



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: Final rule.

SUMMARY: OSHA is amending the Hazard Communication Standard (HCS) to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS), primarily Revision 7 (Rev. 7), 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, while enhancing the effectiveness of the standard. Consistent with Executive Order 13563 and the Regulatory Flexibility Act, which call for assessment and, where appropriate, modification and improvement of existing rules, OSHA has reviewed the existing HCS. The agency has determined that the revisions in this final rule 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 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, new provisions related to trade secrets, technical amendments related to the contents of safety data sheets (SDSs), and related revisions to definitions of terms used in the standard.

DATES: This final rule is effective [INSERT 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of certain publications listed in this final rule is approved by the Director of the Federal Register as of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of certain other publications listed in the rule was approved by the Director as of July 15, 2019.

ADDRESSES: In compliance with 28 USC 2112(a), the agency designates Edmund C. Baird, Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S-4004, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, as the recipient of petitions for review of this final rule.

Docket: To read or download comments or other material in the docket, go to Docket No. OSHA-2019-0001 at 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. 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. For example, the Document ID number for the 2021 HCS Notice of Proposed Rulemaking (NPRM) is OSHA-2019-0001-0258. Some Document ID numbers also include one or more attachments.

When citing exhibits in the docket, OSHA includes the term “Document ID” followed by the last four digits of the Document ID number. For example, document OSHA-2019-0001-0258 would appear as Document ID 0258. Citations may also include the attachment number (designated “Att.”) or other attachment identifier, if applicable, page numbers (designated “p.”, or “Tr.” for pages from a hearing transcript), and in a limited number of cases a footnote number (designated “Fn.”).

This information can be used to search for a supporting document in the docket at www.regulations.gov. Contact the OSHA Docket Office at (202) 693-2350 (TTY number: 877-889-5627) for assistance in locating docket submissions.

FOR FURTHER INFORMATION:

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I. Executive Summary

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) has been implemented around the world. In 2012, OSHA revised its Hazard Communication Standard (HCS), 29 CFR 1910.1200, to align with Revision 3 (Rev. 3) of

the GHS (77 FR 17574). However, the GHS is updated with improvements and clarifications every two years. This rulemaking amends the HCS primarily to align with Revision 7 (Rev. 7) of the GHS, published in 2017, where appropriate. OSHA is also finalizing updates to address specific issues that have arisen since the 2012 rulemaking and to provide better alignment with other U.S. agencies and international trading partners, while enhancing the effectiveness of 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. 601 et seq.) which require retrospective analysis 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) (29 USC 651 et seq.) to assure, as far as possible, safe and healthful working conditions for workers. As part of this effort, OSHA first promulgated the HCS in 1983 to provide a standardized approach to workplace hazard communication associated with exposure to hazardous chemicals. The HCS requires chemical manufacturers or importers to classify the hazards of chemicals they produce or import. It also 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. This final rule does not change the fundamental structure of the HCS.

OSHA has determined that the amendments to the HCS contained in this final rule enhance the effectiveness of the standard by ensuring that employees are appropriately apprised of the chemical hazards to which they may be exposed. The 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 provisions addressing the labeling of small

containers and the relabeling of chemicals that have been released for shipment); 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 Executive Orders 12866 and 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.), OSHA has prepared a Final Economic Analysis (FEA), including a Final Regulatory Flexibility Analysis Certification, for the final modifications to the HCS (see the full FEA in Section VI of this notice). Supporting materials prepared by OSHA, such as cost-estimate spreadsheets, are available in the public docket for this rulemaking, Docket ID OSHA-2019-0001, through www.regulations.gov.

In the FEA, OSHA estimates that, annualized at a 7 percent discount rate, the final rule would result in net cost savings of \$29.8 million per year, 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 final rule would result in net cost savings of \$30.7 million per year. OSHA also expects that the final revisions to the HCS will 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 VI.D: Health and Safety Benefits and Unquantified Positive Economic Effects).

Table ES-1: Total Annualized Costs for All Entities Affected by the Revisions to the Hazard Communication Standard (by Industry and Provision, 7 Percent Discount Rate, 2022 Dollars)

NAICS Code	Industry	Rule Familiarization	Training	Revised SDS/Labels [a]	Released for Shipment	Labels for Very Small Containers	Net Costs
21	Mining, Quarrying, and Oil and Gas Extraction	\$79,932	\$8,645	\$290,885	\$0	\$0	\$379,462
211	Oil and Gas Extraction	\$79,932	\$8,645	\$290,885	\$0	\$0	\$379,462
31-33	Manufacturing	\$839,232	\$128,308	\$3,571,026	-\$13,219,957	-\$1,713,243	-\$10,394,633
324	Petroleum and Coal Products Manufacturing	\$39,931	\$12,402	\$1,545,319	\$0	\$0	\$1,597,653
325	Chemical Manufacturing	\$299,302	\$115,906	\$1,855,602	-\$13,219,957	-\$1,713,243	-\$12,662,389
326	Plastics and Rubber Products Manufacturing	\$72,302	\$0	\$0	\$0	\$0	\$72,302
327	Nonmetallic Mineral Product Manufacturing	\$62,192	\$0	\$0	\$0	\$0	\$62,192
331	Primary Metal Manufacturing	\$26,897	\$0	\$0	\$0	\$0	\$26,897
339	Miscellaneous Manufacturing	\$338,607	\$0	\$170,105	\$0	\$0	\$508,712
42	Wholesale Trade	\$224,298	\$0	\$0	-\$20,038,538	\$0	-\$19,814,240
423	Merchant Wholesalers, Durable Goods	\$63,638	\$0	\$0	\$0	\$0	\$63,638
424	Merchant Wholesalers, Nondurable Goods	\$160,660	\$0	\$0	-\$20,038,538	\$0	-\$19,877,879
Total		\$1,143,462	\$136,953	\$3,861,911	-\$33,258,495	-\$1,713,243	-\$29,829,412

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

[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.

II. Introduction

This preamble includes a review of the events leading to the final rule, a discussion of the reasons why OSHA finds these modifications to the HCS necessary, the final economic analysis and regulatory flexibility analysis for the standard, and an explanation of the specific revisions OSHA is making to the standard.

Section XIV: Summary and Explanation of the Final Rule is organized by paragraph of regulatory text affected by this update, followed by the appendices to the regulatory text. Stakeholders can examine the redline strikeout of the regulatory text (changes from 2012 HCS to this final) at OSHA's HCS webpage (<https://www.osha.gov/dsg/hazcom/>) to view all of the changes to the 2012 HCS made in this final rule.

III. Events Leading to the Revised 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 GHS (Document ID 0085) (77 FR 17574).

On February 16, 2021, OSHA published a Notice of Proposed Rulemaking (NPRM) to modify the HCS, to bring it into alignment with the seventh revision of the

GHS (Document ID 0060) (86 FR 9576), to address specific issues that have arisen since the 2012 rulemaking, and to provide better alignment with other U.S. agencies and international trading partners. On September 21-23, 2021, the agency held an informal public hearing to gather additional input from interested stakeholders. OSHA received more than 170 public submissions (e.g., written comments, exhibits, and briefing materials) during the public comment period. This rulemaking finalizes the amendments proposed in 2021 with modifications based on stakeholder input through the public comment process.

The HCS requires periodic revision 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. Several international and domestic activities have impacted the direction of the HCS and led to the updates of this rule, including international negotiations at the United Nations (UN), coordination with other U.S. agencies, OSHA's participation in the U.S.–Canada Regulatory Cooperation Council (RCC) with Health Canada, and information OSHA has received from HCS stakeholders. Below, the agency 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 rule.

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 UN Economic and Social Council Committee of Experts on the Transport of Dangerous Goods (TDG) and continued in the 1990s through the UN Conference on Environment and Economic Development (UNCED), the UN International Labour Organization (ILO), and the Organization for Economic Cooperation and Development (OECD) (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 (Document ID 0052).

Since OSHA's adoption of Rev. 3 in 2012, the GHS has been updated six times; the latest revision, Rev. 9, was published in July 2021

(<https://unece.org/transport/standards/transport/dangerous-goods/ghs-rev9-2021>).

Updates to the GHS in Rev. 4 (2011) included changes to hazard categories for chemically unstable gases and non-flammable aerosols and updates to, and clarification of, precautionary statements (Document ID 0240). Changes in Rev. 5 (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 (Document ID 0241). Rev. 6 (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 (Document ID 0197). Changes in Rev. 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 labeling of small packages with fold-out labels (Document ID 0094). Rev. 8 (2019) added a table for the classification criteria versus only relying on the decision logics for chemicals under pressure; 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” (Document ID 0065). Rev. 9 (2021) included changes to chapter 2.1 to better address explosive hazards when not in transport, revisions to decision logics, revisions to Annex 1 – classification and labeling summary tables, revisions to precautionary statements, and updates to OECD test guidelines in Annexes 9 and 10 (<https://unece.org/transport/standards/transport/dangerous-goods/ghs-rev9-2021>).

I. U.S. Participation at the United Nations and Interagency Coordination.

OSHA leads the U.S. Interagency GHS Coordinating Group, an interagency group that serves as a U.S. delegation to the UN (“Interagency Group”). 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 UN Sub-Committee of Experts on the GHS (UNSCEGHS). It 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), the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), and

other agencies as appropriate. 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) (Document ID 0175). EPA (which initiated the U.S. working group) finalized changes to its regulations governing significant new uses of chemical substances under the Toxic Substances Control Act (TSCA) that would align with the HCS and the GHS as well as with OSHA's respiratory protection standard (29 CFR 1910.134) and National Institute for Occupational Safety and Health (NIOSH) respirator certification requirements (87 FR 39756).

II. U.S. - Canada Coordination.

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 (Document ID 0057; 0199). 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 (OMB) and the Treasury Board of Canada. 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, this final rule contains 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 (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 to inform the public that OSHA was beginning rulemaking efforts to maintain alignment of the HCS with more recent revisions of the GHS (International/Globally Harmonized System (GHS), Docket No. OSHA-2016-0005). 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 held 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 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 U.S. 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 "bring together senior regulatory officials, industry, and other interested members of the public from both sides of the border to discuss recent accomplishments and new opportunities for regulatory cooperation" (Document ID 0057). 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 2012 HCS update, the agency has published guidance documents, issued letters of interpretation (LOIs), and implemented an enforcement directive. These guidance documents are available 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.

OSHA has issued several LOIs in response to questions from the regulated community. These LOIs 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 LOIs include the labeling of small containers, the labeling of chemicals released for shipment, and the use of concentration ranges for trade secrets. OSHA's LOIs on the HCS may be found at [https://www.osha.gov/laws-](https://www.osha.gov/laws-regs/standardinterpretations/standardnumber/1910/1910.1200%20-%20Index/result)

[regs/standardinterpretations/standardnumber/1910/1910.1200%20-%20Index/result](https://www.osha.gov/laws-regs/standardinterpretations/standardnumber/1910/1910.1200%20-%20Index/result).

Several of the updates in this final rule clarify specific elements of the enforcement guidance the agency has already provided in LOIs and the directive. The agency anticipates publishing an updated directive to provide guidance to OSHA compliance officers; however, the 2015 directive is still in force until rescinded or updated (Document ID 0007).

OSHA requested comments in the NPRM on types of guidance documents that the public may find useful to understand the updated HCS. The American Society of Safety Professionals (ASSP) suggested that OSHA “create training modules focused on the changes to the HCS once the rule is finalized” (Document ID 0284, p. 2). Hugo Hidalgo suggested that the agency “leverage technology to effectively communicate hazards of chemicals to customers and end-users once the information becomes available” (Document ID 0297, p. 4). Other comments received in response to OSHA's request for comments on guidance documents are highlighted in Section XV., Issues and Options Considered. OSHA has considered all requests for guidance and is evaluating the best approaches to implement those requests and suggestions.

IV. Need and Support for the Revised Hazard Communication Standard

Hazardous chemical exposures in workplaces in the United States present a serious and ongoing danger to workers. Acute and chronic exposures to hazardous chemicals in the workplace can have serious health consequences. As described in the 2012 HCS, chemical exposures are either directly responsible for or contribute to serious adverse health effects including cancer; heart, lung, reproductive, and immunological diseases; hearing loss; and eye and skin damage (77 FR 17584). In addition to health effects, exposure to hazardous chemicals can result in physical hazards, such as fires, explosions, and other dangerous incidents (77 FR 17584). Recognition of the significant risk posed by these workplace hazards was the impetus for OSHA to promulgate the original hazard communication standard in order to promote responsible chemical management practices (48 FR 53282-53283).

Hazard communication is a fundamental element of sound chemical management practices. As stated in the GHS, “[a]vailability of information about chemicals, their hazards, and ways to protect people, will provide the foundation for national programmes for the safe management of chemicals” (Document ID 0060, p. iii). An anonymous comment on the NPRM stated that “[a]rming employers with this information, since the 1980s, has undoubtedly reduced the potential for, and severity of, chemical and toxic substance injuries and illnesses, to include a reduced number of fatalities. Globally harmonizing the system for classification and labeling across a big part of the world was also beneficial as it provided consistency, and more simplicity, especially for foreign products utilized domestically” (Document ID 0300, p. 1). The commenter went on to state that “[p]roviding safety and health information to product users is imperative. Ultimately, this information equals a form of protection” (Document ID 0300, p. 1).

OSHA recognized the importance of a robust hazard communication strategy as early as the 1980s, when the agency first promulgated the HCS (48 FR 53282-53284). The agency also recognized the need for a global strategy and was instrumental in the

development of the GHS (48 FR 53287). From its inception, OSHA indicated that the HCS would be updated periodically to keep pace with the advancement of scientific principles underlying the hazard determination process as well as improvements in communication systems (48 FR 53287). In hearing testimony and post-hearing briefs, NIOSH provided documentation supporting the continual updating of occupational safety and health information, stating that the “process should be a never-ending loop of research and translation, allowing for ongoing integration of effective approaches” (Document ID 0456, Att. 15, p. 4).

The “research and translation” described by NIOSH is at the heart of the GHS and HCS process – continually evaluating and updating to improve worker protections and make hazard communication clearer and more effective for both workers and employers. In addition to directly enhancing worker protections through improved hazard communication, updating the HCS to maintain alignment with the GHS also improves the availability of important information to support larger efforts to address workplace hazards. Commenters on the NPRM recognized this principle. For example, Ameren stated that the modifications to the HCS “takes a positive approach in our efforts of eliminating risk events” (Document ID 0309, p. 2). ASSP commented, “[w]e believe that aligning the HCS to international regulations is beneficial overall to the OSH profession and our members will assist in ensuring employers use these enhanced requirements to better protect their workers” (Document ID 0284, p. 1). The following sections provide more detailed information on the need for the updates being finalized in this final rule.

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 a report published by the ILO in 2008,

“[c]ontinuous 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).¹ 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.

The changes finalized in this update to the HCS will result in better alignment between the standard and the continually evolving GHS. The first edition of the GHS, adopted in December 2002 and published in 2003, implemented the 16-section format for SDSs² that is now standard across much of the globe. As information has improved, the GHS has updated the form and content of SDSs to improve readability, minimize

¹ 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 1,700 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 phrases similar to GHS precautionary statements to convey safety and health information about workplace chemicals in a consistent, internationally accessible manner. ICSCs also display classification information (hazard pictograms, signal words, and hazard statements) in line with GHS classification criteria—this information is added during updates. With participation by experts from government agencies around the world, including the U.S. (Centers for Disease Control and Prevention (CDC)/NIOSH), Canada (Quebec - CNESST), Japan (National Institute of Health Sciences), and several European countries, 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).

² 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).

redundancies, and ensure hazards are communicated appropriately (Document ID 0060; Document ID 0237).

Information OSHA has collected since publication of the 2012 update to the HCS indicates that aligning the HCS with the GHS has had a positive impact on workplace hazard communication. 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 (Bechtold, 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 explained distinctions between acute toxicity and chronic health effects (Bechtold, 2014, Document ID 0061). 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).

Labels and SDSs are often the first indication to a worker that they are handling a hazardous chemical, so it is imperative that labels and SDSs be as accurate and complete as possible. While the HCS does not require testing of chemicals, it does require that labels and SDSs have accurate information based on all available evidence and that manufacturers, importers, distributors, and employers provide the complete information on the hazards available to them. Without a complete picture of the hazards associated with a particular chemical, workers cannot know how to adequately protect themselves or safely handle these chemicals. North America's Building Trades Unions (NABTU) commented that "[It] is really important to have . . . the labels on the products that are being used because that's the first source of information. The SDS is the backup source.... [Labels and SDSs are] where they're going to get information on the hazards of

what they're using and the precautions that need to be taken, including . . . any engineering controls or any personal protective equipment" (Document ID 0464, p. 2).

Several studies published since the 2012 HCS adopted the 16-section SDS format indicate that the new format has improved 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 protection. 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 0016; 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 0167).

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. An anonymous commenter stated that “[i]naccurate information makes it difficult for downstream users who have to rely on inaccurate or incomplete information . . .” (Document ID 0308, p. 1). 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. This final rule’s 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, a change in Section 9 (physical characteristics to include particle characteristics) will identify exposure issues that were not addressed by the previous 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 (which correspond to updates in this final rule to Appendix A.2 of the HCS) on skin corrosion/irritation that incorporated new *in vitro* test methods, and computational or *in silico* techniques, to classify chemicals for this category of hazard (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).³ Studies evaluating the effectiveness of precautionary statements and pictograms

³ Holistic programs such as NIOSH’s Total Worker Health program, where behavioral science is integrated into more traditional risk-management practices, require robust hazard communication practices (Tamers, 2019, Document ID 0076).

used in the GHS have led to their evolution and continued revisions (Fagotto, 2003, Document ID 0125; ISHN, 2019, Document ID 0068; Ta, 2010, Document ID 0115; Ta, 2011, Document ID 0194; Chan, 2017, Document ID 0017).

Regularly updating the HCS to align with international practices also eases compliance for global corporations 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 (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), the Center for Protection of Workers' Rights (CPWR), and the Society for Chemical Hazard Communication (SCHC)) publicly supported OSHA's continued updates to the HCS (see 77 FR 17585, 17603). The Society of Toxicology (SOT) also expressed support for updating the HCS to align with the GHS as this "creates consistent communication about the hazards of chemicals across the globe" (see 77 FR 17585).

B. Cooperating with International Trading Partners and Other Federal Agencies

OSHA expects that the updates to the HCS will facilitate cooperation with international trading partners and other federal agencies. The U.S. and Canada participate in the RCC, which has a goal to "enhance regulatory cooperation and economic competitiveness that maintain high standards when it comes to health, safety, and the environment" (Document ID 0127). 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 UNSCEGHS subcommittee. In addition, OSHA and Health Canada share regular updates on regulatory activity. As explained in the Section XIV., Summary and Explanation of the Final Rule,

several updates in this final rule will 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 updating the requirements for bulk shipment under paragraph (f)(5) to provide additional clarity for shipments that are also regulated by the DOT. For bulk shipments, the finalized new paragraph should 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. This allows for the full label information to be available to the downstream user upon receipt while recognizing the unique DOT placarding issues for bulk shipments. And in another effort to facilitate inter-agency cooperation, OSHA is finalizing 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 to acknowledge that the DOT regulations allow for the GHS pictogram to be on the shipped container (49 CFR 172.401(c)(5)).

C. Responding to Stakeholder Experiences Implementing the 2012 HCS

Finally, some of the changes in this final rule, including 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). This final rule includes revisions designed to address these issues with small container labeling as well as revisions addressing other issues raised by commenters. Furthermore, OSHA believes that adopting a uniform approach to labeling small containers will enhance worker protections by ensuring that critical information on the hazards posed by the chemicals is included on the label regardless of the size of the container. For a full discussion of this change, see the Summary and Explanation for (f)(12).

Similarly, the finalized 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 the HCS's requirements to update labels when new information becomes available, especially in the case of chemicals that travel through long distribution cycles (Kenyon, 2017, Document ID 0182). This final rule revises paragraph (f)(11) to address these concerns while maintaining worker protections.

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 after 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, they 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 in Section V.D., Significant Risk, OSHA need not make additional findings on risk for this final rule 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, particularly in the absence of specific permissible exposure limits, 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 issue a rule pursuant to 5 U.S.C. 553 to “make appropriate modifications in the foregoing requirements relating to the use of labels or other forms of warning . . . 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 this final rule.

This final rule, which is an update to the existing HCS, fits well within the authority granted by the last sentence of section 6(b)(7). The changes in the final rule 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 has determined the updates are “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 are a “technological development” that has occurred since the 2012 revisions to the HCS 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;⁴ see also Section III.: Events Leading to the Revised Hazard Communication Standard in this preamble.

⁴ The last sentence of section 6(b)(7) requires consultation with the Secretary of Health and Human Services. OSHA briefed NIOSH on the proposal for this rule during a collaboration meeting held in December 2018, which was attended by the Director of NIOSH, and NIOSH expressed its support. NIOSH continued to express support in its comments on the proposed rule (Document ID 0281) and also supported OSHA's update of the HCS in 2012, see 77 FR 17603.

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 by section 6(b)(5) of the OSH Act, OSHA originally determined that the HCS would substantially reduce a significant risk of material harm when promulgating the standard in 1983. Many 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 those cases, OSHA measures and assesses the hazards of employee exposures 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. 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 53283. Based on that evidence, 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.

For the changes in this final rule, OSHA has not made a new finding of significant risk but is making 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 (DC 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 (DC 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.⁵ 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 analyses to make standards-setting decisions dealing with toxic materials or harmful physical agents.

⁵ 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.

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.” *Id.* 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. OSHA’s determinations regarding feasibility are discussed more fully in Section VI.E., Technological Feasibility, and Section VI.G., Economic Feasibility and Impacts, in this preamble.

VI. Final Economic Analysis and Regulatory Flexibility Analysis

A. Introduction and Summary

Under Executive Order 12866 (E.O.) 12866, OIRA determines whether a regulatory action is significant and, therefore, subject to the requirements of E.O. 12866 and OMB review. Section 3(f) of E.O. 12866, as amended by E.O. 14094, 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 \$200 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 significant under Section 3(f)(1)); (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 E.O. 12866. Upon review, OMB has determined that this final rule is a significant regulatory action under

E.O. 12866.⁶ 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).

OIRA has made a determination that this action is not a significant regulatory action under section 3(f)(1) of E.O. 12866, as amended by E.O. 14094, because it is not likely to have an annual effect on the economy of \$200 million or more. Nor is this final standard a major rule under the Congressional Review Act because this rule will not result in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; nor (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. 5 U.S.C. 804(2). Details on the estimated cost-savings of this rule can be found in the economic analysis below.

E.O. 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. E.O. 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.

Because section 6(b)(5) of the OSH Act explicitly imposes the “to the extent feasible” limitation on the setting of health standards, OSHA is not permitted to use cost-benefit analysis to make its standards-setting decisions (see 29 U.S.C. 655(b)(5); *Cotton Dust*, 452 U.S. at 509). In addition to determining economic feasibility, OSHA estimates

⁶ <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=1218-AC93>.

the costs and benefits of its proposed and final rules to ensure compliance with other requirements such as those in E.O. 12866 and E.O. 13563.

In this FEA, OSHA estimates that the proposed amendments to the HCS would result in annualized net cost savings of \$29.8 million at a seven percent discount rate. Annualized at a three percent discount rate, OSHA estimates that the proposed amendments to the rule would lead to net cost savings of \$30.7 million per year. OSHA expects that the revisions to the HCS will 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.

The remainder of this FEA includes the following sections:

B. Need for Regulation

C. Profile of Affected Industries, Establishments, and Employees

D. Health and Safety Benefits and Unquantified Positive Economic Effects

E. Technological Feasibility

F. Compliance Costs and Cost Savings

G. Economic Feasibility and Impacts

H. Final Regulatory Flexibility Screening Analysis and FRFA Certification

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 HCS contains a set of requirements for chemical products, including mandatory hazard classification, labeling requirements, provisions for communication of detailed information (in SDSs), and label updating requirements. These requirements are based on Rev. 3 of the GHS, which was adopted by the UNSCEGHS in December 2008.

OSHA, in the 2021 Preliminary Economic Analysis (PEA), determined that the revisions to the HCS would make employers' hazard communication programs more worker-protective, efficient, and effective through standardizing practices nationally and internationally (86 FR 9590). In addition, OSHA found that aligning with the GHS Rev. 7 would continue to facilitate international trade, as a number of U.S. trading partners are also preparing to align with Rev. 7 (86 FR 9590-91).

The revisions to the HCS include the following notable changes:

- Maintaining 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.
- Addressing issues identified in implementing the 2012 HCS
 - Updating labeling requirements for small containers;
 - Updating labeling requirements for packaged containers that have been released for shipment or that constitute bulk shipping; and
 - Allowing the withholding of concentration ranges of substances for reasons related to trade secrets.

As discussed in Section VI.F., Compliance Costs and Cost Savings, of this FEA, the estimated costs and cost savings resulting from the final 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 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 changes to Appendices C and D); (2) the cost of management familiarization and other management-related costs (associated with all of the revisions to the standard);

(3) the cost of training employees as necessitated by the changes to the HCS (see paragraph (h)(1) of the 2012 HCS); (4) the cost savings resulting from the new released-for-shipment provision (revisions to paragraph (f)(11)); and (5) the cost savings from limiting labeling requirements for certain very small containers (proposed paragraph (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 changes to the HCS will maintain the uniformity of hazard information with the GHS and will, 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 (Document ID 0050). And 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.⁷

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

⁷ 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.

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 timely alignment with the GHS as it undergoes revision periodically. Additionally, in some cases (e.g., aerosols, desensitized explosives), Rev. 7 contains different hazard classes or classification criteria than the 2012 HCS, and it would be impermissible for a manufacturer to comply with Rev. 7 rather than the criteria in the existing HCS. 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 Rev. 7 as its adoption expands internationally.⁸ 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.⁹ Many

⁸ See UN, 2018, pp. 12-13 (Document ID 0040).

⁹ 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) (Document ID 0234). And 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 (Document ID 0235).

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 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 changes to the HCS will involve costs and cost savings mainly for manufacturers, importers, and distributors. Manufacturers and importers of chemicals will also achieve benefits, in part because they themselves benefit as both producers and users, and in part because 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 VI.D., Health and Safety Benefits and Unquantified Positive Economic Effects).

Of more significance to the concerns of the OSH Act, the changes will also provide health benefits from improved hazard classification and communication; although unquantified in this final rule, these benefits include reductions in worker illnesses, injuries, and fatalities (see additional discussion below in VI.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 whom have direct market relationships with each other, OSHA believes

maintaining a single, uniform standard will best achieve the full benefits available from a hazard communications system.

C. Profile of Affected Industries, Establishments, and Employees

In this section, OSHA presents a final profile of industries affected by this revision to the HCS. The profile data in this section are based upon the 2012 HCS FEA and the PEA supporting the 2021 HCS NPRM, updated in this FEA with the most recent data available.

As a first step, OSHA identifies the North American Industry Classification System (NAICS) industries affected by the changes to the HCS.¹⁰ 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.¹¹ 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)¹² and for “very small” entities, defined by OSHA as those with fewer than 20 employees, in each

¹⁰ For this FEA, OSHA used 2017 NAICS industry categorization and nomenclature. Although the 2017 NAICS categorization was updated in 2022, OSHA notes that all profile data presented in this FEA were published in 2022 or earlier years but are pre-2022 in content, and therefore were assigned 2017 NAICS IDs.

¹¹ 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 (Document ID 0047).

¹² According to the SBA, “The size standards are for the most part expressed in either millions of dollars (those preceded by “\$”) or number of employees (those without the “\$”). A size standard is the largest that a concern can be and still qualify as a small business for Federal Government programs. For the most part, size standards are the average annual receipts or the average employment of a firm. How to calculate average annual receipts and average employment of a firm can be found in 13 CFR § 121.104 and 13 CFR § 121.106, respectively” (SBA, 2019, Table of Small Business Size Standards - Effective Aug 19, 2019, Document ID 0225)). In December 2022, SBA published an update to the table of small business size standards. However, the schedule for this final HCS rulemaking did not allow for a timely adoption of the 2022 table.

affected industry (U.S. Census Bureau, 2020a, Document ID 0231; U.S. Census Bureau, 2020b, Document ID 0232).

The revisions to the HCS affect establishments in a variety of different industries in which employees are exposed to hazardous chemicals or in which hazardous chemicals are produced. The changes to the HCS do not change the overall list of affected industries or establishments. However, some changes specifically affect certain establishment groupings that manufacture aerosols, desensitized explosives, and flammable gases. Other changes 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 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 2012 version of the HCS. Therefore, OSHA believes that the revisions have little or no effect on whether specific establishments fall within the scope of the standard.

OSHA's estimates of the number of employees who will require new training under the revisions to the standard are based on BLS's (2023) Occupational Employment Statistics data for May 2022, 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 are affected by the revised requirements to reclassify aerosols, desensitized explosives, and flammable gases.¹³ (See the analysis and discussion of training costs below in VI.F., Compliance Costs and Cost Savings.)

¹³ The NAICS industries estimated to be affected by the revised 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, 2023). Occupational Employment Statistics - May 2022

Table VI-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 VI-2 and VI-3, respectively, provide parallel information for all affected business entities defined as small by the SBA¹⁵ and all affected very small business entities, defined by OSHA as those with fewer than 20 employees. The data in these tables update the estimates provided in the PEA in support of the 2021 HCS NPRM (Document ID 0258) and rely on the most recent comprehensive set of data (including revenues) available from the Bureau of Labor Statistics (BLS, 2023) and the U.S. Census Bureau (2022a; 2022b; 2022c).¹⁶

(Released April 25, 2023). Available at <https://www.bls.gov/oes/#data> (Accessed April 27, 2023) (Document ID 0482).

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 Document ID 0225.

In Table VI-2 in the PEA, the numbers shown for Total Employees and Employees in Covered Occupations (columns 5 and 6) erroneously understated the correct estimates. However, because OSHA’s underlying calculations utilized the correct estimates, the errors in that table did not affect compliance cost estimates or any other results derived in the PEA.

¹⁶ U.S. Census Bureau, Statistics of U.S. Businesses, 2017 (Document ID 0231; 0232).

Table VI-1: Characteristics of Industries Affected by OSHA's Revisions to the HCS - All Entities

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	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	15,086	18,589	437,428	22,116	4,950	6,137	7,410
211	Oil and Gas Extraction	4,950	6,139	108,128	7,410	4,950	6,137	7,410
211120	Crude Petroleum Extraction	4,250	4,944	75,596	5,181	4,250	4,944	5,181
211130	Natural Gas Extraction	700	1,195	32,532	2,229	700	1,193	2,229
31-33	Manufacturing	254,179	287,626	12,109,803	6,155,771	57,094	71,661	1,463,120
324	Petroleum and Coal Products Manufacturing	967	2,108	107,509	42,582	967	2,103	42,582
324110	Petroleum Refineries	83	175	64,334	25,482	83	175	25,482
324121	Asphalt Paving Mixture and Block Manufacturing	471	1,337	15,929	6,309	471	1,336	6,309
324122	Asphalt Shingle and Coating Materials Manufacturing	110	207	10,685	4,232	110	205	4,232
324191	Petroleum Lubricating Oil and Grease Manufacturing	240	306	13,253	5,249	240	305	5,249
324199	All Other Petroleum and Coal Products Manufacturing	63	83	3,308	1,310	63	82	1,310
325	Chemical Manufacturing	10,745	13,832	817,229	316,910	10,745	13,809	316,910
325110	Petrochemical Manufacturing	31	51	9,966	4,066	31	50	4,066
325120	Industrial Gas Manufacturing	78	496	12,781	5,216	78	495	5,216
325130	Synthetic Dye and Pigment Manufacturing	103	136	8,740	3,566	103	134	3,566
325180	Other Basic Inorganic Chemical Manufacturing	376	645	40,131	16,375	376	645	16,375
325193	Ethyl Alcohol Manufacturing	117	207	10,945	4,466	117	207	4,466
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	49	74	5,870	2,395	49	73	2,395
325199	All Other Basic Organic Chemical Manufacturing	608	837	67,055	27,362	608	837	27,362
325211	Plastics Material and Resin Manufacturing	856	1,154	82,409	33,627	856	1,154	33,627
325212	Synthetic Rubber Manufacturing	137	150	10,615	4,332	137	149	4,332
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	114	131	15,094	6,159	114	130	6,159
325311	Nitrogenous Fertilizer Manufacturing	165	204	6,353	2,593	165	201	2,593
325312	Phosphatic Fertilizer Manufacturing	44	70	6,144	2,507	44	70	2,507
325314	Fertilizer (Mixing Only) Manufacturing	371	494	9,682	3,950	371	494	3,950
325320	Pesticide and Other Agricultural Chemical Manufacturing	184	223	11,585	4,727	184	222	4,727
325411	Medicinal and Botanical Manufacturing	597	642	31,276	10,814	597	640	10,814
325412	Pharmaceutical Preparation Manufacturing	1,117	1,387	146,583	50,682	1,117	1,387	50,682
325413	In-Vitro Diagnostic Substance Manufacturing	189	250	29,082	10,055	189	250	10,055
325414	Biological Product (except Diagnostic) Manufacturing	276	371	58,859	20,351	276	371	20,351
325510	Paint and Coating Manufacturing	958	1,135	38,909	15,877	958	1,135	15,877
325520	Adhesive Manufacturing	401	561	25,514	10,411	401	560	10,411
325611	Soap and Other Detergent Manufacturing	631	699	28,475	11,619	631	699	11,619
325612	Polish and Other Sanitation Good Manufacturing	428	462	15,872	6,477	428	461	6,477

Table VI-1: Characteristics of Industries Affected by OSHA's Revisions to the HCS - All Entities

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
325613	Surface Active Agent Manufacturing	108	135	6,912	2,820	108	132	2,820
325620	Toilet Preparation Manufacturing	1,010	1,060	53,432	21,802	1,010	1,060	21,802
325910	Printing Ink Manufacturing	162	307	9,965	4,066	162	306	4,066
325920	Explosives Manufacturing	53	90	7,413	3,025	53	88	3,025
325991	Custom Compounding of Purchased Resins	347	429	20,597	8,404	347	429	8,404
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	163	175	7,569	3,089	163	174	3,089
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	1,072	1,257	39,401	16,077	1,072	1,256	16,077
326	Plastics and Rubber Products Manufacturing	9,370	11,951	796,520	477,579	9,370	11,939	477,579
326111	Plastics Bag and Pouch Manufacturing	262	333	32,737	19,359	262	332	19,359
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	310	404	34,079	20,153	310	403	20,153
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	388	494	35,030	20,715	388	493	20,715
326121	Unlaminated Plastics Profile Shape Manufacturing	324	376	19,835	11,730	324	375	11,730
326122	Plastics Pipe and Pipe Fitting Manufacturing	256	442	22,579	13,353	256	442	13,353
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	213	232	13,625	8,057	213	232	8,057
326140	Polystyrene Foam Product Manufacturing	306	430	27,028	15,983	306	429	15,983
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	459	674	32,028	18,940	459	672	18,940
326160	Plastics Bottle Manufacturing	194	473	33,312	19,700	194	472	19,700
326191	Plastics Plumbing Fixture Manufacturing	298	334	19,098	11,294	298	334	11,294
326199	All Other Plastics Product Manufacturing	4,965	5,950	386,178	228,368	4,965	5,950	228,368
326211	Tire Manufacturing (except Retreading)	84	136	46,699	29,786	84	136	29,786
326212	Tire Retreading	240	354	6,494	4,142	240	353	4,142
326220	Rubber and Plastics Hoses and Belting Manufacturing	186	264	20,229	12,902	186	263	12,902
326291	Rubber Product Manufacturing for Mechanical Use	336	400	33,512	21,375	336	399	21,375
326299	All Other Rubber Product Manufacturing	549	655	34,057	21,722	549	654	21,722
327	Nonmetallic Mineral Product Manufacturing	9,387	15,008	402,095	139,036	9,387	14,983	139,036
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	546	564	12,886	4,455	546	561	4,455
327120	Clay Building Material and Refractories Manufacturing	356	505	23,618	8,167	356	504	8,167
327211	Flat Glass Manufacturing	103	137	12,242	4,233	103	136	4,233
327212	Other Pressed and Blown Glass and Glassware Manufacturing	404	428	14,159	4,896	404	428	4,896
327213	Glass Container Manufacturing	37	74	13,979	4,834	37	71	4,834
327215	Glass Product Manufacturing Made of Purchased Glass	895	1,031	50,161	17,345	895	1,029	17,345
327310	Cement Manufacturing	88	193	13,321	4,606	88	193	4,606
327320	Ready-Mix Concrete Manufacturing	2,022	5,806	84,236	29,127	2,022	5,806	29,127
327331	Concrete Block and Brick Manufacturing	407	672	15,919	5,505	407	671	5,505

Table VI-1: Characteristics of Industries Affected by OSHA's Revisions to the HCS - All Entities

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
327332	Concrete Pipe Manufacturing	89	185	5,944	2,055	89	183	2,055
327390	Other Concrete Product Manufacturing	1,504	1,882	57,389	19,844	1,504	1,881	19,844
327410	Lime Manufacturing	33	105	4,755	1,645	33	104	1,645
327420	Gypsum Product Manufacturing	119	195	9,779	3,382	119	195	3,382
327910	Abrasive Product Manufacturing	244	290	12,866	4,448	244	288	4,448
327991	Cut Stone and Stone Product Manufacturing	1,954	2,016	31,514	10,897	1,954	2,011	10,897
327992	Ground or Treated Mineral and Earth Manufacturing	151	251	8,692	3,005	151	250	3,005
327993	Mineral Wool Manufacturing	165	246	15,381	5,318	165	244	5,318
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	270	428	15,254	5,274	270	428	5,274
331	Primary Metal Manufacturing	3,296	4,021	385,544	214,521	3,296	4,005	214,521
331110	Iron and Steel Mills and Ferroalloy Manufacturing	312	452	90,066	38,075	312	452	38,075
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	209	282	27,120	15,304	209	282	15,304
331221	Rolled Steel Shape Manufacturing	175	216	9,991	5,638	175	215	5,638
331222	Steel Wire Drawing	186	231	14,674	8,280	186	229	8,280
331313	Alumina Refining and Primary Aluminum Production	37	44	4,363	2,269	37	42	2,269
331314	Secondary Smelting and Alloying of Aluminum	64	87	5,951	3,095	64	85	3,095
331315	Aluminum Sheet, Plate, and Foil Manufacturing	67	92	20,283	10,551	67	92	10,551
331318	Other Aluminum Rolling, Drawing, and Extruding	199	267	32,158	16,728	199	266	16,728
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	118	133	8,093	4,440	118	133	4,440
331420	Copper Rolling, Drawing, Extruding, and Alloying	151	231	25,481	13,983	151	230	13,983
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	226	254	16,187	8,882	226	253	8,882
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	169	205	9,813	5,384	169	205	5,384
331511	Iron Foundries	260	305	35,153	23,720	260	305	23,720
331512	Steel Investment Foundries	95	115	16,123	10,879	95	114	10,879
331513	Steel Foundries (except Investment)	164	176	12,747	8,601	164	176	8,601
331523	Nonferrous Metal Die-Casting Foundries	344	381	32,606	22,002	344	380	22,002
331524	Aluminum Foundries (except Die-Casting)	281	301	14,014	9,456	281	300	9,456
331529	Other Nonferrous Metal Foundries (except Die-Casting)	239	249	10,721	7,234	239	246	7,234
339	Miscellaneous Manufacturing	23,329	24,846	553,452	272,492	23,329	24,822	272,492
339112	Surgical and Medical Instrument Manufacturing	1,099	1,283	117,812	59,621	1,099	1,283	59,621
339113	Surgical Appliance and Supplies Manufacturing	1,622	1,786	88,728	44,902	1,622	1,786	44,902
339114	Dental Equipment and Supplies Manufacturing	533	554	15,489	7,838	533	552	7,838
339115	Ophthalmic Goods Manufacturing	324	476	24,988	12,646	324	476	12,646

Table VI-1: Characteristics of Industries Affected by OSHA's Revisions to the HCS - All Entities

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
339116	Dental Laboratories	5,142	5,464	42,549	21,532	5,142	5,462	21,532
339910	Jewelry and Silverware Manufacturing	1,987	2,010	22,294	12,133	1,987	2,007	12,133
339920	Sporting and Athletic Goods Manufacturing	1,569	1,631	35,839	16,885	1,569	1,630	16,885
339930	Doll, Toy, and Game Manufacturing	507	515	6,268	2,953	507	513	2,953
339940	Office Supplies (except Paper) Manufacturing	413	442	11,930	5,621	413	440	5,621
339950	Sign Manufacturing	5,741	5,865	76,944	36,250	5,741	5,863	36,250
339991	Gasket, Packing, and Sealing Device Manufacturing	475	823	37,564	17,697	475	822	17,697
339992	Musical Instrument Manufacturing	576	597	11,829	5,573	576	594	5,573
339993	Fastener, Button, Needle, and Pin Manufacturing	99	106	4,042	1,904	99	104	1,904
339994	Broom, Brush, and Mop Manufacturing	155	170	9,620	4,532	155	170	4,532
339995	Burial Casket Manufacturing	79	94	3,660	1,725	79	91	1,725
339999	All Other Miscellaneous Manufacturing	3,008	3,030	43,896	20,680	3,008	3,029	20,680
42	Wholesale Trade	257,126	359,358	5,908,219	341,223	49,179	70,034	59,946
423	Merchant Wholesalers, Durable Goods	161,958	233,316	3,540,499	210,644	13,967	19,493	18,153
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	8,156	10,494	245,193	11,271	8,156	10,494	11,271
423840	Industrial Supplies Merchant Wholesalers	5,811	9,001	107,341	6,882	5,811	8,999	6,882
424	Merchant Wholesalers, Nondurable Goods	95,168	126,042	2,367,720	130,579	35,212	50,541	41,793
424210	Drugs and Druggists' Sundries Merchant Wholesalers	7,207	10,524	301,213	16,317	7,207	10,524	16,317
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	2,046	2,752	33,843	1,833	2,046	2,752	1,833
424690	Other Chemical and Allied Products Merchant Wholesalers	5,804	9,357	127,212	6,892	5,804	9,355	6,892
424710	Petroleum Bulk Stations and Terminals	2,172	3,740	67,737	3,670	2,172	3,738	3,670
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,830	2,451	34,350	1,861	1,830	2,451	1,861
424910	Farm Supplies Merchant Wholesalers	4,909	9,027	108,603	5,883	4,909	9,024	5,883
424950	Paint, Varnish, and Supplies Merchant Wholesalers	959	1,881	21,147	1,146	959	1,879	1,146
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,285	10,819	77,358	4,191	10,285	10,818	4,191
Total		6,177,430	7,881,456	152,337,433	9,650,843	111,223	147,832	1,530,476

Sources: U.S. Census Bureau, 2020a (Document ID 0231); U.S. Census Bureau, 2020b (Document ID 0232); U.S. Census Bureau, 2020c (Document ID 0227); U.S. Census Bureau, 2022a (Document ID 0476); U.S. Census Bureau, 2022b (Document ID 0477); U.S. Census Bureau, 2022c (Document ID 0478); BLS, 2023 (Document ID 0482); 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, and employees 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-2: Characteristics of Industries Affected by OSHA’s Revisions to the HCS – Small Entities

