosive	Danger	Unstable explosive	Exploding bomb 

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not subject to grinding/shock/friction/…** – *if the explosive is mechanically sensitive.* …Chemical manufacturer, importer or distributor to specify applicable rough handling. **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Explosion risk. Evacuate area. DO NOT fight fire when fire reaches explosives.**	**Store in accordance with…** …Chemical manufacturer, importer, or distributor to specify local/regional/ national/international regulations as applicable.	**Refer to manufacturer, importer, or distributor… for information on disposal, recovery, or recycling.** … Manufacturer, importer, or distributor to specify appropriate source of information, in accordance with local/regional/national/ international regulations as applicable.

C.4.14 EXPLOSIVES (CONTINUED)
(Classified in Accordance with Appendix B.1 of this Section)

Pictogram
Exploding bomb



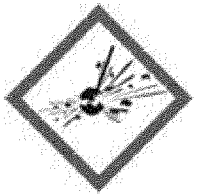
Hazard category	Signal word	Hazard statement
Division 1.1	Danger	Explosive; mass explosion hazard
Division 1.2	Danger	Explosive; severe projection hazard
Division 1.3	Danger	Explosive; fire, blast or projection

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep wetted with...** *for substances and mixtures which are wetted, diluted, dissolved or suspended with a phlegmatizer in order to reduce or suppress their explosive properties (desensitized explosives).* **Keep only in original packaging.** **Ground and bond container and receiving equipment.** - *if the explosive is electrostatically sensitive.* **Do not subject to grinding/shock/…/friction.** - *if the explosive is mechanically sensitive.* …Chemical manufacturer, importer, or distributor to specify applicable rough handling. **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/…** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Explosion risk. Evacuate area. DO NOT fight fire when fire reaches explosives.**	**Store in accordance with…** … Chemical manufacturer, importer, or distributor to specify local/regional/national/ international regulations as applicable.	**Refer to manufacturer, importer, or distributor… for information on disposal, recovery, or recycling.** … Manufacturer, importer, or distributor to specify appropriate source of information, in accordance with local/regional/national/ international regulations as applicable.

Note: Unpackaged explosives or explosives repacked in packaging other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in appendix B.1 of this section, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

C.4.14 EXPLOSIVES (CONTINUED)
(Classified in Accordance with Appendix B.1 of this Section)

Hazard category	Signal word	Hazard statement	Pictogram
Division 1.4	Warning	Fire or projection hazard	Exploding bomb[1] 

Precautionary statements[1]			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep only in original packaging.** **Ground and bond container and receiving equipment.** - *if the explosive is electrostatically sensitive.* **Do not subject to grinding/shock/…/friction.** -*if the explosive is mechanically sensitive.* …Chemical manufacturer, importer, or distributor to specify applicable rough handling. **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Explosion risk. Evacuate area. Do NOT fight fire when fire reaches explosives.** - *except for explosives of division 1.4 (compatibility group S) in transport packaging.* **In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.** - *for explosives of division 1.4 (compatibility group S) in transport packaging.*	**Store in accordance with…** … Chemical manufacturer, importer, or distributor to specify local/regional/ national/international regulations as applicable.	**Refer to manufacturer, importer, or distributor… for information on disposal, recovery, or recycling.** … Manufacturer, importer, or distributor to specify appropriate source of information, in accordance with local/regional/national/ international regulations as applicable.

Note: Unpackaged explosives or explosives repacked in packaging other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in appendix B.1 of this section, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.[1]

[1] Except no pictogram is required for explosives that are 1.4S small arms ammunition and components thereof. Labels for 1.4S small arms ammunition and components shall include appropriate precautionary statements.

C.4.14 EXPLOSIVES (CONTINUED)
(Classified in Accordance with Appendix B.1 of this Section)

Pictogram
No Pictogram

Hazard category	Signal word	Hazard statement
Division 1.5	Danger	May mass explode in fire

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep wetted with...** *-for substances and mixtures which are wetted, diluted, dissolved or suspended with a phlegmatizer in order to reduce or suppress their explosive properties (desensitized explosives).* … Chemical manufacturer, importer, or distributor to specify appropriate material. **Keep only in original packaging.** **Ground and bond container and receiving equipment.** *- if the explosive is electrostatically sensitive.* **Do not subject to grinding/shock/…/friction.** *-if the explosive is mechanically sensitive.* …Chemical manufacturer, importer, or distributor to specify applicable rough handling. **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Explosion risk. Evacuate area. DO NOT fight fire when fire reaches explosives.**	**Store in accordance with…** …Chemical manufacturer, importer, or distributor to specify local/regional/ national/international regulations as applicable.	**Refer to manufacturer, importer, or distributor… for information on disposal, recovery, or recycling.** … Manufacturer, distributor, or importer to specify appropriate source of information, in accordance with local/regional/national/ international regulations as applicable.