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	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	14,836	15,963	226,094	11,571	4,865	6,137	4,233
211	Oil and Gas Extraction	4,865	5,339	61,765	4,233	4,865	6,137	4,233
211120	Crude Petroleum Extraction	4,204	4,542	46,220	3,168	4,204	4,944	3,168
211130	Natural Gas Extraction	661	797	15,545	1,065	661	1,193	1,065
31-33	Manufacturing	244,858	255,997	5,695,270	2,944,151	54,194	71,661	679,479
324	Petroleum and Coal Products Manufacturing	831	1,115	26,696	10,575	831	2,103	10,575
324110	Petroleum Refineries	52	57	5,783	2,291	52	175	2,291
324121	Asphalt Paving Mixture and Block Manufacturing	421	638	7,890	3,125	421	1,336	3,125
324122	Asphalt Shingle and Coating Materials Manufacturing	95	117	3,415	1,353	95	205	1,353
324191	Petroleum Lubricating Oil and Grease Manufacturing	211	236	7,675	3,040	211	305	3,040
324199	All Other Petroleum and Coal Products Manufacturing	52	67	1,933	766	52	82	766
325	Chemical Manufacturing	9,806	10,781	334,713	130,983	9,806	13,809	130,983
325110	Petrochemical Manufacturing	15	16	766	312	15	50	312
325120	Industrial Gas Manufacturing	64	67	1,049	428	64	495	428
325130	Synthetic Dye and Pigment Manufacturing	90	95	3,576	1,460	90	134	1,460

Table VI-2: Characteristics of Industries Affected by OSHA’s Revisions to the HCS – Small Entities

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
325180	Other Basic Inorganic Chemical Manufacturing	310	451	16,461	6,717	310	645	6,717
325193	Ethyl Alcohol Manufacturing	103	139	6,071	2,478	103	207	2,478
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	32	33	957	391	32	73	391
325199	All Other Basic Organic Chemical Manufacturing	530	599	23,908	9,756	530	837	9,756
325211	Plastics Material and Resin Manufacturing	771	896	36,365	14,838	771	1,154	14,838
325212	Synthetic Rubber Manufacturing	112	119	5,319	2,170	112	149	2,170
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	90	99	6,112	2,494	90	130	2,494
325311	Nitrogenous Fertilizer Manufacturing	150	169	2,824	1,152	150	201	1,152
325312	Phosphatic Fertilizer Manufacturing	35	43	897	366	35	70	366
325314	Fertilizer (Mixing Only) Manufacturing	353	428	7,031	2,869	353	494	2,869
325320	Pesticide and Other Agricultural Chemical Manufacturing	165	175	5,078	2,072	165	222	2,072
325411	Medicinal and Botanical Manufacturing	567	585	19,199	6,638	567	640	6,638
325412	Pharmaceutical Preparation Manufacturing	1,045	1,099	50,061	17,309	1,045	1,387	17,309
325413	In-Vitro Diagnostic Substance Manufacturing	167	181	8,230	2,845	167	250	2,845
325414	Biological Product (except Diagnostic) Manufacturing	231	257	12,337	4,265	231	371	4,265
325510	Paint and Coating Manufacturing	924	991	22,451	9,161	924	1,135	9,161
325520	Adhesive Manufacturing	345	380	10,165	4,148	345	560	4,148
325611	Soap and Other Detergent Manufacturing	605	624	12,819	5,231	605	699	5,231
325612	Polish and Other Sanitation Good Manufacturing	409	420	10,924	4,458	409	461	4,458
325613	Surface Active Agent Manufacturing	92	100	2,903	1,185	92	132	1,185
325620	Toilet Preparation Manufacturing	981	1,008	32,391	13,217	981	1,060	13,217
325910	Printing Ink Manufacturing	145	228	4,180	1,706	145	306	1,706
325920	Explosives Manufacturing	38	45	1,996	815	38	88	815
325991	Custom Compounding of Purchased Resins	306	331	9,804	4,000	306	429	4,000
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	151	155	2,244	915	151	174	915
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	980	1,048	18,595	7,587	980	1,256	7,587
326	Plastics and Rubber Products Manufacturing	8,666	9,504	374,508	223,841	8,666	11,939	223,841
326111	Plastics Bag and Pouch Manufacturing	233	249	11,232	6,642	233	332	6,642
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	273	289	16,195	9,577	273	403	9,577
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	347	378	14,166	8,377	347	493	8,377
326121	Unlaminated Plastics Profile Shape Manufacturing	289	313	10,527	6,225	289	375	6,225
326122	Plastics Pipe and Pipe Fitting Manufacturing	222	273	9,232	5,459	222	442	5,459
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	182	188	5,885	3,480	182	232	3,480

Table VI-2: Characteristics of Industries Affected by OSHA’s Revisions to the HCS – Small Entities

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
326140	Polystyrene Foam Product Manufacturing	282	337	13,742	8,127	282	429	8,127
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	415	479	16,371	9,682	415	672	9,682
326160	Plastics Bottle Manufacturing	181	235	11,910	7,043	181	472	7,043
326191	Plastics Plumbing Fixture Manufacturing	290	302	12,919	7,640	290	334	7,640
326199	All Other Plastics Product Manufacturing	4,693	5,065	201,259	119,016	4,693	5,950	119,016
326211	Tire Manufacturing (except Retreading)	70	72	5,951	3,795	70	136	3,795
326212	Tire Retreading	224	261	3,660	2,334	224	353	2,334
326220	Rubber and Plastics Hoses and Belting Manufacturing	167	188	8,678	5,535	167	263	5,535
326291	Rubber Product Manufacturing for Mechanical Use	306	330	16,098	10,268	306	399	10,268
326299	All Other Rubber Product Manufacturing	492	545	16,683	10,641	492	654	10,641
327	Nonmetallic Mineral Product Manufacturing	8,987	10,995	204,353	70,661	8,987	14,983	70,661
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	534	540	7,583	2,622	534	561	2,622
327120	Clay Building Material and Refractories Manufacturing	326	370	13,190	4,561	326	504	4,561
327211	Flat Glass Manufacturing	91	95	2,802	969	91	136	969
327212	Other Pressed and Blown Glass and Glassware Manufacturing	388	400	6,950	2,403	388	428	2,403
327213	Glass Container Manufacturing	29	32	1,454	503	29	71	503
327215	Glass Product Manufacturing Made of Purchased Glass	861	896	22,144	7,657	861	1,029	7,657
327310	Cement Manufacturing	73	82	1,988	687	73	193	687
327320	Ready-Mix Concrete Manufacturing	1,958	3,369	49,657	17,170	1,958	5,806	17,170
327331	Concrete Block and Brick Manufacturing	382	505	9,774	3,380	382	671	3,380
327332	Concrete Pipe Manufacturing	83	111	3,224	1,115	83	183	1,115
327390	Other Concrete Product Manufacturing	1,451	1,594	35,769	12,369	1,451	1,881	12,369
327410	Lime Manufacturing	24	40	1,634	565	24	104	565
327420	Gypsum Product Manufacturing	109	111	1,152	398	109	195	398
327910	Abrasive Product Manufacturing	233	255	6,095	2,107	233	288	2,107
327991	Cut Stone and Stone Product Manufacturing	1,931	1,967	26,562	9,185	1,931	2,011	9,185
327992	Ground or Treated Mineral and Earth Manufacturing	123	155	3,533	1,221	123	250	1,221
327993	Mineral Wool Manufacturing	152	193	6,100	2,109	152	244	2,109
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	239	280	4,742	1,640	239	428	1,640
331	Primary Metal Manufacturing	2,932	3,174	159,358	91,967	2,932	4,005	91,967
331110	Iron and Steel Mills and Ferroalloy Manufacturing	281	311	21,262	8,988	281	452	8,988
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	175	214	14,595	8,236	175	282	8,236
331221	Rolled Steel Shape Manufacturing	154	172	6,459	3,645	154	215	3,645
331222	Steel Wire Drawing	166	190	8,814	4,974	166	229	4,974
331313	Alumina Refining and Primary Aluminum Production	27	27	1,083	563	27	42	563
331314	Secondary Smelting and Alloying of Aluminum	52	58	3,120	1,623	52	85	1,623

Table VI-2: Characteristics of Industries Affected by OSHA’s Revisions to the HCS – Small Entities

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
331315	Aluminum Sheet, Plate, and Foil Manufacturing	56	67	5,179	2,694	56	92	2,694
331318	Other Aluminum Rolling, Drawing, and Extruding	172	188	13,225	6,880	172	266	6,880
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	103	107	3,763	2,064	103	133	2,064
331420	Copper Rolling, Drawing, Extruding, and Alloying	129	152	12,069	6,622	129	230	6,622
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	201	204	4,932	2,707	201	253	2,707
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	151	171	6,285	3,448	151	205	3,448
331511	Iron Foundries	231	245	14,616	9,862	231	305	9,862
331512	Steel Investment Foundries	88	97	8,228	5,552	88	114	5,552
331513	Steel Foundries (except Investment)	145	150	6,909	4,662	145	176	4,662
331523	Nonferrous Metal Die-Casting Foundries	309	315	13,791	9,306	309	380	9,306
331524	Aluminum Foundries (except Die-Casting)	267	276	9,735	6,569	267	300	6,569
331529	Other Nonferrous Metal Foundries (except Die-Casting)	225	230	5,293	3,572	225	246	3,572
339	Miscellaneous Manufacturing	22,972	23,413	309,740	151,452	22,972	24,822	151,452
339112	Surgical and Medical Instrument Manufacturing	1,029	1,068	38,752	19,611	1,029	1,283	19,611
339113	Surgical Appliance and Supplies Manufacturing	1,562	1,662	40,262	20,375	1,562	1,786	20,375
339114	Dental Equipment and Supplies Manufacturing	522	532	8,903	4,506	522	552	4,506
339115	Ophthalmic Goods Manufacturing	306	318	6,195	3,135	306	476	3,135
339116	Dental Laboratories	5,126	5,186	33,119	16,760	5,126	5,462	16,760
339910	Jewelry and Silverware Manufacturing	1,972	1,981	14,748	8,026	1,972	2,007	8,026
339920	Sporting and Athletic Goods Manufacturing	1,549	1,581	25,747	12,131	1,549	1,630	12,131
339930	Doll, Toy, and Game Manufacturing	503	511	5,416	2,552	503	513	2,552
339940	Office Supplies (except Paper) Manufacturing	401	425	8,968	4,225	401	440	4,225
339950	Sign Manufacturing	5,708	5,801	65,652	30,931	5,708	5,863	30,931
339991	Gasket, Packing, and Sealing Device Manufacturing	434	450	11,990	5,649	434	822	5,649
339992	Musical Instrument Manufacturing	570	577	7,249	3,415	570	594	3,415
339993	Fastener, Button, Needle, and Pin Manufacturing	92	94	1,659	782	92	104	782
339994	Broom, Brush, and Mop Manufacturing	143	150	5,083	2,395	143	170	2,395
339995	Burial Casket Manufacturing	76	82	1,501	707	76	91	707
339999	All Other Miscellaneous Manufacturing	2,979	2,995	34,496	16,252	2,979	3,029	16,252
42	Wholesale Trade	246,092	265,707	2,434,457	142,374	46,958	70,034	22,658
423	Merchant Wholesalers, Durable Goods	154,855	168,729	1,530,441	92,225	13,355	19,493	6,077
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	7,907	8,110	61,627	2,832	7,907	10,494	2,832
423840	Industrial Supplies Merchant Wholesalers	5,448	6,001	50,617	3,245	5,448	8,999	3,245
424	Merchant Wholesalers, Nondurable Goods	91,237	96,978	904,016	50,149	33,603	50,541	16,581

Table VI-2: Characteristics of Industries Affected by OSHA’s Revisions to the HCS – Small Entities

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
424210	Drugs and Druggists’ Sundries Merchant Wholesalers	6,918	7,202	77,992	4,225	6,918	10,524	4,225
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	1,923	2,138	19,518	1,057	1,923	2,752	1,057
424690	Other Chemical and Allied Products Merchant Wholesalers	5,508	5,983	51,315	2,780	5,508	9,355	2,780
424710	Petroleum Bulk Stations and Terminals	1,929	2,349	33,857	1,834	1,929	3,738	1,834
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,671	1,775	15,660	848	1,671	2,451	848
424910	Farm Supplies Merchant Wholesalers	4,722	5,451	46,027	2,494	4,722	9,024	2,494
424950	Paint, Varnish, and Supplies Merchant Wholesalers	910	1,096	9,201	498	910	1,879	498
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,022	10,159	52,522	2,845	10,022	10,818	2,845
Total		6,059,071	6,395,386	61,636,251	4,014,137	106,017	114,529	706,370

Sources: U.S. Census Bureau, 2020a (Document ID 0231); U.S. Census Bureau, 2020b (Document ID 0232); U.S. Census Bureau, 2020c (Document ID 0227); U.S. Census Bureau, 2022a (Document ID 0476); U.S. Census Bureau, 2022b (Document ID 0477); U.S. Census Bureau, 2022c (Document ID 0478); BLS, 2023 (Document ID 0482); SBA, 2019 (Document ID 0472); and BEA, 2023 (Document ID 0480). 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, and employees 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-3: Characteristics of Industries Affected by OSHA's Revisions to the HCS – Entities With <20 Employees

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	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	12,463	12,552	46,813	2,439	4,348	4,389	999
211	Oil and Gas Extraction	4,348	4,389	14,575	999	4,348	4,389	999
211120	Crude Petroleum Extraction	3,825	3,860	12,414	851	3,825	3,860	851
211130	Natural Gas Extraction	523	529	2,161	148	523	529	148
31-33	Manufacturing	181,194	181,652	984,347	509,122	39,001	39,165	94,373
324	Petroleum and Coal Products Manufacturing	479	488	2,932	1,162	479	488	1,162
324110	Petroleum Refineries	24	25	147	58	24	25	58
324121	Asphalt Paving Mixture and Block Manufacturing	240	244	1,399	555	240	244	555
324122	Asphalt Shingle and Coating Materials Manufacturing	57	57	361	143	57	57	143
324191	Petroleum Lubricating Oil and Grease Manufacturing	126	128	871	345	126	128	345
324199	All Other Petroleum and Coal Products Manufacturing	32	34	154	61	32	34	61
325	Chemical Manufacturing	6,289	6,304	34,884	13,832	6,289	6,304	13,832
325110	Petrochemical Manufacturing	8	8	61	24	8	8	24
325120	Industrial Gas Manufacturing	51	51	272	111	51	51	111
325130	Synthetic Dye and Pigment Manufacturing	52	52	310	126	52	52	126
325180	Other Basic Inorganic Chemical Manufacturing	151	151	936	382	151	151	382
325193	Ethyl Alcohol Manufacturing	16	17	92	38	16	17	38
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	19	19	122	50	19	19	50
325199	All Other Basic Organic Chemical Manufacturing	283	284	1,605	655	283	284	655
325211	Plastics Material and Resin Manufacturing	352	352	2,525	1,030	352	352	1,030
325212	Synthetic Rubber Manufacturing	59	59	307	125	59	59	125
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	38	38	252	103	38	38	103
325311	Nitrogenous Fertilizer Manufacturing	109	109	624	254	109	109	254
325312	Phosphatic Fertilizer Manufacturing	10	10	80	33	10	10	33
325314	Fertilizer (Mixing Only) Manufacturing	241	242	1,393	569	241	242	569
325320	Pesticide and Other Agricultural Chemical Manufacturing	111	111	546	223	111	111	223
325411	Medicinal and Botanical Manufacturing	397	397	1,908	659	397	397	659
325412	Pharmaceutical Preparation Manufacturing	662	664	3,209	1,110	662	664	1,110
325413	In-Vitro Diagnostic Substance Manufacturing	93	95	557	192	93	95	192
325414	Biological Product (except Diagnostic) Manufacturing	139	139	792	274	139	139	274
325510	Paint and Coating Manufacturing	629	630	3,944	1,609	629	630	1,609
325520	Adhesive Manufacturing	215	216	1,424	581	215	216	581
325611	Soap and Other Detergent Manufacturing	464	464	2,469	1,008	464	464	1,008
325612	Polish and Other Sanitation Good Manufacturing	295	296	1,547	632	295	296	632
325613	Surface Active Agent Manufacturing	59	59	356	145	59	59	145
325620	Toilet Preparation Manufacturing	697	698	3,448	1,407	697	698	1,407

Table VI-3: Characteristics of Industries Affected by OSHA's Revisions to the HCS – Entities With <20 Employees

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
325910	Printing Ink Manufacturing	98	99	668	273	98	99	273
325920	Explosives Manufacturing	18	18	146	60	18	18	60
325991	Custom Compounding of Purchased Resins	184	184	1,133	463	184	184	463
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	120	122	479	195	120	122	195
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	719	720	3,679	1,501	719	720	1,501
326	Plastics and Rubber Products Manufacturing	4,794	4,801	31,239	18,687	4,794	4,801	18,687
326111	Plastics Bag and Pouch Manufacturing	115	115	806	477	115	115	477
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	108	108	749	443	108	108	443
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	189	189	1,197	708	189	189	708
326121	Unlaminated Plastics Profile Shape Manufacturing	151	151	917	542	151	151	542
326122	Plastics Pipe and Pipe Fitting Manufacturing	113	114	697	412	113	114	412
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	111	111	660	391	111	111	391
326140	Polystyrene Foam Product Manufacturing	149	149	1,063	629	149	149	629
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	221	221	1,623	960	221	221	960
326160	Plastics Bottle Manufacturing	67	67	399	236	67	67	236
326191	Plastics Plumbing Fixture Manufacturing	171	172	1,158	685	171	172	685
326199	All Other Plastics Product Manufacturing	2,682	2,687	17,402	10,291	2,682	2,687	10,291
326211	Tire Manufacturing (except Retreading)	43	43	217	138	43	43	138
326212	Tire Retreading	140	140	861	549	140	140	549
326220	Rubber and Plastics Hoses and Belting Manufacturing	90	90	519	331	90	90	331
326291	Rubber Product Manufacturing for Mechanical Use	153	153	1,017	649	153	153	649
326299	All Other Rubber Product Manufacturing	291	291	1,954	1,246	291	291	1,246
327	Nonmetallic Mineral Product Manufacturing	6,308	6,392	37,682	13,028	6,308	6,392	13,028
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	448	449	1,747	604	448	449	604
327120	Clay Building Material and Refractories Manufacturing	181	181	1,135	392	181	181	392
327211	Flat Glass Manufacturing	57	57	246	85	57	57	85
327212	Other Pressed and Blown Glass and Glassware Manufacturing	325	326	1,288	446	325	326	446
327213	Glass Container Manufacturing	20	20	76	26	20	20	26
327215	Glass Product Manufacturing Made of Purchased Glass	653	654	2,874	993	653	654	993
327310	Cement Manufacturing	49	50	286	99	49	50	99
327320	Ready-Mix Concrete Manufacturing	1,234	1,285	8,867	3,066	1,234	1,285	3,066
327331	Concrete Block and Brick Manufacturing	225	235	1,641	567	225	235	567
327332	Concrete Pipe Manufacturing	49	49	276	95	49	49	95
327390	Other Concrete Product Manufacturing	958	967	6,328	2,189	958	967	2,189
327410	Lime Manufacturing	12	13	78	27	12	13	27
327420	Gypsum Product Manufacturing	91	91	487	169	91	91	169

Table VI-3: Characteristics of Industries Affected by OSHA's Revisions to the HCS – Entities With <20 Employees

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
327910	Abrasive Product Manufacturing	147	147	1,063	367	147	147	367
327991	Cut Stone and Stone Product Manufacturing	1,541	1,547	9,273	3,206	1,541	1,547	3,206
327992	Ground or Treated Mineral and Earth Manufacturing	64	64	400	138	64	64	138
327993	Mineral Wool Manufacturing	87	88	663	229	87	88	229
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	167	169	954	330	167	169	330
331	Primary Metal Manufacturing	1,533	1,538	9,471	5,685	1,533	1,538	5,685
331110	Iron and Steel Mills and Ferroalloy Manufacturing	174	174	734	310	174	174	310
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	70	70	339	192	70	70	192
331221	Rolled Steel Shape Manufacturing	77	77	484	273	77	77	273
331222	Steel Wire Drawing	87	87	538	303	87	87	303
331313	Alumina Refining and Primary Aluminum Production	19	19	82	42	19	19	42
331314	Secondary Smelting and Alloying of Aluminum	20	20	106	55	20	20	55
331315	Aluminum Sheet, Plate, and Foil Manufacturing	30	30	159	82	30	30	82
331318	Other Aluminum Rolling, Drawing, and Extruding	76	76	460	239	76	76	239
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	64	64	333	183	64	64	183
331420	Copper Rolling, Drawing, Extruding, and Alloying	41	41	294	162	41	41	162
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	142	143	804	441	142	143	441
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	82	85	504	276	82	85	276
331511	Iron Foundries	101	101	776	523	101	101	523
331512	Steel Investment Foundries	24	24	241	162	24	24	162
331513	Steel Foundries (except Investment)	73	74	533	360	73	74	360
331523	Nonferrous Metal Die-Casting Foundries	167	167	1,209	816	167	167	816
331524	Aluminum Foundries (except Die-Casting)	146	146	975	658	146	146	658
331529	Other Nonferrous Metal Foundries (except Die-Casting)	140	140	900	608	140	140	608
339	Miscellaneous Manufacturing	19,598	19,642	85,873	41,979	19,598	19,642	41,979
339112	Surgical and Medical Instrument Manufacturing	689	689	3,787	1,916	689	689	1,916
339113	Surgical Appliance and Supplies Manufacturing	1,138	1,149	6,099	3,086	1,138	1,149	3,086
339114	Dental Equipment and Supplies Manufacturing	447	447	1,980	1,002	447	447	1,002
339115	Ophthalmic Goods Manufacturing	240	240	1,225	620	240	240	620
339116	Dental Laboratories	4,792	4,796	17,350	8,780	4,792	4,796	8,780
339910	Jewelry and Silverware Manufacturing	1,795	1,797	6,260	3,407	1,795	1,797	3,407
339920	Sporting and Athletic Goods Manufacturing	1,278	1,280	6,116	2,881	1,278	1,280	2,881
339930	Doll, Toy, and Game Manufacturing	442	442	1,803	849	442	442	849
339940	Office Supplies (except Paper) Manufacturing	320	329	1,638	772	320	329	772
339950	Sign Manufacturing	4,918	4,931	22,583	10,640	4,918	4,931	10,640

Table VI-3: Characteristics of Industries Affected by OSHA's Revisions to the HCS – Entities With <20 Employees

NAICS Code	Industry	Total Firms[a]	Total Establishments[a]	Total Employees [a]	Employees in Covered Occupations [a]	Affected Firms	Affected Establishments	Affected Employees in Covered Occupations
339991	Gasket, Packing, and Sealing Device Manufacturing	269	269	1,944	916	269	269	916
339992	Musical Instrument Manufacturing	495	495	2,209	1,041	495	495	1,041
339993	Fastener, Button, Needle, and Pin Manufacturing	71	71	308	146	71	71	146
339994	Broom, Brush, and Mop Manufacturing	90	92	569	268	90	92	268
339995	Burial Casket Manufacturing	59	60	305	144	59	60	144
339999	All Other Miscellaneous Manufacturing	2,555	2,555	11,697	5,511	2,555	2,555	5,511
42	Wholesale Trade	210,300	213,656	930,094	54,911	40,603	41,200	8,984
423	Merchant Wholesalers, Durable Goods	132,271	134,599	601,096	36,518	11,738	11,882	2,551
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	7,146	7,180	24,729	1,137	7,146	7,180	1,137
423840	Industrial Supplies Merchant Wholesalers	4,592	4,702	22,051	1,414	4,592	4,702	1,414
424	Merchant Wholesalers, Nondurable Goods	78,029	79,057	328,998	18,393	28,865	29,318	6,433
424210	Drugs and Druggists' Sundries Merchant Wholesalers	5,903	5,939	23,756	1,287	5,903	5,939	1,287
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	1,630	1,679	8,014	434	1,630	1,679	434
424690	Other Chemical and Allied Products Merchant Wholesalers	4,725	4,828	20,977	1,136	4,725	4,828	1,136
424710	Petroleum Bulk Stations and Terminals	1,226	1,291	8,025	435	1,226	1,291	435
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,319	1,335	5,665	307	1,319	1,335	307
424910	Farm Supplies Merchant Wholesalers	3,952	4,035	17,797	964	3,952	4,035	964
424950	Paint, Varnish, and Supplies Merchant Wholesalers	758	812	3,809	206	758	812	206
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	9,352	9,399	30,715	1,664	9,352	9,399	1,664
Total		5,395,869	5,439,335	21,242,394	855,818	83,952	84,754	104,356

Sources: U.S. Census Bureau, 2020a (Document ID 0231); U.S. Census Bureau, 2020b (Document ID 0232); U.S. Census Bureau, 2020c (Document ID 0227); U.S. Census Bureau, 2022a (Document ID 0476); U.S. Census Bureau, 2022b (Document ID 0477); U.S. Census Bureau, 2022c (Document ID 0478); BLS, 2023 (Document ID 0482); 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, and employees 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 PEA and Initial Regulatory Flexibility Analysis in the NPRM did not include the construction industry (NAICS 23) within its scope and in written comments the Construction Industry Safety Coalition (CISC) questioned the basis for the exclusion (Document ID 0335, pp. 2-3). In response, OSHA notes that the scope and application of the final standard primarily refers to manufacturers, importers, and distributors. OSHA anticipates that the compliance burden of this rule, and therefore the economic impacts, will primarily be borne by the general industry sectors noted above, and although the construction industry is not exempted from the scope and application of the final standard, any economic impact upon construction employers will likely take the form of downstream effects as consumers of affected chemical products.

To the extent that there are costs for the construction industry associated with training workers on new SDSs, OSHA believes that these costs will be de minimis. As OSHA notes below in the section on training costs, the agency estimated training costs for health and safety personnel, but not users of chemicals with new hazards because OSHA concluded that there would only be a trivial amount of training associated with reclassification for those users. OSHA's understanding of the construction industry is that there are relatively few employees who are affected by the HCS standard who are not users of the chemicals, and therefore has not taken costs for that industry.

The costs and cost savings of some of the revised 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 that appears later in this FEA, Table VI-4 presents OSHA's estimate of the number of labels per container by container size (and type).¹⁷ Starting with the fifth row (container type: 250

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

ml container), Table VI-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 17639-40), 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 introduced in (new) paragraph (f)(12). Also, the term “jug” has been changed to the more generic term “container.” The figures in Table VI-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.

1 liter. In the PEA, OSHA requested public comment on the label-container specifications presented in Table VI-4. OSHA received no comments addressing the specifications proposed in Table VI-4; therefore, in this FEA Table VI-4 remains unchanged from its preliminary appearance.

Table VI-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 VI.F., Compliance Costs and Cost Savings, it has been 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 the PEA, the terms “electronic templates” and “electronic files” were used interchangeably with, and as proxies for, the term “SDS.” All three terms refer to electronic files that are used to generate SDSs and labels. Table VI-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’s estimate of the total number of SDSs per NAICS industry, as presented in Table VI-5, was developed by its contractor to support 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 VI-5).

¹⁸ Technical and analytical support for the PEA and this FEA was provided by Eastern Research Group, Inc. (ERG) 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.

Table VI-5: Labels and SDSs Affected by OSHA's 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	190,737,945	56,998,626	58,845	190,737,945	0	58,845
211	Oil and Gas Extraction	190,737,945	56,998,626	58,845	190,737,945	0	58,845
211120	Crude Petroleum Extraction	6,407,790	0	41,370	6,407,790	0	41,370
211130	Natural Gas Extraction	184,330,155	56,998,626	17,475	184,330,155	0	17,475
31-33	Manufacturing	1,256,285,400	138,650,447	1,480,079	1,231,754,477	29,724,752	1,394,929
324	Petroleum and Coal Products Manufacturing	32,223,390	0	874,909	32,223,390	0	874,909
324110	Petroleum Refineries	30,710,191	0	20,680	30,710,191	0	20,680
324121	Asphalt Paving Mixture and Block Manufacturing	562,399	0	130,585	562,399	0	130,585
324122	Asphalt Shingle and Coating Materials Manufacturing	77,731	0	16,995	77,731	0	16,995
324191	Petroleum Lubricating Oil and Grease Manufacturing	687,175	0	701,794	687,175	0	701,794
324199	All Other Petroleum and Coal Products Manufacturing	185,895	0	4,855	185,895	0	4,855
325	Chemical Manufacturing	1,182,704,155	138,650,447	482,749	1,182,704,155	29,724,752	482,749
325110	Petrochemical Manufacturing	101,114,143	31,266,546	4,735	101,114,143	0	4,735
325120	Industrial Gas Manufacturing	17,249,456	5,333,882	4,458	17,249,456	0	4,458
325130	Synthetic Dye and Pigment Manufacturing	11,553,319	3,572,521	3,486	11,553,319	0	3,486
325180	Other Basic Inorganic Chemical Manufacturing	55,880,535	17,279,396	4,852	55,880,535	6,911,758	4,852
325193	Ethyl Alcohol Manufacturing	5,038,676	0	4,835	5,038,676	0	4,835
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	35,391,818	0	3,478	35,391,818	0	3,478
325199	All Other Basic Organic Chemical Manufacturing	131,647,121	40,707,962	30,008	131,647,121	16,283,185	30,008
325211	Plastics Material and Resin Manufacturing	6,936,348	0	114,766	6,936,348	0	114,766
325212	Synthetic Rubber Manufacturing	702,464	0	1,628	702,464	0	1,628
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	1,343,499	0	196	1,343,499	0	196
325311	Nitrogenous Fertilizer Manufacturing	4,513,772	0	261	4,513,772	0	261
325312	Phosphatic Fertilizer Manufacturing	10,414,581	3,220,400	120	10,414,581	0	120
325314	Fertilizer (Mixing Only) Manufacturing	3,918,250	0	3,924	3,918,250	0	3,924
325320	Pesticide and Other Agricultural Chemical Manufacturing	24,849,634	7,684,011	4,824	24,849,634	0	4,824
325411	Medicinal and Botanical Manufacturing	20,720,549	6,407,215	5,830	20,720,549	2,562,886	5,830
325412	Pharmaceutical Preparation Manufacturing	28,326,493	7,477,924	16,560	28,326,493	2,991,169	16,560
325413	In-Vitro Diagnostic Substance Manufacturing	2,153,945	568,621	32,276	2,153,945	227,448	32,276
325414	Biological Product (except Diagnostic) Manufacturing	7,086,482	1,870,764	3,807	7,086,482	748,305	3,807
325510	Paint and Coating Manufacturing	134,121,161	0	71,805	134,121,161	0	71,805
325520	Adhesive Manufacturing	77,133,673	0	29,880	77,133,673	0	29,880
325611	Soap and Other Detergent Manufacturing	42,885,953	13,261,207	18,500	42,885,953	0	18,500
325612	Polish and Other Sanitation Good Manufacturing	29,763,617	0	11,037	29,763,617	0	11,037
325613	Surface Active Agent Manufacturing	39,128,389	0	5,505	39,128,389	0	5,505
325620	Toilet Preparation Manufacturing	205,896,455	0	17,926	205,896,455	0	17,926

Table VI-5: Labels and SDSs Affected by OSHA’s 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]
325910	Printing Ink Manufacturing	19,389,593	0	29,967	19,389,593	0	29,967
325920	Explosives Manufacturing	12,574,669	0	2,856	12,574,669	0	2,856
325991	Custom Compounding of Purchased Resins	885,863	0	4,303	885,863	0	4,303
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	27,774,565	0	1,231	27,774,565	0	1,231
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	124,309,132	0	49,695	124,309,132	0	49,695
339	Miscellaneous Manufacturing	16,826,932	0	37,271	16,826,932	0	37,271
339112	Surgical and Medical Instrument Manufacturing	4,592,056	0	2,990	4,592,056	0	2,990
339113	Surgical Appliance and Supplies Manufacturing	3,959,209	0	3,308	3,959,209	0	3,308
339114	Dental Equipment and Supplies Manufacturing	539,771	0	844	539,771	0	844
339115	Ophthalmic Goods Manufacturing	680,942	0	1,270	680,942	0	1,270
339116	Dental Laboratories	525,011	0	7,146	525,011	0	7,146
339910	Jewelry and Silverware Manufacturing	721,223	0	2,391	721,223	0	2,391
339920	Sporting and Athletic Goods Manufacturing	1,025,637	0	2,417	1,025,637	0	2,417
339930	Doll, Toy, and Game Manufacturing	167,436	0	648	167,436	0	648
339940	Office Supplies (except Paper) Manufacturing	335,748	0	711	335,748	0	711
339950	Sign Manufacturing	1,350,496	0	7,498	1,350,496	0	7,498
339991	Gasket, Packing, and Sealing Device Manufacturing	1,127,469	0	2,634	1,127,469	0	2,634
339992	Musical Instrument Manufacturing	212,998	0	819	212,998	0	819
339993	Fastener, Button, Needle, and Pin Manufacturing	98,351	0	201	98,351	0	201
339994	Broom, Brush, and Mop Manufacturing	302,399	0	365	302,399	0	365
339995	Burial Casket Manufacturing	57,814	0	191	57,814	0	191
339999	All Other Miscellaneous Manufacturing	1,130,371	0	3,838	1,130,371	0	3,838
Total							
Total	Total	2,219,599,486	195,649,073	1,538,924	1,422,492,422	29,724,752	1,453,774

Sources: U.S. Census Bureau, 2022a (Document ID 0476); U.S. Census Bureau, 2022b (Document ID 0477); U.S. Census Bureau, 2022c (Document ID 0478); BLS, 2023 (Document ID 0482); 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” 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 preliminary estimate of the number of labels per NAICS industry was 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, were summarized in the PEA 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. (86 FR 9610)

The label analysis in the PEA began 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).

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 the PEA, the final 2017 CFS data was not yet available. Therefore, 2012 CFS data was the most recent information

available. OSHA requested public comments, and received none, on the estimated percentages for the transported goods identified as hazardous non-consumer products in the preliminary profile. For this FEA, OSHA has revised the preliminary percentages of hazardous non-consumer products to reflect data from the 2017 CFS (U.S. Census Bureau, 2020d, Document ID 0474), which is the most recent available.

The CFS-based percentage estimates are used in conjunction with another CFS dataset (U.S. Census Bureau, 2020e, Document ID 0475) 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, and no commenters provided data that contradicted this approach. 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 were 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 VI-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 (2022) 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 VI-5.²⁰

²⁰ 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 VI-4, the analysis led to an estimate of the total number of labels (600,645,446)

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 labels on very small containers are shown in Column 4 of Table VI-5.

Not every SDS and label, and not every label on very small containers, would be affected by the rule. Only SDSs and labels for certain products (aerosols, desensitized explosives, and flammable gases) would be affected by the new classification criteria. And 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 paragraph (f)(12)(iii), only a product identifier would be required on 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, although the immediate outer packaging would need to include the full label. Thus, in addition to the estimated total number of SDSs, labels, and labels on very small containers, Table VI-5 shows the number of each estimated to be affected by the revised standard.²¹

required by all SCTG Code 20 manufacturers (see Document ID 0481, tab “Labels per NAICS”, cell O11). The percentage of receipts (30.7 percent) for NAICS 211130 relative to total receipts for SCTG Code 20 employers (Document ID 0481, tab “Labels per NAICS”, cells N11-P11) was then applied to this total number of labels. The result, shown in Column 3 in Table VI-5, is an estimated 184,330,155 labels for NAICS 211130. Note that multiplying factors may yield a slightly different total due to rounding of the factors in the table (but not in the spreadsheet).

²¹ Note that OSHA’s cost estimates for reclassifying affected chemicals and revising the corresponding SDSs and labels to achieve consistency with the reclassification (per 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 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 final rule. They are not based on the number of labels or SDSs produced or used. The number of labels and labels affected by revision in the tables provided represent the total number produced; that number is provided to include all relevant information even though it is not being used in calculating costs.

Although OSHA preliminarily determined that this methodology remains sound, in the NPRM the agency invited public comment on the reasonableness of this methodology for the current analysis and on its understanding about the use of electronic template files to create SDSs and labels. One commenter, Ameren Corporation (Ameren), directly addressed OSHA's nomenclature for SDS electronic files and the ability of stakeholders to understand the agency's preliminary methodology for estimating SDSs and labels, with the comment, "Ameren agrees with OSHA's understanding of electronic template files to create SDSs and labels" (Document ID 0309, p. 5). Another commenter, Michele Sullivan, noted that "every HCS SDS will need to be revised" due to the changes in Appendix D. As shown in Table VI-5, OSHA already estimates that almost every SDS will be revised due to the provisions in the final rule.

Responsible Industry for a Sound Environment (RISE) and CropLife America (CropLife) noted that the labeling requirements of the HCS do not apply to pesticides that are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), but Table VI-5 lists over 23 million labels affected by this revision for the Pesticide and Other Agricultural Manufacturing industry. RISE and CropLife requested clarification on this apparent conflict (Document ID 0343, pp. 3-4).

In response to the concerns expressed by the two trade associations about the number of pesticide labels affected by the revised HCS, OSHA notes that the agency lacks data indicating what proportion of chemicals produced by the Pesticide and Other Agricultural Manufacturing industry fall within FIFRA's definition of pesticide, which is the category of chemicals exempt from the HCS. The agency has chosen to err on the side of caution and to the extent that the preliminary estimate overstates the actual number of labels affected, any such differential would only over-estimate the costs of the rule. This assumption has no bearing on the scope of the HCS and the HCS is clear that pesticides that meet FIFRA's definition are exempt.

Several commenters described the common practices found within their industry for updating SDSs and labels, which support OSHA's understanding of the use of electronic templates for SDSs and labels. The Independent Lubricant Manufacturers Association (ILMA) surveyed their membership on several of the technical and economic issues raised in the NPRM. Based on 16 responses to the ILMA survey, all from the association's manufacturing members, ILMA stated that "[t]he majority of ILMA members responding to the survey indicated that they rely on third-party services to generate SDS and labels, whether it be software or contracted work" (Document ID 0460, Att. 1, p. 5).

On the topic of the outsourcing of SDS software development, the National Association of Chemical Distributors (NACD) polled a few of their member companies on how employers process SDSs. At least one member company noted that they outsourced the creation of their SDSs to a firm that specializes in that work because "like many NACD members, most of whom are small businesses," their staff do not have time to do that work (Document ID 0446, p. 2).

The Hach Company (Hach), a manufacturer of chemical reagents and instruments for water quality analysis, indicated during testimony at the public hearing and in a post-hearing comment that it used software it purchased from an outside vendor to create its SDSs (Document ID 0427, pp. 1-2). Tables VI-6 and VI-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.

Table VI-6: Labels and SDSs Affected by OSHA's 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	71,707,638	21,283,441	49,661	71,707,638	0	49,661
211	Oil and Gas Extraction	71,707,638	21,283,441	49,661	71,707,638	0	49,661
211120	Crude Petroleum Extraction	2,878,261	0	38,006	2,878,261	0	38,006
211130	Natural Gas Extraction	68,829,377	21,283,441	11,655	68,829,377	0	11,655
31-33	Manufacturing	376,743,712	31,181,195	1,000,228	367,358,533	8,926,006	944,175
324	Petroleum and Coal Products Manufacturing	2,983,915	0	585,785	2,983,915	0	585,785
324110	Petroleum Refineries	2,389,460	0	6,736	2,389,460	0	6,736
324121	Asphalt Paving Mixture and Block Manufacturing	247,100	0	25,735	247,100	0	25,735
324122	Asphalt Shingle and Coating Materials Manufacturing	21,823	0	9,606	21,823	0	9,606
324191	Petroleum Lubricating Oil and Grease Manufacturing	232,410	0	541,253	232,410	0	541,253
324199	All Other Petroleum and Coal Products Manufacturing	93,122	0	2,455	93,122	0	2,455
325	Chemical Manufacturing	357,839,621	31,181,195	326,495	357,839,621	8,926,006	326,495
325110	Petrochemical Manufacturing	5,169,175	1,598,414	1,485	5,169,175	0	1,485
325120	Industrial Gas Manufacturing	1,404,505	434,301	602	1,404,505	0	602
325130	Synthetic Dye and Pigment Manufacturing	4,318,261	1,335,294	2,435	4,318,261	0	2,435
325180	Other Basic Inorganic Chemical Manufacturing	20,794,930	6,430,215	3,393	20,794,930	2,572,086	3,393
325193	Ethyl Alcohol Manufacturing	2,673,757	0	3,247	2,673,757	0	3,247
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	3,476,938	0	1,551	3,476,938	0	1,551
325199	All Other Basic Organic Chemical Manufacturing	34,651,718	10,715,015	21,475	34,651,718	4,286,006	21,475
325211	Plastics Material and Resin Manufacturing	1,800,326	0	89,108	1,800,326	0	89,108
325212	Synthetic Rubber Manufacturing	344,404	0	1,292	344,404	0	1,292
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	433,373	0	148	433,373	0	148
325311	Nitrogenous Fertilizer Manufacturing	1,340,177	0	216	1,340,177	0	216
325312	Phosphatic Fertilizer Manufacturing	1,252,542	387,312	74	1,252,542	0	74
325314	Fertilizer (Mixing Only) Manufacturing	2,689,237	0	2,274	2,689,237	0	2,274
325320	Pesticide and Other Agricultural Chemical Manufacturing	7,239,361	2,238,558	3,786	7,239,361	0	3,786
325411	Medicinal and Botanical Manufacturing	10,743,725	3,322,178	5,312	10,743,725	1,328,871	5,312
325412	Pharmaceutical Preparation Manufacturing	5,101,262	1,346,684	13,121	5,101,262	538,674	13,121
325413	In-Vitro Diagnostic Substance Manufacturing	513,013	135,430	23,368	513,013	54,172	23,368
325414	Biological Product (except Diagnostic) Manufacturing	1,384,493	365,493	2,637	1,384,493	146,197	2,637
325510	Paint and Coating Manufacturing	47,257,856	0	62,695	47,257,856	0	62,695
325520	Adhesive Manufacturing	22,760,134	0	8,160	22,760,134	0	8,160
325611	Soap and Other Detergent Manufacturing	9,288,851	2,872,301	16,515	9,288,851	0	16,515
325612	Polish and Other Sanitation Good Manufacturing	17,821,361	0	10,034	17,821,361	0	10,034
325613	Surface Active Agent Manufacturing	13,065,722	0	4,078	13,065,722	0	4,078

Table VI-6: Labels and SDSs Affected by OSHA's 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]
325620	Toilet Preparation Manufacturing	81,849,662	0	17,047	81,849,662	0	17,047
325910	Printing Ink Manufacturing	6,852,549	0	10,217	6,852,549	0	10,217
325920	Explosives Manufacturing	2,954,563	0	1,428	2,954,563	0	1,428
325991	Custom Compounding of Purchased Resins	352,524	0	1,363	352,524	0	1,363
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	3,544,283	0	1,090	3,544,283	0	1,090
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	46,760,919	0	18,345	46,760,919	0	18,345
339	Miscellaneous Manufacturing	6,534,998	0	31,894	6,534,998	0	31,894
339112	Surgical and Medical Instrument Manufacturing	1,155,424	0	2,489	1,155,424	0	2,489
339113	Surgical Appliance and Supplies Manufacturing	1,019,245	0	3,078	1,019,245	0	3,078
339114	Dental Equipment and Supplies Manufacturing	254,759	0	810	254,759	0	810
339115	Ophthalmic Goods Manufacturing	127,208	0	848	127,208	0	848
339116	Dental Laboratories	365,067	0	5,756	365,067	0	5,756
339910	Jewelry and Silverware Manufacturing	367,714	0	2,246	367,714	0	2,246
339920	Sporting and Athletic Goods Manufacturing	616,709	0	2,343	616,709	0	2,343
339930	Doll, Toy, and Game Manufacturing	123,625	0	628	123,625	0	628
339940	Office Supplies (except Paper) Manufacturing	232,160	0	684	232,160	0	684
339950	Sign Manufacturing	1,077,650	0	7,178	1,077,650	0	7,178
339991	Gasket, Packing, and Sealing Device Manufacturing	258,541	0	769	258,541	0	769
339992	Musical Instrument Manufacturing	115,377	0	792	115,377	0	792
339993	Fastener, Button, Needle, and Pin Manufacturing	40,981	0	178	40,981	0	178
339994	Broom, Brush, and Mop Manufacturing	142,864	0	265	142,864	0	265
339995	Burial Casket Manufacturing	18,605	0	167	18,605	0	167
339999	All Other Miscellaneous Manufacturing	619,067	0	3,663	619,067	0	3,663
Total							
Total	Total	620,011,140	52,464,635	1,049,889	439,066,171	8,926,006	993,836

Sources: U.S. Census Bureau, 2022a (Document ID 0476); U.S. Census Bureau, 2022b (Document ID 0477); U.S. Census Bureau, 2022c (Document ID 0478); BLS, 2023 (Document ID 0482); 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" 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-7: Labels and SDSs Affected by OSHA's 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	3,780,599	1,081,704	21,945	3,780,599	0	21,945
211	Oil and Gas Extraction	3,780,599	1,081,704	21,945	3,780,599	0	21,945
211120	Crude Petroleum Extraction	282,433	0	19,300	282,433	0	19,300
211130	Natural Gas Extraction	3,498,166	1,081,704	2,645	3,498,166	0	2,645
31-33	Manufacturing	39,087,365	2,064,543	88,647	38,368,102	543,038	75,916
324	Petroleum and Coal Products Manufacturing	84,277	0	29,200	84,277	0	29,200
324110	Petroleum Refineries	8,813	0	250	8,813	0	250
324121	Asphalt Paving Mixture and Block Manufacturing	48,940	0	2,440	48,940	0	2,440
324122	Asphalt Shingle and Coating Materials Manufacturing	2,027	0	570	2,027	0	570
324191	Petroleum Lubricating Oil and Grease Manufacturing	18,938	0	25,600	18,938	0	25,600
324199	All Other Petroleum and Coal Products Manufacturing	5,559	0	340	5,559	0	340
325	Chemical Manufacturing	36,968,440	2,064,543	27,074	36,968,440	543,038	27,074
325110	Petrochemical Manufacturing	85,646	26,484	80	85,646	0	80
325120	Industrial Gas Manufacturing	184,472	57,042	102	184,472	0	102
325130	Synthetic Dye and Pigment Manufacturing	273,613	84,607	416	273,613	0	416
325180	Other Basic Inorganic Chemical Manufacturing	892,075	275,848	604	892,075	110,339	604
325193	Ethyl Alcohol Manufacturing	55,637	0	85	55,637	0	85
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	390,109	0	133	390,109	0	133
325199	All Other Basic Organic Chemical Manufacturing	2,114,626	653,885	1,988	2,114,626	261,554	1,988
325211	Plastics Material and Resin Manufacturing	76,844	0	1,760	76,844	0	1,760
325212	Synthetic Rubber Manufacturing	21,489	0	118	21,489	0	118
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	18,486	0	38	18,486	0	38
325311	Nitrogenous Fertilizer Manufacturing	267,430	0	109	267,430	0	109
325312	Phosphatic Fertilizer Manufacturing	88,838	27,470	10	88,838	0	10
325314	Fertilizer (Mixing Only) Manufacturing	424,715	0	484	424,715	0	484
325320	Pesticide and Other Agricultural Chemical Manufacturing	660,701	204,302	777	660,701	0	777
325411	Medicinal and Botanical Manufacturing	993,779	307,297	1,985	993,779	122,919	1,985
325412	Pharmaceutical Preparation Manufacturing	329,859	87,080	3,320	329,859	34,832	3,320
325413	In-Vitro Diagnostic Substance Manufacturing	29,991	7,917	950	29,991	3,167	950
325414	Biological Product (except Diagnostic) Manufacturing	96,855	25,569	417	96,855	10,228	417
325510	Paint and Coating Manufacturing	7,303,250	0	3,150	7,303,250	0	3,150
325520	Adhesive Manufacturing	3,089,152	0	1,080	3,089,152	0	1,080
325611	Soap and Other Detergent Manufacturing	992,956	307,042	2,320	992,956	0	2,320
325612	Polish and Other Sanitation Good Manufacturing	1,984,097	0	592	1,984,097	0	592
325613	Surface Active Agent Manufacturing	759,097	0	295	759,097	0	295
325620	Toilet Preparation Manufacturing	7,716,412	0	1,396	7,716,412	0	1,396
325910	Printing Ink Manufacturing	1,020,465	0	495	1,020,465	0	495

Table VI-7: Labels and SDSs Affected by OSHA's 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]
325920	Explosives Manufacturing	212,834	0	36	212,834	0	36
325991	Custom Compounding of Purchased Resins	35,539	0	368	35,539	0	368
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	599,733	0	366	599,733	0	366
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	6,249,739	0	3,600	6,249,739	0	3,600
339	Miscellaneous Manufacturing	1,315,385	0	19,642	1,315,385	0	19,642
339112	Surgical and Medical Instrument Manufacturing	100,873	0	689	100,873	0	689
339113	Surgical Appliance and Supplies Manufacturing	163,924	0	1,149	163,924	0	1,149
339114	Dental Equipment and Supplies Manufacturing	30,531	0	447	30,531	0	447
339115	Ophthalmic Goods Manufacturing	22,258	0	240	22,258	0	240
339116	Dental Laboratories	165,297	0	4,796	165,297	0	4,796
339910	Jewelry and Silverware Manufacturing	116,486	0	1,797	116,486	0	1,797
339920	Sporting and Athletic Goods Manufacturing	97,995	0	1,280	97,995	0	1,280
339930	Doll, Toy, and Game Manufacturing	35,995	0	442	35,995	0	442
339940	Office Supplies (except Paper) Manufacturing	23,646	0	329	23,646	0	329
339950	Sign Manufacturing	291,071	0	4,931	291,071	0	4,931
339991	Gasket, Packing, and Sealing Device Manufacturing	42,201	0	269	42,201	0	269
339992	Musical Instrument Manufacturing	25,017	0	495	25,017	0	495
339993	Fastener, Button, Needle, and Pin Manufacturing	4,456	0	71	4,456	0	71
339994	Broom, Brush, and Mop Manufacturing	10,691	0	92	10,691	0	92
339995	Burial Casket Manufacturing	4,187	0	60	4,187	0	60
339999	All Other Miscellaneous Manufacturing	180,757	0	2,555	180,757	0	2,555
Total							
Total	Total	109,787,372	3,146,247	110,592	42,148,701	543,038	97,861

Sources: U.S. Census Bureau, 2022a (Document ID 0476); U.S. Census Bureau, 2022b (Document ID 0477); U.S. Census Bureau, 2022c (Document ID 0478); BLS, 2023 (Document ID 0482); 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” 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 Internal Revenue Service (IRS) (2016) *SOI Tax Stats - Corporation Source Book* profit data for each of the 14 years 2000–2013. OSHA’s final estimate of average profit rates by six-digit NAICS industry replicate the agency’s preliminary estimate of profit rates²² (Document ID 0004).

Table VI-9 presents OSHA’s final estimates of total revenues and total profits by NAICS industry code for all entities, small entities, and very small entities affected by the revised standard rule. For this FEA, OSHA extrapolated the receipts reported in the 2017 Statistics of U.S. Businesses (SUSB) by NAICS industry to 2022 dollars using the Bureau of Economic Advisors (BEA) GDP deflator. To assign revenue for 2022 at the six-digit NAICS level, OSHA benchmarked per-establishment revenue to per-establishment payroll based on 2017 SUSB revenue-payroll ratios and projected to 2022 dollars using the BEA GDP deflator.

OSHA calculated total profits per NAICS industry by multiplying the average profit rate (NAICS industry) (Document ID 0004) by total revenues (NAICS industry) (U.S. Census Bureau, 2022a, Document ID 0476; U.S. Census Bureau, 2022b, Document ID 0477).

Table VI-10 shows, by NAICS industry code, OSHA’s best estimates of the percentage of establishments or entities affected for each element of the proposed revisions to the HCS that is projected to result in costs (see Section VI.F., Compliance Costs and Cost Savings, in this FEA for an explanation of the cost categories presented in this table).²³

²² In the PEA, OSHA requested public comment on the estimated profit rates presented in Table VI-8. OSHA received no comments addressing the estimates proposed in Table VI-8; therefore, in this FEA Table VI-8 remains unchanged from its preliminary appearance.

²³ Note that the provisions that are projected to result in cost savings are not included in Table VI-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 VI-11 summarizes key estimates for the combined covered industries, labels, and SDSs affected by the final rule. The data in this table are drawn from profile tables presented earlier in this FEA and summarize both the magnitude of the global profile metrics (within the scope of OSHA jurisdiction) and the magnitude of affected inputs critical to the agency's analysis of the final economic impacts.

Table VI-8: Estimated Profit Rates for Industries Affected by the Final Rule^(a)

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%
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%

Table VI-8: Estimated Profit Rates for Industries Affected by the Final Rule^(a)

NAICS Code	Industry	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Average
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%
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%

Table VI-8: Estimated Profit Rates for Industries Affected by the Final Rule^(a)

NAICS Code	Industry	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Average
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%
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%

Table VI-8: Estimated Profit Rates for Industries Affected by the Final Rule^(a)

NAICS Code	Industry	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Average
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%

(a) (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]).

Note: IRS profit data are available at varying NAICS levels; Where an estimate was not available OSHA used 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 VI-9: Estimated Total Revenues and Profits for Industries Affected by the 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	\$431,108,657,025	\$27,875,832,950	\$173,001,050,842	\$11,142,435,423	\$17,860,924,223	\$1,175,900,262
211	Oil and Gas Extraction	\$313,363,204,311	\$19,527,451,736	\$130,869,457,380	\$8,155,223,643	\$10,537,100,260	\$656,626,923
211120	Crude Petroleum Extraction	\$182,884,826,557	\$11,396,598,499	\$82,148,479,398	\$5,119,141,126	\$8,060,918,275	\$502,321,876
211130	Natural Gas Extraction	\$130,478,377,754	\$8,130,853,237	\$48,720,977,982	\$3,036,082,517	\$2,476,181,985	\$154,305,048
31-33	Manufacturing	\$6,806,317,226,570	\$307,020,834,126	\$1,974,081,390,875	\$89,015,709,458	\$225,506,587,223	\$9,799,576,017
324	Petroleum and Coal Products Manufacturing	\$618,970,333,766	\$42,184,548,322	\$63,956,507,492	\$4,365,472,912	\$2,597,399,886	\$178,409,508
324110	Petroleum Refineries	\$564,989,119,296	\$38,482,646,505	\$43,959,961,688	\$2,994,209,283	\$162,140,346	\$11,043,734
324121	Asphalt Paving Mixture and Block Manufacturing	\$16,051,429,566	\$1,107,071,965	\$7,052,481,538	\$486,411,791	\$1,396,799,347	\$96,337,675
324122	Asphalt Shingle and Coating Materials Mfg.	\$13,011,486,147	\$897,406,146	\$3,653,060,342	\$251,952,680	\$339,283,941	\$23,400,516
324191	Petroleum Lubricating Oil and Grease Mfg.	\$19,612,657,227	\$1,336,005,706	\$6,633,215,757	\$451,851,781	\$540,523,482	\$36,820,225
324199	All Other Petroleum and Coal Products Mfg.	\$5,305,641,530	\$361,418,000	\$2,657,788,167	\$181,047,377	\$158,652,770	\$10,807,358
325	Chemical Manufacturing	\$909,458,774,282	\$74,456,661,262	\$241,435,425,905	\$19,085,810,350	\$18,235,705,890	\$1,506,200,730
325110	Petrochemical Manufacturing	\$71,573,798,420	\$2,442,253,916	\$3,659,008,422	\$124,853,338	\$60,624,988	\$2,068,657
325120	Industrial Gas Manufacturing	\$12,210,053,190	\$416,633,613	\$994,180,801	\$33,923,615	\$130,578,433	\$4,455,621
325130	Synthetic Dye and Pigment Manufacturing	\$8,178,034,130	\$279,052,339	\$3,056,687,652	\$104,300,841	\$193,677,160	\$6,608,687
325180	Other Basic Inorganic Chemical Manufacturing	\$39,555,120,764	\$1,349,706,886	\$14,719,722,613	\$502,269,000	\$631,456,804	\$21,546,682
325193	Ethyl Alcohol Manufacturing	\$36,969,480,194	\$1,261,479,197	\$19,617,730,458	\$669,399,698	\$408,219,776	\$13,929,348
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	\$8,235,635,343	\$281,017,818	\$809,079,434	\$27,607,553	\$90,777,978	\$3,097,542
325199	All Other Basic Organic Chemical Manufacturing	\$93,186,612,758	\$3,179,730,222	\$24,528,270,906	\$836,958,035	\$1,496,841,354	\$51,075,488
325211	Plastics Material and Resin Manufacturing	\$111,992,427,793	\$6,652,894,083	\$29,067,585,548	\$1,726,755,743	\$1,240,697,602	\$73,703,463
325212	Synthetic Rubber Manufacturing	\$11,341,788,771	\$673,757,332	\$5,560,652,947	\$330,329,789	\$346,949,549	\$20,610,488
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	\$9,438,755,096	\$560,707,890	\$3,044,666,867	\$180,867,998	\$129,870,134	\$7,714,917
325311	Nitrogenous Fertilizer Manufacturing	\$7,516,577,865	\$730,224,121	\$2,231,734,699	\$216,809,636	\$445,338,390	\$43,263,948
325312	Phosphatic Fertilizer Manufacturing	\$7,371,977,155	\$716,176,381	\$886,613,999	\$86,133,203	\$62,883,763	\$6,109,062
325314	Fertilizer (Mixing Only) Manufacturing	\$6,524,881,780	\$633,882,353	\$4,478,262,789	\$435,056,427	\$707,258,894	\$68,709,127
325320	Pesticide and Other Agricultural Chemical Mfg.	\$17,589,850,557	\$1,708,827,260	\$5,124,392,930	\$497,826,988	\$467,677,961	\$45,434,203
325411	Medicinal and Botanical Manufacturing	\$14,667,072,169	\$2,034,425,026	\$7,604,961,980	\$1,054,861,174	\$703,448,129	\$97,573,153
325412	Pharmaceutical Preparation Manufacturing	\$189,438,629,432	\$26,276,456,821	\$34,115,627,906	\$4,732,075,112	\$2,205,989,708	\$305,986,131
325413	In-Vitro Diagnostic Substance Manufacturing	\$14,404,900,211	\$1,998,059,950	\$3,430,867,757	\$475,885,245	\$200,568,005	\$27,820,179
325414	Biological Product (except Diagnostic) Manufacturing	\$47,392,153,058	\$6,573,621,585	\$9,259,049,356	\$1,284,294,610	\$647,737,915	\$89,845,758
325510	Paint and Coating Manufacturing	\$31,466,389,652	\$1,312,642,728	\$11,087,244,588	\$462,512,260	\$1,713,427,745	\$71,476,852
325520	Adhesive Manufacturing	\$18,096,459,850	\$754,906,638	\$5,339,793,027	\$222,753,248	\$724,751,206	\$30,233,510
325611	Soap and Other Detergent Manufacturing	\$30,356,886,805	\$3,747,210,330	\$6,575,127,168	\$811,624,216	\$702,865,750	\$86,760,735
325612	Polish and Other Sanitation Good Manufacturing	\$6,982,891,985	\$861,958,117	\$4,181,099,162	\$516,108,851	\$465,492,370	\$57,459,707
325613	Surface Active Agent Manufacturing	\$9,179,976,693	\$1,133,163,085	\$3,065,370,876	\$378,384,960	\$178,093,078	\$21,983,553

Table VI-9: Estimated Total Revenues and Profits for Industries Affected by the 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
325620	Toilet Preparation Manufacturing	\$48,305,711,210	\$5,962,787,330	\$19,202,886,031	\$2,370,376,559	\$1,810,360,235	\$223,468,257
325910	Printing Ink Manufacturing	\$4,549,024,893	\$230,691,977	\$1,607,687,931	\$81,529,716	\$239,413,089	\$12,141,213
325920	Explosives Manufacturing	\$2,950,164,188	\$149,609,911	\$693,174,902	\$35,152,564	\$49,933,397	\$2,532,242
325991	Custom Compounding of Purchased Resins	\$14,302,910,074	\$725,334,919	\$5,691,757,644	\$288,642,699	\$573,806,381	\$29,099,100
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	\$6,516,237,026	\$330,454,029	\$831,530,162	\$42,168,891	\$140,704,350	\$7,135,455
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	\$29,164,373,220	\$1,478,995,406	\$10,970,657,349	\$556,348,381	\$1,466,261,747	\$74,357,655
326	Plastics and Rubber Products Manufacturing	\$293,111,850,980	\$7,025,558,430	\$113,843,163,052	\$2,778,952,596	\$9,062,205,224	\$221,349,868
326111	Plastics Bag and Pouch Manufacturing	\$13,780,960,233	\$353,564,046	\$3,812,593,720	\$97,815,830	\$372,892,930	\$9,566,934
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	\$16,908,003,774	\$433,791,414	\$6,905,129,008	\$177,157,855	\$270,653,850	\$6,943,890
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	\$18,960,257,252	\$486,443,989	\$6,490,745,777	\$166,526,447	\$400,875,366	\$10,284,851
326121	Unlaminated Plastics Profile Shape Manufacturing	\$9,772,806,684	\$250,730,937	\$3,006,801,686	\$77,142,445	\$242,073,449	\$6,210,632
326122	Plastics Pipe and Pipe Fitting Manufacturing	\$12,950,209,374	\$332,250,318	\$5,090,463,190	\$130,600,824	\$346,062,366	\$8,878,569
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	\$5,495,811,902	\$141,000,443	\$1,924,078,647	\$49,364,124	\$214,552,045	\$5,504,543
326140	Polystyrene Foam Product Manufacturing	\$11,073,975,465	\$284,113,698	\$5,002,292,097	\$128,338,708	\$323,600,980	\$8,302,300
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	\$12,578,381,854	\$322,710,719	\$4,983,561,033	\$127,858,144	\$544,328,494	\$13,965,281
326160	Plastics Bottle Manufacturing	\$13,763,312,952	\$353,111,288	\$4,036,459,444	\$103,559,324	\$150,592,201	\$3,863,591
326191	Plastics Plumbing Fixture Manufacturing	\$5,107,745,957	\$131,044,230	\$3,190,882,780	\$81,865,226	\$238,751,101	\$6,125,394
326199	All Other Plastics Product Manufacturing	\$115,986,293,418	\$2,975,742,073	\$53,131,238,757	\$1,363,134,021	\$4,678,627,783	\$120,034,783
326211	Tire Manufacturing (except Retreading)	\$23,833,071,544	\$403,723,728	\$4,133,384,788	\$70,018,064	\$101,104,608	\$1,712,676
326212	Tire Retreading	\$1,935,137,482	\$32,780,538	\$1,000,658,631	\$16,950,800	\$220,477,498	\$3,734,810
326220	Rubber and Plastics Hoses and Belting Manufacturing	\$6,643,026,648	\$112,530,501	\$2,589,388,690	\$43,863,321	\$222,030,797	\$3,761,122
326291	Rubber Product Manufacturing for Mechanical Use	\$10,846,648,515	\$183,738,356	\$3,847,583,240	\$65,176,687	\$254,295,991	\$4,307,683
326299	All Other Rubber Product Manufacturing	\$13,476,207,926	\$228,282,154	\$4,697,901,564	\$79,580,776	\$481,285,766	\$8,152,809
327	Nonmetallic Mineral Product Manufacturing	\$154,544,056,601	\$2,861,464,251	\$62,726,868,770	\$1,096,997,964	\$9,998,012,804	\$171,530,222
327110	Pottery, Ceramics, and Plumbing Fixture Mfg.	\$2,645,196,393	\$41,609,154	\$1,337,553,762	\$21,039,829	\$267,360,823	\$4,205,607
327120	Clay Building Material and Refractories Mfg.	\$6,997,944,980	\$110,078,243	\$3,630,120,546	\$57,102,091	\$395,235,836	\$6,217,092
327211	Flat Glass Mfg.	\$5,187,579,508	\$146,875,896	\$656,715,335	\$18,593,576	\$62,267,200	\$1,762,971
327212	Other Pressed and Blown Glass and Glassware Manufacturing	\$4,142,806,131	\$117,295,236	\$1,691,789,270	\$47,899,616	\$207,207,815	\$5,866,673
327213	Glass Container Manufacturing	\$5,955,648,705	\$168,622,233	\$418,420,544	\$11,846,737	\$24,117,972	\$682,852
327215	Glass Product Manufacturing Made of Purchased Glass	\$14,841,065,034	\$420,194,952	\$5,525,809,632	\$156,452,203	\$654,768,471	\$18,538,454
327310	Cement Manufacturing	\$10,648,613,615	\$156,571,203	\$1,470,724,087	\$21,624,697	\$127,333,263	\$1,872,236

Table VI-9: Estimated Total Revenues and Profits for Industries Affected by the 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
327320	Ready-Mix Concrete Manufacturing	\$39,799,326,235	\$585,186,824	\$20,717,511,691	\$304,618,596	\$3,586,065,405	\$52,727,481
327331	Concrete Block and Brick Manufacturing	\$5,418,582,863	\$79,671,783	\$3,291,709,756	\$48,399,442	\$486,482,538	\$7,152,965
327332	Concrete Pipe Manufacturing	\$1,988,848,996	\$29,242,913	\$1,139,522,325	\$16,754,893	\$87,336,057	\$1,284,140
327390	Other Concrete Product Manufacturing	\$14,671,597,768	\$215,722,891	\$8,682,164,472	\$127,657,645	\$1,369,068,605	\$20,130,012
327410	Lime Manufacturing	\$2,857,924,564	\$53,468,686	\$865,109,167	\$16,185,259	\$31,125,544	\$582,325
327420	Gypsum Product Manufacturing	\$7,794,626,759	\$145,829,059	\$447,053,257	\$8,363,884	\$175,091,880	\$3,275,780
327910	Abrasive Product Manufacturing	\$5,975,599,555	\$111,797,022	\$2,021,424,195	\$37,818,666	\$292,134,504	\$5,465,521
327991	Cut Stone and Stone Product Manufacturing	\$5,892,862,370	\$110,249,098	\$4,812,522,458	\$90,037,104	\$1,586,363,191	\$29,679,144
327992	Ground or Treated Mineral and Earth Mfg.	\$5,372,406,995	\$100,511,940	\$1,769,433,795	\$33,104,198	\$132,189,310	\$2,473,119
327993	Mineral Wool Manufacturing	\$7,164,934,666	\$134,048,199	\$2,174,407,766	\$40,680,824	\$179,411,030	\$3,356,587
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	\$7,188,491,466	\$134,488,921	\$2,074,876,712	\$38,818,705	\$334,453,360	\$6,257,262
331	Primary Metal Manufacturing	\$278,321,428,037	\$6,030,623,440	\$88,586,613,067	\$2,072,195,314	\$3,755,440,016	\$101,522,155
331110	Iron and Steel Mills and Ferroalloy Manufacturing	\$108,052,118,040	\$1,341,213,035	\$20,890,760,432	\$259,309,680	\$444,969,193	\$5,523,246
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	\$15,024,519,874	\$312,759,731	\$7,367,292,854	\$153,362,141	\$105,590,702	\$2,198,042
331221	Rolled Steel Shape Manufacturing	\$8,526,720,600	\$177,497,508	\$4,972,953,187	\$103,520,080	\$270,241,311	\$5,625,511
331222	Steel Wire Drawing	\$6,320,821,549	\$131,578,144	\$3,612,084,969	\$75,191,403	\$164,181,203	\$3,417,698
331313	Alumina Refining and Primary Aluminum Production	\$4,061,390,323	\$100,276,030	\$1,088,654,321	\$26,878,956	\$26,820,959	\$662,211
331314	Secondary Smelting and Alloying of Aluminum	\$7,705,398,563	\$190,246,866	\$2,885,391,854	\$71,240,540	\$204,216,733	\$5,042,126
331315	Aluminum Sheet, Plate, and Foil Manufacturing	\$20,173,019,985	\$488,414,212	\$4,335,142,654	\$104,959,262	\$45,959,515	\$1,112,738
331318	Other Aluminum Rolling, Drawing, and Extruding	\$14,796,021,517	\$365,314,876	\$5,182,592,041	\$127,958,584	\$150,948,962	\$3,726,941
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	\$12,402,811,471	\$258,184,622	\$5,758,979,536	\$119,882,492	\$384,069,065	\$7,995,020
331420	Copper Rolling, Drawing, Extruding, and Alloying	\$26,387,701,142	\$549,302,765	\$11,476,098,480	\$238,893,589	\$219,847,551	\$4,576,483
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	\$8,805,349,915	\$183,297,629	\$2,131,430,995	\$44,369,191	\$341,819,219	\$7,115,521
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	\$9,207,562,757	\$191,670,341	\$5,502,650,423	\$114,546,587	\$433,295,001	\$9,019,738
331511	Iron Foundries	\$11,652,176,810	\$550,352,766	\$3,324,719,712	\$157,032,348	\$193,712,363	\$9,149,375
331512	Steel Investment Foundries	\$5,054,331,260	\$238,724,938	\$1,888,851,815	\$89,213,787	\$35,707,136	\$1,686,511
331513	Steel Foundries (except Investment)	\$4,645,543,651	\$219,417,182	\$1,763,331,460	\$83,285,240	\$141,887,422	\$6,701,592
331523	Nonferrous Metal Die-Casting Foundries	\$8,674,105,016	\$409,693,207	\$3,030,786,640	\$143,149,373	\$243,374,270	\$11,494,994
331524	Aluminum Foundries (except Die-Casting)	\$3,374,793,250	\$159,397,410	\$1,929,923,454	\$91,153,673	\$185,143,921	\$8,744,672
331529	Other Nonferrous Metal Foundries (except Die-Casting)	\$3,457,042,315	\$163,282,177	\$1,444,968,241	\$68,248,387	\$163,655,489	\$7,729,736
339	Miscellaneous Manufacturing	\$189,133,999,054	\$11,447,078,976	\$73,453,095,870	\$4,046,248,288	\$14,784,871,603	\$775,436,649
339112	Surgical and Medical Instrument Manufacturing	\$51,614,518,085	\$3,784,573,568	\$12,986,915,927	\$952,250,269	\$1,133,808,267	\$83,135,152

Table VI-9: Estimated Total Revenues and Profits for Industries Affected by the 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
339113	Surgical Appliance and Supplies Manufacturing	\$44,501,343,055	\$3,263,008,411	\$11,456,275,670	\$840,017,880	\$1,842,494,560	\$135,098,737
339114	Dental Equipment and Supplies Manufacturing	\$6,067,000,616	\$444,855,653	\$2,863,485,268	\$209,961,675	\$343,167,920	\$25,162,382
339115	Ophthalmic Goods Manufacturing	\$7,653,760,457	\$561,202,944	\$1,429,817,777	\$104,839,699	\$250,178,784	\$18,344,064
339116	Dental Laboratories	\$5,901,104,979	\$432,691,552	\$4,103,332,771	\$300,872,028	\$1,857,933,643	\$136,230,790
339910	Jewelry and Silverware Manufacturing	\$8,106,516,294	\$327,010,377	\$4,133,091,237	\$166,725,592	\$1,309,295,696	\$52,815,940
339920	Sporting and Athletic Goods Manufacturing	\$11,528,116,895	\$465,035,006	\$6,931,778,350	\$279,622,389	\$1,101,462,640	\$44,432,121
339930	Doll, Toy, and Game Manufacturing	\$1,881,976,976	\$75,917,445	\$1,389,538,569	\$56,052,873	\$404,576,662	\$16,320,299
339940	Office Supplies (except Paper) Manufacturing	\$3,773,797,375	\$152,231,965	\$2,609,465,889	\$105,263,765	\$265,785,648	\$10,721,580
339950	Sign Manufacturing	\$15,179,515,980	\$612,329,522	\$12,112,744,969	\$488,618,435	\$3,271,628,483	\$131,974,874
339991	Gasket, Packing, and Sealing Device Mfg.	\$12,672,706,713	\$511,206,843	\$2,905,995,145	\$117,225,518	\$474,333,716	\$19,134,242
339992	Musical Instrument Manufacturing	\$2,394,085,265	\$96,575,483	\$1,296,829,108	\$52,313,048	\$281,190,846	\$11,343,014
339993	Fastener, Button, Needle, and Pin Manufacturing	\$1,105,456,492	\$44,593,230	\$460,624,786	\$18,581,235	\$50,089,383	\$2,020,566
339994	Broom, Brush, and Mop Manufacturing	\$3,398,953,469	\$137,111,062	\$1,605,789,812	\$64,776,275	\$120,163,350	\$4,847,293
339995	Burial Casket Manufacturing	\$649,829,866	\$26,213,617	\$209,122,381	\$8,435,829	\$47,059,450	\$1,898,341
339999	All Other Miscellaneous Manufacturing	\$12,705,316,537	\$512,522,297	\$6,958,288,212	\$280,691,776	\$2,031,702,555	\$81,957,255
42	Wholesale Trade	\$9,730,413,309,855	\$220,158,015,274	\$2,295,651,888,873	\$52,515,638,142	\$743,595,128,838	\$17,807,705,446
423	Merchant Wholesalers, Durable Goods	\$4,536,406,714,671	\$95,091,185,603	\$1,168,050,693,858	\$25,935,567,178	\$397,195,318,323	\$9,087,240,922
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	\$305,193,211,815	\$7,576,452,211	\$40,925,023,490	\$1,015,967,829	\$14,318,982,233	\$355,470,176
423840	Industrial Supplies Merchant Wholesalers	\$93,267,046,705	\$2,877,574,387	\$29,980,830,090	\$925,000,542	\$13,802,474,015	\$425,848,648
424	Merchant Wholesalers, Nondurable Goods	\$5,194,006,595,185	\$125,066,829,671	\$1,127,601,195,015	\$26,580,070,964	\$346,399,810,515	\$8,720,464,524
424210	Drugs and Druggists' Sundries Merchant Wholesalers	\$1,071,874,399,470	\$37,196,508,248	\$88,078,481,901	\$3,056,526,007	\$22,650,320,243	\$786,018,235
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	\$53,481,476,596	\$1,633,412,923	\$21,121,343,462	\$645,080,831	\$9,538,190,909	\$291,312,157
424690	Other Chemical and Allied Products Merchant Wholesalers	\$240,052,181,069	\$7,331,591,416	\$56,137,224,375	\$1,714,523,861	\$22,653,633,421	\$691,879,505
424710	Petroleum Bulk Stations and Terminals	\$646,542,781,628	\$6,237,984,142	\$125,662,478,049	\$1,212,418,679	\$22,113,348,900	\$213,354,357
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	\$675,361,005,744	\$6,516,028,581	\$141,971,019,579	\$1,369,767,004	\$30,382,540,215	\$293,137,298
424910	Farm Supplies Merchant Wholesalers	\$169,043,606,251	\$4,586,156,656	\$53,997,866,896	\$1,464,963,285	\$17,787,338,503	\$482,570,874
424950	Paint, Varnish, and Supplies Merchant Wholesalers	\$21,267,042,880	\$494,008,349	\$4,790,420,318	\$111,275,820	\$1,850,425,514	\$42,983,204
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	\$52,401,274,940	\$1,217,219,876	\$30,363,527,905	\$705,308,978	\$17,105,834,948	\$397,348,391
Total							
Total	Total	\$50,256,838,711,534	\$6,647,779,865,027	\$14,465,946,958,024	\$1,460,460,327,939	\$4,989,404,703,505	\$190,373,831,916

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health based on U.S. Census Bureau, 2022a (Document ID 0476); U.S. Census Bureau, 2022b (Document ID 0477).

Table VI-10: Percentage of Establishments (or, for Training, Entities) Affected for Each Cost Provision in the Revisions to the HCS, by Industry

NAICS	NAICS Industry	Rule Familiarization - NAICS with Additional Costs	Rule Familiarization - NAICS without Additional Costs	Training	Reclassification - Flammable Aerosols	Reclassification - Desensitized Explosives	Reclassification - Flammable Gases	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%

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NAICS	NAICS Industry	Rule Familiarization - NAICS with Additional Costs	Rule Familiarization - NAICS without Additional Costs	Training	Reclassification - Flammable Aerosols	Reclassification - Desensitized Explosives	Reclassification - Flammable Gases	Appendix
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%
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%

Table VI-10: Percentage of Establishments (or, for Training, Entities) Affected for Each Cost Provision in the Revisions to the HCS, by Industry

NAICS	NAICS Industry	Rule Familiarization - NAICS with Additional Costs	Rule Familiarization - NAICS without Additional Costs	Training	Reclassification - Flammable Aerosols	Reclassification - Desensitized Explosives	Reclassification - Flammable Gases	Appendix
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%
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%

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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%
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%

Table VI-10: Percentage of Establishments (or, for Training, Entities) Affected for Each Cost Provision in the Revisions to the HCS, by Industry

NAICS	NAICS Industry	Rule Familiarization - NAICS with Additional Costs	Rule Familiarization - NAICS without Additional Costs	Training	Reclassification - Flammable Aerosols	Reclassification - Desensitized Explosives	Reclassification - Flammable Gases	Appendix

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Table VI-11: Summary of Industries and Labels/SDSs Affected by OSHA’s Revisions to the HCS[a]

	Total	Percentage Affected	Affected
Firms	6,177,430	1.800%	111,223
Establishments	7,881,456	1.877%	147,832
Relevant Employees	152,337,433	2.819%	4,294,474
Labels Being Revised Due to Chemical Reclassification and Labels Revisions	2,219,599,486	64.088%	1,422,492,422
Labels for Very Small Containers	195,649,073	15.193%	29,724,752
Firms w/ Warehoused Labels that Change	216	1.000%	2.16
SDSs	1,538,924	94.467%	1,453,774

Sources: U.S. Census Bureau, 2022a (Document ID 0476); U.S. Census Bureau, 2022b (Document ID 0477); U.S. Census Bureau, 2022c (Document ID 0478); BLS, 2023 (Document ID 0482); U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

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 FEA (for firms, establishments, and employees, see Table VI-1; for labels and SDSs, see Table VI-5).

D. Health and Safety Benefits and Unquantified Positive Economic Effects

As part of the rulemakings that resulted in the 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 estimates from the 1983 rulemaking with those from the 1987 update, 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 annually (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 1 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, the revisions to the HCS finalized in this current rulemaking are incremental and minor. Accordingly, OSHA expects that the 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 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 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 revised 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, or packaged containers to replace labels when new hazards were identified.

Although OSHA expects that the revisions to the HCS will reduce injuries, illnesses, and fatalities, the limited scope and nature of the changes being finalized have led OSHA to a determination that it cannot reasonably quantify an estimate of how many injuries, illnesses, and fatalities will 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, broadens the range of uncertainty associated with the original estimates (77 FR 17621).²⁴ In the NPRM, OSHA invited interested parties to provide comments and evidence on how the proposed revisions to the HCS are likely to affect worker safety and health.

NABTU commented that the organization “strongly supports OSHA’s proposal to improve elements of the standard, as it is imperative to have accurate information available to workers on the hazards of the chemicals to which they are exposed” (Document ID 0334, p. 1). NIOSH commended OSHA for proposing to update the HCS to reflect revisions to the GHS and for applying “sound reasoning” as the basis for using Rev. 7 as the primary guidance (Document ID 0281, Att. 2, p. 2). Also voicing broad approval of the proposed standard was the Ameren, who stated, “whenever worker

²⁴ As described above, OSHA estimated that the 2012 revisions to the HCS would result in benefits equal to 1 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).

knowledge is increased on the hazards of working with chemicals, such as is done in the proposed revision to the HCS, worker safety will be increased” (Document ID 0309, p. 5). Furthermore, Ameren concurred with OSHA’s preliminary assessment of the benefits of the proposed standard, noting that it agreed with OSHA that the proposed changes would enhance the clarity and accessibility of hazard information and workers would receive better training (Document ID 0309, p. 2).

OSHA received many other comments supporting the positive impact of specific provisions on worker safety. Several commenters argued that the proposed changes would reduce worker safety and referred to specific proposed changes (see, e.g., Document ID 0322, Att. 1, p. 1; 0354, p. 1). OSHA has addressed both kinds of comments and explained why it disagrees with commenters suggesting that the rule will negatively impact worker safety throughout the relevant parts of Section XIV., Summary and Explanation of the Final Rule.

In addition to health and safety benefits, OSHA expects that the revisions to the HCS will result in other positive economic effects. For example, being better aligned with the GHS will 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 will 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.²⁵ Maintaining alignment with the GHS in U.S. laws and policies through appropriate legislative and 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 (SAICM, 2006, Document ID 0039).

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 will be imposed by the final rule and determined that compliance with the final rule is technologically feasible for all affected industries.

The revisions to OSHA's HCS will 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 will mainly involve revisions to the presentation of information and is not expected to involve any technological obstacles.

²⁵ The European Union (EU), Canada, Australia, and New Zealand have also indicated that they are proposing updates to align with Rev. 7 (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). For the history of U.S. government support for adoption and implementation of the GHS, see the 2012 Final HCS Rule, Document ID OSHA-H022K-2006-0062-0656, Section II. Events Leading to the Revised Hazard Communication Standard (77 FR 17577).

On the question of the technological feasibility of compliance with the proposed provisions for reclassification criteria and the subsequent revisions to SDSs and labels, ILMA expressed concern about “whether software will even be capable of adopting the proposed rule changes. Currently, the technology aims to make it easy to select applicable fields for inclusion in the final SDS, but under the proposed rule, the software would likely need narrative fields for explanation, something that is not included in the widely-used authoring programs” (Document ID 0460, Att. 1, p. 5). The agency believes ILMA’s membership misunderstands the extent of what was intended by the addition of clarifying language in paragraph (d), as discussed elsewhere. Many commenters indicated a belief that the information required on the SDS would be much more extensive and comprehensive than OSHA intends. Because these revisions will not in fact require a fundamental change to how SDSs and labels are prepared, the agency does not believe that the available software is incapable of generating compliant SDSs and labels. Additionally, even if ILMA’s understanding of the impact of these revisions was correct, sample product data sheets and SDSs submitted into the record by NABTU (see, for example, Document ID 0450, Atts. 2, 3, 4, 6, and 7) indicate that narrative text is routinely provided in succinct form for sections on hazard identification and safety warning, and thus there should be existing software capable of including narrative content, contrary to ILMA’s statement. Further, as an industry partner with a large number of chemical producers, importers, and distributors, ILMA seemingly would have access to a wide range of SDSs for chemicals handled by ILMA members and would therefore encounter multiple examples of the use of narrative fields in SDS production. Regardless, even if some programs do not currently have this feature, a requirement is not technologically infeasible simply because existing software programs are not tailored to that requirement. See *Lead I*, 647 F.2d at 1272. ILMA has not demonstrated that

technological barriers prevent the development of compliant software or otherwise hinder compliance with the revised requirements for reclassification criteria on SDSs.

The revised requirements for the labeling of very small containers, which would eliminate full labeling requirements for some containers with a volume capacity of three ml or less, are expected to address current feasibility issues related to labeling these 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 rule will permit the container to bear only the product identifier, which could be etched onto the container itself. Similarly, the revised released-for-shipment provisions will 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 requested public comment on any employer concerns about technological feasibility associated with the provisions for labeling very small containers or addressing the relabeling of containers that have been released for shipment. No commenter challenged the feasibility of the revised provisions. For comments affirming the benefits of adopting this new labeling flexibility, see the section on paragraph (f) in Section XIV, Summary and Explanation of the Final Rule.

OSHA has determined that compliance with all of the requirements of the final rule can be achieved with widely available technologies. No new technologies are required for compliance with the modifications to the HCS. Therefore, OSHA finds that there are no technological constraints associated with compliance with any of the provisions in this final rule.

F. Compliance Costs and Cost Savings

I. Introduction.

This section presents OSHA's estimates of the costs and cost savings expected to result from the revisions to the HCS. The estimated costs and cost savings are based on employers achieving full compliance with the new requirements of the rule. They do not include prior costs and cost savings associated with firms whose current practices are already in compliance with the revised requirements (where prior compliance is possible).

The estimated costs and cost savings resulting from the 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 changes to Appendix B) and to conform to language criteria in precautionary statements and other mandatory language (per changes to Appendices C and D); (2) the cost of management familiarization and other management-related costs (associated with all of the revisions to the standard); (3) the cost of training employees as necessitated by the revisions to the HCS (see paragraph (h)(1)); (4) the cost savings due to the new released-for-shipment provision (revisions to paragraph (f)(11)); and (5) the cost savings from limiting labeling requirements for certain very small containers (paragraph (f)(12)). The first three categories are considered to be one-time costs and the last two categories are cost savings that will accrue to employers annually. Although OSHA in the PEA preliminarily determined that these were the only elements of the revisions to the HCS that were expected to result in more than *de minimis* costs or cost savings, the agency requested comments on whether any other changes to the standard could cause employers to incur costs or obtain cost savings.

The discussion following this introduction addresses public comments on OSHA's preliminary analysis of compliance costs for each of the five main cost categories listed above, as well as a section on costs of the proposed changes regarding trade secrets, which OSHA received several comments about.

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. In the PEA, OSHA requested input from stakeholders on such changes but received none. Therefore, no costs or other impacts resulting from significant changes in the use or application of affected chemicals are assessed in this FEA. This is consistent with the determination OSHA made with regard to reclassification costs for the 2012 final rule (77 FR 17625).

This FEA presents compliance costs and cost savings on a consistent and comparable basis across various regulatory activities and expresses all costs in annualized terms in the final summation. Annualized costs and cost savings represent the most appropriate measure for assessing the longer-term potential impacts of this 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 FEA (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.²⁶ The economic effects using a

²⁶ OSHA annualized costs for this final rule over a 10-year period in accordance with E.O. 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 regulatory 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 because of the 5-year phase-in of some

three-percent discount rate are also provided in the Excel spreadsheets that support this FEA, which can be found in the docket (Document ID 0481).

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 (DOL) 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 FEA, 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 FEA, OSHA has adopted an overhead rate of 17 percent of base wages, which is consistent with the overhead rate and methodology used for, among others: (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); and (2) the FEA in support of OSHA’s 2016 final standard on Occupational Exposure to Respirable Crystalline Silica (81 FR 16285, 16488-16492).²⁷

provisions. This HCS final rule does not have any phase-in provisions longer than 42 months, supporting OSHA’s decision to use a 10-year annualization period for this FEA.

²⁷ This methodology was modeled after an approach used by the EPA. 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 (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 (Document ID 0048).

To calculate the total labor cost for an occupational category, OSHA added together three components: base wage + fringe benefits (45 percent of the base wage)²⁸ + applicable overhead costs (17 percent of the base wage). For example, the median hourly wage of an Occupational Health and Safety Specialist is \$37.77. Applying a fringe markup of 45 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 \$ \$61.18 ($\$37.77 \times .450 = \$17.00$; $\$37.77 \times 0.17 = \$6.42$; $\$37.77 + \$17.00 + \$6.42 = \$61.18$ (unrounded)). Using this methodology, OSHA calculated the fully-loaded labor cost for four occupational categories: (1) Manager, Standard Occupational Classification (SOC) code 11-0000, \$83.62; (2) Logistics Personnel, SOC code 13-1081, \$60.37; (3) Production Worker, SOC code 51-0000, \$31.09; and (4) Occupational Health and Safety Specialist, SOC code 19-5011, \$61.18. (For further details, see Document ID 0481, tab “Wages”).