Note: Unpackaged explosives or explosives repacked in packaging other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in appendix B.1 of this section, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

C.4.14 EXPLOSIVES (CONTINUED)
(Classified in Accordance with Appendix B.1 of this Section)

Pictogram
No Pictogram

Hazard category	Signal word	Hazard statement
Division 1.6	No signal word	No hazard statement

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
None assigned	None assigned	None assigned	None assigned

Note: Unpackaged explosives or explosives repacked in packaging other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in appendix B.1 of this section, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

C.4.15 FLAMMABLE GASES
(Classified in Accordance with Appendix B.2 of this Section)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
1A	Danger	Extremely flammable gas
1B	Danger	Flammable gas

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.	**Leaking gas fire:** **Do not extinguish, unless leak can be stopped safely.** **In case of leakage, eliminate all ignition sources.**	**Store in well-ventilated place.**	

NOTE: For flammable gas Category 1A, pyrophoric gas and Category 1A, chemically unstable gas A and B, see statements below.

C.4.15 FLAMMABLE GASES (CONTINUED)
(Classified in Accordance with Appendix B.2 of this Section)

Hazard category	Signal word	Hazard statement	Pictogram Flame
1A, Pyrophoric gas	Danger	Extremely flammable gas May ignite spontaneously if exposed to air	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Do not allow contact with air.** *– if emphasis of the hazard statement is deemed necessary.* **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/….** Chemical manufacturer, importer or distributor to specify the appropriate personal protective equipment.	**Leaking gas fire: Do not extinguish, unless leak can be stopped safely.** **In case of leakage, eliminate all ignition sources.**	**Store in a well-ventilated place.**	

Note: This table lists only precautionary statements that are assigned due to the flammability and the pyrophoricity of the gas. For the other precautionary statements that are assigned based on chemical instability, see the respective table for chemically unstable gases A and B.

C.4.15 FLAMMABLE GASES (CONTINUED)
(Classified in Accordance with Appendix B.2 of this Section)

Hazard category	Signal word	Hazard statement	Pictogram Flame
1A, Chemically unstable gas A	Danger	Extremely flammable gas May react explosively even in the absence of air.	
1A, Chemically unstable gas B	Danger	Extremely flammable gas May react explosively even in the absence of air at elevated pressure and/or temperature.	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not handle until all safety precautions have been read and understood. **Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.**	**Leaking gas fire: Do not extinguish, unless leak can be stopped safely.** **In case of leakage, eliminate all ignition sources.**	**Store in a well-ventilated place.**	

Note: This table lists only the precautionary statements that are assigned due to the flammability and the chemical instability of the gas. For the other precautionary statements that are assigned based on pyrophoricity, see the respective table for pyrophoric gas.

C.4.15 FLAMMABLE GASES (CONTINUED)
(Classified in Accordance with Appendix B.2 of this Section)

Pictogram
No Pictogram

Hazard category	Signal word	Hazard statement
2	Warning	Flammable gas

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces sparks, open flames and other ignition sources. No smoking.	**Leaking gas fire: Do not extinguish, unless leak can be stopped safely.** **In case of leakage, eliminate all ignition sources.**	**Store in a well-ventilated place.**	

C.4.16 AEROSOLS
(Classified in Accordance with Appendix B.3 of this Section)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
1	Danger	Extremely flammable aerosol Pressurized container: may burst if heated.
2	Warning	Flammable aerosol Pressurized container: may burst if heated.

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Do not spray on an open flame or other ignition source.** **Do not pierce or burn, even after use.**		**Protect from sunlight. Do not expose to temperatures exceeding 122 °F (50 °C).**	

C.4.16 AEROSOLS
(Classified in Accordance with Appendix B.3 of this Section)

Pictogram
No symbol

Hazard category	Signal word	Hazard statement
3	Warning	Pressurized container: may burst if heated.