Table VI-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 2022 dollars. As shown in Table VI-12, the total annualized net cost savings of compliance with the final rule is estimated to be \$29.8 million—consisting of about \$5.1 million of annualized costs and \$35.0 million of annual cost savings. Note that where tables in this FEA report estimated annualized costs, as in Table VI-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 VI-12, most of the estimated compliance costs and cost savings associated with the final rule will be incurred or realized by the chemical manufacturing industry and its distributors.

²⁸ In March 2023, the Bureau of Labor Statistics (BLS) reported: “Total employer compensation costs for civilian workers averaged \$42.48 per hour worked in December 2022 . . . Wages and salaries cost employers \$29.32 while benefits cost \$13.17. . .” The fringe markup of 31 percent of total compensation ($\$13.17 / \$42.48$) is equivalent to a benefits markup of 45.0 percent (technically 0.449, or 0.45 after rounding) in relation to the base wage ($\$13.17 / \$29.32$). (BLS, 2022b, Document ID 0471).

However, the table also shows that familiarization costs will 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.

For purposes of annualizing costs for this FEA, OSHA estimated that all compliance costs will be incurred in the first year. This simplifying methodological assumption may upwardly bias the compliance costs for chemical reclassification, revised precautionary statements, management familiarization, and training, insofar as the final rule schedules compliance dates in phases of 18 months, 24 months, 36 months, and 42 months after the effective date. Nonetheless, despite the simplifying assumption of an immediate implementation of all provisions in the final rule, OSHA believes that its final determination of economic feasibility and regulatory flexibility certification is supported by the rulemaking evidence.

Table VI-12: Total Annualized Costs of Provisions in the Revised Standard, by Six-Digit NAICS for All Entities (7 Percent Discount Rate, 2022 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	\$79,932	\$8,645	\$290,885	\$0	\$0	\$379,462
211	Oil and Gas Extraction	\$79,932	\$8,645	\$290,885	\$0	\$0	\$379,462
211120	Crude Petroleum Extraction	\$61,073	\$0	\$162,544	\$0	\$0	\$223,617
211130	Natural Gas Extraction	\$18,859	\$8,645	\$128,341	\$0	\$0	\$155,845
31-33	Manufacturing	\$839,232	\$128,308	\$3,571,026	-\$13,219,957	-\$1,713,243	-\$10,394,633
324	Petroleum and Coal Products Manufacturing	\$39,931	\$12,402	\$1,545,319	\$0	\$0	\$1,597,653
324110	Petroleum Refineries	\$10,384	\$12,402	\$106,150	\$0	\$0	\$128,936
324121	Asphalt Paving Mixture and Block Manufacturing	\$16,525	\$0	\$169,862	\$0	\$0	\$186,386
324122	Asphalt Shingle and Coating Materials Manufacturing	\$4,817	\$0	\$24,468	\$0	\$0	\$29,285
324191	Petroleum Lubricating Oil and Grease Manufacturing	\$6,394	\$0	\$1,233,703	\$0	\$0	\$1,240,097
324199	All Other Petroleum and Coal Products Manufacturing	\$1,812	\$0	\$11,136	\$0	\$0	\$12,948
325	Chemical Manufacturing	\$299,302	\$115,906	\$1,855,602	-\$13,219,957	-\$1,713,243	-\$12,662,389
325110	Petrochemical Manufacturing	\$2,004	\$2,165	\$25,315	\$0	\$0	\$29,484
325120	Industrial Gas Manufacturing	\$8,676	\$3,195	\$21,923	\$0	\$0	\$33,794
325130	Synthetic Dye and Pigment Manufacturing	\$3,049	\$0	\$7,384	\$0	\$0	\$10,433
325180	Other Basic Inorganic Chemical Manufacturing	\$15,575	\$0	\$12,623	\$0	-\$398,372	-\$370,174
325193	Ethyl Alcohol Manufacturing	\$6,638	\$0	\$9,147	\$0	\$0	\$15,785
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	\$1,760	\$0	\$4,073	\$0	\$0	\$5,832
325199	All Other Basic Organic Chemical Manufacturing	\$21,455	\$0	\$49,962	\$0	-\$938,513	-\$867,095
325211	Plastics Material and Resin Manufacturing	\$30,462	\$0	\$151,367	\$0	\$0	\$181,829
325212	Synthetic Rubber Manufacturing	\$3,545	\$0	\$3,252	\$0	\$0	\$6,797
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	\$3,772	\$0	\$628	\$0	\$0	\$4,400
325311	Nitrogenous Fertilizer Manufacturing	\$3,450	\$0	\$1,015	-\$1,879,144	\$0	-\$1,874,680
325312	Phosphatic Fertilizer Manufacturing	\$1,864	\$0	\$262	-\$1,842,994	\$0	-\$1,840,868
325314	Fertilizer (Mixing Only) Manufacturing	\$8,249	\$0	\$11,110	-\$1,631,220	\$0	-\$1,611,861
325320	Pesticide and Other Agricultural Chemical Manufacturing	\$4,260	\$4,129	\$39,832	\$0	\$0	\$48,221
325411	Medicinal and Botanical Manufacturing	\$12,161	\$0	\$22,662	\$0	-\$147,717	-\$112,894
325412	Pharmaceutical Preparation Manufacturing	\$34,034	\$34,953	\$146,119	\$0	-\$172,402	\$42,705
325413	In-Vitro Diagnostic Substance Manufacturing	\$7,692	\$0	\$39,506	\$0	-\$13,109	\$34,089
325414	Biological Product (except Diagnostic) Manufacturing	\$11,281	\$0	\$7,243	\$0	-\$43,130	-\$24,607
325510	Paint and Coating Manufacturing	\$21,621	\$17,570	\$497,370	-\$7,866,597	\$0	-\$7,330,037
325520	Adhesive Manufacturing	\$12,013	\$9,047	\$202,074	\$0	\$0	\$223,133
325611	Soap and Other Detergent Manufacturing	\$12,230	\$12,095	\$138,932	\$0	\$0	\$163,257
325612	Polish and Other Sanitation Good Manufacturing	\$7,883	\$7,572	\$80,129	\$0	\$0	\$95,585
325613	Surface Active Agent Manufacturing	\$2,822	\$2,444	\$37,003	\$0	\$0	\$42,269
325620	Toilet Preparation Manufacturing	\$20,183	\$20,800	\$159,758	\$0	\$0	\$200,741
325910	Printing Ink Manufacturing	\$5,357	\$0	\$50,176	\$0	\$0	\$55,533

Table VI-12: Total Annualized Costs of Provisions in the Revised Standard, by Six-Digit NAICS for All Entities (7 Percent Discount Rate, 2022 Dollars)

NAICS Code	Industry	Rule Familiarization	Training	Revised SDS/ Labels [a]	Release for Shipment	Labels for Very Small Containers	Total Costs
325920	Explosives Manufacturing	\$1,864	\$1,937	\$16,782	\$0	\$0	\$20,584
325991	Custom Compounding of Purchased Resins	\$9,904	\$0	\$8,593	\$0	\$0	\$18,497
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	\$3,110	\$0	\$4,385	\$0	\$0	\$7,495
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	\$22,387	\$0	\$106,978	\$0	\$0	\$129,365
326	Plastics and Rubber Products Manufacturing	\$72,302	\$0	\$0	\$0	\$0	\$72,302
326111	Plastics Bag and Pouch Manufacturing	\$2,265	\$0	\$0	\$0	\$0	\$2,265
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	\$2,909	\$0	\$0	\$0	\$0	\$2,909
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	\$3,073	\$0	\$0	\$0	\$0	\$3,073
326121	Unlaminated Plastics Profile Shape Manufacturing	\$2,156	\$0	\$0	\$0	\$0	\$2,156
326122	Plastics Pipe and Pipe Fitting Manufacturing	\$2,909	\$0	\$0	\$0	\$0	\$2,909
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	\$1,315	\$0	\$0	\$0	\$0	\$1,315
326140	Polystyrene Foam Product Manufacturing	\$2,698	\$0	\$0	\$0	\$0	\$2,698
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	\$3,959	\$0	\$0	\$0	\$0	\$3,959
326160	Plastics Bottle Manufacturing	\$3,360	\$0	\$0	\$0	\$0	\$3,360
326191	Plastics Plumbing Fixture Manufacturing	\$1,858	\$0	\$0	\$0	\$0	\$1,858
326199	All Other Plastics Product Manufacturing	\$34,955	\$0	\$0	\$0	\$0	\$34,955
326211	Tire Manufacturing (except Retreading)	\$1,505	\$0	\$0	\$0	\$0	\$1,505
326212	Tire Retreading	\$1,474	\$0	\$0	\$0	\$0	\$1,474
326220	Rubber and Plastics Hoses and Belting Manufacturing	\$1,579	\$0	\$0	\$0	\$0	\$1,579
326291	Rubber Product Manufacturing for Mechanical Use	\$2,600	\$0	\$0	\$0	\$0	\$2,600
326299	All Other Rubber Product Manufacturing	\$3,685	\$0	\$0	\$0	\$0	\$3,685
327	Nonmetallic Mineral Product Manufacturing	\$62,192	\$0	\$0	\$0	\$0	\$62,192
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	\$1,986	\$0	\$0	\$0	\$0	\$1,986
327120	Clay Building Material and Refractories Manufacturing	\$2,829	\$0	\$0	\$0	\$0	\$2,829
327211	Flat Glass Manufacturing	\$780	\$0	\$0	\$0	\$0	\$780
327212	Other Pressed and Blown Glass and Glassware Manufacturing	\$1,723	\$0	\$0	\$0	\$0	\$1,723
327213	Glass Container Manufacturing	\$501	\$0	\$0	\$0	\$0	\$501
327215	Glass Product Manufacturing Made of Purchased Glass	\$4,841	\$0	\$0	\$0	\$0	\$4,841
327310	Cement Manufacturing	\$1,087	\$0	\$0	\$0	\$0	\$1,087
327320	Ready-Mix Concrete Manufacturing	\$20,948	\$0	\$0	\$0	\$0	\$20,948
327331	Concrete Block and Brick Manufacturing	\$3,127	\$0	\$0	\$0	\$0	\$3,127
327332	Concrete Pipe Manufacturing	\$1,039	\$0	\$0	\$0	\$0	\$1,039
327390	Other Concrete Product Manufacturing	\$8,807	\$0	\$0	\$0	\$0	\$8,807
327410	Lime Manufacturing	\$566	\$0	\$0	\$0	\$0	\$566
327420	Gypsum Product Manufacturing	\$1,026	\$0	\$0	\$0	\$0	\$1,026
327910	Abrasive Product Manufacturing	\$1,352	\$0	\$0	\$0	\$0	\$1,352
327991	Cut Stone and Stone Product Manufacturing	\$7,058	\$0	\$0	\$0	\$0	\$7,058

Table VI-12: Total Annualized Costs of Provisions in the Revised Standard, by Six-Digit NAICS for All Entities (7 Percent Discount Rate, 2022 Dollars)

NAICS Code	Industry	Rule Familiarization	Training	Revised SDS/ Labels [a]	Release for Shipment	Labels for Very Small Containers	Total Costs
327992	Ground or Treated Mineral and Earth Manufacturing	\$1,191	\$0	\$0	\$0	\$0	\$1,191
327993	Mineral Wool Manufacturing	\$1,309	\$0	\$0	\$0	\$0	\$1,309
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	\$2,023	\$0	\$0	\$0	\$0	\$2,023
331	Primary Metal Manufacturing	\$26,897	\$0	\$0	\$0	\$0	\$26,897
331110	Iron and Steel Mills and Ferroalloy Manufacturing	\$3,944	\$0	\$0	\$0	\$0	\$3,944
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	\$2,051	\$0	\$0	\$0	\$0	\$2,051
331221	Rolled Steel Shape Manufacturing	\$1,239	\$0	\$0	\$0	\$0	\$1,239
331222	Steel Wire Drawing	\$1,361	\$0	\$0	\$0	\$0	\$1,361
331313	Alumina Refining and Primary Aluminum Production	\$209	\$0	\$0	\$0	\$0	\$209
331314	Secondary Smelting and Alloying of Aluminum	\$610	\$0	\$0	\$0	\$0	\$610
331315	Aluminum Sheet, Plate, and Foil Manufacturing	\$906	\$0	\$0	\$0	\$0	\$906
331318	Other Aluminum Rolling, Drawing, and Extruding	\$1,964	\$0	\$0	\$0	\$0	\$1,964
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	\$754	\$0	\$0	\$0	\$0	\$754
331420	Copper Rolling, Drawing, Extruding, and Alloying	\$1,768	\$0	\$0	\$0	\$0	\$1,768
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	\$1,374	\$0	\$0	\$0	\$0	\$1,374
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	\$1,106	\$0	\$0	\$0	\$0	\$1,106
331511	Iron Foundries	\$2,324	\$0	\$0	\$0	\$0	\$2,324
331512	Steel Investment Foundries	\$980	\$0	\$0	\$0	\$0	\$980
331513	Steel Foundries (except Investment)	\$1,076	\$0	\$0	\$0	\$0	\$1,076
331523	Nonferrous Metal Die-Casting Foundries	\$2,467	\$0	\$0	\$0	\$0	\$2,467
331524	Aluminum Foundries (except Die-Casting)	\$1,575	\$0	\$0	\$0	\$0	\$1,575
331529	Other Nonferrous Metal Foundries (except Die-Casting)	\$1,189	\$0	\$0	\$0	\$0	\$1,189
339	Miscellaneous Manufacturing	\$338,607	\$0	\$170,105	\$0	\$0	\$508,712
339112	Surgical and Medical Instrument Manufacturing	\$31,168	\$0	\$9,340	\$0	\$0	\$40,508
339113	Surgical Appliance and Supplies Manufacturing	\$32,414	\$0	\$13,861	\$0	\$0	\$46,275
339114	Dental Equipment and Supplies Manufacturing	\$7,605	\$0	\$3,770	\$0	\$0	\$11,375
339115	Ophthalmic Goods Manufacturing	\$9,242	\$0	\$2,819	\$0	\$0	\$12,061
339116	Dental Laboratories	\$57,641	\$0	\$34,664	\$0	\$0	\$92,305
339910	Jewelry and Silverware Manufacturing	\$22,448	\$0	\$13,203	\$0	\$0	\$35,651
339920	Sporting and Athletic Goods Manufacturing	\$23,424	\$0	\$11,685	\$0	\$0	\$35,109
339930	Doll, Toy, and Game Manufacturing	\$6,115	\$0	\$3,557	\$0	\$0	\$9,672
339940	Office Supplies (except Paper) Manufacturing	\$6,394	\$0	\$3,242	\$0	\$0	\$9,636
339950	Sign Manufacturing	\$73,626	\$0	\$40,858	\$0	\$0	\$114,484
339991	Gasket, Packing, and Sealing Device Manufacturing	\$15,837	\$0	\$5,158	\$0	\$0	\$20,994
339992	Musical Instrument Manufacturing	\$7,500	\$0	\$4,098	\$0	\$0	\$11,599
339993	Fastener, Button, Needle, and Pin Manufacturing	\$1,742	\$0	\$772	\$0	\$0	\$2,514

Table VI-12: Total Annualized Costs of Provisions in the Revised Standard, by Six-Digit NAICS for All Entities (7 Percent Discount Rate, 2022 Dollars)

NAICS Code	Industry	Rule Familiarization	Training	Revised SDS/ Labels [a]	Release for Shipment	Labels for Very Small Containers	Total Costs
339994	Broom, Brush, and Mop Manufacturing	\$3,702	\$0	\$1,383	\$0	\$0	\$5,085
339995	Burial Casket Manufacturing	\$1,420	\$0	\$699	\$0	\$0	\$2,119
339999	All Other Miscellaneous Manufacturing	\$38,329	\$0	\$20,997	\$0	\$0	\$59,325
42	Wholesale Trade	\$224,298	\$0	\$0	-\$20,038,538	\$0	-\$19,814,240
423	Merchant Wholesalers, Durable Goods	\$63,638	\$0	\$0	\$0	\$0	\$63,638
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	\$36,273	\$0	\$0	\$0	\$0	\$36,273
423840	Industrial Supplies Merchant Wholesalers	\$27,366	\$0	\$0	\$0	\$0	\$27,366
424	Merchant Wholesalers, Nondurable Goods	\$160,660	\$0	\$0	-\$20,038,538	\$0	-\$19,877,879
424210	Drugs and Druggists' Sundries Merchant Wholesalers	\$38,684	\$0	\$0	\$0	\$0	\$38,684
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	\$8,437	\$0	\$0	\$0	\$0	\$8,437
424690	Other Chemical and Allied Products Merchant Wholesalers	\$30,160	\$0	\$0	\$0	\$0	\$30,160
424710	Petroleum Bulk Stations and Terminals	\$13,870	\$0	\$0	\$0	\$0	\$13,870
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	\$7,833	\$0	\$0	\$0	\$0	\$7,833
424910	Farm Supplies Merchant Wholesalers	\$27,701	\$0	\$0	-\$15,678,794	\$0	-\$15,651,093
424950	Paint, Varnish, and Supplies Merchant Wholesalers	\$5,307	\$0	\$0	-\$4,359,744	\$0	-\$4,354,437
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	\$28,668	\$0	\$0	\$0	\$0	\$28,668
Total		\$1,143,462	\$136,953	\$3,861,911	-\$33,258,495	-\$1,713,243	-\$29,829,412

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

[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.

II. Estimation of Compliance Costs and Cost Savings.

The remainder of this section explains how OSHA calculated the estimated compliance costs and cost savings arising from the final rule by describing the data and methodology used and addresses relevant comments from stakeholders.

As explained above, the major elements of the 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 changes to Appendix B) and to conform to language criteria in precautionary statements and other mandatory language (per 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 revisions to the standard); (3) the cost of training employees as necessitated by the changes to the HCS (see HCS 2012 paragraph (h)(1)); (4) cost savings from the new released-for-shipment provision (revisions to paragraph (f)(11)); and (5) cost savings from limiting labeling requirements for certain very small containers (new paragraph (f)(12)).

The estimated compliance costs and cost savings presented in this analysis of the 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 final 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 provisions 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 titled Revisions to SDSs and Labels Due to Revised Precautionary Statements.

III. Costs Associated with Reclassifications and Revisions to Safety Data Sheets and Labels.

The 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 final rule will 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).

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 the FEA of the 2012 final rule (77 FR 17634-17637) for a discussion of factors that compel employers to update SDSs and labels voluntarily). OSHA received comments from the American Cleaning Institute (ACI) indicating that a longer compliance window would facilitate companies only needing to make one round of revisions to their labels

because if a company knows they already need to make one revision to an SDS or label within a certain window of time they will make all changes at the same time, thereby reducing costs (Document ID 0424, Tr. 53-54). As explained in the paragraph (j) discussion in Section XIV., Summary and Explanation of the Final Rule), OSHA is extending the phase-in period beyond what the agency proposed in the NPRM.

Also similar to the rule in 2012, OSHA anticipates that many firms have implemented or are beginning to implement hazard reclassifications, SDS revisions, software modifications, and other changes associated with this proposed rule, because these provisions are generally anticipated to be adopted as part of the implementation of the GHS in countries and regions around the world and Canada has already amended the HPR to align with Rev. 7. Since some other countries are already implementing the GHS, companies in the U.S. that ship to those countries are already having to comply with the GHS for products being exported (77 FR 17636).

The final rule requires limited changes to some SDSs and labels. Given the phase-in period for the changes to the standard,²⁹ which OSHA has extended from what was proposed in the NPRM, the agency expects that chemical manufacturers and importers will be able to phase in revisions to their labels and SDSs in accordance with the normal cycle of change, and therefore will not need to replace existing labels or SDSs.

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 revisions to the HCS. OSHA developed cost estimates based on the methodology used in

²⁹ The final standard requires that the revisions become effective 60 days after publication (paragraph (j)(1)); chemical manufacturers, importers, and distributors evaluating substances comply with all modified provisions within eighteen months after the effective date (paragraph (j)(2)(i)); employers updating alternative labeling, hazard communication programs, and training for substances comply with all modified provisions within two years after the effective date (paragraph (j)(2)(ii)); chemical manufacturers, importers, and distributors evaluating mixtures comply with all modified provisions within three years after the effective date (paragraph (j)(3)(i)); and employers updating alternative labeling, hazard communication programs, and training for mixtures comply with all modified provisions within three and a half years (paragraph (j)(3)(ii)).

its FEA in support of the 2012 HCS final rule (77 FR 17634 - 17637). The estimated compliance costs represent the incremental costs that will be incurred to achieve compliance with the final rule. These estimated costs will be in addition to the costs that already need to be incurred to comply with applicable requirements of the 2012 HCS that remain in place and represent the time it will 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 had an obligation under the 2012 HCS, which continues unchanged in this final rule, to ensure that the information provided in their SDSs and labels is accurate and current (paragraphs (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 (paragraphs (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 2012 HCS and this final rule, to review the available hazard information (paragraph (d)(2)), to classify the chemical in accordance with applicable hazard criteria (paragraph (d)(1)), and to develop corresponding SDSs (paragraph (g)) and labels (paragraph (f)). OSHA is not estimating costs for activities already required; rather, the agency is estimating costs for activities that will 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).

IV. Revisions to SDSs and Labels Due to Chemical Reclassification.

In the PEA, OSHA identified the NAICS industries involved in the manufacture of aerosols, desensitized explosives, or flammable gases and affected by the proposed

requirements for chemical reclassification. Of course, not all chemicals covered in these NAICS industries are aerosols, desensitized explosives, or flammable gases. In the PEA, OSHA estimated 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)³⁰ in these NAICS industries would be affected by the proposed requirements for aerosols, desensitized explosives, and flammable gases.

OSHA in the PEA derived the number of directly affected electronic files for SDSs and labels by applying the 50 percent factor to the overall number of affected SDSs (electronic files). For example, in NAICS 211130, the overall number of affected SDSs (technically, the number of electronic files) was 15,810 (Table VI-5 in the PEA). Applying a factor of 50 percent, OSHA estimated the number of SDSs (electronic files) that would be directly affected by the reclassification provision as 7,905. All of the preliminary estimates of directly affected SDSs (electronic files) were similarly derived from Table VI-5 (in the PEA), but only those NAICS industries with affected SDSs (electronic files) were reported in the PEA.

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 VI-5). In the PEA, OSHA expected that 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

³⁰ In this section OSHA uses the terms “SDSs” and “SDSs and labels” interchangeably because the agency’s understanding is that one electronic file is used, from which both SDSs and labels can be generated, and therefore there is not a separate calculation of the number of electronic files for labels.

with chemical reclassification under the proposed revisions to the HCS. It was OSHA's understanding that this has been the practice for decades, and no comments in the record challenged that understanding.

In the PEA, OSHA presented preliminary estimates of the amount of time the agency expected it will take to update electronic files for SDSs and labels under the proposed revisions to the standard. OSHA believed that the estimates provided in the PEA were reasonable because they reflected 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 believed that the estimated time to update SDSs and labels (electronic files) used in this analysis represented 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 in this final rule are significantly more limited in scope than the 2012 final rule, with fewer affected hazard categories and more limited changes; however, they still present opportunities for scale efficiencies in reclassification. As a result, OSHA estimated 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).³¹ At a loaded hourly wage (including overhead) of \$58.00 for a Health and Safety Specialist, this resulted in unit costs in the PEA 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 yielded 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 seven percent discount rate over a ten-year period results in estimated annualized costs of approximately \$915,095. OSHA invited public comments on its preliminary projection that 50 percent of the electronic files for SDSs and labels would be affected in these industries and the other preliminary assumptions and unit estimates presented in the PEA and described above.

OSHA received some comments on its general analysis in this section. NACD characterized the updates to SDSs as “a major undertaking for chemical manufacturers and distributors” and further noted, “[t]aking into account not only the actual updates to these documents by vendors or company personnel, but also company staff review time, supply chain communications, and training, NACD members estimate that the cost of updating a single SDS ranges from \$400 to nearly \$1600” (Document ID 0465, p. 2).

As noted earlier in this FEA, ILMA surveyed its members on impacts of the proposed standard. On the question of the incremental costs of updating SDSs, ILMA submitted the following summary of survey responses. They noted that, of 16 respondents, 12 indicated they authored 400 or more SDSs (one company reported between 7,000 and 8,000), and that they estimated the cost of updating each SDS as \$400-600. They also stated that “Some respondents to the survey noted that, while

³¹ 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.

updates to labels and SDS occur on a regular basis, these updates usually involve editorial changes made to incorporate information such as name changes. Therefore...the \$400-\$600 cost estimate to review *each* and *every* SDS needs to be included as incremental costs, as those costs would not be part of the companies' 'routine' compliance costs" (Document ID 0444, Att. 1, pp. 1-2).

In their comments, the North American Insulation Manufacturers Association (NAIMA) described the contractual arrangements and operational practices typically conducted by their members when there arises the need for updating SDSs and labels. In particular, they noted that every time a change is made to a label, the manufacturer must redesign the entire label to make sure it all fits on the packaging, which is expensive, and some label printers still use printing plates which need to be replaced. They also noted that they spent time reviewing materials received from contractors and getting labels translated into other languages, and that there were often costly delays in receiving packaging materials. They argued that OSHA needed to account for these costs (Document ID 0461, pp. 3-4). Several commenters discussed costs of labels specifically. The American Coatings Association (ACA) testified that member employers would incur substantial additional expense to update labels if the proposed revisions were published as the final rule and stated that members had indicated costs between \$300,000 and \$800,000 to update their labels alone. They also noted that disposal of existing labels can be two to three percent of labeling costs and that small businesses cannot absorb these costs as operating expenses (Document ID 0425, Tr. 109-110). Similarly, Ameren stated "Ameren would incur an additional cost for having to re-print and replace current labels based on the new OSHA changes. The cost is estimated at \$5 [m]illion and would take over two years to complete" (Document ID 0309, p. 5). OSHA notes that ACA and Ameren did not provide details underlying their estimates so the magnitude and severity of the cost increase cannot be evaluated by OSHA without further information on

baseline costs and company revenue that factor into these estimates. Moreover, the final standard does not include the proposed requirement that a released-for-shipment date appear on the label, which will lower the labeling costs for manufacturers, importers, and distributors compared to what they anticipated at the time comments were submitted.

The Sporting Arms and Ammunition Manufacturers' Institute (SAAMI) voiced concerns similar to those of ACA with regard to labeling costs and noted the costs of new printing plates and disposal of existing labels, particularly for manufacturers who may have as many as 4,000 products that need to go through this process (Document ID 0423, Att. 1, Tr. 84). Hach also noted skepticism regarding the idea that these costs could be absorbed under the normal costs of business, partly due to the limited space on their labels (Document ID 0425, Tr. 102). Hach further commented on the costs of the proposed rule by providing information on its cost data for SDS templates provided by a software service vendor. They provided data on two different vendors, one of which cost \$230,000 to purchase, \$120,000 in annual maintenance costs for global regulatory updates and another \$1,100 for annual maintenance specific to SDSs for the United States. The other vendor cost \$60,215 for the initial implementation of the templates and \$100,825 for an annual license (Document ID 0427, p. 2).

OSHA does not agree with these commenters' arguments that the preliminary cost analysis did not account for the costs for new or updated printing plates, the disposal of existing labels, and other operational changes associated with the proposed revisions to the reclassification requirements in HCS. As noted earlier, OSHA's understanding is that in many cases responsible parties would have needed to update their SDSs and labels within the extended compliance time frame even if there were no updates to the HCS, and therefore some of these costs (such as label disposal and new printing plates) would already be incurred. The agency expects that responsible parties will fold the HCS updates into those standard updating cycles so that they only need to incur these costs

once and this means the HCS updates are not creating those costs. Therefore, OSHA is not persuaded that the compliance burden described by the stakeholders discussed above will exceed the customary and usual business practices or the business practices expected during the implementation timeline prescribed in final paragraph (j) for chemical employers affected by the final rule and is thus not taking additional costs for those issues. OSHA is, however, adjusting the time it expects it to take responsible parties to update the electronic SDS and label files, partly based on the content of these comments (see discussion below).

OSHA also received several comments expressing concerns regarding the economic costs of the proposed language in paragraph (d)(1). The United States Beet Sugar Association, the National Grain and Feed Association, the North American Millers Association, Corn Refiners Association, the National Oilseed Processors Association, and the United States Chamber of Commerce (USBSA et al.) stated that the proposed language in (d)(1) would “greatly increase the cost of chemical classification” (Document ID 0325, p. 9). The American Chemistry Council (ACC) surveyed their membership to identify and characterize current practices on communicating hazards within their industry. Based on that information, ACC stated that OSHA had failed to account for hazard classification costs associated with the proposed revisions to paragraph (d)(1), including the large number of SDSs that would need to be changed, the amount of time required to produce the SDSs, and the software costs associated with needing new or updated technology to comply. They argued that this could cost manufacturers and importers millions of dollars (Document ID 0468, pp. 3-5). The ACC survey results included statements from their membership with estimates about the time and costs associated with the proposed paragraph (d)(1), including an estimate that it would take about 16 hours to update each SDS and about 50 percent of products would require communication with customers to ascertain downstream uses, which would result in an

additional 17,500-70,000 hours of work. Concern was also expressed that this would cover as many as 5,000-7,000 products that were not previously within the scope of the HCS (Document ID 0468, p. 10).

The NAIMA expressed concerns about the proposed implementation schedule and the costs of compliance moving forward under the proposed language in paragraph (d)(1). Specifically, they noted “it appears that every newly discovered hazard of the substance identified by a chemical manufacturer’s ongoing investigation of downstream hazards would trigger the three- and six-month updating provisions of the HCS for SDSs and labels, which could lead to a continuous series of reclassifications triggering those updating requirements” and argued that “[e]ach SDS revision cascading down would incur costs which do not seem to have been adequately accounted in OSHA’s cost-benefit analysis” (Document ID 0461, p. 2).

The American Composite Manufacturers Association (ACMA) stated that the proposed changes to paragraph (d)(1) would result in upstream chemical suppliers needing to perform a hazard analysis similar to what is required under OSHA’s Process Safety Management of Highly Hazardous Chemicals (PSM) standard and that “[t]he [process hazard analyses (PHAs)] that would be required by OSHA’s proposed change to 1910.1200(d)(1) would extend to every hazardous chemical in the U.S. and would cover every use of a flammable liquid or gas as a fuel.” They also noted that “[a]ccording to EPA, the TSCA chemical inventory contains 86,557 chemicals of which 41,864 are active. Any reasonably chosen ratio of the number of active hazardous chemicals in the EPA inventory to the 110 HHCs covered by the PSM standard suggests the costs of compliance with OSHA’s proposed change to 1910.1200(d)(1) would be enormous” (Document ID 0318, p. 8). OSHA notes that ACMA also asserted in their comment that the proposed language in paragraph (d)(1) is economically infeasible but did not provide financial data to corroborate the assertion. As explained in Section G of this FEA, OSHA

has determined based on the record evidence that the requirements of this final rule are economically feasible.

The Plastics Industry Association (PLASTICS) also likened the proposed language in paragraph (d)(1) to PHAs and discussed the associated burden of collecting the process safety information for “nearly one million hazardous chemical products... previously estimated...to be in U.S. workplaces” as well as the need to determine foreseeable emergencies, “some of which may produce new chemicals” (Document ID 0314, Att. 1, p. 12) (footnote omitted). They indicated that such a requirement would require upstream suppliers to hire personnel to collect the necessary information as well. They argued that OSHA needed to incorporate the costs of this provision and stated that OSHA had not done so (Document ID 0314, Att. 1, pp. 10-12). They stated that “[f]or a chemical with broad applications, classifying it to include all of the classified hazards of every downstream reaction, and then creating an SDS to cover all of these issues would be a monumental, infeasible and counterproductive task.” (Document ID 0467, p. 21). ACC’s survey of its members also discussed the role of PHAs in company operations and the rigorous procedures necessary to develop and communicate such analyses (Document ID 0468, pp. 6-7).

In the Summary and Explanation for paragraph (d), OSHA responds to the concerns voiced by stakeholders about the scope of paragraph (d) and the comparisons to PHAs. In its response, OSHA states that it did not intend for an upstream supplier or manufacturer to identify and classify every single hazard associated with the downstream use of chemicals, only those where the manufacturer knows or can reasonably anticipate the chemical’s uses. OSHA has changed the language in paragraph (d)(1) from the proposed language in the NPRM to clarify this scope and concludes that many of the comments discussing the economic ramifications of this proposed language were based on this misunderstanding of what OSHA intended SDS and label preparers to do.

In response to the comments on OSHA's preliminary unit cost estimates for chemical reclassification on SDSs and labels in relation to paragraph (d)(1), the agency has reviewed the preliminary number of affected SDSs and labels and the preliminary time estimates for updating and expanding the use of SDSs and labels.

As noted earlier, OSHA in the PEA derived the number of directly affected electronic files for SDSs and labels by applying the 50 percent factor to the overall number of affected SDSs (electronic files) from Table VI-5. None of the public criticisms quoted above specifically referenced the 50 percent factor. Many of the commenters indicated that they believed the HCS updates to paragraph (d)(1) would impact many more SDSs than OSHA accounted for in its PEA but, as OSHA states in the Summary and Explanation for paragraph (d), this requirement already existed under the 2012 HCS and the language in paragraph (d) is merely a clarification of the existing requirements. Because many commenters misinterpreted the scope of what OSHA was proposing, the agency does not believe these comments are representative of the number of SDSs that will need to be updated and the agency does not take costs associated with clarifications that do not change the underlying requirements of the standard. Therefore, for this FEA OSHA has maintained the percentage factor of affected SDSs and labels estimated in the PEA at 50 percent and the industries it expects will be impacted by reclassification requirements.

As discussed earlier in this section, OSHA presented in the PEA estimates of the amount of time it will take to update electronic files for SDSs and labels under the proposed revisions to the standard. OSHA's estimates in the PEA reflected the agency's initial assessment of 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.

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 in this final rulemaking are significantly more limited in scope than the 2012 final rule, with fewer affected hazard categories and more limited changes; nonetheless, based on public comments, OSHA recognizes that affected employers may face adjustments to their schedule for updating SDSs and labels due to chemical reclassification. OSHA also recognizes based on comments that it may have underestimated in the 2012 HCS FEA and the 2021 PEA the time and costs associated with identifying hazards from downstream uses. While those costs have already been incurred for all existing products because this is an existing requirement, OSHA recognizes that for the products undergoing reclassification (aerosols, flammable gases, and desensitized explosives), these costs will be incurred again and is therefore adjusting upwards its time estimates. As a result, OSHA in this FEA estimates that a Health and Safety Specialist would spend about 30 percent (increased from 25 percent in the PEA) as much time to reclassify a chemical as OSHA estimated for the 2012 HCS rule – depending on establishment size, from 0.90 hours to 2.10 hours per SDS (electronic file) requiring reclassification (2.10 hours per SDS for establishments with fewer than 100 employees; 1.50 hours per SDS for establishments with 100-499 employees; and 0.90 hours per SDS for establishments with 500 or more employees).³² At a loaded hourly wage (including overhead) of \$61.18 for a Health and Safety Specialist, this would result in unit costs of \$128.48, \$91.77, and \$55.06 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

³² Note that OSHA estimated no baseline compliance for chemical manufacturers already having revised electronic files to reflect reclassified chemicals as specified in the final rule; the current HCS does not allow SDSs or labels to display chemical classifications that are not in conformance with the current rule.

yields an undiscounted one-time estimated cost of \$8.2 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 \$1,168,932 for reclassification in accordance with the criteria specified in the revisions to the HCS.

OSHA does not agree, however, with commenters who argued that the proposed language in paragraph (d)(1) would create burdens that are cost prohibitive. First, as discussed, the requirement to classify based on downstream hazards already existed and OSHA is simply clarifying that requirement by adding this language to paragraph (d)(1). Additionally, OSHA received comments and testimony from several entities regarding existing SDSs that include information about downstream hazards and companies that maintain product stewardship programs to address these issues. NABTU cited field observation of companies who routinely include on SDSs and labels information on reasonably anticipated downstream use of products: “[i]t is . . . worth noting that there are companies producing building materials that are responsibly anticipating the downstream uses of their products and creating product stewardship programs aimed at improving recognition and control of hazards during the life cycle of their products. Where it is reasonable to assume that manufacturers can anticipate their products’ ‘normal conditions of use,’ it is equally reasonable – and critically important – to require those manufacturers to include the attendant chemical reaction hazard information on their SDSs and labels, and to do so in a consistent manner” (Document ID 0464, p. 5).

NIOSH stated that they are aware of more manufacturers developing this type of product stewardship to inform downstream users (Document ID 0423, Tr. 39; 0456, Att. 2, p. 2). ACC also submitted information on several product stewardship programs their organization undertakes to inform downstream users of potential hazards that may result upon use of their chemicals (Document ID 0468, p. 5). ACC product stewardship resources include technical and regulatory data sheets, literature, product handling

guidelines, site visits, and special instructions for safe handling of materials of more concern (Document ID 0468, p. 5).

These comments highlight the significant and ongoing stewardship initiatives among chemical producers, importers, and distributors and substantiate OSHA's preliminary judgment of the economic feasibility of the revised HCS standard. Therefore, in OSHA's view, the modest adjustment to the preliminary unit cost estimate in this FEA reflects, in approximate terms, current industry practices in the reclassification of chemical hazards on SDSs and labels.

Table VI-13: Total Costs Associated with Chemical Reclassifications and Related Revisions to Safety Data Sheets and Labels under the Revisions to the HCS (2022 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%	1,323	2.10	\$128.48	\$169,920	\$24,193
324110	Petroleum Refineries	50%	125	2.10	\$128.48	\$16,060	\$2,287
325110	Petrochemical Manufacturing	50%	40	2.10	\$128.48	\$5,139	\$732
325120	Industrial Gas Manufacturing	50%	51	2.10	\$128.48	\$6,553	\$933
325320	Pesticide and Other Agricultural Chemical Manufacturing	50%	389	2.10	\$128.48	\$49,916	\$7,107
325412	Pharmaceutical Preparation Manufacturing	50%	1,660	2.10	\$128.48	\$213,283	\$30,367
325510	Paint and Coating Manufacturing	50%	1,575	2.10	\$128.48	\$202,362	\$28,812
325520	Adhesive Manufacturing	50%	540	2.10	\$128.48	\$69,381	\$9,878
325611	Soap and Other Detergent Manufacturing	50%	1,160	2.10	\$128.48	\$149,041	\$21,220
325612	Polish and Other Sanitation Good Manufacturing	50%	296	2.10	\$128.48	\$38,031	\$5,415
325613	Surface Active Agent Manufacturing	50%	148	2.10	\$128.48	\$18,951	\$2,698
325620	Toilet Preparation Manufacturing	50%	698	2.10	\$128.48	\$89,682	\$12,769
325920	Explosives Manufacturing	50%	18	2.10	\$128.48	\$2,313	\$329
Subtotal		–	8,022	2.10	\$128.48	\$1,030,631	\$146,739
SDSs at Establishments with 20-99 Employees							
211130	Natural Gas Extraction	50%	593	2.10	\$128.48	\$76,127	\$10,839
324110	Petroleum Refineries	50%	90	2.10	\$128.48	\$11,564	\$1,646
325110	Petrochemical Manufacturing	50%	60	2.10	\$128.48	\$7,709	\$1,098
325120	Industrial Gas Manufacturing	50%	11	2.10	\$128.48	\$1,349	\$192
325320	Pesticide and Other Agricultural Chemical Manufacturing	50%	218	2.10	\$128.48	\$27,945	\$3,979
325412	Pharmaceutical Preparation Manufacturing	50%	985	2.10	\$128.48	\$126,556	\$18,019
325510	Paint and Coating Manufacturing	50%	2,190	2.10	\$128.48	\$281,379	\$40,062
325520	Adhesive Manufacturing	50%	1,650	2.10	\$128.48	\$211,998	\$30,184
325611	Soap and Other Detergent Manufacturing	50%	765	2.10	\$128.48	\$98,290	\$13,994
325612	Polish and Other Sanitation Good Manufacturing	50%	548	2.10	\$128.48	\$70,345	\$10,016
325613	Surface Active Agent Manufacturing	50%	180	2.10	\$128.48	\$23,127	\$3,293
325620	Toilet Preparation Manufacturing	50%	1,890	2.10	\$128.48	\$242,834	\$34,574
325920	Explosives Manufacturing	50%	35	2.10	\$128.48	\$4,497	\$640
Subtotal		–	9,213	2.10	\$128.48	\$1,183,719	\$168,535
SDSs at Establishments with 100-499 Employees							
211130	Natural Gas Extraction	50%	773	1.50	\$91.77	\$70,895	\$10,094
324110	Petroleum Refineries	50%	675	1.50	\$91.77	\$61,947	\$8,820
325110	Petrochemical Manufacturing	50%	150	1.50	\$91.77	\$13,766	\$1,960
325120	Industrial Gas Manufacturing	50%	23	1.50	\$91.77	\$2,065	\$294

Table VI-13: Total Costs Associated with Chemical Reclassifications and Related Revisions to Safety Data Sheets and Labels under the Revisions to the HCS (2022 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%)
325320	Pesticide and Other Agricultural Chemical Manufacturing	50%	480	1.50	\$91.77	\$44,052	\$6,272
325412	Pharmaceutical Preparation Manufacturing	50%	1,410	1.50	\$91.77	\$129,401	\$18,424
325510	Paint and Coating Manufacturing	50%	8,625	1.50	\$91.77	\$791,551	\$112,699
325520	Adhesive Manufacturing	50%	1,890	1.50	\$91.77	\$173,453	\$24,696
325611	Soap and Other Detergent Manufacturing	50%	1,325	1.50	\$91.77	\$121,601	\$17,313
325612	Polish and Other Sanitation Good Manufacturing	50%	1,150	1.50	\$91.77	\$105,540	\$15,027
325613	Surface Active Agent Manufacturing	50%	475	1.50	\$91.77	\$43,593	\$6,207
325620	Toilet Preparation Manufacturing	50%	2,275	1.50	\$91.77	\$208,786	\$29,726
325920	Explosives Manufacturing	50%	250	1.50	\$91.77	\$22,943	\$3,267
Subtotal		–	19,500	1.50	\$91.77	\$1,789,593	\$254,798
SDSs at Establishments with 500+ Employees							
211130	Natural Gas Extraction	50%	6,050	0.90	\$55.06	\$333,140	\$47,432
324110	Petroleum Refineries	50%	9,450	0.90	\$55.06	\$520,358	\$74,087
325110	Petrochemical Manufacturing	50%	2,118	0.90	\$55.06	\$116,599	\$16,601
325120	Industrial Gas Manufacturing	50%	2,145	0.90	\$55.06	\$118,113	\$16,817
325320	Pesticide and Other Agricultural Chemical Manufacturing	50%	1,326	0.90	\$55.06	\$73,015	\$10,396
325412	Pharmaceutical Preparation Manufacturing	50%	4,225	0.90	\$55.06	\$232,647	\$33,124
325510	Paint and Coating Manufacturing	50%	23,513	0.90	\$55.06	\$1,294,701	\$184,336
325520	Adhesive Manufacturing	50%	10,860	0.90	\$55.06	\$597,999	\$85,142
325611	Soap and Other Detergent Manufacturing	50%	6,000	0.90	\$55.06	\$330,386	\$47,040
325612	Polish and Other Sanitation Good Manufacturing	50%	3,525	0.90	\$55.06	\$194,102	\$27,636
325613	Surface Active Agent Manufacturing	50%	1,950	0.90	\$55.06	\$107,376	\$15,288
325620	Toilet Preparation Manufacturing	50%	4,100	0.90	\$55.06	\$225,764	\$32,144
325920	Explosives Manufacturing	50%	1,125	0.90	\$55.06	\$61,947	\$8,820
Subtotal		–	76,386	0.90	\$55.06	\$4,206,148	\$598,861
Total/Average							
211130	Natural Gas Extraction	50%	8,738	1.22	\$74.40	\$650,081	\$92,557
324110	Petroleum Refineries	50%	10,340	0.96	\$58.99	\$609,930	\$86,840
325110	Petrochemical Manufacturing	50%	2,368	0.99	\$60.49	\$143,213	\$20,390
325120	Industrial Gas Manufacturing	50%	2,229	0.94	\$57.46	\$128,080	\$18,236
325320	Pesticide and Other Agricultural Chemical Manufacturing	50%	2,412	1.32	\$80.82	\$194,928	\$27,753
325412	Pharmaceutical Preparation Manufacturing	50%	8,280	1.39	\$84.77	\$701,887	\$99,933
325510	Paint and Coating Manufacturing	50%	35,903	1.17	\$71.58	\$2,569,993	\$365,909
325520	Adhesive Manufacturing	50%	14,940	1.15	\$70.47	\$1,052,831	\$149,899
325611	Soap and Other Detergent Manufacturing	50%	9,250	1.24	\$75.60	\$699,318	\$99,567

Table VI-13: Total Costs Associated with Chemical Reclassifications and Related Revisions to Safety Data Sheets and Labels under the Revisions to the HCS (2022 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%)
325612	Polish and Other Sanitation Good Manufacturing	50%	5,519	1.21	\$73.94	\$408,018	\$58,093
325613	Surface Active Agent Manufacturing	50%	2,753	1.15	\$70.13	\$193,047	\$27,485
325620	Toilet Preparation Manufacturing	50%	8,963	1.40	\$85.58	\$767,065	\$109,213
325920	Explosives Manufacturing	50%	1,428	1.05	\$64.22	\$91,701	\$13,056
Total		—	113,121	1.19	\$72.58	\$8,210,091	\$1,168,932

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Note: Figures may not add to totals due to rounding.

V. Revisions to SDSs and Labels Due to Revised Precautionary Statements, etc.

The revisions to the HCS 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 changes to the standard, affected establishments must 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 paragraphs (f) and (g)). The modification of SDSs and labels under the revisions in Appendices C and D involves conforming to formatting and language standards, but does not require any 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 changes to the appendices require only limited changes to the electronic content of SDSs and labels, and, as explained previously and in the PEA, OSHA expects that the phase-in period for the changes to the standard will 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 will not be necessary to replace existing labels or SDSs. OSHA also believes that the extended phase-in period will accommodate the need for the purchase of software packages or renewal of licenses for SDSs and labels, impacts noted by ILMA at the public hearings (Document ID 0404, Att. 1, p. 2).

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 revisions to Appendices C and D represent the

³³ See discussion in the preamble to the 2012 HCS final rule (77 FR 17634).

incremental costs that will be incurred to achieve compliance with the final changes to the appendices. In the PEA, OSHA estimated 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 three to seven 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 2012.³⁴ OSHA estimated 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.

As in the FEA for the 2012 HCS final rule, OSHA anticipates that some manufacturers, particularly larger ones heavily involved in international trade, are more likely because of their size to have created SDSs and labels that need to be GHS-compliant and therefore are likely to 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.³⁵ These baseline compliance rates are the same ones OSHA used in the 2012 FEA (77 FR 17636).

³⁴ 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.

³⁵ 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

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,³⁶ results in an estimated total one-time cost of \$18.9 million associated with revising SDSs and labels to conform to the proposed appendix language on precautionary statements and other mandatory language. Annualizing this one-time cost using a seven percent discount rate over a 10-year period results in estimated annualized costs of approximately \$2.7 million for affected employers to revise SDSs and labels to comply with the proposed revisions to Appendices C and D.

OSHA requested comments on the preliminary unit cost estimates and other underlying assumptions for the preliminary cost analysis of revisions to the mandatory appendices. There were no comments specifically addressing the unit cost estimates and other methodological assumptions underlying OSHA's preliminary cost estimate.

Earlier in this FEA, OSHA responds to the comments voiced by commenters about label costs specifically. To the extent that new precautionary statements are needed on labels due to reclassification, OSHA believes it has incorporated those costs into its upward adjustment of the costs of reclassification and will not double count those costs by also increasing its estimate of costs for updating precautionary statements and other mandatory language. Thus, for this final analysis of the incremental compliance costs associated with the mandatory appendices, OSHA applied the unit labor time and baseline compliance assumptions from the PEA, and, combined with fully-loaded 2022 wage rates, generated final cost estimates, by NAICS category. As noted earlier, these

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.

³⁶ That is, mathematically, $(1 - \text{the relevant baseline compliance rate})$. Estimated non-compliance rates are shown in Column 6 of Table VI-14 by employment size for each affected NAICS industry.

estimated costs are in addition to the costs that are already incurred to comply with applicable requirements of the existing HCS.

NACD questioned OSHA's preliminary time allocation to the employer class sizes (small, medium and large companies) in the estimation of costs. NACD cited an estimate for a member company that has "10,000 SDSs to review to meet the new standard and 4,000 to update. Even at OSHA's .7 hours per SDS, that is 16 months of dedicated work" (Document ID 0329, p. 11). Additionally, they stated that "OSHA's estimates are only somewhat realistic if a company has in-house SDS authoring software and has maintained formulas and data used in classification. If updated formulas or other data need to be obtained...these documents will take significantly longer to update." Alternatively, they noted that if companies use a vendor, they will likely be charged between \$400 and \$800 for the production of an SDS and label for a single product (Document ID 0329, p. 11).

To the extent that NACD is concerned that some chemical distributors may need additional time to comply, either with additional in-house staff or with contractors, OSHA has updated the final rule to provide for eighteen to thirty-six months (depending on the nature of the chemical compound) following publication of the rule for chemical distributors to implement compliance with all modified provisions. To the extent that NACD is arguing that OSHA has underestimated the in-house labor costs for updating SDSs and labels, they have only argued that OSHA has possibly underestimated for a subset of companies and has not provided data on how OSHA could differentiate which companies this would be true for or how significant they think OSHA's underestimates are, so OSHA is unable to evaluate this claim. And finally, to the extent that NACD is arguing that the vendor prices will result in higher costs than the agency estimates, as OSHA has previously stated it believes that updates are going to be folded into the normal cycle of updates for which companies would also use these contractors so the full

cost of a contractor producing an SDS or label is not attributable to the HCS updates as NACD suggests.

Table VI-14 shows the estimated costs associated with modifications to electronic templates for SDSs and labels to conform to formatting and language criteria in precautionary statements and other mandatory language specified in the revisions to Appendices C and D by NAICS industry and establishment size. The NAICS industries listed in Columns 1 and 2 of Table VI-14 are those that OSHA expects will need to update SDSs and labels under the 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 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 VI-5, VI-6, and VI-7.

The estimates of total costs in Table VI-14 are included within a broader cost category shown earlier in the aggregate costs presented in Table VI-12. Column 5 of Table VI-12 displays, by NAICS code, the combined annualized cost estimates for reclassifying chemicals (from Table VI-13) and revising SDSs and labels to be consistent with the precautionary statements and other language specified in the revisions to the mandatory appendices (from Table VI-14).

Table VI-14: Total Costs Associated with Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2022 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	19,300	0.7	\$42.83	99%	\$818,312	\$116,509
211130	Natural Gas Extraction	2,645	0.7	\$42.83	99%	\$112,147	\$15,967
324110	Petroleum Refineries	250	0.7	\$42.83	99%	\$10,600	\$1,509
324121	Asphalt Paving Mixture and Block Manufacturing	2,440	0.7	\$42.83	99%	\$103,455	\$14,730
324122	Asphalt Shingle and Coating Materials Manufacturing	570	0.7	\$42.83	99%	\$24,168	\$3,441
324191	Petroleum Lubricating Oil and Grease Manufacturing	25,600	0.7	\$42.83	99%	\$1,085,429	\$154,541
324199	All Other Petroleum and Coal Products Manufacturing	340	0.7	\$42.83	99%	\$14,416	\$2,052
325110	Petrochemical Manufacturing	80	0.7	\$42.83	99%	\$3,392	\$483
325120	Industrial Gas Manufacturing	102	0.7	\$42.83	99%	\$4,325	\$616
325130	Synthetic Dye and Pigment Manufacturing	416	0.7	\$42.83	99%	\$17,638	\$2,511
325180	Other Basic Inorganic Chemical Manufacturing	604	0.7	\$42.83	99%	\$25,609	\$3,646
325193	Ethyl Alcohol Manufacturing	85	0.7	\$42.83	99%	\$3,604	\$513
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	133	0.7	\$42.83	99%	\$5,639	\$803
325199	All Other Basic Organic Chemical Manufacturing	1,988	0.7	\$42.83	99%	\$84,290	\$12,001
325211	Plastics Material and Resin Manufacturing	1,760	0.7	\$42.83	99%	\$74,623	\$10,625
325212	Synthetic Rubber Manufacturing	118	0.7	\$42.83	99%	\$5,003	\$712
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	38	0.7	\$42.83	99%	\$1,611	\$229
325311	Nitrogenous Fertilizer Manufacturing	109	0.7	\$42.83	99%	\$4,622	\$658
325312	Phosphatic Fertilizer Manufacturing	10	0.7	\$42.83	99%	\$424	\$60
325314	Fertilizer (Mixing Only) Manufacturing	484	0.7	\$42.83	99%	\$20,521	\$2,922
325320	Pesticide and Other Agricultural Chemical Manufacturing	777	0.7	\$42.83	99%	\$32,944	\$4,691
325411	Medicinal and Botanical Manufacturing	1,985	0.7	\$42.83	99%	\$84,163	\$11,983
325412	Pharmaceutical Preparation Manufacturing	3,320	0.7	\$42.83	99%	\$140,767	\$20,042
325413	In-Vitro Diagnostic Substance Manufacturing	950	0.7	\$42.83	99%	\$40,280	\$5,735
325414	Biological Product (except Diagnostic) Manufacturing	417	0.7	\$42.83	99%	\$17,681	\$2,517
325510	Paint and Coating Manufacturing	3,150	0.7	\$42.83	99%	\$133,559	\$19,016
325520	Adhesive Manufacturing	1,080	0.7	\$42.83	99%	\$45,792	\$6,520
325611	Soap and Other Detergent Manufacturing	2,320	0.7	\$42.83	99%	\$98,367	\$14,005
325612	Polish and Other Sanitation Good Manufacturing	592	0.7	\$42.83	99%	\$25,101	\$3,574
325613	Surface Active Agent Manufacturing	295	0.7	\$42.83	99%	\$12,508	\$1,781
325620	Toilet Preparation Manufacturing	1,396	0.7	\$42.83	99%	\$59,190	\$8,427
325910	Printing Ink Manufacturing	495	0.7	\$42.83	99%	\$20,988	\$2,988
325920	Explosives Manufacturing	36	0.7	\$42.83	99%	\$1,526	\$217
325991	Custom Compounding of Purchased Resins	368	0.7	\$42.83	99%	\$15,603	\$2,222

Table VI-14: Total Costs Associated with Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2022 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%)
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	366	0.7	\$42.83	99%	\$15,518	\$2,209
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	3,600	0.7	\$42.83	99%	\$152,638	\$21,732
339112	Surgical and Medical Instrument Manufacturing	689	0.7	\$42.83	99%	\$29,213	\$4,159
339113	Surgical Appliance and Supplies Manufacturing	1,149	0.7	\$42.83	99%	\$48,717	\$6,936
339114	Dental Equipment and Supplies Manufacturing	447	0.7	\$42.83	99%	\$18,953	\$2,698
339115	Ophthalmic Goods Manufacturing	240	0.7	\$42.83	99%	\$10,176	\$1,449
339116	Dental Laboratories	4,796	0.7	\$42.83	99%	\$203,348	\$28,952
339910	Jewelry and Silverware Manufacturing	1,797	0.7	\$42.83	99%	\$76,192	\$10,848
339920	Sporting and Athletic Goods Manufacturing	1,280	0.7	\$42.83	99%	\$54,271	\$7,727
339930	Doll, Toy, and Game Manufacturing	442	0.7	\$42.83	99%	\$18,741	\$2,668
339940	Office Supplies (except Paper) Manufacturing	329	0.7	\$42.83	99%	\$13,949	\$1,986
339950	Sign Manufacturing	4,931	0.7	\$42.83	99%	\$209,072	\$29,767
339991	Gasket, Packing, and Sealing Device Manufacturing	269	0.7	\$42.83	99%	\$11,405	\$1,624
339992	Musical Instrument Manufacturing	495	0.7	\$42.83	99%	\$20,988	\$2,988
339993	Fastener, Button, Needle, and Pin Manufacturing	71	0.7	\$42.83	99%	\$3,010	\$429
339994	Broom, Brush, and Mop Manufacturing	92	0.7	\$42.83	99%	\$3,901	\$555
339995	Burial Casket Manufacturing	60	0.7	\$42.83	99%	\$2,544	\$362
339999	All Other Miscellaneous Manufacturing	2,555	0.7	\$42.83	99%	\$108,331	\$15,424
Subtotal		97,861	0.7	\$42.83	99%	\$4,149,265	\$590,762
SDSs at Establishments with 20-99 Employees							
211120	Crude Petroleum Extraction	4,710	0.7	\$42.83	95%	\$191,633	\$27,284
211130	Natural Gas Extraction	1,185	0.7	\$42.83	95%	\$48,213	\$6,865
324110	Petroleum Refineries	180	0.7	\$42.83	95%	\$7,324	\$1,043
324121	Asphalt Paving Mixture and Block Manufacturing	4,170	0.7	\$42.83	95%	\$169,663	\$24,156
324122	Asphalt Shingle and Coating Materials Manufacturing	1,050	0.7	\$42.83	95%	\$42,721	\$6,082
324191	Petroleum Lubricating Oil and Grease Manufacturing	63,000	0.7	\$42.83	95%	\$2,563,247	\$364,949
324199	All Other Petroleum and Coal Products Manufacturing	240	0.7	\$42.83	95%	\$9,765	\$1,390
325110	Petrochemical Manufacturing	120	0.7	\$42.83	95%	\$4,882	\$695
325120	Industrial Gas Manufacturing	21	0.7	\$42.83	95%	\$854	\$122
325130	Synthetic Dye and Pigment Manufacturing	390	0.7	\$42.83	95%	\$15,868	\$2,259
325180	Other Basic Inorganic Chemical Manufacturing	564	0.7	\$42.83	95%	\$22,947	\$3,267
325193	Ethyl Alcohol Manufacturing	710	0.7	\$42.83	95%	\$28,887	\$4,113
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	150	0.7	\$42.83	95%	\$6,103	\$869
325199	All Other Basic Organic Chemical Manufacturing	2,070	0.7	\$42.83	95%	\$84,221	\$11,991

Table VI-14: Total Costs Associated with Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2022 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%)
325211	Plastics Material and Resin Manufacturing	6,050	0.7	\$42.83	95%	\$246,153	\$35,047
325212	Synthetic Rubber Manufacturing	175	0.7	\$42.83	95%	\$7,120	\$1,014
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	28	0.7	\$42.83	95%	\$1,139	\$162
325311	Nitrogenous Fertilizer Manufacturing	38	0.7	\$42.83	95%	\$1,546	\$220
325312	Phosphatic Fertilizer Manufacturing	10	0.7	\$42.83	95%	\$407	\$58
325314	Fertilizer (Mixing Only) Manufacturing	500	0.7	\$42.83	95%	\$20,343	\$2,896
325320	Pesticide and Other Agricultural Chemical Manufacturing	435	0.7	\$42.83	95%	\$17,699	\$2,520
325411	Medicinal and Botanical Manufacturing	1,040	0.7	\$42.83	95%	\$42,314	\$6,025
325412	Pharmaceutical Preparation Manufacturing	1,970	0.7	\$42.83	95%	\$80,152	\$11,412
325413	In-Vitro Diagnostic Substance Manufacturing	860	0.7	\$42.83	95%	\$34,990	\$4,982
325414	Biological Product (except Diagnostic) Manufacturing	280	0.7	\$42.83	95%	\$11,392	\$1,622
325510	Paint and Coating Manufacturing	4,380	0.7	\$42.83	95%	\$178,207	\$25,373
325520	Adhesive Manufacturing	3,300	0.7	\$42.83	95%	\$134,265	\$19,116
325611	Soap and Other Detergent Manufacturing	1,530	0.7	\$42.83	95%	\$62,250	\$8,863
325612	Polish and Other Sanitation Good Manufacturing	1,095	0.7	\$42.83	95%	\$44,552	\$6,343
325613	Surface Active Agent Manufacturing	360	0.7	\$42.83	95%	\$14,647	\$2,085
325620	Toilet Preparation Manufacturing	3,780	0.7	\$42.83	95%	\$153,795	\$21,897
325910	Printing Ink Manufacturing	1,000	0.7	\$42.83	95%	\$40,686	\$5,793
325920	Explosives Manufacturing	70	0.7	\$42.83	95%	\$2,848	\$405
325991	Custom Compounding of Purchased Resins	475	0.7	\$42.83	95%	\$19,326	\$2,752
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	260	0.7	\$42.83	95%	\$10,578	\$1,506
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	6,570	0.7	\$42.83	95%	\$267,310	\$38,059
339112	Surgical and Medical Instrument Manufacturing	446	0.7	\$42.83	95%	\$18,146	\$2,584
339113	Surgical Appliance and Supplies Manufacturing	684	0.7	\$42.83	95%	\$27,830	\$3,962
339114	Dental Equipment and Supplies Manufacturing	92	0.7	\$42.83	95%	\$3,743	\$533
339115	Ophthalmic Goods Manufacturing	100	0.7	\$42.83	95%	\$4,069	\$579
339116	Dental Laboratories	660	0.7	\$42.83	95%	\$26,853	\$3,823
339910	Jewelry and Silverware Manufacturing	314	0.7	\$42.83	95%	\$12,776	\$1,819
339920	Sporting and Athletic Goods Manufacturing	412	0.7	\$42.83	95%	\$16,763	\$2,387
339930	Doll, Toy, and Game Manufacturing	106	0.7	\$42.83	95%	\$4,313	\$614
339940	Office Supplies (except Paper) Manufacturing	122	0.7	\$42.83	95%	\$4,964	\$707
339950	Sign Manufacturing	1,402	0.7	\$42.83	95%	\$57,042	\$8,122
339991	Gasket, Packing, and Sealing Device Manufacturing	270	0.7	\$42.83	95%	\$10,985	\$1,564
339992	Musical Instrument Manufacturing	124	0.7	\$42.83	95%	\$5,045	\$718
339993	Fastener, Button, Needle, and Pin Manufacturing	30	0.7	\$42.83	95%	\$1,221	\$174

Table VI-14: Total Costs Associated with Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2022 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%)
339994	Broom, Brush, and Mop Manufacturing	78	0.7	\$42.83	95%	\$3,174	\$452
339995	Burial Casket Manufacturing	26	0.7	\$42.83	95%	\$1,058	\$151
339999	All Other Miscellaneous Manufacturing	728	0.7	\$42.83	95%	\$29,620	\$4,217
Subtotal		118,360	0.7	\$42.83	95%	\$4,815,650	\$685,640
SDSs at Establishments with 100-499 Employees							
211120	Crude Petroleum Extraction	2,835	0.5	\$30.59	75%	\$65,045	\$9,261
211130	Natural Gas Extraction	1,545	0.5	\$30.59	75%	\$35,448	\$5,047
324110	Petroleum Refineries	1,350	0.5	\$30.59	75%	\$30,974	\$4,410
324121	Asphalt Paving Mixture and Block Manufacturing	19,125	0.5	\$30.59	75%	\$438,794	\$62,474
324122	Asphalt Shingle and Coating Materials Manufacturing	1,875	0.5	\$30.59	75%	\$43,019	\$6,125
324191	Petroleum Lubricating Oil and Grease Manufacturing	120,000	0.5	\$30.59	75%	\$2,753,219	\$391,996
324199	All Other Petroleum and Coal Products Manufacturing	1,875	0.5	\$30.59	75%	\$43,019	\$6,125
325110	Petrochemical Manufacturing	300	0.5	\$30.59	75%	\$6,883	\$980
325120	Industrial Gas Manufacturing	45	0.5	\$30.59	75%	\$1,032	\$147
325130	Synthetic Dye and Pigment Manufacturing	330	0.5	\$30.59	75%	\$7,571	\$1,078
325180	Other Basic Inorganic Chemical Manufacturing	1,264	0.5	\$30.59	75%	\$29,001	\$4,129
325193	Ethyl Alcohol Manufacturing	720	0.5	\$30.59	75%	\$16,519	\$2,352
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	120	0.5	\$30.59	75%	\$2,753	\$392
325199	All Other Basic Organic Chemical Manufacturing	3,450	0.5	\$30.59	75%	\$79,155	\$11,270
325211	Plastics Material and Resin Manufacturing	13,706	0.5	\$30.59	75%	\$314,464	\$44,773
325212	Synthetic Rubber Manufacturing	250	0.5	\$30.59	75%	\$5,736	\$817
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	58	0.5	\$30.59	75%	\$1,331	\$189
325311	Nitrogenous Fertilizer Manufacturing	24	0.5	\$30.59	75%	\$551	\$78
325312	Phosphatic Fertilizer Manufacturing	30	0.5	\$30.59	75%	\$688	\$98
325314	Fertilizer (Mixing Only) Manufacturing	1,290	0.5	\$30.59	75%	\$29,597	\$4,214
325320	Pesticide and Other Agricultural Chemical Manufacturing	960	0.5	\$30.59	75%	\$22,026	\$3,136
325411	Medicinal and Botanical Manufacturing	1,080	0.5	\$30.59	75%	\$24,779	\$3,528
325412	Pharmaceutical Preparation Manufacturing	2,820	0.5	\$30.59	75%	\$64,701	\$9,212
325413	In-Vitro Diagnostic Substance Manufacturing	3,400	0.5	\$30.59	75%	\$78,008	\$11,107
325414	Biological Product (except Diagnostic) Manufacturing	410	0.5	\$30.59	75%	\$9,407	\$1,339
325510	Paint and Coating Manufacturing	17,250	0.5	\$30.59	75%	\$395,775	\$56,349
325520	Adhesive Manufacturing	3,780	0.5	\$30.59	75%	\$86,726	\$12,348
325611	Soap and Other Detergent Manufacturing	2,650	0.5	\$30.59	75%	\$60,800	\$8,657
325612	Polish and Other Sanitation Good Manufacturing	2,300	0.5	\$30.59	75%	\$52,770	\$7,513
325613	Surface Active Agent Manufacturing	950	0.5	\$30.59	75%	\$21,796	\$3,103

Table VI-14: Total Costs Associated with Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2022 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%)
325620	Toilet Preparation Manufacturing	4,550	0.5	\$30.59	75%	\$104,393	\$14,863
325910	Printing Ink Manufacturing	8,722	0.5	\$30.59	75%	\$200,113	\$28,492
325920	Explosives Manufacturing	500	0.5	\$30.59	75%	\$11,472	\$1,633
325991	Custom Compounding of Purchased Resins	520	0.5	\$30.59	75%	\$11,931	\$1,699
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	105	0.5	\$30.59	75%	\$2,409	\$343
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	8,175	0.5	\$30.59	75%	\$187,563	\$26,705
339112	Surgical and Medical Instrument Manufacturing	530	0.5	\$30.59	75%	\$12,160	\$1,731
339113	Surgical Appliance and Supplies Manufacturing	765	0.5	\$30.59	75%	\$17,552	\$2,499
339114	Dental Equipment and Supplies Manufacturing	130	0.5	\$30.59	75%	\$2,983	\$425
339115	Ophthalmic Goods Manufacturing	70	0.5	\$30.59	75%	\$1,606	\$229
339116	Dental Laboratories	300	0.5	\$30.59	75%	\$6,883	\$980
339910	Jewelry and Silverware Manufacturing	135	0.5	\$30.59	75%	\$3,097	\$441
339920	Sporting and Athletic Goods Manufacturing	420	0.5	\$30.59	75%	\$9,636	\$1,372
339930	Doll, Toy, and Game Manufacturing	80	0.5	\$30.59	75%	\$1,835	\$261
339940	Office Supplies (except Paper) Manufacturing	145	0.5	\$30.59	75%	\$3,327	\$474
339950	Sign Manufacturing	845	0.5	\$30.59	75%	\$19,387	\$2,760
339991	Gasket, Packing, and Sealing Device Manufacturing	230	0.5	\$30.59	75%	\$5,277	\$751
339992	Musical Instrument Manufacturing	100	0.5	\$30.59	75%	\$2,294	\$327
339993	Fastener, Button, Needle, and Pin Manufacturing	40	0.5	\$30.59	75%	\$918	\$131
339994	Broom, Brush, and Mop Manufacturing	95	0.5	\$30.59	75%	\$2,180	\$310
339995	Burial Casket Manufacturing	45	0.5	\$30.59	75%	\$1,032	\$147
339999	All Other Miscellaneous Manufacturing	380	0.5	\$30.59	75%	\$8,719	\$1,241
Subtotal		232,674	0.5	\$30.59	75%	\$5,338,354	\$760,062
SDSs at Establishments with 500+ Employees							
211120	Crude Petroleum Extraction	14,525	0.3	\$18.35	25%	\$66,651	\$9,490
211130	Natural Gas Extraction	12,100	0.3	\$18.35	25%	\$55,523	\$7,905
324110	Petroleum Refineries	18,900	0.3	\$18.35	25%	\$86,726	\$12,348
324121	Asphalt Paving Mixture and Block Manufacturing	104,850	0.3	\$18.35	25%	\$481,125	\$68,501
324122	Asphalt Shingle and Coating Materials Manufacturing	13,500	0.3	\$18.35	25%	\$61,947	\$8,820
324191	Petroleum Lubricating Oil and Grease Manufacturing	493,194	0.3	\$18.35	25%	\$2,263,121	\$322,217
324199	All Other Petroleum and Coal Products Manufacturing	2,400	0.3	\$18.35	25%	\$11,013	\$1,568
325110	Petrochemical Manufacturing	4,235	0.3	\$18.35	25%	\$19,433	\$2,767
325120	Industrial Gas Manufacturing	4,290	0.3	\$18.35	25%	\$19,686	\$2,803
325130	Synthetic Dye and Pigment Manufacturing	2,350	0.3	\$18.35	25%	\$10,783	\$1,535
325180	Other Basic Inorganic Chemical Manufacturing	2,420	0.3	\$18.35	25%	\$11,105	\$1,581

Table VI-14: Total Costs Associated with Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2022 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%)
325193	Ethyl Alcohol Manufacturing	3,320	0.3	\$18.35	25%	\$15,234	\$2,169
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	3,075	0.3	\$18.35	25%	\$14,110	\$2,009
325199	All Other Basic Organic Chemical Manufacturing	22,500	0.3	\$18.35	25%	\$103,246	\$14,700
325211	Plastics Material and Resin Manufacturing	93,250	0.3	\$18.35	25%	\$427,896	\$60,923
325212	Synthetic Rubber Manufacturing	1,085	0.3	\$18.35	25%	\$4,979	\$709
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	72	0.3	\$18.35	25%	\$330	\$47
325311	Nitrogenous Fertilizer Manufacturing	90	0.3	\$18.35	25%	\$413	\$59
325312	Phosphatic Fertilizer Manufacturing	70	0.3	\$18.35	25%	\$321	\$46
325314	Fertilizer (Mixing Only) Manufacturing	1,650	0.3	\$18.35	25%	\$7,571	\$1,078
325320	Pesticide and Other Agricultural Chemical Manufacturing	2,652	0.3	\$18.35	25%	\$12,169	\$1,733
325411	Medicinal and Botanical Manufacturing	1,725	0.3	\$18.35	25%	\$7,916	\$1,127
325412	Pharmaceutical Preparation Manufacturing	8,450	0.3	\$18.35	25%	\$38,775	\$5,521
325413	In-Vitro Diagnostic Substance Manufacturing	27,066	0.3	\$18.35	25%	\$124,198	\$17,683
325414	Biological Product (except Diagnostic) Manufacturing	2,700	0.3	\$18.35	25%	\$12,389	\$1,764
325510	Paint and Coating Manufacturing	47,025	0.3	\$18.35	25%	\$215,784	\$30,723
325520	Adhesive Manufacturing	21,720	0.3	\$18.35	25%	\$99,667	\$14,190
325611	Soap and Other Detergent Manufacturing	12,000	0.3	\$18.35	25%	\$55,064	\$7,840
325612	Polish and Other Sanitation Good Manufacturing	7,050	0.3	\$18.35	25%	\$32,350	\$4,606
325613	Surface Active Agent Manufacturing	3,900	0.3	\$18.35	25%	\$17,896	\$2,548
325620	Toilet Preparation Manufacturing	8,200	0.3	\$18.35	25%	\$37,627	\$5,357
325910	Printing Ink Manufacturing	19,750	0.3	\$18.35	25%	\$90,627	\$12,903
325920	Explosives Manufacturing	2,250	0.3	\$18.35	25%	\$10,325	\$1,470
325991	Custom Compounding of Purchased Resins	2,940	0.3	\$18.35	25%	\$13,491	\$1,921
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	500	0.3	\$18.35	25%	\$2,294	\$327
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	31,350	0.3	\$18.35	25%	\$143,856	\$20,482
339112	Surgical and Medical Instrument Manufacturing	1,325	0.3	\$18.35	25%	\$6,080	\$866
339113	Surgical Appliance and Supplies Manufacturing	710	0.3	\$18.35	25%	\$3,258	\$464
339114	Dental Equipment and Supplies Manufacturing	175	0.3	\$18.35	25%	\$803	\$114
339115	Ophthalmic Goods Manufacturing	860	0.3	\$18.35	25%	\$3,946	\$562
339116	Dental Laboratories	1,390	0.3	\$18.35	25%	\$6,378	\$908
339910	Jewelry and Silverware Manufacturing	145	0.3	\$18.35	25%	\$665	\$95
339920	Sporting and Athletic Goods Manufacturing	305	0.3	\$18.35	25%	\$1,400	\$199
339930	Doll, Toy, and Game Manufacturing	20	0.3	\$18.35	25%	\$92	\$13
339940	Office Supplies (except Paper) Manufacturing	115	0.3	\$18.35	25%	\$528	\$75

Table VI-14: Total Costs Associated with Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2022 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%)
339950	Sign Manufacturing	320	0.3	\$18.35	25%	\$1,468	\$209
339991	Gasket, Packing, and Sealing Device Manufacturing	1,865	0.3	\$18.35	25%	\$8,558	\$1,218
339992	Musical Instrument Manufacturing	100	0.3	\$18.35	25%	\$459	\$65
339993	Fastener, Button, Needle, and Pin Manufacturing	60	0.3	\$18.35	25%	\$275	\$39
339994	Broom, Brush, and Mop Manufacturing	100	0.3	\$18.35	25%	\$459	\$65
339995	Burial Casket Manufacturing	60	0.3	\$18.35	25%	\$275	\$39
339999	All Other Miscellaneous Manufacturing	175	0.3	\$18.35	25%	\$803	\$114
Subtotal		1,004,879	0.3	\$18.35	25%	\$4,611,089	\$656,515
Total/Average							
211120	Crude Petroleum Extraction	41,370	0.5	\$33.40	83%	\$1,141,641	\$162,544
211130	Natural Gas Extraction	17,475	0.4	\$24.80	58%	\$251,331	\$35,784
324110	Petroleum Refineries	20,680	0.3	\$19.66	33%	\$135,624	\$19,310
324121	Asphalt Paving Mixture and Block Manufacturing	130,585	0.3	\$21.39	43%	\$1,193,037	\$169,862
324122	Asphalt Shingle and Coating Materials Manufacturing	16,995	0.4	\$22.04	46%	\$171,855	\$24,468
324191	Petroleum Lubricating Oil and Grease Manufacturing	701,794	0.4	\$23.54	52%	\$8,665,016	\$1,233,703
324199	All Other Petroleum and Coal Products Manufacturing	4,855	0.4	\$26.00	62%	\$78,213	\$11,136
325110	Petrochemical Manufacturing	4,735	0.3	\$20.16	36%	\$34,591	\$4,925
325120	Industrial Gas Manufacturing	4,458	0.3	\$19.15	30%	\$25,897	\$3,687
325130	Synthetic Dye and Pigment Manufacturing	3,486	0.4	\$25.17	59%	\$51,861	\$7,384
325180	Other Basic Inorganic Chemical Manufacturing	4,852	0.4	\$27.43	67%	\$88,662	\$12,623
325193	Ethyl Alcohol Manufacturing	4,835	0.4	\$24.20	55%	\$64,245	\$9,147
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	3,478	0.3	\$20.77	40%	\$28,606	\$4,073
325199	All Other Basic Organic Chemical Manufacturing	30,008	0.4	\$23.07	51%	\$350,912	\$49,962
325211	Plastics Material and Resin Manufacturing	114,766	0.4	\$21.48	43%	\$1,063,136	\$151,367
325212	Synthetic Rubber Manufacturing	1,628	0.4	\$24.64	57%	\$22,838	\$3,252
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	196	0.5	\$30.22	74%	\$4,412	\$628
325311	Nitrogenous Fertilizer Manufacturing	261	0.5	\$33.26	82%	\$7,131	\$1,015
325312	Phosphatic Fertilizer Manufacturing	120	0.4	\$25.49	60%	\$1,840	\$262
325314	Fertilizer (Mixing Only) Manufacturing	3,924	0.5	\$28.51	70%	\$78,033	\$11,110
325320	Pesticide and Other Agricultural Chemical Manufacturing	4,824	0.4	\$26.94	65%	\$84,838	\$12,079
325411	Medicinal and Botanical Manufacturing	5,830	0.5	\$33.32	82%	\$159,172	\$22,662
325412	Pharmaceutical Preparation Manufacturing	16,560	0.5	\$28.26	69%	\$324,394	\$46,186
325413	In-Vitro Diagnostic Substance Manufacturing	32,276	0.3	\$21.02	41%	\$277,476	\$39,506
325414	Biological Product (except Diagnostic) Manufacturing	3,807	0.4	\$24.15	55%	\$50,869	\$7,243
325510	Paint and Coating Manufacturing	71,805	0.4	\$23.86	54%	\$923,324	\$131,461

Table VI-14: Total Costs Associated with Revisions to Appendix Language on Precautionary Statements and Other Mandatory Language (2022 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%)
325520	Adhesive Manufacturing	29,880	0.4	\$23.49	52%	\$366,450	\$52,174
325611	Soap and Other Detergent Manufacturing	18,500	0.4	\$25.20	59%	\$276,482	\$39,365
325612	Polish and Other Sanitation Good Manufacturing	11,037	0.4	\$24.65	57%	\$154,773	\$22,036
325613	Surface Active Agent Manufacturing	5,505	0.4	\$23.38	52%	\$66,847	\$9,518
325620	Toilet Preparation Manufacturing	17,926	0.5	\$28.53	69%	\$355,005	\$50,545
325910	Printing Ink Manufacturing	29,967	0.4	\$23.14	51%	\$352,414	\$50,176
325920	Explosives Manufacturing	2,856	0.3	\$21.41	43%	\$26,171	\$3,726
325991	Custom Compounding of Purchased Resins	4,303	0.4	\$24.63	57%	\$60,351	\$8,593
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	1,231	0.5	\$31.84	79%	\$30,800	\$4,385
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	49,695	0.4	\$25.38	60%	\$751,367	\$106,978
339112	Surgical and Medical Instrument Manufacturing	2,990	0.5	\$29.81	74%	\$65,600	\$9,340
339113	Surgical Appliance and Supplies Manufacturing	3,308	0.6	\$34.75	85%	\$97,356	\$13,861
339114	Dental Equipment and Supplies Manufacturing	844	0.6	\$35.87	87%	\$26,481	\$3,770
339115	Ophthalmic Goods Manufacturing	1,270	0.4	\$25.58	61%	\$19,797	\$2,819
339116	Dental Laboratories	7,146	0.6	\$37.55	91%	\$243,463	\$34,664
339910	Jewelry and Silverware Manufacturing	2,391	0.7	\$40.65	95%	\$92,730	\$13,203
339920	Sporting and Athletic Goods Manufacturing	2,417	0.6	\$37.61	90%	\$82,070	\$11,685
339930	Doll, Toy, and Game Manufacturing	648	0.7	\$40.56	95%	\$24,981	\$3,557
339940	Office Supplies (except Paper) Manufacturing	711	0.6	\$36.37	88%	\$22,768	\$3,242
339950	Sign Manufacturing	7,498	0.7	\$40.40	95%	\$286,970	\$40,858
339991	Gasket, Packing, and Sealing Device Manufacturing	2,634	0.4	\$24.43	56%	\$36,226	\$5,158
339992	Musical Instrument Manufacturing	819	0.6	\$38.35	92%	\$28,786	\$4,098
339993	Fastener, Button, Needle, and Pin Manufacturing	201	0.5	\$33.09	82%	\$5,424	\$772
339994	Broom, Brush, and Mop Manufacturing	365	0.5	\$32.94	81%	\$9,713	\$1,383
339995	Burial Casket Manufacturing	191	0.5	\$32.26	80%	\$4,910	\$699
339999	All Other Miscellaneous Manufacturing	3,838	0.7	\$40.50	95%	\$147,472	\$20,997
Total		1,453,774	0.4	\$23.95	54%	\$18,914,358	\$2,692,979

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Note: Figures may not add to totals due to rounding.

VI. Management Familiarization and Other Management-Related Costs.

In order to implement the 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 will need to become familiar with the updates OSHA is making in this final rule. The nature and extent of the familiarization required will 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.³⁷ This final rule requires some changes to hazard communication programs in affected establishments, but those changes are significantly less extensive than those required by the 2012 rule. Therefore, OSHA believes that much less time will be needed for familiarization and implementation under this rule than was necessary under the 2012 rule.

For the present rule, OSHA in the PEA estimated that management familiarization time would vary by establishment size and would also vary depending on whether an establishment would simply be familiarizing itself with the revised standard or would also need to take further action because it would be affected by one or more of the revisions to the standard. Above in Section VI.C, Profile of Affected Industries, Establishments, and Employees, Table VI-10 presents, by NAICS industry, the percentage of establishments (and for training, entities) expected to be affected by rule familiarization and whether those establishments or entities will incur additional costs or no additional costs—that is, whether those establishments or entities will incur additional

³⁷ Larger employers were estimated to have greater familiarization costs for the 2012 HCS final rule because they have more managers.

costs for revising SDSs/labels or for training employees as a result of the final rule.³⁸ In terms of manufacturing establishments that would have costs in addition to management familiarization costs, OSHA in the PEA estimated 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, OSHA estimated in the PEA that there are 79,500 small establishments, 22,657 medium establishments, and 467 large establishments; their only costs associated with this final standard would be as a result of rule familiarization.³⁹

To estimate unit costs, OSHA in the PEA 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 (Document ID 0005, Section VI, pp. 17612-17613, 17623; Document ID 0029). For the PEA, because the new requirements are significantly less extensive than those in the 2012 rule, OSHA expected 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 invited public comment on the agency's preliminary assumptions for estimating the cost of management familiarization. As discussed above in the section on the revised hazard classification provisions, commenters tended to focus on the overall effect of the proposed standard on labor efforts required to update SDS software and labels. For example, in response to a request for comment on costs for management familiarization in relation to the proposed rule, Ameren stated that it did not agree with OSHA's assumptions on the cost of

³⁸ 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.

³⁹ Note that the numbers of small, medium, and large establishments reported above are derived in the "Rule Fam" tab of the OSHA spreadsheets in support of this proposed rule (see Document ID 0049).

management familiarization but based that statement on the time required to train all of the employees, which is a separate cost that OSHA accounts for (Document ID 0309, p. 8).

CISC, however, disagreed with OSHA's preliminary assessment of the unit time burden for management familiarization and specifically noted that the estimate of 4 hours, 1 hour, and .25 hours for large, medium, and small establishments that are not chemical manufacturers respectively were too low and particularly for small entities who were unlikely to employ a safety and health specialist and therefore would need more time for familiarization (Document ID 0335, p. 2).

In estimating costs for establishments that would incur costs in addition to rule familiarization costs, for small establishments OSHA preliminarily estimated management familiarization costs of 0.5 hours of a Health and Safety Specialist's labor time. For medium establishments, OSHA in the PEA estimated two hours of a Health and Safety Specialist's labor time. For large establishments, OSHA estimated eight hours of a Health and Safety Specialist's labor time for the purpose of estimating costs of management familiarization. Multiplying these labor burdens by the loaded hourly wage of \$58.00 resulted in preliminary management familiarization costs per establishment of \$29.00, \$116.01, and \$464.04 for small, medium, and large establishments, respectively.

For this FEA, based on the evidence submitted by commenters regarding the complexity of some of the updates, as well as the need for managers to understand the substantive revisions to the Appendices, OSHA believes that it would be appropriate to double the preliminary time estimates for management familiarization for employers affected by other provisions in the revised standard. Therefore, for small establishments, OSHA in this FEA estimates management familiarization costs of one hour of a Health and Safety Specialist's labor time. For medium establishments, OSHA in this FEA estimates four hours of a Health and Safety Specialist's labor time. For large

establishments, OSHA estimates 16 hours of a Health and Safety Specialist's labor time for the purpose of estimating costs of management familiarization. Multiplying these labor burdens by the loaded hourly wage of \$61.18 results in final management familiarization costs per establishment of \$61.18, \$244.73, and \$978.92 for small, medium, and large establishments, respectively.

For establishments that would *not* incur other costs as a result of the proposed rule (below, these employers are termed "indirectly affected establishments"), OSHA in the PEA estimated that rule familiarization will take half as long as the time estimated in the PEA for establishments that would incur other costs under the proposed rule. 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, and they would primarily need to familiarize themselves with the rule only to the extent of understanding that they did not fall within the scope of the changes being made. 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. CISC's comment on the estimate of hours required for indirectly affected establishments did not provide evidence to support the argument that OSHA's understanding of these management familiarization costs was incorrect because they did not provide information about how many small entities might not employ a Safety and Health Specialist, what person other than a Health and Safety Specialist would perform the work, or how long it would take them, nor did they explain how downstream users would be more directly impacted by any of the proposed changes, so OSHA has left unchanged the preliminary per-establishment labor burden estimates for indirectly affected establishments. Multiplying the labor burdens by the loaded hourly wage of \$61.18 results in management familiarization costs per establishment of \$15.30 for small establishments, \$61.18 for medium establishments, and \$244.73 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 \$8.0 million. Annualizing this one-time cost using a seven percent discount rate over a 10-year period results in an estimate of annualized costs of \$1.1 million. Table VI-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 VI-12.