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Do not pierce or burn, even after use.**		**Protect from sunlight. Do not expose to temperatures exceeding 122°F (50 °C).**	

C.4.17 OXIDIZING GASES
(Classified in Accordance with Appendix B.4 of this Section)

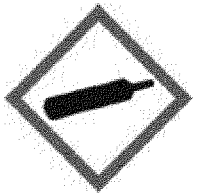
Pictogram
Flame over circle

Hazard category	Signal word	Hazard statement
1	Danger	May cause or intensify fire; oxidizer

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from clothing and other combustible materials. **Keep valves and fittings free from oil and grease.**	**In case of fire: Stop leak if safe to do so.**	**Store in well-ventilated place.**	

C.4.18 GASES UNDER PRESSURE
(Classified in Accordance with Appendix B.5 of this Section)

Pictogram
Gas cylinder



Hazard category	Signal word	Hazard statement
Compressed gas	Warning	Contains gas under pressure; may explode if heated
Liquefied gas	Warning	Contains gas under pressure; may explode if heated
Dissolved gas	Warning	Contains gas under pressure; may explode if heated

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
		Protect from sunlight. Store in a well-ventilated place.	

C.4.18 GASES UNDER PRESSURE (CONTINUED)
(Classified in Accordance with Appendix B.5 of this Section)

Pictogram
Gas cylinder

Hazard category	Signal word	Hazard statement
Refrigerated liquefied gas	Warning	Contains refrigerated gas; may cause cryogenic burns or injury

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear cold insulating gloves and either face shield or eye protection.	**Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.** Chemical manufacturer, importer, or distributor to select medical advice or attention as appropriate.	**Store in a well-ventilated place.**	

C.4.19 FLAMMABLE LIQUIDS
(Classified in Accordance with Appendix B.6 of this Section)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
1	Danger	Extremely flammable liquid and vapor
2	Danger	Highly flammable liquid and vapor
3	Warning	Flammable liquid and vapor

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep container tightly closed.** *– if the liquid is volatile and may generate an explosive atmosphere.* **Ground and bond container and receiving equipment.** *- if the liquid is volatile and may generate an explosive atmosphere.* **Use explosion-proof [electrical/ventilating/lighting/...] equipment.** *- if the liquid is volatile and may generate an explosive atmosphere* *- text in square brackets may be used to specify specific electrical, ventilating, lighting or other equipment if necessary and as appropriate.* **Use non-sparking tools.** *- if the liquid is volatile and may generate an explosive atmosphere and if the minimum ignition energy is very low. (This applies to substances and mixtures where the minimum ignition energy is <0.1mJ,* e.g. *carbon disulfide).* **Take action to prevent static discharge.** *- if the liquid is volatile and may generate an explosive atmosphere.* **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/…** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].** *- text in square brackets to be included where the chemical manufacturer, importer or distributor considers it appropriate for the specific chemical.* **In case of fire: Use ... to extinguish.** *- if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.	**Store in a well-ventilated place. Keep cool.** *- for flammable liquids Category 1 and other flammable liquids that are volatile and may generate an explosive atmosphere.*	**Dispose of contents/container to...** … in accordance with local/regional/national/ international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.19 FLAMMABLE LIQUIDS (CONTINUED)
(Classified in Accordance with Appendix B.6 of this Section)

Pictogram
No Pictogram

Hazard category	Signal word	Hazard statement
4	Warning	Combustible liquid

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/…** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Use ... to extinguish.** *- if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.	**Store in a well-ventilated place.** **-** *for flammable liquids Category 1 and other flammable liquids that are volatile and may generate an explosive atmosphere.*	**Dispose of contents/container to...** in accordance with local/regional/ national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.20 FLAMMABLE SOLIDS
(Classified in Accordance with Appendix B.7 of this Section)

Pictogram
Flame

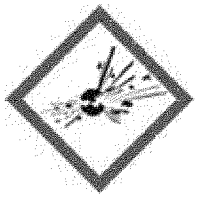
Hazard category	Signal word	Hazard statement
1	Danger	Flammable solid
2	Warning	Flammable solid

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Ground and bond container and receiving equipment.** - *if the solid is electrostatically sensitive.* **Use explosion-proof [electrical/ventilating/ lighting/...] equipment.** - *if dust clouds can occur.* - *text in square brackets may be used to specify specific electrical, ventilating, lighting or other equipment if necessary and as appropriate.* **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/…** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Use ... to extinguish** - *if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.		

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES
(Classified in Accordance with Appendix B.8 of this Section)

Hazard category	Signal word	Hazard statement
Type A	Danger	Heating may cause an explosion

Pictogram
Exploding bomb



Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep only in original packaging.** **Keep cool.** *- may be omitted if storage temperatures are listed on the label.* **Ground and bond container and receiving equipment.** *– if electrostatically sensitive and able to generate an explosive atmosphere.* **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Explosion risk. Evacuate area. DO NOT fight fire when fire reaches explosives.**	**Store in a well-ventilated place.** *- except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.* **Store at temperatures not exceeding …°F (°C).** ... Chemical manufacturer, importer, or distributor to specify temperature using applicable temperature scale. *- if temperature control is required (see appendix B.2.3 of this section) or if otherwise deemed necessary.* **Store separately.**	**Dispose of contents/container to...** … in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES (CONTINUED)
(Classified in Accordance with Appendix B.8 of this Section)

Hazard category	Signal word	Hazard statement	Pictogram Exploding bomb and flame
Type B	Danger	Heating may cause a fire or explosion	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep only in original packaging.** **Keep cool.** *- may be omitted if storage temperatures are listed on the label.* **Ground and bond container and receiving equipment.** *– if electrostatically sensitive and able to generate an explosive atmosphere.* **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion. [Use ... to extinguish]** *- text in square brackets to be included if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.	**Store in a well-ventilated place.** *- except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.* **Store at temperatures not exceeding …°F (°C).** **if temperature control is required** (see appendix B.2.3 of this section) or if otherwise deemed necessary ... Chemical manufacturer, importer, or distributor to specify temperature using applicable temperature scale. **Store separately.**	**Dispose of contents/container to...** …in accordance with local/regional/national/ international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES(CONTINUED)
(Classified in Accordance with Appendix B.8 of this Section)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
Type C	Danger	Heating may cause a fire
Type D	Danger	Heating may cause a fire
Type E	Warning	Heating may cause a fire
Type F	Warning	Heating may cause a fire

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep only in original packaging.** **Keep cool.** *- may be omitted if storage temperatures are listed on the label.* **Ground and bond container and receiving equipment.** *– if electrostatically sensitive and able to generate an explosive atmosphere.* **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Use ... to extinguish** *- if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.	**Store in a well-ventilated place.** *- except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.* **Store at temperatures not exceeding …°F (°C).** *– if temperature control is required (see appendix B.2.3 of this section) or if otherwise deemed necessary.* ...Chemical manufacturer, importer, or distributor to specify temperature using applicable temperature scale. **Store separately.**	**Dispose of contents/container to...** …in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.22 PYROPHORIC LIQUIDS
(Classified in Accordance with Appendix B.9 of this Section)

Hazard category	Signal word	Hazard statement
1	Danger	Catches fire spontaneously if exposed to air

Pictogram
Flame

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Do not allow contact with air.** - *if emphasis of the hazard statement is deemed necessary.* **Handle and store contents under inert gas/….** …Manufacturer, importer, or distributor to specify appropriate liquid or gas if "inert gas" is not appropriate. **Keep container tightly closed.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**If on skin: Immerse in cool water or wrap in wet bandages.** **In case of fire: Use ... to extinguish** - *if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.		

C.4.23 PYROPHORIC SOLIDS
(Classified in Accordance with Appendix B.10 of this Section)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
1	Danger	Catches fire spontaneously if exposed to air

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Do not allow contact with air.** - *if emphasis of the hazard statement is deemed necessary.* **Handle and store contents under inert gas/….** …Manufacturer, importer, or distributor to specify appropriate liquid or gas if "inert gas" is not appropriate. **Keep container tightly closed.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/…** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**If on skin: Brush off loose particles from skin. Immerse in cool water or wrap in wet bandages.** **In case of fire: Use ... to extinguish** - *if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.		

C.4.24 SELF-HEATING SUBSTANCES AND MIXTURES
(Classified in Accordance with Appendix B.11 of this Section)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
1	Danger	Self-heating; may catch fire
2	Warning	Self-heating in large quantities; may catch fire

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep cool. - *may be omitted if storage temperatures are listed on the label.* **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.		**Maintain air gap between stacks or pallets.** **Protect from sunlight.** **Store bulk masses greater than … kg/…lbs at temperatures not exceeding …°F (°C).** ... Chemical manufacturer, importer, or distributor to specify mass and temperature using applicable scale. **Store separately.**	

C.4.25 SUBSTANCES AND MIXTURES WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES
(Classified in Accordance with Appendix B.12 of this Section)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
1	Danger	In contact with water releases flammable gases, which may ignite spontaneously
2	Danger	In contact with water releases flammable gas