Table VI-15: Total Costs Associated with Management Familiarization with the Revisions to the HCS (by Establishment Size, 2022 Dollars)

	Small Establishments (<20 Employees) Affected	Medium Establishments (20-499 Employees) Affected	Large Establishments (≥ 500 Employees) Affected	Total
Directly Affected Establishments				
Total Establishments	35,114	11,353	404	46,871
Wage	\$61.18	\$61.18	\$61.18	–
Hours	1.00	4.00	16.00	–
Unit Cost Per Establishment	\$61.18	\$244.73	\$978.92	–
Total One-Time Cost	\$2,148,368	\$2,778,426	\$395,485	\$5,322,279
Total Annualized Cost (7%)	\$305,879	\$395,585	\$56,308	\$757,773
Indirectly Affected Establishments				
Total Establishments	77,572	22,891	498	100,961
Wage	\$61.18	\$61.18	\$61.18	–
Hours	0.25	1.00	4.00	–
Unit Cost Per Establishment	\$15.30	\$61.18	\$244.73	–
Total One-Time Cost	\$1,186,515	\$1,400,532	\$121,876	\$2,708,923
Total Annualized Cost (7%)	\$168,933	\$199,404	\$17,352	\$385,690
Total				
Total Establishments	112,686	34,244	902	147,832
Total One-Time Cost	\$3,334,883	\$4,178,959	\$517,360	\$8,031,202
Total Annualized Cost (7%)	\$474,812	\$594,990	\$73,660	\$1,143,462

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Note: Figures may not add to totals due to rounding.

VII. Costs Associated with Training Employees.

In the PEA, OSHA estimated the incremental costs to train health and safety personnel who are covered by the HCS and are already trained in accordance with the 2012 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. This analysis is described below.

OSHA preliminarily concluded that these would be the only training costs associated with the revisions to the HCS. The agency requested comments on this determination and received comments, from NACD, indicating that they believed OSHA should include training costs for retraining workers across all areas (Document ID 0329, p. 11).

As OSHA noted in the PEA, however, OSHA did not estimate any training costs for *users* of aerosols, desensitized explosives, or flammable gases in the workplace because the agency 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 is changing under the 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, whereas health and safety personnel who are processing the inputs to the gases upstream or reviewing revised SDSs and labels for the first time may need additional training to learn about the hazards. At most, downstream 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. For this final analysis of costs for training, OSHA declines to add costs for retraining because such additional time would double-count the costs associated with both (1) the baseline training already assigned costs in the 2012 FEA and (2) the incremental training estimated in this FEA. Therefore, OSHA does

not agree with NACD that it should take costs for all the workers who are required to receive training under the HCS.

OSHA also received a comment from NAIMA indicating that “NAIMA and its members conduct training, but the cost would not be in more training, but in the review of the training materials to make certain that the different changes are captured in the training materials” (Document ID 0461, p. 3). OSHA notes that, as indicated in Table VI-16 below, the agency has already incorporated the cost for the preparation of training materials and has used an estimate of 2.5 hours of labor for a safety and health specialist to develop the materials necessary for instructing personnel on chemical hazards communicated through the revised standard.

OSHA considered whether some increase in user training might be required for some aerosols, since a small portion of these may not currently be classified as either flammable aerosols or gas under pressure; as noted in the discussion of Appendix B in Section XIV., Summary and Explanation of the Final Rule, 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 aerosols that are neither flammable nor fall under gases under pressure are fairly uncommon and, therefore, OSHA preliminarily concluded that the total user training time required for non-flammable aerosols not under pressure would also be negligible.

As discussed above, under the final rule, some health and safety personnel who are covered by, and are already trained in accordance with, the existing standard will 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.

In the PEA, OSHA estimated that each affected chemical manufacturing firm⁴⁰ 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 these unit time estimates by the respective hourly wage and by the number of affected firms (2,754), the number of affected logistics managers (1,179), and the number of affected production workers (76,447) yielded a preliminary undiscounted one-time cost of \$843,940. Annualizing this one-time cost using a seven percent discount rate over a 10-year period resulted in estimated annualized costs of \$120,158.

OSHA invited interested parties to provide comments on the preliminary total cost estimates and the assumptions underlying them. Specifically, the agency requested comments on its preliminary conclusions regarding training time for users of reclassified chemicals.

Ameren described the scope of their organization's current GHS training program and outlined the impact of the proposed training requirements in OSHA's 2021 NPRM. They estimated that for their corporation, which has 9,231 employees, the total spent on training would be approximately \$3,000,000 and it would take one year to update all of their training materials. This estimate was based on an assumption that they would need

⁴⁰ OSHA anticipates that, in practice, training would be organized more efficiently at the corporate (firm) level than at the establishment level.

to retrain all of their employees, including on the combustible dust provisions and the labels on small containers (Document ID 0309, p. 4).

As discussed above, however, OSHA has concluded that the training times necessary for informing workers will be trivial because they will not need to be trained on fundamental changes to hazards. The information Ameren provided only indicated that they thought they needed to train all of their workers on all of the changes but did not provide estimates of how much time each worker would need to spend on receiving such training under their assumptions, and therefore their comment is difficult to compare with OSHA's assumption that only a trivial amount of time will be spent on training based on these updates for users of chemicals. Similarly, NAIMA briefly commented on the compliance burden imposed by the proposed training requirements, stating workers would need to be trained on the new hazard class and hazard categories and that OSHA needed to account for these costs (Document ID 0338, p. 4). In response, OSHA notes that this FEA accounts for the incremental compliance burden imposed by the proposed training requirements and that NAIMA did not elaborate further on the costs of employee training, nor did the association provide any quantitative details on the expected cost burden that would allow comparison with the estimates in the PEA.

Therefore, because stakeholders in this rulemaking provided few if any details on specific changes in OSHA's preliminary estimate of incremental training costs necessary to align with employer expectations of changes to training programs, and because these expectations are based on an incorrect assumption about the amount of training required, the agency has no basis in the record to depart from its preliminary estimate of incremental training costs and believes that it adequately reflects the real-world changes among affected employers.

Multiplying the labor burden for each labor category by the loaded hourly wages of \$61.18 for a Health and Safety Specialist, \$60.37 for logistics personnel, and \$31.09 for production workers, results in unit costs of \$152.96, \$12.07, and \$6.22, respectively.

As shown in Table VI-16, expressed in 2022 dollars, the incremental one-time undiscounted final training costs are expected to total \$0.96 million and, annualized over ten years, incremental final training costs are expected to total \$136,953 at a 7 percent discount rate. The unit values that factored into OSHA’s estimate of training costs are shown in Table VI-16.⁴¹ The distribution of these training costs by NAICS code is displayed in Column 4 of Table VI-12.

Table VI-16: Training Costs Associated with the Revisions to the HCS Standard (2022 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	2,891	–	–	2,891
Employees Needing Training	–	1,461	80,756	83,106
Wage	\$61.18	\$60.37	\$31.09	–
Hours	2.5	0.2	0.2	2.9
Unit Cost	\$152.96	\$12.07	\$6.22	\$171.25
Total One-Time Cost	\$442,198	\$17,635	\$502,066	\$961,899
Total Annualized Cost (7%)	\$62,959	\$2,511	\$71,483	\$136,953

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Note: Figures may not add to totals due to rounding.

VIII. Cost Savings Associated with the New Released for Shipment Provisions.

In paragraph (f)(11) of the 2012 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. In the NPRM, OSHA proposed to modify paragraph (f)(11) such that chemicals that have been released

⁴¹ The estimated number of affected firms, logistics managers and production workers are derived in Document ID 0481, tab “Training”. The affected number of firms (3,469) 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).

for shipment and are awaiting future distribution need not be relabeled; however, if the manufacturer or importer opts not to relabel the chemicals they must provide an updated label for each individual container with each shipment. Relatedly, OSHA also proposed in the NPRM to add new paragraph (f)(1)(vii) to require the inclusion of a released for shipment date on labels on shipped containers.

OSHA anticipated 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. OSHA invited public comment on the agency’s preliminary determination that the proposed modifications to paragraph (f)(11) would generate cost savings and on its preliminary analysis of the factors that would contribute to the cost savings. Specifically, in its preliminary determination of technological feasibility, OSHA invited public comment “on any employer concerns associated with . . . the proposed provision addressing the relabeling of containers that have been released for shipment.

In the PEA, OSHA identified six industries (four manufacturing and two wholesale) that it expected would be impacted by the proposed modifications to paragraph (f)(11).⁴² These are primarily fertilizer manufacturers, paint manufacturers, and wholesalers of related farm and paint supplies. OSHA invited 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 had not considered in its proposal.

⁴² In principle, pesticide manufacturers would also be affected by the revision to the standard, but pesticide labeling in the United States is covered by the U.S. EPA under 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.

The Society of Chemical Manufacturers & Affiliates (SOCMA) supported proposed (f)(11) and noted that “SOCMA . . . believes it will significantly reduce the compliance burdens for chemicals that have been released for distribution” (Document ID 0447, p. 3).

Ameren commented that it “would incur an additional cost for having to re-print and replace current labels based on the new OSHA changes. The cost is estimated at \$5 Million and would take over two years to complete” (Document ID 0309, p. 6). The National Propane Gas Association (NPGA) also addressed the cost associated with the addition of a released for shipment date. They indicated that there are at least 40 million propane gas cylinders that are up to 20 pounds and another 10 million tanks and cylinders that range from 33.5 to 420 pounds. They estimated that the cost of updating all the labels to add a released for shipment date would be about \$55 million, with a \$1 cost per label for the smaller size tanks and a cost of \$1.50 per label for the larger tanks (Document ID 0440, pp. 1-2). Carbide Industries LLC also indicated concerns with the requirement to add a release for shipment date and noted that “the additional cost to chemical manufacturers, importers, or distributors of implementing and complying with [the] proposed requirement will be significant in many cases (Document ID 0290, p. 1). Industrial Minerals Association – North America (IMA-NA) stated their belief that “[t]his exemption, while well-meaning will not alleviate any burden to manufacturers” because of the released for shipment date requirement” (Document ID 0363, pp. 7-8).

In response to these and other comments discussed in the discussion of paragraph (f) in Section XIV., Summary and Explanation of the Final Rule, OSHA has removed the proposal to include a released for shipment date, and therefore the costs that these commenters highlight for needing to update all labels to include the release for shipment date will not be incurred.

Commenters also expressed concerns about the costs of this provision that indicated they did not understand the provision is optional. ACI argued that “Complying with these proposed requirements could slow the release of products, needlessly complicate the timing of shipments, and cause confusion on labels with a process that has an unclear safety outcome. These requirements could also cascade down to the storage and distribution chain causing logistical burdens and additional labor costs” (Document ID 0319, p. 2). NACD stated that the impacts of the proposed requirement to send printed labels with each shipment “would be prohibitively expensive” and that tracking shipments on label status is “not feasible.” NACD further stated that “[e]xtensive new programming and software would be needed to handle this” (Document ID 0465, p. 3).

The language that was proposed and is being finalized in paragraph (f)(11) only creates a new option for companies to comply with the HCS. If they want to, they can choose not to relabel chemicals that have been released for shipment, in which case they would have to provide an updated label with the shipment (although the label no longer includes the proposed requirement for the release for shipment date). OSHA believes that this revision to the proposed regulatory text addresses comments about the feasibility of this provision. However, if the company believes that choosing to not relabel their chemicals before shipment would, as ACI indicated, slow the release of products or create additional labor costs, or would be prohibitively expensive, as NACD suggested, then they can simply choose to relabel the chemicals before they are shipped, as is already allowed by the standard. OSHA believes that these companies are rational actors who will choose to relabel their shipments if choosing the option to not relabel would be more expensive. Regardless of whether the company chooses to relabel or not, they would need to create an updated label, just as they do under the 2012 HCS, so the creation of the label itself is not a new cost. Therefore, OSHA is not accounting for additional costs when these companies have the option to continue complying with the

HCS as they have and therefore will not face an increase in compliance costs above their current baseline.

For the PEA, the first factor used to estimate the cost savings resulting from the proposed changes to paragraph (f)(11) was 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 (Document ID 0006). 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 (Document ID 0006, pp. 4-6).

For OSHA's purposes, the critical costing information from CPDA was 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 (Document ID 0006, p. 8). 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. With an effective range of labeling costs from 1.5 percent to 100 percent of the value of the product, OSHA estimated, 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 assumed that this same estimate would also apply to relabeling paints and related chemical products in distribution.

The agency invited comments on this assumption. No commenters addressed specifically the estimate of 50 percent of product value as a measure of cost savings. As discussed above, several commenters broadly criticized OSHA's preliminary analysis of costs for paragraph (f)(11) for omitting substantial administrative and handling expenses but did not provide specific data with which OSHA could evaluate these purported costs. Based on professional judgment in evaluating these comments, OSHA is not convinced that it has underestimated costs associated with the provision and has decided to leave unchanged the preliminary product-value cost savings of 50 percent for the final cost analysis of paragraph (f)(11). The agency anticipates that the above clarification of the intent of paragraph (f)(11) along with the discussion on (f)(11) in Section XIV., Summary and Explanation of the Final Rule, will address any misconceptions concerning additional compliance burden imposed by final paragraph (f)(11).

The 50 percent average cost savings estimate would apply only to those products that previously required relabeling and are likely to take advantage of this option under (f)(11). In order to estimate the expected cost savings for all products in the NAICS codes affected by the revisions to paragraph (f)(11), OSHA also needed 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, under the 2012 HCS, be relabeled in any particular year due to a manufacturer becoming newly aware of significant information regarding the hazards of the product; and (3) the percentage of all products in the NAICS industries that are covered by the HCS.

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 5 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 anticipated that manufacturer-initiated relabeling would be rare and estimated that only 1 percent of products warehoused for more than six months would be relabeled in any particular year due to a manufacturer-initiated labeling change. OSHA invited comments on the preliminary estimates described above and received no comments specifically on the estimates.

For factor (3) above, OSHA assumed that 100 percent of the products in the four NAICS manufacturing industries are covered by the HCS.⁴³ For the two wholesale industries, however, a 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 supplies are non-fertilizers, such as grains (e.g., alfalfa, hay, livestock feeds) and nursery stock (e.g., plant seeds and plant bulbs) that are not subject

⁴³ A review of the products covered under the manufacturing NAICS codes reveals they are all, or almost all, chemicals.

to the HCS. Based on data from the 2012 Economic Census,⁴⁴ 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 “Variables”). OSHA used ERG’s estimates to develop the expected cost savings attributable to the proposed revisions to paragraph (f)(11). The agency invited comments on the preliminary estimates of factor (3) in the cost model and received no comments specifically on the estimates.⁴⁵

For this FEA, OSHA updated factor (3) to reflect the affected product line sales data (as a percentage of total sales) reported in the 2017 Economic Census for the two affected NAICS industries in the wholesale sector. OSHA estimated that 37.1 percent of the wholesale supplies in NAICS 424910 would be fertilizers affected by the released-for-shipment provision. For NAICS 424950, OSHA estimated that 82.0 percent of the wholesale supplies would be paints and related chemicals affected by the released-for-shipment provision.⁴⁶

⁴⁴ 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).

⁴⁵ Under the 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. However, the manufacturer and importer already had to provide an updated label under the 2012 HCS, so this is not a new cost.

⁴⁶ 2017 Economic Census for Wholesale Trade: All Sectors: Industry by Products for the U.S. and States. (Series EC1700NAPCSINDPRD) Release Date: December 16, 2021. (Document ID 0479). According to the census data for wholesale trade, OSHA derived an estimate of 37.1 percent of wholesale agricultural chemicals and fertilizers that are affected by the released-for-shipment provision for NAICS 424910 Farm Supplies Merchant Wholesalers – derived as product line sales as a percentage of total sales of all establishments for North American Product Code System code 4004550015 Other agricultural chemicals and fertilizers. For NAICS 424950 Paint, Varnish, and Supplies Merchant Wholesalers, based on the wholesale trade census data, OSHA estimated that 82.0 percent of wholesale paints and related chemicals are affected by the released-for-shipment provision (merchant wholesalers product line sales as a

Column 3 of Table VI-18 shows the average product value (revenue) for each of the six NAICS industries that OSHA expects will be affected by the modification to paragraph (f)(11).⁴⁷ And Column 4 of Table VI-18 shows the number of affected firms (entities) for each of these six NAICS industries.⁴⁸ Column 5 of Table VI-18 shows the estimated loss avoided due to the 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 will be warehoused for more than six months; (3) the percentage of products warehoused for more than six months that would have required generation of a new label in any particular year due to a manufacturer-initiated labeling change; and (4) the percentage of all products in the NAICS industries covered by the HCS.

Table VI-17 presents, by NAICS industry, these four factors and the calculated percentage loss in revenue OSHA anticipates will be avoided under the revised released-for-shipment provision.

Table VI-17: Calculation of the Percentage Loss Avoided Due to the Released-For-Shipment Provision

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%	0.025%
325312	Phosphatic Fertilizer Manufacturing	50%	5%	1%	100%	0.025%
325314	Fertilizer (Mixing Only) Manufacturing	50%	5%	1%	100%	0.025%
325510	Paint and Coating Manufacturing	50%	5%	1%	100%	0.025%
424910	Farm Supplies Merchant Wholesalers	50%	5%	1%	37.1%	0.009%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	50%	5%	1%	82.0%	0.021%

percentage of total sales of all establishments for NAPCS products codes 4004875003 Architectural coatings, enamels, primers, stains, solvents, and lacquers; 4004875006 Industrial/Original Equipment Manufacturer (OEM) coatings; and 4005485012 Special purpose coatings, including automotive, refinish, marine, and traffic coatings). (Document ID 0481, tab "Variables")

⁴⁷ Derived for each NAICS by dividing Column 3 of Table VI-9 (total industry revenues) by Column 7 of Table VI-1 (number of affected firms).

⁴⁸ Obtained from Column 7 of Table VI-1.

The estimated cost savings for each of the six affected industries arising from the modifications to paragraph (f)(11) then is simply the product of Columns 3, 4, and 5 in Table VI-18. Summing the cost savings for each of the six industries yields an estimated annual cost savings of \$33.3 million.

Table VI-18: Cost Savings Associated with the Released-for-Shipment Provision (2022 Dollars)

NAICS	NAICS Industry	Average Product Value (Revenue)	Affected Firms	Loss Avoided as a % of Revenue	Loss Avoided
325311	Nitrogenous Fertilizer Manufacturing	\$45,555,017	165	0.025%	\$1,879,144
325312	Phosphatic Fertilizer Manufacturing	\$167,544,935	44	0.025%	\$1,842,994
325314	Fertilizer (Mixing Only) Manufacturing	\$17,587,282	371	0.025%	\$1,631,220
325510	Paint and Coating Manufacturing	\$32,845,918	958	0.025%	\$7,866,597
424910	Farm Supplies Merchant Wholesalers	\$34,435,446	4,909	0.009%	\$15,678,794
424950	Paint, Varnish, and Supplies Merchant Wholesalers	\$22,176,270	959	0.021%	\$4,359,744
Total		–	7,406	–	\$33,258,495

Source: US DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Note: Figures may not add to totals due to rounding.

In the PEA OSHA requested comments on the reasonableness of the agency’s preliminary cost estimate for the proposed revision to paragraph (f)(11) and the assumptions underlying it (including the various factor percentage estimates listed in Table VI-17). Ameren agreed that there are “potential cost savings” resulting from the revision to (f)(11) (Document ID 0309, p. 11) and SOCMA agreed that this would “reduce the compliance burdens” (Document ID 0447, p. 3); no other commenters addressed this issue.

Therefore, OSHA’s estimate of cost savings shown in Table VI-18 reflects, in the agency’s view, a reasonable determination of the impacts of final paragraph (f)(11).

Cost Savings Associated with the New Provisions for Labels on Very Small Containers

Proposed new paragraph (f)(12), which addresses the labeling of small and very small containers, limits 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 specified 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 FEA. As specified 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 FEA—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., Document ID 0170; 0174; 0200). Paragraph (f)(12)(ii) in this final rule incorporates the accommodations for small containers described in these letters of interpretation. However, the letters of interpretation did not contain any guidance unique to very small containers, which are now covered by paragraph (f)(12)(iii).

For costing purposes, OSHA in the PEA estimated that no cost savings will arise from proposed paragraph (f)(12)(ii) (small containers); OSHA expected that employers are already benefitting from the practical accommodations on the labeling of small packages described in the aforementioned letters of interpretation. OSHA invited public comments on that preliminary determination and the magnitude of any cost savings that should be attributed to proposed paragraph (f)(12)(ii). OSHA received no comments on either of the two questions pertaining to the agency's preliminary determination of current practical benefits and zero cost savings associated with paragraph (f)(12)(ii).

In the PEA, OSHA 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 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 Table VI-19 in the PEA, OSHA estimated that there are approximately 63.5 million labels on very small containers in these six 6-digit NAICS manufacturing industries that could be affected by that part of the proposed rule.⁴⁹

Even in these six NAICS industries, however, OSHA in the PEA expected that 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 estimated in the PEA 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 VI-19 and, equivalently, Column 7 of Table VI-5 in the PEA).

Manufacturers with containers falling under paragraph (f)(12)(iii) could expect to obtain cost savings from avoided labeling costs on very small containers (with only the

⁴⁹ The number of very small containers in Column 3 of Table VI-19 for each of these six NAICS industries was obtained from Column 4 of Table VI-5, both in the PEA and in this FEA.

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). In the PEA, OSHA estimated an incremental unit cost savings of \$0.051 per label for very small containers.⁵⁰ That unit cost savings was 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 paragraph (f)(12)(iv)(A). OSHA requested public comment on the agency’s preliminary estimate (\$0.051) of unit cost savings for paragraph (f)(12)(iii). OSHA did not receive any comments objecting to the preliminary estimate of unit cost savings; therefore, updating the preliminary estimate to 2022 dollars, the agency estimates unit cost savings of \$0.058 per label for paragraph (f)(12)(iii).

As shown in Table VI-19, multiplying the number of affected labels by the unit cost savings of \$0.058 per label for very small containers yields estimated annual cost savings of \$1.7 million.

Table VI-19: Estimated Cost Savings Associated with Abbreviated Labels on Very Small Containers under the Revised HCS Standard (2022 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	17,279,396	40%	6,911,758	\$398,372
325199	All Other Basic Organic Chemical Manufacturing	40,707,962	40%	16,283,185	\$938,513
325411	Medicinal and Botanical Manufacturing	6,407,215	40%	2,562,886	\$147,717
325412	Pharmaceutical Preparation Manufacturing	7,477,924	40%	2,991,169	\$172,402
325413	In-Vitro Diagnostic Substance Manufacturing	568,621	40%	227,448	\$13,109

⁵⁰ The Flavor and Extract Manufacturers Association of the United States provided to OSHA (in a letter 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). In the PEA, OSHA stated that it is likely that most of the cost savings reported from the Flavor and Extract Manufacturers Association survey would be attributable to the expensive types of labels. Based on the unit cost data provided by the Flavor and Extract Manufacturers Association, 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 in the PEA derived an estimate of \$0.05087 (or rounding, \$0.051) in cost savings per label (with the unrounded estimate used in the analysis).

325414	Biological Product (except Diagnostic) Manufacturing	1,870,764	40%	748,305	\$43,130
Total		74,311,881	40%	29,724,752	\$1,713,243

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Note: Figures may not add to totals due to rounding.

In the PEA, OSHA invited interested parties to provide comments on the preliminary cost estimates for the proposed paragraph (f)(12) and the assumptions underlying them. Elsewhere in the NPRM, the agency requested comments on the feasibility of, and any cost savings associated with, the proposed provisions for the labeling of small and very small containers and whether the proposed labeling requirements would be adequate to provide for safe handling and storage of chemicals in small containers. Ameren noted the costs of needing to re-print and replace current labels but stated, “experience [within Ameren] indicates there is potential cost savings associated with the proposed provisions for the labeling of small containers (both 100 ml and 3 ml and less). . . . Ameren agrees that the proposed labeling requirements would be adequate to provide for safe handling and storage of chemicals in small containers” (Document ID 0309, p. 12). OSHA infers from Ameren’s comment and the absence of any opposing comments that the proposed labeling requirement (paragraph (f)(12)) for small containers could, and in OSHA’s estimation likely will, provide cost savings. Therefore, OSHA’s final estimate of cost savings for paragraph (f)(12)(iii) is \$1.7 million, as reported above and shown in Table VI-19.

IX. Concentration Ranges.

In addition to the five categories discussed above where significant costs or cost savings are expected, OSHA received comments on a set of provisions addressing concentration ranges in relation to confidential business information that, in OSHA’s final assessment, will not create significant economic impacts.

IMA-NA expressed concern that compliance with paragraph (i) will impose labeling costs that were not recognized in OSHA’s economic analysis because “it will take considerable time and money to realign product lines with the new ranged approach

to CBI” (Document ID 0363, p. 6). The Vinyl Institute warned that “a significant anti-competitive impact on the market” could result from too-narrow prescribed concentration ranges (Document ID 0369, Att. 2, p. 9). ILMA also predicted that the concentration range requirement would create market disruptions, noting that the majority of its members who responded to ILMA’s survey indicated that overly narrow concentration ranges would erode competitive advantage (Document ID 0460, Att. 2, p. 2). Ameren recommended that the final rule allow combinations of concentration ranges across all conceivable percentages because such flexibility would potentially yield cost savings (Document ID 0309, p. 13).

In response to stakeholder concerns about the loss of competitive advantage through the reverse engineering of confidential information on chemical concentration ranges, OSHA’s final set of requirements in paragraph (i) prescribe reasonably narrow concentration ranges that may be used in combination to preserve trade secrets. OSHA believes that final paragraph (i) strikes a responsible balance between averting significant economic impacts among affected employers and the disclosure of sufficient information on the chemical properties of commercial products to communicate workplace hazards. And because stakeholders provide no evidence demonstrating that loss of CBI and trade secrets were likely outcomes under any scenarios that incorporate OSHA’s final set of requirements in paragraph (i), the agency foresees no additional significant costs. In response to comments that it will take time to update labels to align with this provision, OSHA expects that many companies have already created labels that align with Canada’s system and therefore will have already aligned their labels with these ranges. IMA-NA also did not provide any suggestion of what the costs might be in order to do such updating for companies that have not already aligned with Canada, so OSHA does not have any basis for incorporating an estimate of time needed for compliance. Additionally, because it is optional for companies to claim trade secrets and therefore to use these

ranges, companies that are concerned about costs can simply choose not to claim trade secrets and not incur costs related to this provision.

X. 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 this FEA 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 VI-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 revised released-for-shipment provision. Table VI-20 shows that the estimated net cost savings from the final rule would decline by \$16.6 million annually, from \$29.8 million to \$13.2 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 released-for-shipment provision. Table VI-20 shows that the estimated net cost savings from the final rule would increase by \$33.3 million annually, from \$29.8 million to \$63.1 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 revised paragraph (f)(12). As shown in Table VI-20, if OSHA's estimates of other input parameters remained unchanged, the estimated net cost savings from the final rule would decline by \$0.9 million annually (after rounding), from \$29.8 million to \$29.0 million annually, or by about three 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 final rule, i.e., OSHA did not reduce estimated familiarization time for firms that are not affected by other parts of the standard. The effect of this change would be to raise compliance costs for 100,961 establishments in manufacturing and wholesale trade; the estimated net cost savings from the final rule would be reduced by a little under \$1.2 million annually, from \$29.8 million to \$28.7 million annually, or by about four 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 VI-13 and VI-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 \$3.9 million annually, from \$29.8 million to \$26.0 million, or by about 13 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 final rule would increase by \$0.5 million annually, or by about two percent, resulting in a total estimate of annualized net cost savings of \$30.4 million.

Not part of this table but discussed in the Introduction and Summary of this FEA, the agency examined the effect of lowering the discount rate for annualizing costs from seven percent to three percent. Lowering the discount rate to three percent would yield annualized net cost savings of \$30.7 million, approximately \$908,000 more in annual cost savings than the net cost savings at a seven percent discount rate.

XI. Regulatory Alternatives.

This section discusses two regulatory alternatives to the changes OSHA is promulgating in this final standard: (1) removing the 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 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 VI-20, each regulatory alternative is described and analyzed relative to the final rule. Midpoint estimates are presented in all

cases. Under Regulatory Alternative (1) (elimination of changes related to labeling of very small containers), cost impacts total \$1.7 million (5.7 percent of baseline cost savings), resulting in a reduction of estimated annualized net cost savings to a total of \$28.1 million (after rounding). Under Regulatory Alternative (2) (elimination of changes related to labels on packages that have been released for shipment), cost impacts on manufacturers, distributors, and importers total \$33.3 million (112 percent of baseline cost savings), resulting in an overall estimate of annualized net costs of \$3.4 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). Neither alternative, however, would alter the agency's determination of economic feasibility for the proposed revisions to the HCS as a whole. Nor would these alternatives result in a significant impact on a substantial number of small entities (see Section VI.G., Economic Feasibility and Impacts).

**Table VI-20: Sensitivity Tests and Regulatory Alternatives – Impacts on Net Cost Savings
(7 Percent Discount Rate, 2022 Dollars)**

Uncertainty (Cost) Scenarios	Change from OSHA's Best Estimate	Difference from Final Rule	Percentage Impact on Net Cost Savings	Net Cost Savings
Final Rule - OSHA's midpoint estimate	N/A	\$0	0.0%	\$29,829,412
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	-\$16,629,247	-55.7%	\$13,200,164
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	\$33,258,495	111.5%	\$63,087,906
Reduce from 40% to 20% the percentage of very small containers that would be affected by revised paragraph (f)(12)	Halves cost savings for affected firms	-\$856,622	-2.9%	\$28,972,790
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 30,927 establishments in NAICS 31-33 – Manufacturing, and the 70,034 establishments in NAICS 42 – Wholesale Trade not affected by other provisions	-\$1,157,069	-3.9%	\$28,672,342
Doubles labor hours for the reclassification of chemicals and compliance with the new mandatory language in the appendices to the final standard	Doubles labor costs for the approximately 13 six-digit NAICS industries affected by changes to Appendices B, C, and D	-\$3,861,911	-12.9%	\$25,967,500
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	\$539,669	1.8%	\$30,369,080
Remove the provisions that result in cost savings for very small labels	Eliminates cost savings for affected employers	-\$1,713,243	-5.7%	\$28,116,168
Eliminate the released-for-shipment provisions and associated cost savings	Eliminates cost savings for affected employers	-\$33,258,495	-111.5%	-\$3,429,083

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481, tab “Tables”).

G. Economic Feasibility and Impacts

This section presents OSHA’s analysis of the economic impacts of the final 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 Final 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.⁵¹ 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.⁵²

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 VI.F., Compliance Costs and Cost Savings, of this preamble were compared with industry revenues and profits to provide a measure of potential economic impacts. Table VI-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 revisions to the HCS is such that all affected firms will incur some costs, but only a small subset will derive the cost savings that are monetized in this FEA (although most or all will enjoy non-monetized benefits, e.g., in foreign trade). To

⁵¹ OSHA, 2016, Silica FEA Chapter VI: Economic Feasibility Analysis and Regulatory Flexibility Determination, pp. VI-20 to VI-23, and Table VI-3 (Document ID 0045).

⁵² OSHA, 2016, Silica FEA Chapter VI: Economic Feasibility Analysis and Regulatory Flexibility Determination, pp. VI-20 to VI-23, and Table VI-5 (Document ID 0045).

examine the economic impacts of the revisions to the standard for those affected establishments that obtain no monetized cost savings from any of the final changes 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 VI-22 presents this part of the agency's screening analysis.

Table VI-21: Screening Analysis for Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2022 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	15,086	4,950	\$379,462	\$431,108,657,025	\$27,875,832,950	0.00%	0.00%
211	Oil and Gas Extraction	4,950	4,950	\$379,462	\$313,363,204,311	\$19,527,451,736	0.00%	0.00%
211120	Crude Petroleum Extraction	4,250	4,250	\$223,617	\$182,884,826,557	\$11,396,598,499	0.00%	0.00%
211130	Natural Gas Extraction	700	700	\$155,845	\$130,478,377,754	\$8,130,853,237	0.00%	0.00%
31-33	Manufacturing	254,179	57,094	-\$10,394,633	\$6,806,317,226,570	\$307,020,834,126	0.00%	0.00%
324	Petroleum and Coal Products Manufacturing	967	967	\$1,597,653	\$618,970,333,766	\$42,184,548,322	0.00%	0.00%
324110	Petroleum Refineries	83	83	\$128,936	\$564,989,119,296	\$38,482,646,505	0.00%	0.00%
324121	Asphalt Paving Mixture and Block Manufacturing	471	471	\$186,386	\$16,051,429,566	\$1,107,071,965	0.00%	0.02%
324122	Asphalt Shingle and Coating Materials Manufacturing	110	110	\$29,285	\$13,011,486,147	\$897,406,146	0.00%	0.00%
324191	Petroleum Lubricating Oil and Grease Manufacturing	240	240	\$1,240,097	\$19,612,657,227	\$1,336,005,706	0.01%	0.09%
324199	All Other Petroleum and Coal Products Manufacturing	63	63	\$12,948	\$5,305,641,530	\$361,418,000	0.00%	0.00%
325	Chemical Manufacturing	10,745	10,745	-\$12,662,389	\$909,458,774,282	\$74,456,661,262	0.00%	-0.02%
325110	Petrochemical Manufacturing	31	31	\$29,484	\$71,573,798,420	\$2,442,253,916	0.00%	0.00%
325120	Industrial Gas Manufacturing	78	78	\$33,794	\$12,210,053,190	\$416,633,613	0.00%	0.01%
325130	Synthetic Dye and Pigment Manufacturing	103	103	\$10,433	\$8,178,034,130	\$279,052,339	0.00%	0.00%
325180	Other Basic Inorganic Chemical Manufacturing	376	376	-\$370,174	\$39,555,120,764	\$1,349,706,886	0.00%	-0.03%
325193	Ethyl Alcohol Manufacturing	117	117	\$15,785	\$36,969,480,194	\$1,261,479,197	0.00%	0.00%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	49	49	\$5,832	\$8,235,635,343	\$281,017,818	0.00%	0.00%
325199	All Other Basic Organic Chemical Manufacturing	608	608	-\$867,095	\$93,186,612,758	\$3,179,730,222	0.00%	-0.03%
325211	Plastics Material and Resin Manufacturing	856	856	\$181,829	\$111,992,427,793	\$6,652,894,083	0.00%	0.00%
325212	Synthetic Rubber Manufacturing	137	137	\$6,797	\$11,341,788,771	\$673,757,332	0.00%	0.00%
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	114	114	\$4,400	\$9,438,755,096	\$560,707,890	0.00%	0.00%
325311	Nitrogenous Fertilizer Manufacturing	165	165	-\$1,874,680	\$7,516,577,865	\$730,224,121	-0.02%	-0.26%
325312	Phosphatic Fertilizer Manufacturing	44	44	-\$1,840,868	\$7,371,977,155	\$716,176,381	-0.02%	-0.26%
325314	Fertilizer (Mixing Only) Manufacturing	371	371	-\$1,611,861	\$6,524,881,780	\$633,882,353	-0.02%	-0.25%
325320	Pesticide and Other Agricultural Chemical Manufacturing	184	184	\$48,221	\$17,589,850,557	\$1,708,827,260	0.00%	0.00%
325411	Medicinal and Botanical Manufacturing	597	597	-\$112,894	\$14,667,072,169	\$2,034,425,026	0.00%	-0.01%
325412	Pharmaceutical Preparation Manufacturing	1,117	1,117	\$42,705	\$189,438,629,432	\$26,276,456,821	0.00%	0.00%
325413	In-Vitro Diagnostic Substance Manufacturing	189	189	\$34,089	\$14,404,900,211	\$1,998,059,950	0.00%	0.00%
325414	Biological Product (except Diagnostic) Manufacturing	276	276	-\$24,607	\$47,392,153,058	\$6,573,621,585	0.00%	0.00%
325510	Paint and Coating Manufacturing	958	958	-\$7,330,037	\$31,466,389,652	\$1,312,642,728	-0.02%	-0.56%
325520	Adhesive Manufacturing	401	401	\$223,133	\$18,096,459,850	\$754,906,638	0.00%	0.03%
325611	Soap and Other Detergent Manufacturing	631	631	\$163,257	\$30,356,886,805	\$3,747,210,330	0.00%	0.00%
325612	Polish and Other Sanitation Good Manufacturing	428	428	\$95,585	\$6,982,891,985	\$861,958,117	0.00%	0.01%
325613	Surface Active Agent Manufacturing	108	108	\$42,269	\$9,179,976,693	\$1,133,163,085	0.00%	0.00%
325620	Toilet Preparation Manufacturing	1,010	1,010	\$200,741	\$48,305,711,210	\$5,962,787,330	0.00%	0.00%

Table VI-21: Screening Analysis for Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2022 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
325910	Printing Ink Manufacturing	162	162	\$55,533	\$4,549,024,893	\$230,691,977	0.00%	0.02%
325920	Explosives Manufacturing	53	53	\$20,584	\$2,950,164,188	\$149,609,911	0.00%	0.01%
325991	Custom Compounding of Purchased Resins	347	347	\$18,497	\$14,302,910,074	\$725,334,919	0.00%	0.00%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	163	163	\$7,495	\$6,516,237,026	\$330,454,029	0.00%	0.00%
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	1,072	1,072	\$129,365	\$29,164,373,220	\$1,478,995,406	0.00%	0.01%
326	Plastics and Rubber Products Manufacturing	9,370	9,370	\$72,302	\$293,111,850,980	\$7,025,558,430	0.00%	0.00%
326111	Plastics Bag and Pouch Manufacturing	262	262	\$2,265	\$13,780,960,233	\$353,564,046	0.00%	0.00%
326112	Plastics Packaging Film and Sheet (including Laminated) Mfg.	310	310	\$2,909	\$16,908,003,774	\$433,791,414	0.00%	0.00%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Mfg.	388	388	\$3,073	\$18,960,257,252	\$486,443,989	0.00%	0.00%
326121	Unlaminated Plastics Profile Shape Manufacturing	324	324	\$2,156	\$9,772,806,684	\$250,730,937	0.00%	0.00%
326122	Plastics Pipe and Pipe Fitting Manufacturing	256	256	\$2,909	\$12,950,209,374	\$332,250,318	0.00%	0.00%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	213	213	\$1,315	\$5,495,811,902	\$141,000,443	0.00%	0.00%
326140	Polystyrene Foam Product Manufacturing	306	306	\$2,698	\$11,073,975,465	\$284,113,698	0.00%	0.00%
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	459	459	\$3,959	\$12,578,381,854	\$322,710,719	0.00%	0.00%
326160	Plastics Bottle Manufacturing	194	194	\$3,360	\$13,763,312,952	\$353,111,288	0.00%	0.00%
326191	Plastics Plumbing Fixture Manufacturing	298	298	\$1,858	\$5,107,745,957	\$131,044,230	0.00%	0.00%
326199	All Other Plastics Product Manufacturing	4,965	4,965	\$34,955	\$115,986,293,418	\$2,975,742,073	0.00%	0.00%
326211	Tire Manufacturing (except Retreading)	84	84	\$1,505	\$23,833,071,544	\$403,723,728	0.00%	0.00%
326212	Tire Retreading	240	240	\$1,474	\$1,935,137,482	\$32,780,538	0.00%	0.00%
326220	Rubber and Plastics Hoses and Belting Manufacturing	186	186	\$1,579	\$6,643,026,648	\$112,530,501	0.00%	0.00%
326291	Rubber Product Manufacturing for Mechanical Use	336	336	\$2,600	\$10,846,648,515	\$183,738,356	0.00%	0.00%
326299	All Other Rubber Product Manufacturing	549	549	\$3,685	\$13,476,207,926	\$228,282,154	0.00%	0.00%
327	Nonmetallic Mineral Product Manufacturing	9,387	9,387	\$62,192	\$154,544,056,601	\$2,861,464,251	0.00%	0.00%
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	546	546	\$1,986	\$2,645,196,393	\$41,609,154	0.00%	0.00%
327120	Clay Building Material and Refractories Manufacturing	356	356	\$2,829	\$6,997,944,980	\$110,078,243	0.00%	0.00%
327211	Flat Glass Manufacturing	103	103	\$780	\$5,187,579,508	\$146,875,896	0.00%	0.00%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	404	404	\$1,723	\$4,142,806,131	\$117,295,236	0.00%	0.00%
327213	Glass Container Manufacturing	37	37	\$501	\$5,955,648,705	\$168,622,233	0.00%	0.00%
327215	Glass Product Manufacturing Made of Purchased Glass	895	895	\$4,841	\$14,841,065,034	\$420,194,952	0.00%	0.00%
327310	Cement Manufacturing	88	88	\$1,087	\$10,648,613,615	\$156,571,203	0.00%	0.00%
327320	Ready-Mix Concrete Manufacturing	2,022	2,022	\$20,948	\$39,799,326,235	\$585,186,824	0.00%	0.00%
327331	Concrete Block and Brick Manufacturing	407	407	\$3,127	\$5,418,582,863	\$79,671,783	0.00%	0.00%
327332	Concrete Pipe Manufacturing	89	89	\$1,039	\$1,988,848,996	\$29,242,913	0.00%	0.00%
327390	Other Concrete Product Manufacturing	1,504	1,504	\$8,807	\$14,671,597,768	\$215,722,891	0.00%	0.00%
327410	Lime Manufacturing	33	33	\$566	\$2,857,924,564	\$53,468,686	0.00%	0.00%

Table VI-21: Screening Analysis for Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2022 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
327420	Gypsum Product Manufacturing	119	119	\$1,026	\$7,794,626,759	\$145,829,059	0.00%	0.00%
327910	Abrasive Product Manufacturing	244	244	\$1,352	\$5,975,599,555	\$111,797,022	0.00%	0.00%
327991	Cut Stone and Stone Product Manufacturing	1,954	1,954	\$7,058	\$5,892,862,370	\$110,249,098	0.00%	0.01%
327992	Ground or Treated Mineral and Earth Manufacturing	151	151	\$1,191	\$5,372,406,995	\$100,511,940	0.00%	0.00%
327993	Mineral Wool Manufacturing	165	165	\$1,309	\$7,164,934,666	\$134,048,199	0.00%	0.00%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	270	270	\$2,023	\$7,188,491,466	\$134,488,921	0.00%	0.00%
331	Primary Metal Manufacturing	3,296	3,296	\$26,897	\$278,321,428,037	\$6,030,623,440	0.00%	0.00%
331110	Iron and Steel Mills and Ferroalloy Manufacturing	312	312	\$3,944	\$108,052,118,040	\$1,341,213,035	0.00%	0.00%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	209	209	\$2,051	\$15,024,519,874	\$312,759,731	0.00%	0.00%
331221	Rolled Steel Shape Manufacturing	175	175	\$1,239	\$8,526,720,600	\$177,497,508	0.00%	0.00%
331222	Steel Wire Drawing	186	186	\$1,361	\$6,320,821,549	\$131,578,144	0.00%	0.00%
331313	Alumina Refining and Primary Aluminum Production	37	37	\$209	\$4,061,390,323	\$100,276,030	0.00%	0.00%
331314	Secondary Smelting and Alloying of Aluminum	64	64	\$610	\$7,705,398,563	\$190,246,866	0.00%	0.00%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	67	67	\$906	\$20,173,019,985	\$488,414,212	0.00%	0.00%
331318	Other Aluminum Rolling, Drawing, and Extruding	199	199	\$1,964	\$14,796,021,517	\$365,314,876	0.00%	0.00%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	118	118	\$754	\$12,402,811,471	\$258,184,622	0.00%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	151	151	\$1,768	\$26,387,701,142	\$549,302,765	0.00%	0.00%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	226	226	\$1,374	\$8,805,349,915	\$183,297,629	0.00%	0.00%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal	169	169	\$1,106	\$9,207,562,757	\$191,670,341	0.00%	0.00%
331511	Iron Foundries	260	260	\$2,324	\$11,652,176,810	\$550,352,766	0.00%	0.00%
331512	Steel Investment Foundries	95	95	\$980	\$5,054,331,260	\$238,724,938	0.00%	0.00%
331513	Steel Foundries (except Investment)	164	164	\$1,076	\$4,645,543,651	\$219,417,182	0.00%	0.00%
331523	Nonferrous Metal Die-Casting Foundries	344	344	\$2,467	\$8,674,105,016	\$409,693,207	0.00%	0.00%
331524	Aluminum Foundries (except Die-Casting)	281	281	\$1,575	\$3,374,793,250	\$159,397,410	0.00%	0.00%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	239	239	\$1,189	\$3,457,042,315	\$163,282,177	0.00%	0.00%
339	Miscellaneous Manufacturing	23,329	23,329	\$508,712	\$189,133,999,054	\$11,447,078,976	0.00%	0.00%
339112	Surgical and Medical Instrument Manufacturing	1,099	1,099	\$40,508	\$51,614,518,085	\$3,784,573,568	0.00%	0.00%
339113	Surgical Appliance and Supplies Manufacturing	1,622	1,622	\$46,275	\$44,501,343,055	\$3,263,008,411	0.00%	0.00%
339114	Dental Equipment and Supplies Manufacturing	533	533	\$11,375	\$6,067,000,616	\$444,855,653	0.00%	0.00%
339115	Ophthalmic Goods Manufacturing	324	324	\$12,061	\$7,653,760,457	\$561,202,944	0.00%	0.00%
339116	Dental Laboratories	5,142	5,142	\$92,305	\$5,901,104,979	\$432,691,552	0.00%	0.02%
339910	Jewelry and Silverware Manufacturing	1,987	1,987	\$35,651	\$8,106,516,294	\$327,010,377	0.00%	0.01%
339920	Sporting and Athletic Goods Manufacturing	1,569	1,569	\$35,109	\$11,528,116,895	\$465,035,006	0.00%	0.01%
339930	Doll, Toy, and Game Manufacturing	507	507	\$9,672	\$1,881,976,976	\$75,917,445	0.00%	0.01%
339940	Office Supplies (except Paper) Manufacturing	413	413	\$9,636	\$3,773,797,375	\$152,231,965	0.00%	0.01%

Table VI-21: Screening Analysis for Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2022 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
339950	Sign Manufacturing	5,741	5,741	\$114,484	\$15,179,515,980	\$612,329,522	0.00%	0.02%
339991	Gasket, Packing, and Sealing Device Manufacturing	475	475	\$20,994	\$12,672,706,713	\$511,206,843	0.00%	0.00%
339992	Musical Instrument Manufacturing	576	576	\$11,599	\$2,394,085,265	\$96,575,483	0.00%	0.01%
339993	Fastener, Button, Needle, and Pin Manufacturing	99	99	\$2,514	\$1,105,456,492	\$44,593,230	0.00%	0.01%
339994	Broom, Brush, and Mop Manufacturing	155	155	\$5,085	\$3,398,953,469	\$137,111,062	0.00%	0.00%
339995	Burial Casket Manufacturing	79	79	\$2,119	\$649,829,866	\$26,213,617	0.00%	0.01%
339999	All Other Miscellaneous Manufacturing	3,008	3,008	\$59,325	\$12,705,316,537	\$512,522,297	0.00%	0.01%
42	Wholesale Trade	257,126	49,179	-\$19,814,240	\$9,730,413,309,855	\$220,158,015,274	0.00%	-0.01%
423	Merchant Wholesalers, Durable Goods	161,958	13,967	\$63,638	\$4,536,406,714,671	\$95,091,185,603	0.00%	0.00%
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	8,156	8,156	\$36,273	\$305,193,211,815	\$7,576,452,211	0.00%	0.00%
423840	Industrial Supplies Merchant Wholesalers	5,811	5,811	\$27,366	\$93,267,046,705	\$2,877,574,387	0.00%	0.00%
424	Merchant Wholesalers, Nondurable Goods	95,168	35,212	-\$19,877,879	\$5,194,006,595,185	\$125,066,829,671	0.00%	-0.02%
424210	Drugs and Druggists' Sundries Merchant Wholesalers	7,207	7,207	\$38,684	\$1,071,874,399,470	\$37,196,508,248	0.00%	0.00%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	2,046	2,046	\$8,437	\$53,481,476,596	\$1,633,412,923	0.00%	0.00%
424690	Other Chemical and Allied Products Merchant Wholesalers	5,804	5,804	\$30,160	\$240,052,181,069	\$7,331,591,416	0.00%	0.00%
424710	Petroleum Bulk Stations and Terminals	2,172	2,172	\$13,870	\$646,542,781,628	\$6,237,984,142	0.00%	0.00%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,830	1,830	\$7,833	\$675,361,005,744	\$6,516,028,581	0.00%	0.00%
424910	Farm Supplies Merchant Wholesalers	4,909	4,909	-\$15,651,093	\$169,043,606,251	\$4,586,156,656	-0.01%	-0.34%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	959	959	-\$4,354,437	\$21,267,042,880	\$494,008,349	-0.02%	-0.88%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,285	10,285	\$28,668	\$52,401,274,940	\$1,217,219,876	0.00%	0.00%
Total		6,177,430	111,223	-\$29,829,412	\$50,256,838,711,534	\$6,647,779,865,027	0.00%	0.00%

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Note: "Affected" firms are based on the maximum number affected by any one provision of the rule.