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not allow contact with water. - *if emphasis of the hazard statement is deemed necessary.* **Handle and store contents under inert gas/... Protect from moisture.** - *if the substance or mixture reacts readily with moisture in air.* … Chemical manufacturer, importer, or distributor to specify appropriate liquid or gas if "inert gas" is not appropriate. **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**If on skin: Brush off loose particles from skin and immerse in cool water.** **In case of fire: Use ... to extinguish** - *if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.	**Store in a dry place. Store in a closed container.**	**Dispose of contents/container to...** …in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.25 SUBSTANCES AND MIXTURES WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES (CONTINUED)
(Classified in Accordance with Appendix B.12 of this Section)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
3	Warning	In contact with water releases flammable gas

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Handle and store contents under inert gas/… Protect from moisture. - *if the substance or mixture reacts readily with moisture in air.* … Chemical manufacturer, importer, or distributor to specify appropriate liquid or gas if "inert gas" is not appropriate. **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Use ... to extinguish.** - *if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.	**Store in a dry place. Store in a closed container.**	**Dispose of contents/container to...** …in accordance with local/regional/national/ international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.26 OXIDIZING LIQUIDS
(Classified in Accordance with Appendix B.13 of this Section)

Pictogram
Flame over circle

Hazard category	Signal word	Hazard statement
1	Danger	May cause fire or explosion; strong oxidizer

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep away from clothing and other combustible materials.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/....** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment. **Wear fire resistant or flame retardant clothing.**	**If on clothing: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.** **In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.** **In case of fire: Use ... to extinguish.** - *if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.	**Store separately.**	**Dispose of contents/container to...** …in accordance with local/regional/ national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.26 OXIDIZING LIQUIDS (CONTINUED)
(Classified in Accordance with Appendix B.13 of this Section)

Hazard category	Signal word	Hazard statement	Pictogram Flame over circle
2	Danger	May intensify fire; oxidizer	
3	Warning	May intensify fire; oxidizer	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep away from clothing and other combustible materials.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Use ... to extinguish.** - *if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.		**Dispose of contents/container to...** …in accordance with local/regional/ national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

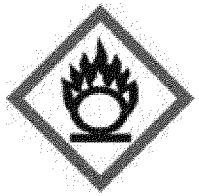
C.4.27 OXIDIZING SOLIDS
(Classified in Accordance with Appendix B.14 of this Section)

Hazard category	Signal word	Hazard statement	Pictogram
1	Danger	May cause fire or explosion; strong oxidizer	Flame over circle

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep away from clothing and other combustible materials.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify appropriate personal protective equipment. **Wear fire resistant or flame retardant clothing.**	**If on clothing: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.** **In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.** **In case of fire: Use ... to extinguish.** - *if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.	**Store separately.**	**Dispose of contents/container to...** …in accordance with local/regional/ national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.27 OXIDIZING SOLIDS (CONTINUED)
(Classified in Accordance with Appendix B.14 of this Section)

Pictogram
Flame over circle

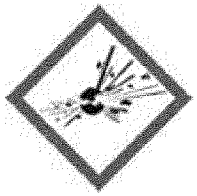


Hazard category	Signal word	Hazard statement
2	Danger	May intensify fire; oxidizer
3	Warning	May intensify fire; oxidizer

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep away from clothing and other combustible materials.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Use ... to extinguish.** - *if water increases risk.* ... Chemical manufacturer, importer, or distributor to specify appropriate media.		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.28 ORGANIC PEROXIDES
(Classified in Accordance with Appendix B.15 of this Section)

Pictogram
Exploding bomb



Hazard category	Signal word	Hazard statement
Type A	Danger	Heating may cause an explosion

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep only in original packaging.** **Keep cool.** *– may be omitted if storage temperatures are listed on the label.* **Ground and bond container and receiving equipment.** *– if electrostatically sensitive and able to generate an explosive atmosphere.* **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Explosion risk. Evacuate area. DO NOT fight fire when fire reaches explosives.**	**Store in a well-ventilated place.** *– except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.* **Protect from sunlight.** **Store at temperatures not exceeding …°F (°C).** *- if temperature control is required or if otherwise deemed necessary.* ... Chemical manufacturer, importer, or distributor to specify temperature using applicable temperature scale. **Store separately.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.28 ORGANIC PEROXIDES (CONTINUED)
(Classified in Accordance with Appendix B.15 of this Section)

Hazard category	Signal word	Hazard statement
Type B	Danger	Heating may cause a fire or explosion

Pictogram
Exploding bomb and flame

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep only in original packaging.** **Keep cool.** *- may be omitted if storage temperatures are listed on the label.* **Ground and bond container and receiving equipment.** *– if electrostatically sensitive and able to generate an explosive atmosphere.* **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion. [Use...to extinguish]** *– text in square brackets to be used if water increases risk.* ... Chemical manufacturer, importer, distributor to specify appropriate media.	**Store in a well-ventilated place.** *– except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.* **Protect from sunlight.** **Store at temperatures not exceeding …°F (°C).** *- if temperature control is required or if otherwise deemed necessary.* Chemical manufacturer, importer, or distributor to specify temperature using applicable temperature scale. **Store separately.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/ international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.28 ORGANIC PEROXIDES (CONTINUED)
(Classified in Accordance with Appendix B.15 of this Section)

Pictogram
Flame

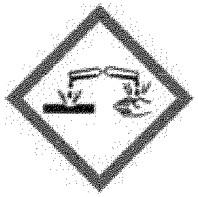
Hazard category	Signal word	Hazard statement
Type C	Danger	Heating may cause a fire
Type D	Danger	Heating may cause a fire
Type E	Warning	Heating may cause a fire
Type F	Warning	Heating may cause a fire

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Keep only in original packaging.** **Keep cool.** *- may be omitted if storage temperatures are listed on the label.* **Ground and bond container and receiving equipment.** *– if electrostatically sensitive and able to generate an explosive atmosphere.* **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of fire: Use ... to extinguish.** *- if water increases risk.* ... Chemical manufacturer, importer, distributor to specify appropriate media.	**Store in a well-ventilated place.** *– except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.* **Protect from sunlight.** **Store at temperatures not exceeding …°F (°C).** *- if temperature control is required or if otherwise deemed necessary.* Chemical manufacturer, importer, or distributor to specify temperature using applicable temperature scale. **Store separately.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/ international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.29 CORROSIVE TO METALS
(Classified in Accordance with Appendix B.16 of this Section)

Pictogram
Corrosion



Hazard category	Signal word	Hazard statement
1	Warning	May be corrosive to metals

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep only in original packaging.	**Absorb spillage to prevent material damage.**	**Store in corrosion resistant/... container with a resistant inner liner.** - *may be omitted if "Keep only in original packaging" is on the label* ... Chemical manufacturer, importer, or distributor to specify other compatible materials.	

C.4.30 DESENSITIZED EXPLOSIVES
(Classified in Accordance with Appendix B.17 of this Section)

Hazard category	Signal word	Hazard statement
1	Danger	Fire, blast or projection hazard; increased risk of explosion if desensitizing agent is reduced.
2	Danger	Fire or projection hazard; increased risk of explosion if desensitizing agent is reduced.
3	Warning	Fire or projection hazard; increased risk of explosion if desensitizing agent is reduced.

Pictogram
Flame

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Avoid heating under confinement or reduction of the desensitizing agent.** **Keep wetted with…** ...Chemical manufacturer, importer or distributor to specify appropriate material. **Keep container tightly closed.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...** Chemical manufacturer, importer or distributor to specify the appropriate personal protective equipment.	**In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.**	**Store in accordance with…** ... Chemical manufacturer, importer, or distributor to specify local/regional/national/ international regulations as applicable.	**Dispose of contents/container to...** ...in accordance with local/regional/national/ international regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.30 DESENSITIZED EXPLOSIVES
(Classified in Accordance with Appendix B.17 of this Section)

Hazard category	Signal word	Hazard statement	Pictogram
4	Warning	Fire hazard; increased risk of explosion if desensitizing agent is reduced.	Flame

Precautionary Statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **Avoid heating under confinement or reduction of the desensitizing agent.** **Keep wetted with…** ... Chemical manufacturer, importer, or distributor to specify appropriate material. **Keep container tightly closed.** **Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/....** Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment.	**In case of major fire: Evacuate area. Fight fire remotely due to the risk of explosion.**	**Store in accordance with…** ... Chemical manufacturer, importer, or distributor to specify local/regional/national/ international regulations as applicable.	**Dispose of contents/container to...** ...in accordance with local/regional/national/inter national regulations (to be specified). Chemical manufacturer, importer, or distributor to specify whether disposal requirements apply to contents, container or both.