**Table VI-22: Screening Analysis for Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate
(Exclusive of Cost Savings, 2022 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	15,086	4,950	\$379,462	\$431,108,657,025	\$27,875,832,950	0.00%	0.00%
211	Oil and Gas Extraction	4,950	4,950	\$379,462	\$313,363,204,311	\$19,527,451,736	0.00%	0.00%
211120	Crude Petroleum Extraction	4,250	4,250	\$223,617	\$182,884,826,557	\$11,396,598,499	0.00%	0.00%
211130	Natural Gas Extraction	700	700	\$155,845	\$130,478,377,754	\$8,130,853,237	0.00%	0.00%
31-33	Manufacturing	254,179	57,094	\$4,538,566	\$6,806,317,226,570	\$307,020,834,126	0.00%	0.00%
324	Petroleum and Coal Products Manufacturing	967	967	\$1,597,653	\$618,970,333,766	\$42,184,548,322	0.00%	0.00%
324110	Petroleum Refineries	83	83	\$128,936	\$564,989,119,296	\$38,482,646,505	0.00%	0.00%
324121	Asphalt Paving Mixture and Block Manufacturing	471	471	\$186,386	\$16,051,429,566	\$1,107,071,965	0.00%	0.02%
324122	Asphalt Shingle and Coating Materials Manufacturing	110	110	\$29,285	\$13,011,486,147	\$897,406,146	0.00%	0.00%
324191	Petroleum Lubricating Oil and Grease Manufacturing	240	240	\$1,240,097	\$19,612,657,227	\$1,336,005,706	0.01%	0.09%
324199	All Other Petroleum and Coal Products Manufacturing	63	63	\$12,948	\$5,305,641,530	\$361,418,000	0.00%	0.00%
325	Chemical Manufacturing	10,745	10,745	\$2,270,811	\$909,458,774,282	\$74,456,661,262	0.00%	0.00%
325110	Petrochemical Manufacturing	31	31	\$29,484	\$71,573,798,420	\$2,442,253,916	0.00%	0.00%
325120	Industrial Gas Manufacturing	78	78	\$33,794	\$12,210,053,190	\$416,633,613	0.00%	0.01%
325130	Synthetic Dye and Pigment Manufacturing	103	103	\$10,433	\$8,178,034,130	\$279,052,339	0.00%	0.00%
325180	Other Basic Inorganic Chemical Manufacturing	376	376	\$28,199	\$39,555,120,764	\$1,349,706,886	0.00%	0.00%
325193	Ethyl Alcohol Manufacturing	117	117	\$15,785	\$36,969,480,194	\$1,261,479,197	0.00%	0.00%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Mfg.	49	49	\$5,832	\$8,235,635,343	\$281,017,818	0.00%	0.00%
325199	All Other Basic Organic Chemical Manufacturing	608	608	\$71,417	\$93,186,612,758	\$3,179,730,222	0.00%	0.00%
325211	Plastics Material and Resin Manufacturing	856	856	\$181,829	\$111,992,427,793	\$6,652,894,083	0.00%	0.00%
325212	Synthetic Rubber Manufacturing	137	137	\$6,797	\$11,341,788,771	\$673,757,332	0.00%	0.00%
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	114	114	\$4,400	\$9,438,755,096	\$560,707,890	0.00%	0.00%
325311	Nitrogenous Fertilizer Manufacturing	165	165	\$4,465	\$7,516,577,865	\$730,224,121	0.00%	0.00%
325312	Phosphatic Fertilizer Manufacturing	44	44	\$2,126	\$7,371,977,155	\$716,176,381	0.00%	0.00%
325314	Fertilizer (Mixing Only) Manufacturing	371	371	\$19,360	\$6,524,881,780	\$633,882,353	0.00%	0.00%
325320	Pesticide and Other Agricultural Chemical Manufacturing	184	184	\$48,221	\$17,589,850,557	\$1,708,827,260	0.00%	0.00%
325411	Medicinal and Botanical Manufacturing	597	597	\$34,823	\$14,667,072,169	\$2,034,425,026	0.00%	0.00%
325412	Pharmaceutical Preparation Manufacturing	1,117	1,117	\$215,106	\$189,438,629,432	\$26,276,456,821	0.00%	0.00%
325413	In-Vitro Diagnostic Substance Manufacturing	189	189	\$47,198	\$14,404,900,211	\$1,998,059,950	0.00%	0.00%

**Table VI-22: Screening Analysis for Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate
(Exclusive of Cost Savings, 2022 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
325414	Biological Product (except Diagnostic) Manufacturing	276	276	\$18,523	\$47,392,153,058	\$6,573,621,585	0.00%	0.00%
325510	Paint and Coating Manufacturing	958	958	\$536,560	\$31,466,389,652	\$1,312,642,728	0.00%	0.04%
325520	Adhesive Manufacturing	401	401	\$223,133	\$18,096,459,850	\$754,906,638	0.00%	0.03%
325611	Soap and Other Detergent Manufacturing	631	631	\$163,257	\$30,356,886,805	\$3,747,210,330	0.00%	0.00%
325612	Polish and Other Sanitation Good Manufacturing	428	428	\$95,585	\$6,982,891,985	\$861,958,117	0.00%	0.01%
325613	Surface Active Agent Manufacturing	108	108	\$42,269	\$9,179,976,693	\$1,133,163,085	0.00%	0.00%
325620	Toilet Preparation Manufacturing	1,010	1,010	\$200,741	\$48,305,711,210	\$5,962,787,330	0.00%	0.00%
325910	Printing Ink Manufacturing	162	162	\$55,533	\$4,549,024,893	\$230,691,977	0.00%	0.02%
325920	Explosives Manufacturing	53	53	\$20,584	\$2,950,164,188	\$149,609,911	0.00%	0.01%
325991	Custom Compounding of Purchased Resins	347	347	\$18,497	\$14,302,910,074	\$725,334,919	0.00%	0.00%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	163	163	\$7,495	\$6,516,237,026	\$330,454,029	0.00%	0.00%
325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	1,072	1,072	\$129,365	\$29,164,373,220	\$1,478,995,406	0.00%	0.01%
326	Plastics and Rubber Products Manufacturing	9,370	9,370	\$72,302	\$293,111,850,980	\$7,025,558,430	0.00%	0.00%
326111	Plastics Bag and Pouch Manufacturing	262	262	\$2,265	\$13,780,960,233	\$353,564,046	0.00%	0.00%
326112	Plastics Packaging Film and Sheet (including Laminated) Mfg.	310	310	\$2,909	\$16,908,003,774	\$433,791,414	0.00%	0.00%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Mfg.	388	388	\$3,073	\$18,960,257,252	\$486,443,989	0.00%	0.00%
326121	Unlaminated Plastics Profile Shape Mfg.	324	324	\$2,156	\$9,772,806,684	\$250,730,937	0.00%	0.00%
326122	Plastics Pipe and Pipe Fitting Mfg.	256	256	\$2,909	\$12,950,209,374	\$332,250,318	0.00%	0.00%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Mfg.	213	213	\$1,315	\$5,495,811,902	\$141,000,443	0.00%	0.00%
326140	Polystyrene Foam Product Manufacturing	306	306	\$2,698	\$11,073,975,465	\$284,113,698	0.00%	0.00%
326150	Urethane and Other Foam Product (except Polystyrene) Mfg.	459	459	\$3,959	\$12,578,381,854	\$322,710,719	0.00%	0.00%
326160	Plastics Bottle Manufacturing	194	194	\$3,360	\$13,763,312,952	\$353,111,288	0.00%	0.00%
326191	Plastics Plumbing Fixture Manufacturing	298	298	\$1,858	\$5,107,745,957	\$131,044,230	0.00%	0.00%
326199	All Other Plastics Product Manufacturing	4,965	4,965	\$34,955	\$115,986,293,418	\$2,975,742,073	0.00%	0.00%
326211	Tire Manufacturing (except Retreading)	84	84	\$1,505	\$23,833,071,544	\$403,723,728	0.00%	0.00%
326212	Tire Retreading	240	240	\$1,474	\$1,935,137,482	\$32,780,538	0.00%	0.00%
326220	Rubber and Plastics Hoses and Belting Manufacturing	186	186	\$1,579	\$6,643,026,648	\$112,530,501	0.00%	0.00%
326291	Rubber Product Manufacturing for Mechanical Use	336	336	\$2,600	\$10,846,648,515	\$183,738,356	0.00%	0.00%
326299	All Other Rubber Product Manufacturing	549	549	\$3,685	\$13,476,207,926	\$228,282,154	0.00%	0.00%
327	Nonmetallic Mineral Product Manufacturing	9,387	9,387	\$62,192	\$154,544,056,601	\$2,861,464,251	0.00%	0.00%
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	546	546	\$1,986	\$2,645,196,393	\$41,609,154	0.00%	0.00%
327120	Clay Building Material and Refractories Manufacturing	356	356	\$2,829	\$6,997,944,980	\$110,078,243	0.00%	0.00%
327211	Flat Glass Manufacturing	103	103	\$780	\$5,187,579,508	\$146,875,896	0.00%	0.00%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	404	404	\$1,723	\$4,142,806,131	\$117,295,236	0.00%	0.00%
327213	Glass Container Manufacturing	37	37	\$501	\$5,955,648,705	\$168,622,233	0.00%	0.00%
327215	Glass Product Manufacturing Made of Purchased Glass	895	895	\$4,841	\$14,841,065,034	\$420,194,952	0.00%	0.00%

**Table VI-22: Screening Analysis for Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate
(Exclusive of Cost Savings, 2022 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
327310	Cement Manufacturing	88	88	\$1,087	\$10,648,613,615	\$156,571,203	0.00%	0.00%
327320	Ready-Mix Concrete Manufacturing	2,022	2,022	\$20,948	\$39,799,326,235	\$585,186,824	0.00%	0.00%
327331	Concrete Block and Brick Manufacturing	407	407	\$3,127	\$5,418,582,863	\$79,671,783	0.00%	0.00%
327332	Concrete Pipe Manufacturing	89	89	\$1,039	\$1,988,848,996	\$29,242,913	0.00%	0.00%
327390	Other Concrete Product Manufacturing	1,504	1,504	\$8,807	\$14,671,597,768	\$215,722,891	0.00%	0.00%
327410	Lime Manufacturing	33	33	\$566	\$2,857,924,564	\$53,468,686	0.00%	0.00%
327420	Gypsum Product Manufacturing	119	119	\$1,026	\$7,794,626,759	\$145,829,059	0.00%	0.00%
327910	Abrasive Product Manufacturing	244	244	\$1,352	\$5,975,599,555	\$111,797,022	0.00%	0.00%
327991	Cut Stone and Stone Product Manufacturing	1,954	1,954	\$7,058	\$5,892,862,370	\$110,249,098	0.00%	0.01%
327992	Ground or Treated Mineral and Earth Manufacturing	151	151	\$1,191	\$5,372,406,995	\$100,511,940	0.00%	0.00%
327993	Mineral Wool Manufacturing	165	165	\$1,309	\$7,164,934,666	\$134,048,199	0.00%	0.00%
327999	All Other Miscellaneous Nonmetallic Mineral Product Mfg.	270	270	\$2,023	\$7,188,491,466	\$134,488,921	0.00%	0.00%
331	Primary Metal Manufacturing	3,296	3,296	\$26,897	\$278,321,428,037	\$6,030,623,440	0.00%	0.00%
331110	Iron and Steel Mills and Ferroalloy Manufacturing	312	312	\$3,944	\$108,052,118,040	\$1,341,213,035	0.00%	0.00%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	209	209	\$2,051	\$15,024,519,874	\$312,759,731	0.00%	0.00%
331221	Rolled Steel Shape Manufacturing	175	175	\$1,239	\$8,526,720,600	\$177,497,508	0.00%	0.00%
331222	Steel Wire Drawing	186	186	\$1,361	\$6,320,821,549	\$131,578,144	0.00%	0.00%
331313	Alumina Refining and Primary Aluminum Production	37	37	\$209	\$4,061,390,323	\$100,276,030	0.00%	0.00%
331314	Secondary Smelting and Alloying of Aluminum	64	64	\$610	\$7,705,398,563	\$190,246,866	0.00%	0.00%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	67	67	\$906	\$20,173,019,985	\$488,414,212	0.00%	0.00%
331318	Other Aluminum Rolling, Drawing, and Extruding	199	199	\$1,964	\$14,796,021,517	\$365,314,876	0.00%	0.00%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	118	118	\$754	\$12,402,811,471	\$258,184,622	0.00%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	151	151	\$1,768	\$26,387,701,142	\$549,302,765	0.00%	0.00%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	226	226	\$1,374	\$8,805,349,915	\$183,297,629	0.00%	0.00%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal	169	169	\$1,106	\$9,207,562,757	\$191,670,341	0.00%	0.00%
331511	Iron Foundries	260	260	\$2,324	\$11,652,176,810	\$550,352,766	0.00%	0.00%
331512	Steel Investment Foundries	95	95	\$980	\$5,054,331,260	\$238,724,938	0.00%	0.00%
331513	Steel Foundries (except Investment)	164	164	\$1,076	\$4,645,543,651	\$219,417,182	0.00%	0.00%
331523	Nonferrous Metal Die-Casting Foundries	344	344	\$2,467	\$8,674,105,016	\$409,693,207	0.00%	0.00%
331524	Aluminum Foundries (except Die-Casting)	281	281	\$1,575	\$3,374,793,250	\$159,397,410	0.00%	0.00%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	239	239	\$1,189	\$3,457,042,315	\$163,282,177	0.00%	0.00%
339	Miscellaneous Manufacturing	23,329	23,329	\$508,712	\$189,133,999,054	\$11,447,078,976	0.00%	0.00%
339112	Surgical and Medical Instrument Manufacturing	1,099	1,099	\$40,508	\$51,614,518,085	\$3,784,573,568	0.00%	0.00%
339113	Surgical Appliance and Supplies Manufacturing	1,622	1,622	\$46,275	\$44,501,343,055	\$3,263,008,411	0.00%	0.00%
339114	Dental Equipment and Supplies Manufacturing	533	533	\$11,375	\$6,067,000,616	\$444,855,653	0.00%	0.00%

**Table VI-22: Screening Analysis for Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate
(Exclusive of Cost Savings, 2022 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
339115	Ophthalmic Goods Manufacturing	324	324	\$12,061	\$7,653,760,457	\$561,202,944	0.00%	0.00%
339116	Dental Laboratories	5,142	5,142	\$92,305	\$5,901,104,979	\$432,691,552	0.00%	0.02%
339910	Jewelry and Silverware Manufacturing	1,987	1,987	\$35,651	\$8,106,516,294	\$327,010,377	0.00%	0.01%
339920	Sporting and Athletic Goods Manufacturing	1,569	1,569	\$35,109	\$11,528,116,895	\$465,035,006	0.00%	0.01%
339930	Doll, Toy, and Game Manufacturing	507	507	\$9,672	\$1,881,976,976	\$75,917,445	0.00%	0.01%
339940	Office Supplies (except Paper) Manufacturing	413	413	\$9,636	\$3,773,797,375	\$152,231,965	0.00%	0.01%
339950	Sign Manufacturing	5,741	5,741	\$114,484	\$15,179,515,980	\$612,329,522	0.00%	0.02%
339991	Gasket, Packing, and Sealing Device Manufacturing	475	475	\$20,994	\$12,672,706,713	\$511,206,843	0.00%	0.00%
339992	Musical Instrument Manufacturing	576	576	\$11,599	\$2,394,085,265	\$96,575,483	0.00%	0.01%
339993	Fastener, Button, Needle, and Pin Manufacturing	99	99	\$2,514	\$1,105,456,492	\$44,593,230	0.00%	0.01%
339994	Broom, Brush, and Mop Manufacturing	155	155	\$5,085	\$3,398,953,469	\$137,111,062	0.00%	0.00%
339995	Burial Casket Manufacturing	79	79	\$2,119	\$649,829,866	\$26,213,617	0.00%	0.01%
339999	All Other Miscellaneous Manufacturing	3,008	3,008	\$59,325	\$12,705,316,537	\$512,522,297	0.00%	0.01%
42	Wholesale Trade	257,126	49,179	\$224,298	\$9,730,413,309,855	\$220,158,015,274	0.00%	0.00%
423	Merchant Wholesalers, Durable Goods	161,958	13,967	\$63,638	\$4,536,406,714,671	\$95,091,185,603	0.00%	0.00%
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	8,156	8,156	\$36,273	\$305,193,211,815	\$7,576,452,211	0.00%	0.00%
423840	Industrial Supplies Merchant Wholesalers	5,811	5,811	\$27,366	\$93,267,046,705	\$2,877,574,387	0.00%	0.00%
424	Merchant Wholesalers, Nondurable Goods	95,168	35,212	\$160,660	\$5,194,006,595,185	\$125,066,829,671	0.00%	0.00%
424210	Drugs and Druggists' Sundries Merchant Wholesalers	7,207	7,207	\$38,684	\$1,071,874,399,470	\$37,196,508,248	0.00%	0.00%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	2,046	2,046	\$8,437	\$53,481,476,596	\$1,633,412,923	0.00%	0.00%
424690	Other Chemical and Allied Products Merchant Wholesalers	5,804	5,804	\$30,160	\$240,052,181,069	\$7,331,591,416	0.00%	0.00%
424710	Petroleum Bulk Stations and Terminals	2,172	2,172	\$13,870	\$646,542,781,628	\$6,237,984,142	0.00%	0.00%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,830	1,830	\$7,833	\$675,361,005,744	\$6,516,028,581	0.00%	0.00%
424910	Farm Supplies Merchant Wholesalers	4,909	4,909	\$27,701	\$169,043,606,251	\$4,586,156,656	0.00%	0.00%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	959	959	\$5,307	\$21,267,042,880	\$494,008,349	0.00%	0.00%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,285	10,285	\$28,668	\$52,401,274,940	\$1,217,219,876	0.00%	0.00%
Total		6,177,430	111,223	\$5,142,326	\$50,256,838,711,534	\$6,647,779,865,027	0.00%	0.00%

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Note: "Affected" firms are based on the maximum number affected by any one provision of the rule.

In the case of costs incurred due to the requirements of the revisions to the HCS, all businesses within each of the covered industry sectors will 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, 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 GHS-based requirements 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 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 (\$1,240,097; see Table VI-22), revenue impacts (0.0063 percent, rounded to 0.01 percent) and profit impacts (0.092 percent, rounded to 0.1 percent) fall well below OSHA's screening criteria associated with economic feasibility concerns. OSHA therefore concludes that the final rule is economically feasible. To supplement OSHA's determination of economic feasibility, the agency conducted a final regulatory flexibility screening analysis, discussed immediately below.

H. Final Regulatory Flexibility Screening Analysis and FRFA Certification

The Regulatory Flexibility Act (5 U.S.C. 601-612), as amended in 1996, requires the preparation of a Final Regulatory Flexibility Analysis (FRFA) for rules where there would be a significant economic impact on a substantial number of small firms. Under the provisions of the law, each such analysis shall contain:

1. A statement of the need for, and objectives of, the rule;
2. A statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. The response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
4. A description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
5. A description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record; and
6. A description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of the applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

The Regulatory Flexibility Act further states that the required elements of the FRFA may be performed in conjunction with or as part of any other agenda or analysis required by any other law if such other analysis satisfies the relevant provisions (5 U.S.C. 605(a)).

As explained below, OSHA has determined that the final rule will not have a significant economic impact on a substantial number of small entities, and therefore a FRFA is not required by the Regulatory Flexibility Act. Nonetheless, OSHA has prepared a voluntary Final Regulatory Flexibility Screening Assessment (FRFSA) to assure the regulated community that the agency has considered the impacts of the final rule on small entities. While a full understanding of OSHA's analysis and conclusions with respect to costs and economic impacts on small businesses requires a reading of the complete FEA and its supporting materials, this voluntary FRFSA will summarize the key aspects of OSHA's analysis as they affect small businesses and includes a description of the impact of the rule on small entities, which is not required under the Regulatory Flexibility Act.

I. Final Regulatory Flexibility Screening Assessment.

(A). Description of the impact of the rule on small entities.

To determine whether the final 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 final rule will impose costs on impacted industries for training; for reclassification of aerosols, desensitized explosives, and flammable gases; and for becoming familiar with the final changes to the standard. The rule will also result in cost savings to the extent it limits employers' duties with respect to the labeling of some very small containers and provides more flexible relabeling requirements for packaged chemicals released for shipment.

Although the phase-in periods for evaluation and training on the hazards of chemical substances and mixtures under the final rule range from eighteen months to forty-two months, as an analytical simplification for this FEA, OSHA has estimated costs as one-time costs that will be incurred during the first year after the rule is promulgated. In addition, as mentioned above, there will be annual cost savings due to the flexibilities introduced in the provision related to the labeling of very small containers and in the released-for-shipment provision.

Tables VI-23 and VI-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 VI-25 and VI-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.⁵³

The total annualized cost savings resulting from the revisions to the HCS for small entities and very small entities are estimated to be approximately \$25.5 million and \$1.6 million, respectively (see Tables VI-23 and VI-24). To assess the economic impact of the final 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 VI-23 (small entities) and VI-24 (very small entities). Those tables show that in no industries do the annualized costs of the revisions to the standard exceed one percent of annual revenues or five percent of annual profits, either for small entities

⁵³ 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; E.O.s 12866, 13563, and 13771; and the Unfunded Mandates Reform Act. For a recent example of the application of these screening criteria, see the FEA and FRFA for the Final Rule for Occupational Exposure to Respirable Crystalline Silica, Chapter VI: Economic Feasibility Analysis and Regulatory Flexibility Determination, Document ID 0045.

or for very small entities. Similarly, under a cost scenario exclusive of cost savings (shown in Tables VI-25 and VI-26), in no industries do the annualized costs of the final 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 revision to the HCS, OSHA certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Table VI-23: Screening Analysis for SBA-Defined Small Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2022 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	14,836	4,865	\$311,295	\$173,001,050,842	\$11,142,435,423	0.00%	0.00%
211	Oil and Gas Extraction	4,865	4,865	\$311,295	\$130,869,457,380	\$8,155,223,643	0.00%	0.00%
211120	Crude Petroleum Extraction	4,204	4,204	\$205,435	\$82,148,479,398	\$5,119,141,126	0.00%	0.00%
211130	Natural Gas Extraction	661	661	\$105,860	\$48,720,977,982	\$3,036,082,517	0.00%	0.00%
31-33	Manufacturing	244,858	54,194	-\$6,710,072	\$1,974,081,390,875	\$89,015,709,458	0.00%	-0.01%
324	Petroleum and Coal Products Manufacturing	831	831	\$1,061,024	\$63,956,507,492	\$4,365,472,912	0.00%	0.02%
324110	Petroleum Refineries	52	52	\$39,557	\$43,959,961,688	\$2,994,209,283	0.00%	0.00%
324121	Asphalt Paving Mixture and Block Manufacturing	421	421	\$41,378	\$7,052,481,538	\$486,411,791	0.00%	0.01%
324122	Asphalt Shingle and Coating Materials Manufacturing	95	95	\$16,553	\$3,653,060,342	\$251,952,680	0.00%	0.01%
324191	Petroleum Lubricating Oil and Grease Manufacturing	211	211	\$956,415	\$6,633,215,757	\$451,851,781	0.01%	0.21%
324199	All Other Petroleum and Coal Products Manufacturing	52	52	\$7,122	\$2,657,788,167	\$181,047,377	0.00%	0.00%
325	Chemical Manufacturing	9,806	9,806	-\$8,358,479	\$241,435,425,905	\$19,085,810,350	0.00%	-0.04%
325110	Petrochemical Manufacturing	15	15	\$8,874	\$3,659,008,422	\$124,853,338	0.00%	0.01%
325120	Industrial Gas Manufacturing	64	64	\$5,023	\$994,180,801	\$33,923,615	0.00%	0.01%
325130	Synthetic Dye and Pigment Manufacturing	90	90	\$7,288	\$3,056,687,652	\$104,300,841	0.00%	0.01%
325180	Other Basic Inorganic Chemical Manufacturing	310	310	-\$128,530	\$14,719,722,613	\$502,269,000	0.00%	-0.03%
325193	Ethyl Alcohol Manufacturing	103	103	\$10,600	\$19,617,730,458	\$669,399,698	0.00%	0.00%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Mfg.	32	32	\$2,601	\$809,079,434	\$27,607,553	0.00%	0.01%
325199	All Other Basic Organic Chemical Manufacturing	530	530	-\$195,922	\$24,528,270,906	\$836,958,035	0.00%	-0.02%
325211	Plastics Material and Resin Manufacturing	771	771	\$141,178	\$29,067,585,548	\$1,726,755,743	0.00%	0.01%
325212	Synthetic Rubber Manufacturing	112	112	\$5,392	\$5,560,652,947	\$330,329,789	0.00%	0.00%
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	90	90	\$3,325	\$3,044,666,867	\$180,867,998	0.00%	0.00%
325311	Nitrogenous Fertilizer Manufacturing	150	150	-\$554,235	\$2,231,734,699	\$216,809,636	-0.02%	-0.26%
325312	Phosphatic Fertilizer Manufacturing	35	35	-\$220,347	\$886,613,999	\$86,133,203	-0.02%	-0.26%
325314	Fertilizer (Mixing Only) Manufacturing	353	353	-\$1,105,980	\$4,478,262,789	\$435,056,427	-0.02%	-0.25%
325320	Pesticide and Other Agricultural Chemical Manufacturing	165	165	\$37,330	\$5,124,392,930	\$497,826,988	0.00%	0.01%
325411	Medicinal and Botanical Manufacturing	567	567	-\$44,861	\$7,604,961,980	\$1,054,861,174	0.00%	0.00%
325412	Pharmaceutical Preparation Manufacturing	1,045	1,045	\$130,861	\$34,115,627,906	\$4,732,075,112	0.00%	0.00%
325413	In-Vitro Diagnostic Substance Manufacturing	167	167	\$31,049	\$3,430,867,757	\$475,885,245	0.00%	0.01%
325414	Biological Product (except Diagnostic) Manufacturing	231	231	\$4,405	\$9,259,049,356	\$1,284,294,610	0.00%	0.00%
325510	Paint and Coating Manufacturing	924	924	-\$7,120,082	\$11,087,244,588	\$462,512,260	-0.06%	-1.54%
325520	Adhesive Manufacturing	345	345	\$68,967	\$5,339,793,027	\$222,753,248	0.00%	0.03%
325611	Soap and Other Detergent Manufacturing	605	605	\$143,883	\$6,575,127,168	\$811,624,216	0.00%	0.02%
325612	Polish and Other Sanitation Good Manufacturing	409	409	\$86,469	\$4,181,099,162	\$516,108,851	0.00%	0.02%
325613	Surface Active Agent Manufacturing	92	92	\$31,035	\$3,065,370,876	\$378,384,960	0.00%	0.01%
325620	Toilet Preparation Manufacturing	981	981	\$187,738	\$19,202,886,031	\$2,370,376,559	0.00%	0.01%
325910	Printing Ink Manufacturing	145	145	\$21,112	\$1,607,687,931	\$81,529,716	0.00%	0.03%

Table VI-23: Screening Analysis for SBA-Defined Small Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2022 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
325920	Explosives Manufacturing	38	38	\$10,104	\$693,174,902	\$35,152,564	0.00%	0.03%
325991	Custom Compounding of Purchased Resins	306	306	\$10,122	\$5,691,757,644	\$288,642,699	0.00%	0.00%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	151	151	\$6,639	\$831,530,162	\$42,168,891	0.00%	0.02%
325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	980	980	\$57,488	\$10,970,657,349	\$556,348,381	0.00%	0.01%
326	Plastics and Rubber Products Manufacturing	8,666	8,666	\$56,864	\$113,843,163,052	\$2,778,952,596	0.00%	0.00%
326111	Plastics Bag and Pouch Manufacturing	233	233	\$1,694	\$3,812,593,720	\$97,815,830	0.00%	0.00%
326112	Plastics Packaging Film and Sheet (including Laminated) Mfg.	273	273	\$2,081	\$6,905,129,008	\$177,157,855	0.00%	0.00%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Mfg.	347	347	\$2,351	\$6,490,745,777	\$166,526,447	0.00%	0.00%
326121	Unlaminated Plastics Profile Shape Mfg.	289	289	\$1,802	\$3,006,801,686	\$77,142,445	0.00%	0.00%
326122	Plastics Pipe and Pipe Fitting Mfg.	222	222	\$1,797	\$5,090,463,190	\$130,600,824	0.00%	0.00%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Mfg.	182	182	\$981	\$1,924,078,647	\$49,364,124	0.00%	0.00%
326140	Polystyrene Foam Product Manufacturing	282	282	\$2,115	\$5,002,292,097	\$128,338,708	0.00%	0.00%
326150	Urethane and Other Foam Product (except Polystyrene) Mfg.	415	415	\$2,814	\$4,983,561,033	\$127,858,144	0.00%	0.00%
326160	Plastics Bottle Manufacturing	181	181	\$1,669	\$4,036,459,444	\$103,559,324	0.00%	0.00%
326191	Plastics Plumbing Fixture Manufacturing	290	290	\$1,680	\$3,190,882,780	\$81,865,226	0.00%	0.00%
326199	All Other Plastics Product Manufacturing	4,693	4,693	\$29,756	\$53,131,238,757	\$1,363,134,021	0.00%	0.00%
326211	Tire Manufacturing (except Retreading)	70	70	\$797	\$4,133,384,788	\$70,018,064	0.00%	0.00%
326212	Tire Retreading	224	224	\$1,093	\$1,000,658,631	\$16,950,800	0.00%	0.01%
326220	Rubber and Plastics Hoses and Belting Manufacturing	167	167	\$1,124	\$2,589,388,690	\$43,863,321	0.00%	0.00%
326291	Rubber Product Manufacturing for Mechanical Use	306	306	\$2,145	\$3,847,583,240	\$65,176,687	0.00%	0.00%
326299	All Other Rubber Product Manufacturing	492	492	\$2,964	\$4,697,901,564	\$79,580,776	0.00%	0.00%
327	Nonmetallic Mineral Product Manufacturing	8,987	8,987	\$45,621	\$62,726,868,770	\$1,096,997,964	0.00%	0.00%
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	534	534	\$1,902	\$1,337,553,762	\$21,039,829	0.00%	0.01%
327120	Clay Building Material and Refractories Manufacturing	326	326	\$2,073	\$3,630,120,546	\$57,102,091	0.00%	0.00%
327211	Flat Glass Manufacturing	91	91	\$541	\$656,715,335	\$18,593,576	0.00%	0.00%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	388	388	\$1,610	\$1,691,789,270	\$47,899,616	0.00%	0.00%
327213	Glass Container Manufacturing	29	29	\$217	\$418,420,544	\$11,846,737	0.00%	0.00%
327215	Glass Product Manufacturing Made of Purchased Glass	861	861	\$4,207	\$5,525,809,632	\$156,452,203	0.00%	0.00%
327310	Cement Manufacturing	73	73	\$462	\$1,470,724,087	\$21,624,697	0.00%	0.00%
327320	Ready-Mix Concrete Manufacturing	1,958	1,958	\$12,155	\$20,717,511,691	\$304,618,596	0.00%	0.00%
327331	Concrete Block and Brick Manufacturing	382	382	\$2,357	\$3,291,709,756	\$48,399,442	0.00%	0.00%
327332	Concrete Pipe Manufacturing	83	83	\$623	\$1,139,522,325	\$16,754,893	0.00%	0.00%
327390	Other Concrete Product Manufacturing	1,451	1,451	\$7,467	\$8,682,164,472	\$127,657,645	0.00%	0.01%
327410	Lime Manufacturing	24	24	\$216	\$865,109,167	\$16,185,259	0.00%	0.00%
327420	Gypsum Product Manufacturing	109	109	\$584	\$447,053,257	\$8,363,884	0.00%	0.01%
327910	Abrasive Product Manufacturing	233	233	\$1,189	\$2,021,424,195	\$37,818,666	0.00%	0.00%
327991	Cut Stone and Stone Product Manufacturing	1,931	1,931	\$6,929	\$4,812,522,458	\$90,037,104	0.00%	0.01%

Table VI-23: Screening Analysis for SBA-Defined Small Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2022 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
327992	Ground or Treated Mineral and Earth Manufacturing	123	123	\$741	\$1,769,433,795	\$33,104,198	0.00%	0.00%
327993	Mineral Wool Manufacturing	152	152	\$1,027	\$2,174,407,766	\$40,680,824	0.00%	0.00%
327999	All Other Miscellaneous Nonmetallic Mineral Product Mfg.	239	239	\$1,324	\$2,074,876,712	\$38,818,705	0.00%	0.00%
331	Primary Metal Manufacturing	2,932	2,932	\$20,678	\$88,586,613,067	\$2,072,195,314	0.00%	0.00%
331110	Iron and Steel Mills and Ferroalloy Manufacturing	281	281	\$2,714	\$20,890,760,432	\$259,309,680	0.00%	0.00%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	175	175	\$1,557	\$7,367,292,854	\$153,362,141	0.00%	0.00%
331221	Rolled Steel Shape Manufacturing	154	154	\$987	\$4,972,953,187	\$103,520,080	0.00%	0.00%
331222	Steel Wire Drawing	166	166	\$1,120	\$3,612,084,969	\$75,191,403	0.00%	0.00%
331313	Alumina Refining and Primary Aluminum Production	27	27	\$128	\$1,088,654,321	\$26,878,956	0.00%	0.00%
331314	Secondary Smelting and Alloying of Aluminum	52	52	\$407	\$2,885,391,854	\$71,240,540	0.00%	0.00%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	56	56	\$660	\$4,335,142,654	\$104,959,262	0.00%	0.00%
331318	Other Aluminum Rolling, Drawing, and Extruding	172	172	\$1,383	\$5,182,592,041	\$127,958,584	0.00%	0.00%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	103	103	\$606	\$5,758,979,536	\$119,882,492	0.00%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	129	129	\$1,164	\$11,476,098,480	\$238,893,589	0.00%	0.00%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	201	201	\$1,104	\$2,131,430,995	\$44,369,191	0.00%	0.00%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal	151	151	\$923	\$5,502,650,423	\$114,546,587	0.00%	0.00%
331511	Iron Foundries	231	231	\$1,867	\$3,324,719,712	\$157,032,348	0.00%	0.00%
331512	Steel Investment Foundries	88	88	\$827	\$1,888,851,815	\$89,213,787	0.00%	0.00%
331513	Steel Foundries (except Investment)	145	145	\$850	\$1,763,331,460	\$83,285,240	0.00%	0.00%
331523	Nonferrous Metal Die-Casting Foundries	309	309	\$1,810	\$3,030,786,640	\$143,149,373	0.00%	0.00%
331524	Aluminum Foundries (except Die-Casting)	267	267	\$1,452	\$1,929,923,454	\$91,153,673	0.00%	0.00%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	225	225	\$1,122	\$1,444,968,241	\$68,248,387	0.00%	0.00%
339	Miscellaneous Manufacturing	22,972	22,972	\$464,220	\$73,453,095,870	\$4,046,248,288	0.00%	0.01%
339112	Surgical and Medical Instrument Manufacturing	1,029	1,029	\$33,720	\$12,986,915,927	\$952,250,269	0.00%	0.00%
339113	Surgical Appliance and Supplies Manufacturing	1,562	1,562	\$43,062	\$11,456,275,670	\$840,017,880	0.00%	0.01%
339114	Dental Equipment and Supplies Manufacturing	522	522	\$10,923	\$2,863,485,268	\$209,961,675	0.00%	0.01%
339115	Ophthalmic Goods Manufacturing	306	306	\$8,058	\$1,429,817,777	\$104,839,699	0.00%	0.01%
339116	Dental Laboratories	5,126	5,126	\$82,695	\$4,103,332,771	\$300,872,028	0.00%	0.03%
339910	Jewelry and Silverware Manufacturing	1,972	1,972	\$34,630	\$4,133,091,237	\$166,725,592	0.00%	0.02%
339920	Sporting and Athletic Goods Manufacturing	1,549	1,549	\$34,033	\$6,931,778,350	\$279,622,389	0.00%	0.01%
339930	Doll, Toy, and Game Manufacturing	503	503	\$9,584	\$1,389,538,569	\$56,052,873	0.00%	0.02%
339940	Office Supplies (except Paper) Manufacturing	401	401	\$9,265	\$2,609,465,889	\$105,263,765	0.00%	0.01%
339950	Sign Manufacturing	5,708	5,708	\$112,006	\$12,112,744,969	\$488,618,435	0.00%	0.02%
339991	Gasket, Packing, and Sealing Device Manufacturing	434	434	\$9,612	\$2,905,995,145	\$117,225,518	0.00%	0.01%
339992	Musical Instrument Manufacturing	570	570	\$11,210	\$1,296,829,108	\$52,313,048	0.00%	0.02%
339993	Fastener, Button, Needle, and Pin Manufacturing	92	92	\$2,230	\$460,624,786	\$18,581,235	0.00%	0.01%

Table VI-23: Screening Analysis for SBA-Defined Small Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2022 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
339994	Broom, Brush, and Mop Manufacturing	143	143	\$3,902	\$1,605,789,812	\$64,776,275	0.00%	0.01%
339995	Burial Casket Manufacturing	76	76	\$1,848	\$209,122,381	\$8,435,829	0.00%	0.02%
339999	All Other Miscellaneous Manufacturing	2,979	2,979	\$57,443	\$6,958,288,212	\$280,691,776	0.00%	0.02%
42	Wholesale Trade	246,092	46,958	-\$19,062,282	\$2,295,651,888,873	\$52,515,638,142	0.00%	-0.04%
423	Merchant Wholesalers, Durable Goods	154,855	13,355	\$44,805	\$1,168,050,693,858	\$25,935,567,178	0.00%	0.00%
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	7,907	7,907	\$26,619	\$40,925,023,490	\$1,015,967,829	0.00%	0.00%
423840	Industrial Supplies Merchant Wholesalers	5,448	5,448	\$18,187	\$29,980,830,090	\$925,000,542	0.00%	0.00%
424	Merchant Wholesalers, Nondurable Goods	91,237	33,603	-\$19,107,087	\$1,127,601,195,015	\$26,580,070,964	0.00%	-0.07%
424210	Drugs and Druggists' Sundries Merchant Wholesalers	6,918	6,918	\$24,953	\$88,078,481,901	\$3,056,526,007	0.00%	0.00%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	1,923	1,923	\$6,554	\$21,121,343,462	\$645,080,831	0.00%	0.00%
424690	Other Chemical and Allied Products Merchant Wholesalers	5,508	5,508	\$19,162	\$56,137,224,375	\$1,714,523,861	0.00%	0.00%
424710	Petroleum Bulk Stations and Terminals	1,929	1,929	\$8,640	\$125,662,478,049	\$1,212,418,679	0.00%	0.00%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,671	1,671	\$5,559	\$141,971,019,579	\$1,369,767,004	0.00%	0.00%
424910	Farm Supplies Merchant Wholesalers	4,722	4,722	-\$15,064,794	\$53,997,866,896	\$1,464,963,285	-0.03%	-1.03%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	910	910	-\$4,133,942	\$4,790,420,318	\$111,275,820	-0.09%	-3.72%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,022	10,022	\$26,780	\$30,363,527,905	\$705,308,978	0.00%	0.00%
Total		6,059,071	106,017	-\$25,461,059	\$14,465,946,958,024	\$1,460,460,327,939	0.00%	0.00%

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Note: "Affected" firms are based on the maximum number affected by any one provision of the rule.