C.4.31 Label elements for OSHA defined hazards

Hazard category	Signal word	Hazard statement	Pictogram
Simple Asphyxiant	Warning	May displace oxygen and cause rapid suffocation	*No Pictogram*

Hazard category	Signal word	Hazard statement	Pictogram
Combustible Dust[2]	Warning	May form combustible dust concentrations in air [if small particles are generated during further processing, handling or by other means.] or May form explosible dust-air mixture [if small particles are generated during further processing, handling or by other means.]	*No Pictogram*

[2] The chemical manufacturer or importer shall label chemicals that are shipped in dust form, and present a combustible dust hazard in that form when used downstream, under paragraph (f)(1) of this section; 2) the chemical manufacturer or importer shipping chemicals that are in a form that is not yet a dust must provide a label to customers under paragraph (f)(4) of this section if, under normal conditions of use, the chemicals are processed in a downstream workplace in such a way that they present a combustible dust hazard; and 3) the employer shall follow the workplace labeling requirements under paragraph (f)(6) of this section where combustible dust hazards are present.

BILLING CODE 4510–26–C

Appendix D to § 1910.1200—Safety Data Sheets (Mandatory)

A safety data sheet (SDS) shall include the information specified in Table D.1 under the section number and heading indicated for sections 1–11 and 16. While each section of the SDS must contain all of the specified information, preparers of safety data sheets are not required to present the information in any particular order within each section. If no relevant information is found for any given subheading within a section, the SDS shall clearly indicate that no applicable information is available. Sections 12–15 may be included in the SDS, but are not mandatory.

TABLE D.1—MINIMUM INFORMATION FOR AN SDS

Heading	Subheading
1. Identification	(a) Product identifier used on the label; (b) Other means of identification; (c) Recommended use of the chemical and restrictions on use; (d) Name, U.S. address, and U.S. telephone number of the chemical manufacturer, importer, or other responsible party; (e) Emergency phone number.
2. Hazard(s) identification	(a) Classification of the chemical in accordance with paragraph (d) of § 1910.1200, including any hazards associated with a change in the chemical's physical form under normal conditions of use; (b) Signal word, hazard statement(s), symbol(s) and precautionary statement(s) in accordance with paragraph (f) of § 1910.1200. (Hazard symbols may be provided as graphical reproductions in black and white or the name of the symbol, *e.g.,* flame, skull and crossbones); (c) Hazards identified under normal conditions of use that result from a chemical reaction (changing the chemical structure of the original substance or mixture); (d) Describe any hazards not otherwise classified that have been identified during the classification process; (e) Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥1% and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required.
3. Composition/information on ingredients.	Except as provided for in paragraph (i) of § 1910.1200 on trade secrets: *For Substances* (a) Chemical name; (b) Common name and synonyms; (c) CAS number and other unique identifiers; (d) Impurities and stabilizing additives (constituents) which are themselves classified and which contribute to the classification of the substance. *For Mixtures* In addition to the information required for substances: (a) The chemical name, CAS number or other unique identifier, and concentration (exact percentage) or concentration ranges of all ingredients which are classified as health hazards in accordance with paragraph (d) of § 1910.1200 and (1) are present above their cut-off/concentration limits; or (2) present a health risk below the cut-off/concentration limits. (b) The concentration (exact percentage) shall be specified unless a trade secret claim is made in accordance with paragraph (i) of § 1910.1200, when there is batch-to-batch variability in the production of a mixture, or for a group of substantially similar mixtures (See A.0.5.1.2) with similar chemical composition. In these cases, concentration ranges may be used. *For All Chemicals Where a Trade Secret is Claimed* Where a trade secret is claimed in accordance with paragraph (i) of § 1910.1200, a statement that the specific chemical identity, exact percentage (concentration), or concentration range of composition has been withheld as a trade secret is required. When the concentration or concentration range is withheld as a trade secret, the chemical composition must be provided in accordance with the prescribed concentration ranges in § 1910.1200(i)(1)(iv).
4. First-aid measures	(a) Description of necessary measures, subdivided according to the different routes of exposure, *i.e.,* inhalation, skin and eye contact, and ingestion; (b) Most important symptoms/effects, acute and delayed. (c) Indication of immediate medical attention and special treatment needed, if necessary.
5. Fire-fighting measures	(a) Suitable (and unsuitable) extinguishing media. (b) Specific hazards arising from the chemical (*e.g.,* nature of any hazardous combustion products). (c) Special protective equipment and precautions for fire-fighters.
6. Accidental release measures	(a) Personal precautions, protective equipment, and emergency procedures. (b) Methods and materials for containment and cleaning up.
7. Handling and storage	(a) Precautions for safe handling. (b) Conditions for safe storage, including any incompatibilities.
8. Exposure controls/personal protection.	(a) For all ingredients or constituents listed in Section 3, the OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit or range used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available. (b) Appropriate engineering controls. (c) Individual protection measures, such as personal protective equipment.
9. Physical and chemical properties	(a) Physical state. (b) Color. (c) Odor. (d) Melting point/freezing point. (e) Boiling point (or initial boiling point or boiling range). (f) Flammability.

TABLE D.1—MINIMUM INFORMATION FOR AN SDS—Continued

Heading	Subheading
	(g) Lower and upper explosion limit/flammability limit.
	(h) Flash point.
	(i) Auto-ignition temperature.
	(j) Decomposition temperature.
	(k) pH.
	(l) Kinematic viscosity.
	(m) Solubility.
	(n) Partition coefficient n-octanol/water (log value).
	(o) Vapor pressure.
	(p) Density and/or relative density.
	(q) Relative vapor density.
	(r) Particle characteristics.
10. Stability and reactivity	(a) Reactivity;
	(b) Chemical stability;
	(c) Possibility of hazardous reactions, including those associated with foreseeable emergencies;
	(d) Conditions to avoid (*e.g.,* static discharge, shock, or vibration);
	(e) Incompatible materials;
	(f) Hazardous decomposition products.
11. Toxicological information	Description of the various toxicological (health) effects and the available data used to identify those effects, including:
	(a) Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact);
	(b) Symptoms related to the physical, chemical and toxicological characteristics;
	(c) Delayed and immediate effects and also chronic effects from short- and long-term exposure;
	(d) Numerical measures of toxicity (such as acute toxicity estimates);
	(e) Interactive effects; information on interactions should be included if relevant and readily available;
	(f) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA.
	(g) When specific chemical data or information is not available, the preparer must indicate if alternative information is used and the method used to derive the information (*e.g.,* where the preparer is using information from a class of chemicals rather than the exact chemical in question and using SAR to derive the toxicological information).
12. Ecological information (Nonmandatory).	(a) Ecotoxicity (aquatic and terrestrial, where available);
	(b) Persistence and degradability;
	(c) Bioaccumulative potential;
	(d) Mobility in soil;
	(e) Other adverse effects (such as hazardous to the ozone layer).
13. Disposal considerations (Nonmandatory).	Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.
14. Transport information (Nonmandatory).	(a) UN number;
	(b) UN proper shipping name;
	(c) Transport hazard class(es);
	(d) Packing group, if applicable;
	(e) Environmental hazards (*e.g.,* Marine pollutant (Yes/No));
	(f) Transport in bulk according to IMO instruments;
	(g) Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises.
15. Regulatory information (Nonmandatory).	Safety, health and environmental regulations specific for the product in question.
16. Other information, including date of preparation or last revision.	The date of preparation of the SDS or the last change to it.

* * * * *

[FR Doc. 2020–28987 Filed 2–5–21; 8:45 am]

BILLING CODE 4510–26–P

FEDERAL REGISTER

Vol. 86 Tuesday,

No. 29 February 16, 2021

Part III

The President

Notice of February 11, 2021—Continuation of the National Emergency With Respect to Libya

Federal Register
Vol. 86, No. 29
Tuesday, February 16, 2021

Presidential Documents

Title 3—

The President

Notice of February 11, 2021

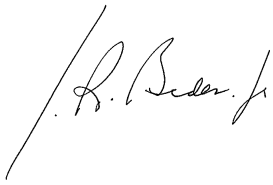
Continuation of the National Emergency With Respect to Libya

On February 25, 2011, by Executive Order 13566, the President declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions of Colonel Muammar Qadhafi, his government, and close associates, which took extreme measures against the people of Libya, including by using weapons of war, mercenaries, and wanton violence against unarmed civilians. In addition, there was a serious risk that Libyan state assets would be misappropriated by Qadhafi, members of his government, members of his family, or his close associates if those assets were not protected. The foregoing circumstances, the prolonged attacks, and the increased numbers of Libyans seeking refuge in other countries from the attacks caused a deterioration in the security of Libya and posed a serious risk to its stability.

The situation in Libya continues to pose an unusual and extraordinary threat to the national security and foreign policy of the United States, and measures are needed to protect against the diversion of assets or other abuses by members of Qadhafi's family, their associates, and other persons hindering Libyan national reconciliation.

For this reason, the national emergency declared on February 25, 2011, must continue in effect beyond February 25, 2021. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13566.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
February 11, 2021.

[FR Doc. 2021–03262
Filed 2–12–21; 1:00 pm]
Billing code 3295–F1–P

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