Table VI-24: Screening Analysis for Very Small Entities (Fewer than 20 Employees) Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2022 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	12,463	4,348	\$200,665	\$17,860,924,223	\$1,175,900,262	0.00%	0.02%
211	Oil and Gas Extraction	4,348	4,348	\$200,665	\$10,537,100,260	\$656,626,923	0.00%	0.03%
211120	Crude Petroleum Extraction	3,825	3,825	\$150,134	\$8,060,918,275	\$502,321,876	0.00%	0.03%
211130	Natural Gas Extraction	523	523	\$50,531	\$2,476,181,985	\$154,305,048	0.00%	0.03%
31-33	Manufacturing	181,194	39,001	\$113,634	\$225,506,587,223	\$9,799,576,017	0.00%	0.00%
324	Petroleum and Coal Products Manufacturing	479	479	\$183,098	\$2,597,399,886	\$178,409,508	0.01%	0.10%
324110	Petroleum Refineries	24	24	\$4,301	\$162,140,346	\$11,043,734	0.00%	0.04%
324121	Asphalt Paving Mixture and Block Manufacturing	240	240	\$16,855	\$1,396,799,347	\$96,337,675	0.00%	0.02%
324122	Asphalt Shingle and Coating Materials Manufacturing	57	57	\$3,937	\$339,283,941	\$23,400,516	0.00%	0.02%
324191	Petroleum Lubricating Oil and Grease Manufacturing	126	126	\$155,656	\$540,523,482	\$36,820,225	0.03%	0.42%
324199	All Other Petroleum and Coal Products Manufacturing	32	32	\$2,349	\$158,652,770	\$10,807,358	0.00%	0.02%
325	Chemical Manufacturing	6,289	6,289	-\$386,865	\$18,235,705,890	\$1,506,200,730	0.00%	-0.03%
325110	Petrochemical Manufacturing	8	8	\$1,382	\$60,624,988	\$2,068,657	0.00%	0.07%
325120	Industrial Gas Manufacturing	51	51	\$2,598	\$130,578,433	\$4,455,621	0.00%	0.06%
325130	Synthetic Dye and Pigment Manufacturing	52	52	\$2,964	\$193,677,160	\$6,608,687	0.00%	0.04%
325180	Other Basic Inorganic Chemical Manufacturing	151	151	-\$1,398	\$631,456,804	\$21,546,682	0.00%	-0.01%
325193	Ethyl Alcohol Manufacturing	16	16	\$661	\$408,219,776	\$13,929,348	0.00%	0.00%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	19	19	\$968	\$90,777,978	\$3,097,542	0.00%	0.03%
325199	All Other Basic Organic Chemical Manufacturing	283	283	-\$600	\$1,496,841,354	\$51,075,488	0.00%	0.00%
325211	Plastics Material and Resin Manufacturing	352	352	\$13,691	\$1,240,697,602	\$73,703,463	0.00%	0.02%
325212	Synthetic Rubber Manufacturing	59	59	\$1,226	\$346,949,549	\$20,610,488	0.00%	0.01%
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	38	38	\$560	\$129,870,134	\$7,714,917	0.00%	0.01%
325311	Nitrogenous Fertilizer Manufacturing	109	109	-\$109,727	\$445,338,390	\$43,263,948	-0.02%	-0.25%
325312	Phosphatic Fertilizer Manufacturing	10	10	-\$15,573	\$62,883,763	\$6,109,062	-0.02%	-0.25%
325314	Fertilizer (Mixing Only) Manufacturing	241	241	-\$171,785	\$707,258,894	\$68,709,127	-0.02%	-0.25%
325320	Pesticide and Other Agricultural Chemical Manufacturing	111	111	\$14,073	\$467,677,961	\$45,434,203	0.00%	0.03%
325411	Medicinal and Botanical Manufacturing	397	397	\$8,357	\$703,448,129	\$97,573,153	0.00%	0.01%
325412	Pharmaceutical Preparation Manufacturing	662	662	\$61,893	\$2,205,989,708	\$305,986,131	0.00%	0.02%
325413	In-Vitro Diagnostic Substance Manufacturing	93	93	\$6,380	\$200,568,005	\$27,820,179	0.00%	0.02%
325414	Biological Product (except Diagnostic) Manufacturing	139	139	\$3,139	\$647,737,915	\$89,845,758	0.00%	0.00%
325510	Paint and Coating Manufacturing	629	629	-\$367,469	\$1,713,427,745	\$71,476,852	-0.02%	-0.51%
325520	Adhesive Manufacturing	215	215	\$20,882	\$724,751,206	\$30,233,510	0.00%	0.07%
325611	Soap and Other Detergent Manufacturing	464	464	\$44,773	\$702,865,750	\$86,760,735	0.01%	0.05%
325612	Polish and Other Sanitation Good Manufacturing	295	295	\$15,063	\$465,492,370	\$57,459,707	0.00%	0.03%
325613	Surface Active Agent Manufacturing	59	59	\$5,700	\$178,093,078	\$21,983,553	0.00%	0.03%
325620	Toilet Preparation Manufacturing	697	697	\$35,498	\$1,810,360,235	\$223,468,257	0.00%	0.02%

Table VI-24: Screening Analysis for Very Small Entities (Fewer than 20 Employees) Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2022 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
325910	Printing Ink Manufacturing	98	98	\$3,851	\$239,413,089	\$12,141,213	0.00%	0.03%
325920	Explosives Manufacturing	18	18	\$926	\$49,933,397	\$2,532,242	0.00%	0.04%
325991	Custom Compounding of Purchased Resins	184	184	\$3,824	\$573,806,381	\$29,099,100	0.00%	0.01%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	120	120	\$3,272	\$140,704,350	\$7,135,455	0.00%	0.05%
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	719	719	\$28,004	\$1,466,261,747	\$74,357,655	0.00%	0.04%
326	Plastics and Rubber Products Manufacturing	4,794	4,794	\$10,455	\$9,062,205,224	\$221,349,868	0.00%	0.00%
326111	Plastics Bag and Pouch Manufacturing	115	115	\$250	\$372,892,930	\$9,566,934	0.00%	0.00%
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	108	108	\$235	\$270,653,850	\$6,943,890	0.00%	0.00%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	189	189	\$412	\$400,875,366	\$10,284,851	0.00%	0.00%
326121	Unlaminated Plastics Profile Shape Manufacturing	151	151	\$329	\$242,073,449	\$6,210,632	0.00%	0.01%
326122	Plastics Pipe and Pipe Fitting Manufacturing	113	113	\$248	\$346,062,366	\$8,878,569	0.00%	0.00%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	111	111	\$242	\$214,552,045	\$5,504,543	0.00%	0.00%
326140	Polystyrene Foam Product Manufacturing	149	149	\$324	\$323,600,980	\$8,302,300	0.00%	0.00%
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	221	221	\$481	\$544,328,494	\$13,965,281	0.00%	0.00%
326160	Plastics Bottle Manufacturing	67	67	\$146	\$150,592,201	\$3,863,591	0.00%	0.00%
326191	Plastics Plumbing Fixture Manufacturing	171	171	\$375	\$238,751,101	\$6,125,394	0.00%	0.01%
326199	All Other Plastics Product Manufacturing	2,682	2,682	\$5,852	\$4,678,627,783	\$120,034,783	0.00%	0.00%
326211	Tire Manufacturing (except Retreading)	43	43	\$94	\$101,104,608	\$1,712,676	0.00%	0.01%
326212	Tire Retreading	140	140	\$305	\$220,477,498	\$3,734,810	0.00%	0.01%
326220	Rubber and Plastics Hoses and Belting Manufacturing	90	90	\$196	\$222,030,797	\$3,761,122	0.00%	0.01%
326291	Rubber Product Manufacturing for Mechanical Use	153	153	\$333	\$254,295,991	\$4,307,683	0.00%	0.01%
326299	All Other Rubber Product Manufacturing	291	291	\$634	\$481,285,766	\$8,152,809	0.00%	0.01%
327	Nonmetallic Mineral Product Manufacturing	6,308	6,308	\$13,920	\$9,998,012,804	\$171,530,222	0.00%	0.01%
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	448	448	\$978	\$267,360,823	\$4,205,607	0.00%	0.02%
327120	Clay Building Material and Refractories Manufacturing	181	181	\$394	\$395,235,836	\$6,217,092	0.00%	0.01%
327211	Flat Glass Manufacturing	57	57	\$124	\$62,267,200	\$1,762,971	0.00%	0.01%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	325	325	\$710	\$207,207,815	\$5,866,673	0.00%	0.01%
327213	Glass Container Manufacturing	20	20	\$44	\$24,117,972	\$682,852	0.00%	0.01%
327215	Glass Product Manufacturing Made of Purchased Glass	653	653	\$1,424	\$654,768,471	\$18,538,454	0.00%	0.01%
327310	Cement Manufacturing	49	49	\$109	\$127,333,263	\$1,872,236	0.00%	0.01%
327320	Ready-Mix Concrete Manufacturing	1,234	1,234	\$2,798	\$3,586,065,405	\$52,727,481	0.00%	0.01%
327331	Concrete Block and Brick Manufacturing	225	225	\$512	\$486,482,538	\$7,152,965	0.00%	0.01%
327332	Concrete Pipe Manufacturing	49	49	\$107	\$87,336,057	\$1,284,140	0.00%	0.01%
327390	Other Concrete Product Manufacturing	958	958	\$2,106	\$1,369,068,605	\$20,130,012	0.00%	0.01%
327410	Lime Manufacturing	12	12	\$28	\$31,125,544	\$582,325	0.00%	0.00%

Table VI-24: Screening Analysis for Very Small Entities (Fewer than 20 Employees) Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2022 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
327420	Gypsum Product Manufacturing	91	91	\$198	\$175,091,880	\$3,275,780	0.00%	0.01%
327910	Abrasive Product Manufacturing	147	147	\$320	\$292,134,504	\$5,465,521	0.00%	0.01%
327991	Cut Stone and Stone Product Manufacturing	1,541	1,541	\$3,369	\$1,586,363,191	\$29,679,144	0.00%	0.01%
327992	Ground or Treated Mineral and Earth Manufacturing	64	64	\$139	\$132,189,310	\$2,473,119	0.00%	0.01%
327993	Mineral Wool Manufacturing	87	87	\$192	\$179,411,030	\$3,356,587	0.00%	0.01%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	167	167	\$368	\$334,453,360	\$6,257,262	0.00%	0.01%
331	Primary Metal Manufacturing	1,533	1,533	\$3,349	\$3,755,440,016	\$101,522,155	0.00%	0.00%
331110	Iron and Steel Mills and Ferroalloy Manufacturing	174	174	\$379	\$444,969,193	\$5,523,246	0.00%	0.01%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	70	70	\$152	\$105,590,702	\$2,198,042	0.00%	0.01%
331221	Rolled Steel Shape Manufacturing	77	77	\$168	\$270,241,311	\$5,625,511	0.00%	0.00%
331222	Steel Wire Drawing	87	87	\$189	\$164,181,203	\$3,417,698	0.00%	0.01%
331313	Alumina Refining and Primary Aluminum Production	19	19	\$41	\$26,820,959	\$662,211	0.00%	0.01%
331314	Secondary Smelting and Alloying of Aluminum	20	20	\$44	\$204,216,733	\$5,042,126	0.00%	0.00%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	30	30	\$65	\$45,959,515	\$1,112,738	0.00%	0.01%
331318	Other Aluminum Rolling, Drawing, and Extruding	76	76	\$166	\$150,948,962	\$3,726,941	0.00%	0.00%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	64	64	\$139	\$384,069,065	\$7,995,020	0.00%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	41	41	\$89	\$219,847,551	\$4,576,483	0.00%	0.00%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	142	142	\$311	\$341,819,219	\$7,115,521	0.00%	0.00%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	82	82	\$185	\$433,295,001	\$9,019,738	0.00%	0.00%
331511	Iron Foundries	101	101	\$220	\$193,712,363	\$9,149,375	0.00%	0.00%
331512	Steel Investment Foundries	24	24	\$52	\$35,707,136	\$1,686,511	0.00%	0.00%
331513	Steel Foundries (except Investment)	73	73	\$161	\$141,887,422	\$6,701,592	0.00%	0.00%
331523	Nonferrous Metal Die-Casting Foundries	167	167	\$364	\$243,374,270	\$11,494,994	0.00%	0.00%
331524	Aluminum Foundries (except Die-Casting)	146	146	\$318	\$185,143,921	\$8,744,672	0.00%	0.00%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	140	140	\$305	\$163,655,489	\$7,729,736	0.00%	0.00%
339	Miscellaneous Manufacturing	19,598	19,598	\$289,676	\$14,784,871,603	\$775,436,649	0.00%	0.04%
339112	Surgical and Medical Instrument Manufacturing	689	689	\$10,161	\$1,133,808,267	\$83,135,152	0.00%	0.01%
339113	Surgical Appliance and Supplies Manufacturing	1,138	1,138	\$16,945	\$1,842,494,560	\$135,098,737	0.00%	0.01%
339114	Dental Equipment and Supplies Manufacturing	447	447	\$6,592	\$343,167,920	\$25,162,382	0.00%	0.03%
339115	Ophthalmic Goods Manufacturing	240	240	\$3,539	\$250,178,784	\$18,344,064	0.00%	0.02%
339116	Dental Laboratories	4,792	4,792	\$70,730	\$1,857,933,643	\$136,230,790	0.00%	0.05%
339910	Jewelry and Silverware Manufacturing	1,795	1,795	\$26,502	\$1,309,295,696	\$52,815,940	0.00%	0.05%
339920	Sporting and Athletic Goods Manufacturing	1,278	1,278	\$18,877	\$1,101,462,640	\$44,432,121	0.00%	0.04%
339930	Doll, Toy, and Game Manufacturing	442	442	\$6,519	\$404,576,662	\$16,320,299	0.00%	0.04%
339940	Office Supplies (except Paper) Manufacturing	320	320	\$4,852	\$265,785,648	\$10,721,580	0.00%	0.05%

Table VI-24: Screening Analysis for Very Small Entities (Fewer than 20 Employees) Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (2022 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
339950	Sign Manufacturing	4,918	4,918	\$72,721	\$3,271,628,483	\$131,974,874	0.00%	0.06%
339991	Gasket, Packing, and Sealing Device Manufacturing	269	269	\$3,967	\$474,333,716	\$19,134,242	0.00%	0.02%
339992	Musical Instrument Manufacturing	495	495	\$7,300	\$281,190,846	\$11,343,014	0.00%	0.06%
339993	Fastener, Button, Needle, and Pin Manufacturing	71	71	\$1,047	\$50,089,383	\$2,020,566	0.00%	0.05%
339994	Broom, Brush, and Mop Manufacturing	90	90	\$1,357	\$120,163,350	\$4,847,293	0.00%	0.03%
339995	Burial Casket Manufacturing	59	59	\$885	\$47,059,450	\$1,898,341	0.00%	0.05%
339999	All Other Miscellaneous Manufacturing	2,555	2,555	\$37,681	\$2,031,702,555	\$81,957,255	0.00%	0.05%
42	Wholesale Trade	210,300	40,603	-\$1,939,389	\$743,595,128,838	\$17,807,705,446	0.00%	-0.01%
423	Merchant Wholesalers, Durable Goods	132,271	11,738	\$25,876	\$397,195,318,323	\$9,087,240,922	0.00%	0.00%
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	7,146	7,146	\$15,636	\$14,318,982,233	\$355,470,176	0.00%	0.00%
423840	Industrial Supplies Merchant Wholesalers	4,592	4,592	\$10,240	\$13,802,474,015	\$425,848,648	0.00%	0.00%
424	Merchant Wholesalers, Nondurable Goods	78,029	28,865	-\$1,965,265	\$346,399,810,515	\$8,720,464,524	0.00%	-0.02%
424210	Drugs and Druggists' Sundries Merchant Wholesalers	5,903	5,903	\$12,934	\$22,650,320,243	\$786,018,235	0.00%	0.00%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	1,630	1,630	\$3,656	\$9,538,190,909	\$291,312,157	0.00%	0.00%
424690	Other Chemical and Allied Products Merchant Wholesalers	4,725	4,725	\$10,514	\$22,653,633,421	\$691,879,505	0.00%	0.00%
424710	Petroleum Bulk Stations and Terminals	1,226	1,226	\$2,811	\$22,113,348,900	\$213,354,357	0.00%	0.00%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,319	1,319	\$2,907	\$30,382,540,215	\$293,137,298	0.00%	0.00%
424910	Farm Supplies Merchant Wholesalers	3,952	3,952	-\$1,640,988	\$17,787,338,503	\$482,570,874	-0.01%	-0.34%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	758	758	-\$377,569	\$1,850,425,514	\$42,983,204	-0.02%	-0.88%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	9,352	9,352	\$20,469	\$17,105,834,948	\$397,348,391	0.00%	0.01%
Total		5,395,869	83,952	-\$1,625,090	\$4,989,404,703,505	\$190,373,831,916	0.00%	0.00%

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Note: "Affected" firms are based on the maximum number affected by any one provision of the rule.

Table VI-25: Screening Analysis for SBA-Defined Small Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2022 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	14,836	4,865	\$311,295	\$173,001,050,842	\$11,142,435,423	0.00%	0.00%
211	Oil and Gas Extraction	4,865	4,865	\$311,295	\$130,869,457,380	\$8,155,223,643	0.00%	0.00%
211120	Crude Petroleum Extraction	4,204	4,204	\$205,435	\$82,148,479,398	\$5,119,141,126	0.00%	0.00%
211130	Natural Gas Extraction	661	661	\$105,860	\$48,720,977,982	\$3,036,082,517	0.00%	0.00%
31-33	Manufacturing	244,858	54,194	\$3,290,955	\$1,974,081,390,875	\$89,015,709,458	0.00%	0.00%

Table VI-25: Screening Analysis for SBA-Defined Small Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2022 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
324	Petroleum and Coal Products Manufacturing	831	831	\$1,061,024	\$63,956,507,492	\$4,365,472,912	0.00%	0.02%
324110	Petroleum Refineries	52	52	\$39,557	\$43,959,961,688	\$2,994,209,283	0.00%	0.00%
324121	Asphalt Paving Mixture and Block Manufacturing	421	421	\$41,378	\$7,052,481,538	\$486,411,791	0.00%	0.01%
324122	Asphalt Shingle and Coating Materials Manufacturing	95	95	\$16,553	\$3,653,060,342	\$251,952,680	0.00%	0.01%
324191	Petroleum Lubricating Oil and Grease Manufacturing	211	211	\$956,415	\$6,633,215,757	\$451,851,781	0.01%	0.21%
324199	All Other Petroleum and Coal Products Manufacturing	52	52	\$7,122	\$2,657,788,167	\$181,047,377	0.00%	0.00%
325	Chemical Manufacturing	9,806	9,806	\$1,642,549	\$241,435,425,905	\$19,085,810,350	0.00%	0.01%
325110	Petrochemical Manufacturing	15	15	\$8,874	\$3,659,008,422	\$124,853,338	0.00%	0.01%
325120	Industrial Gas Manufacturing	64	64	\$5,023	\$994,180,801	\$33,923,615	0.00%	0.01%
325130	Synthetic Dye and Pigment Manufacturing	90	90	\$7,288	\$3,056,687,652	\$104,300,841	0.00%	0.01%
325180	Other Basic Inorganic Chemical Manufacturing	310	310	\$19,717	\$14,719,722,613	\$502,269,000	0.00%	0.00%
325193	Ethyl Alcohol Manufacturing	103	103	\$10,600	\$19,617,730,458	\$669,399,698	0.00%	0.00%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Mfg.	32	32	\$2,601	\$809,079,434	\$27,607,553	0.00%	0.01%
325199	All Other Basic Organic Chemical Manufacturing	530	530	\$51,110	\$24,528,270,906	\$836,958,035	0.00%	0.01%
325211	Plastics Material and Resin Manufacturing	771	771	\$141,178	\$29,067,585,548	\$1,726,755,743	0.00%	0.01%
325212	Synthetic Rubber Manufacturing	112	112	\$5,392	\$5,560,652,947	\$330,329,789	0.00%	0.00%
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	90	90	\$3,325	\$3,044,666,867	\$180,867,998	0.00%	0.00%
325311	Nitrogenous Fertilizer Manufacturing	150	150	\$3,699	\$2,231,734,699	\$216,809,636	0.00%	0.00%
325312	Phosphatic Fertilizer Manufacturing	35	35	\$1,306	\$886,613,999	\$86,133,203	0.00%	0.00%
325314	Fertilizer (Mixing Only) Manufacturing	353	353	\$13,586	\$4,478,262,789	\$435,056,427	0.00%	0.00%
325320	Pesticide and Other Agricultural Chemical Manufacturing	165	165	\$37,330	\$5,124,392,930	\$497,826,988	0.00%	0.01%
325411	Medicinal and Botanical Manufacturing	567	567	\$31,731	\$7,604,961,980	\$1,054,861,174	0.00%	0.00%
325412	Pharmaceutical Preparation Manufacturing	1,045	1,045	\$161,908	\$34,115,627,906	\$4,732,075,112	0.00%	0.00%
325413	In-Vitro Diagnostic Substance Manufacturing	167	167	\$34,171	\$3,430,867,757	\$475,885,245	0.00%	0.01%
325414	Biological Product (except Diagnostic) Manufacturing	231	231	\$12,832	\$9,259,049,356	\$1,284,294,610	0.00%	0.00%
325510	Paint and Coating Manufacturing	924	924	\$467,325	\$11,087,244,588	\$462,512,260	0.00%	0.10%
325520	Adhesive Manufacturing	345	345	\$68,967	\$5,339,793,027	\$222,753,248	0.00%	0.03%
325611	Soap and Other Detergent Manufacturing	605	605	\$143,883	\$6,575,127,168	\$811,624,216	0.00%	0.02%
325612	Polish and Other Sanitation Good Manufacturing	409	409	\$86,469	\$4,181,099,162	\$516,108,851	0.00%	0.02%
325613	Surface Active Agent Manufacturing	92	92	\$31,035	\$3,065,370,876	\$378,384,960	0.00%	0.01%
325620	Toilet Preparation Manufacturing	981	981	\$187,738	\$19,202,886,031	\$2,370,376,559	0.00%	0.01%
325910	Printing Ink Manufacturing	145	145	\$21,112	\$1,607,687,931	\$81,529,716	0.00%	0.03%
325920	Explosives Manufacturing	38	38	\$10,104	\$693,174,902	\$35,152,564	0.00%	0.03%
325991	Custom Compounding of Purchased Resins	306	306	\$10,122	\$5,691,757,644	\$288,642,699	0.00%	0.00%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	151	151	\$6,639	\$831,530,162	\$42,168,891	0.00%	0.02%
325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	980	980	\$57,488	\$10,970,657,349	\$556,348,381	0.00%	0.01%

Table VI-25: Screening Analysis for SBA-Defined Small Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2022 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
326	Plastics and Rubber Products Manufacturing	8,666	8,666	\$56,864	\$113,843,163,052	\$2,778,952,596	0.00%	0.00%
326111	Plastics Bag and Pouch Manufacturing	233	233	\$1,694	\$3,812,593,720	\$97,815,830	0.00%	0.00%
326112	Plastics Packaging Film and Sheet (including Laminated) Mfg.	273	273	\$2,081	\$6,905,129,008	\$177,157,855	0.00%	0.00%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Mfg.	347	347	\$2,351	\$6,490,745,777	\$166,526,447	0.00%	0.00%
326121	Unlaminated Plastics Profile Shape Mfg.	289	289	\$1,802	\$3,006,801,686	\$77,142,445	0.00%	0.00%
326122	Plastics Pipe and Pipe Fitting Mfg.	222	222	\$1,797	\$5,090,463,190	\$130,600,824	0.00%	0.00%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Mfg.	182	182	\$981	\$1,924,078,647	\$49,364,124	0.00%	0.00%
326140	Polystyrene Foam Product Manufacturing	282	282	\$2,115	\$5,002,292,097	\$128,338,708	0.00%	0.00%
326150	Urethane and Other Foam Product (except Polystyrene) Mfg.	415	415	\$2,814	\$4,983,561,033	\$127,858,144	0.00%	0.00%
326160	Plastics Bottle Manufacturing	181	181	\$1,669	\$4,036,459,444	\$103,559,324	0.00%	0.00%
326191	Plastics Plumbing Fixture Manufacturing	290	290	\$1,680	\$3,190,882,780	\$81,865,226	0.00%	0.00%
326199	All Other Plastics Product Manufacturing	4,693	4,693	\$29,756	\$53,131,238,757	\$1,363,134,021	0.00%	0.00%
326211	Tire Manufacturing (except Retreading)	70	70	\$797	\$4,133,384,788	\$70,018,064	0.00%	0.00%
326212	Tire Retreading	224	224	\$1,093	\$1,000,658,631	\$16,950,800	0.00%	0.01%
326220	Rubber and Plastics Hoses and Belting Manufacturing	167	167	\$1,124	\$2,589,388,690	\$43,863,321	0.00%	0.00%
326291	Rubber Product Manufacturing for Mechanical Use	306	306	\$2,145	\$3,847,583,240	\$65,176,687	0.00%	0.00%
326299	All Other Rubber Product Manufacturing	492	492	\$2,964	\$4,697,901,564	\$79,580,776	0.00%	0.00%
327	Nonmetallic Mineral Product Manufacturing	8,987	8,987	\$45,621	\$62,726,868,770	\$1,096,997,964	0.00%	0.00%
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	534	534	\$1,902	\$1,337,553,762	\$21,039,829	0.00%	0.01%
327120	Clay Building Material and Refractories Manufacturing	326	326	\$2,073	\$3,630,120,546	\$57,102,091	0.00%	0.00%
327211	Flat Glass Manufacturing	91	91	\$541	\$656,715,335	\$18,593,576	0.00%	0.00%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	388	388	\$1,610	\$1,691,789,270	\$47,899,616	0.00%	0.00%
327213	Glass Container Manufacturing	29	29	\$217	\$418,420,544	\$11,846,737	0.00%	0.00%
327215	Glass Product Manufacturing Made of Purchased Glass	861	861	\$4,207	\$5,525,809,632	\$156,452,203	0.00%	0.00%
327310	Cement Manufacturing	73	73	\$462	\$1,470,724,087	\$21,624,697	0.00%	0.00%
327320	Ready-Mix Concrete Manufacturing	1,958	1,958	\$12,155	\$20,717,511,691	\$304,618,596	0.00%	0.00%
327331	Concrete Block and Brick Manufacturing	382	382	\$2,357	\$3,291,709,756	\$48,399,442	0.00%	0.00%
327332	Concrete Pipe Manufacturing	83	83	\$623	\$1,139,522,325	\$16,754,893	0.00%	0.00%
327390	Other Concrete Product Manufacturing	1,451	1,451	\$7,467	\$8,682,164,472	\$127,657,645	0.00%	0.01%
327410	Lime Manufacturing	24	24	\$216	\$865,109,167	\$16,185,259	0.00%	0.00%
327420	Gypsum Product Manufacturing	109	109	\$584	\$447,053,257	\$8,363,884	0.00%	0.01%
327910	Abrasive Product Manufacturing	233	233	\$1,189	\$2,021,424,195	\$37,818,666	0.00%	0.00%
327991	Cut Stone and Stone Product Manufacturing	1,931	1,931	\$6,929	\$4,812,522,458	\$90,037,104	0.00%	0.01%
327992	Ground or Treated Mineral and Earth Manufacturing	123	123	\$741	\$1,769,433,795	\$33,104,198	0.00%	0.00%
327993	Mineral Wool Manufacturing	152	152	\$1,027	\$2,174,407,766	\$40,680,824	0.00%	0.00%
327999	All Other Miscellaneous Nonmetallic Mineral Product Mfg.	239	239	\$1,324	\$2,074,876,712	\$38,818,705	0.00%	0.00%

Table VI-25: Screening Analysis for SBA-Defined Small Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2022 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
331	Primary Metal Manufacturing	2,932	2,932	\$20,678	\$88,586,613,067	\$2,072,195,314	0.00%	0.00%
331110	Iron and Steel Mills and Ferroalloy Manufacturing	281	281	\$2,714	\$20,890,760,432	\$259,309,680	0.00%	0.00%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	175	175	\$1,557	\$7,367,292,854	\$153,362,141	0.00%	0.00%
331221	Rolled Steel Shape Manufacturing	154	154	\$987	\$4,972,953,187	\$103,520,080	0.00%	0.00%
331222	Steel Wire Drawing	166	166	\$1,120	\$3,612,084,969	\$75,191,403	0.00%	0.00%
331313	Alumina Refining and Primary Aluminum Production	27	27	\$128	\$1,088,654,321	\$26,878,956	0.00%	0.00%
331314	Secondary Smelting and Alloying of Aluminum	52	52	\$407	\$2,885,391,854	\$71,240,540	0.00%	0.00%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	56	56	\$660	\$4,335,142,654	\$104,959,262	0.00%	0.00%
331318	Other Aluminum Rolling, Drawing, and Extruding	172	172	\$1,383	\$5,182,592,041	\$127,958,584	0.00%	0.00%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	103	103	\$606	\$5,758,979,536	\$119,882,492	0.00%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	129	129	\$1,164	\$11,476,098,480	\$238,893,589	0.00%	0.00%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	201	201	\$1,104	\$2,131,430,995	\$44,369,191	0.00%	0.00%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal	151	151	\$923	\$5,502,650,423	\$114,546,587	0.00%	0.00%
331511	Iron Foundries	231	231	\$1,867	\$3,324,719,712	\$157,032,348	0.00%	0.00%
331512	Steel Investment Foundries	88	88	\$827	\$1,888,851,815	\$89,213,787	0.00%	0.00%
331513	Steel Foundries (except Investment)	145	145	\$850	\$1,763,331,460	\$83,285,240	0.00%	0.00%
331523	Nonferrous Metal Die-Casting Foundries	309	309	\$1,810	\$3,030,786,640	\$143,149,373	0.00%	0.00%
331524	Aluminum Foundries (except Die-Casting)	267	267	\$1,452	\$1,929,923,454	\$91,153,673	0.00%	0.00%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	225	225	\$1,122	\$1,444,968,241	\$68,248,387	0.00%	0.00%
339	Miscellaneous Manufacturing	22,972	22,972	\$464,220	\$73,453,095,870	\$4,046,248,288	0.00%	0.01%
339112	Surgical and Medical Instrument Manufacturing	1,029	1,029	\$33,720	\$12,986,915,927	\$952,250,269	0.00%	0.00%
339113	Surgical Appliance and Supplies Manufacturing	1,562	1,562	\$43,062	\$11,456,275,670	\$840,017,880	0.00%	0.01%
339114	Dental Equipment and Supplies Manufacturing	522	522	\$10,923	\$2,863,485,268	\$209,961,675	0.00%	0.01%
339115	Ophthalmic Goods Manufacturing	306	306	\$8,058	\$1,429,817,777	\$104,839,699	0.00%	0.01%
339116	Dental Laboratories	5,126	5,126	\$82,695	\$4,103,332,771	\$300,872,028	0.00%	0.03%
339910	Jewelry and Silverware Manufacturing	1,972	1,972	\$34,630	\$4,133,091,237	\$166,725,592	0.00%	0.02%
339920	Sporting and Athletic Goods Manufacturing	1,549	1,549	\$34,033	\$6,931,778,350	\$279,622,389	0.00%	0.01%
339930	Doll, Toy, and Game Manufacturing	503	503	\$9,584	\$1,389,538,569	\$56,052,873	0.00%	0.02%
339940	Office Supplies (except Paper) Manufacturing	401	401	\$9,265	\$2,609,465,889	\$105,263,765	0.00%	0.01%
339950	Sign Manufacturing	5,708	5,708	\$112,006	\$12,112,744,969	\$488,618,435	0.00%	0.02%
339991	Gasket, Packing, and Sealing Device Manufacturing	434	434	\$9,612	\$2,905,995,145	\$117,225,518	0.00%	0.01%
339992	Musical Instrument Manufacturing	570	570	\$11,210	\$1,296,829,108	\$52,313,048	0.00%	0.02%
339993	Fastener, Button, Needle, and Pin Manufacturing	92	92	\$2,230	\$460,624,786	\$18,581,235	0.00%	0.01%
339994	Broom, Brush, and Mop Manufacturing	143	143	\$3,902	\$1,605,789,812	\$64,776,275	0.00%	0.01%
339995	Burial Casket Manufacturing	76	76	\$1,848	\$209,122,381	\$8,435,829	0.00%	0.02%

Table VI-25: Screening Analysis for SBA-Defined Small Entities Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2022 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
339999	All Other Miscellaneous Manufacturing	2,979	2,979	\$57,443	\$6,958,288,212	\$280,691,776	0.00%	0.02%
42	Wholesale Trade	246,092	46,958	\$156,239	\$2,295,651,888,873	\$52,515,638,142	0.00%	0.00%
423	Merchant Wholesalers, Durable Goods	154,855	13,355	\$44,805	\$1,168,050,693,858	\$25,935,567,178	0.00%	0.00%
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	7,907	7,907	\$26,619	\$40,925,023,490	\$1,015,967,829	0.00%	0.00%
423840	Industrial Supplies Merchant Wholesalers	5,448	5,448	\$18,187	\$29,980,830,090	\$925,000,542	0.00%	0.00%
424	Merchant Wholesalers, Nondurable Goods	91,237	33,603	\$111,434	\$1,127,601,195,015	\$26,580,070,964	0.00%	0.00%
424210	Drugs and Druggists' Sundries Merchant Wholesalers	6,918	6,918	\$24,953	\$88,078,481,901	\$3,056,526,007	0.00%	0.00%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	1,923	1,923	\$6,554	\$21,121,343,462	\$645,080,831	0.00%	0.00%
424690	Other Chemical and Allied Products Merchant Wholesalers	5,508	5,508	\$19,162	\$56,137,224,375	\$1,714,523,861	0.00%	0.00%
424710	Petroleum Bulk Stations and Terminals	1,929	1,929	\$8,640	\$125,662,478,049	\$1,212,418,679	0.00%	0.00%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,671	1,671	\$5,559	\$141,971,019,579	\$1,369,767,004	0.00%	0.00%
424910	Farm Supplies Merchant Wholesalers	4,722	4,722	\$16,743	\$53,997,866,896	\$1,464,963,285	0.00%	0.00%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	910	910	\$3,042	\$4,790,420,318	\$111,275,820	0.00%	0.00%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	10,022	10,022	\$26,780	\$30,363,527,905	\$705,308,978	0.00%	0.00%
Total		6,059,071	106,017	\$3,758,489	\$14,465,946,958,024	\$1,460,460,327,939	0.00%	0.01%

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Note: "Affected" firms are based on the maximum number affected by any one provision of the rule.

Table VI-26: Screening Analysis for Very Small Entities (Fewer than 20 Employees) Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate (Exclusive of Cost Savings, 2022 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	12,463	4,348	\$200,665	\$17,860,924,223	\$1,175,900,262	0.00%	0.02%
211	Oil and Gas Extraction	4,348	4,348	\$200,665	\$10,537,100,260	\$656,626,923	0.00%	0.03%
211120	Crude Petroleum Extraction	3,825	3,825	\$150,134	\$8,060,918,275	\$502,321,876	0.00%	0.03%
211130	Natural Gas Extraction	523	523	\$50,531	\$2,476,181,985	\$154,305,048	0.00%	0.03%
31-33	Manufacturing	181,194	39,001	\$877,161	\$225,506,587,223	\$9,799,576,017	0.00%	0.01%
324	Petroleum and Coal Products Manufacturing	479	479	\$183,098	\$2,597,399,886	\$178,409,508	0.01%	0.10%
324110	Petroleum Refineries	24	24	\$4,301	\$162,140,346	\$11,043,734	0.00%	0.04%
324121	Asphalt Paving Mixture and Block Manufacturing	240	240	\$16,855	\$1,396,799,347	\$96,337,675	0.00%	0.02%
324122	Asphalt Shingle and Coating Materials Manufacturing	57	57	\$3,937	\$339,283,941	\$23,400,516	0.00%	0.02%
324191	Petroleum Lubricating Oil and Grease Manufacturing	126	126	\$155,656	\$540,523,482	\$36,820,225	0.03%	0.42%

**Table VI-26: Screening Analysis for Very Small Entities (Fewer than 20 Employees) Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate
(Exclusive of Cost Savings, 2022 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
324199	All Other Petroleum and Coal Products Manufacturing	32	32	\$2,349	\$158,652,770	\$10,807,358	0.00%	0.02%
325	Chemical Manufacturing	6,289	6,289	\$376,662	\$18,235,705,890	\$1,506,200,730	0.00%	0.03%
325110	Petrochemical Manufacturing	8	8	\$1,382	\$60,624,988	\$2,068,657	0.00%	0.07%
325120	Industrial Gas Manufacturing	51	51	\$2,598	\$130,578,433	\$4,455,621	0.00%	0.06%
325130	Synthetic Dye and Pigment Manufacturing	52	52	\$2,964	\$193,677,160	\$6,608,687	0.00%	0.04%
325180	Other Basic Inorganic Chemical Manufacturing	151	151	\$4,962	\$631,456,804	\$21,546,682	0.00%	0.02%
325193	Ethyl Alcohol Manufacturing	16	16	\$661	\$408,219,776	\$13,929,348	0.00%	0.00%
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	19	19	\$968	\$90,777,978	\$3,097,542	0.00%	0.03%
325199	All Other Basic Organic Chemical Manufacturing	283	283	\$14,475	\$1,496,841,354	\$51,075,488	0.00%	0.03%
325211	Plastics Material and Resin Manufacturing	352	352	\$13,691	\$1,240,697,602	\$73,703,463	0.00%	0.02%
325212	Synthetic Rubber Manufacturing	59	59	\$1,226	\$346,949,549	\$20,610,488	0.00%	0.01%
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	38	38	\$560	\$129,870,134	\$7,714,917	0.00%	0.01%
325311	Nitrogenous Fertilizer Manufacturing	109	109	\$1,608	\$445,338,390	\$43,263,948	0.00%	0.00%
325312	Phosphatic Fertilizer Manufacturing	10	10	\$147	\$62,883,763	\$6,109,062	0.00%	0.00%
325314	Fertilizer (Mixing Only) Manufacturing	241	241	\$5,030	\$707,258,894	\$68,709,127	0.00%	0.01%
325320	Pesticide and Other Agricultural Chemical Manufacturing	111	111	\$14,073	\$467,677,961	\$45,434,203	0.00%	0.03%
325411	Medicinal and Botanical Manufacturing	397	397	\$15,441	\$703,448,129	\$97,573,153	0.00%	0.02%
325412	Pharmaceutical Preparation Manufacturing	662	662	\$63,900	\$2,205,989,708	\$305,986,131	0.00%	0.02%
325413	In-Vitro Diagnostic Substance Manufacturing	93	93	\$6,562	\$200,568,005	\$27,820,179	0.00%	0.02%
325414	Biological Product (except Diagnostic) Manufacturing	139	139	\$3,728	\$647,737,915	\$89,845,758	0.00%	0.00%
325510	Paint and Coating Manufacturing	629	629	\$60,888	\$1,713,427,745	\$71,476,852	0.00%	0.09%
325520	Adhesive Manufacturing	215	215	\$20,882	\$724,751,206	\$30,233,510	0.00%	0.07%
325611	Soap and Other Detergent Manufacturing	464	464	\$44,773	\$702,865,750	\$86,760,735	0.01%	0.05%
325612	Polish and Other Sanitation Good Manufacturing	295	295	\$15,063	\$465,492,370	\$57,459,707	0.00%	0.03%
325613	Surface Active Agent Manufacturing	59	59	\$5,700	\$178,093,078	\$21,983,553	0.00%	0.03%
325620	Toilet Preparation Manufacturing	697	697	\$35,498	\$1,810,360,235	\$223,468,257	0.00%	0.02%
325910	Printing Ink Manufacturing	98	98	\$3,851	\$239,413,089	\$12,141,213	0.00%	0.03%
325920	Explosives Manufacturing	18	18	\$926	\$49,933,397	\$2,532,242	0.00%	0.04%
325991	Custom Compounding of Purchased Resins	184	184	\$3,824	\$573,806,381	\$29,099,100	0.00%	0.01%
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing	120	120	\$3,272	\$140,704,350	\$7,135,455	0.00%	0.05%
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	719	719	\$28,004	\$1,466,261,747	\$74,357,655	0.00%	0.04%
326	Plastics and Rubber Products Manufacturing	4,794	4,794	\$10,455	\$9,062,205,224	\$221,349,868	0.00%	0.00%
326111	Plastics Bag and Pouch Manufacturing	115	115	\$250	\$372,892,930	\$9,566,934	0.00%	0.00%

**Table VI-26: Screening Analysis for Very Small Entities (Fewer than 20 Employees) Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate
(Exclusive of Cost Savings, 2022 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
326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing	108	108	\$235	\$270,653,850	\$6,943,890	0.00%	0.00%
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	189	189	\$412	\$400,875,366	\$10,284,851	0.00%	0.00%
326121	Unlaminated Plastics Profile Shape Manufacturing	151	151	\$329	\$242,073,449	\$6,210,632	0.00%	0.01%
326122	Plastics Pipe and Pipe Fitting Manufacturing	113	113	\$248	\$346,062,366	\$8,878,569	0.00%	0.00%
326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing	111	111	\$242	\$214,552,045	\$5,504,543	0.00%	0.00%
326140	Polystyrene Foam Product Manufacturing	149	149	\$324	\$323,600,980	\$8,302,300	0.00%	0.00%
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	221	221	\$481	\$544,328,494	\$13,965,281	0.00%	0.00%
326160	Plastics Bottle Manufacturing	67	67	\$146	\$150,592,201	\$3,863,591	0.00%	0.00%
326191	Plastics Plumbing Fixture Manufacturing	171	171	\$375	\$238,751,101	\$6,125,394	0.00%	0.01%
326199	All Other Plastics Product Manufacturing	2,682	2,682	\$5,852	\$4,678,627,783	\$120,034,783	0.00%	0.00%
326211	Tire Manufacturing (except Retreading)	43	43	\$94	\$101,104,608	\$1,712,676	0.00%	0.01%
326212	Tire Retreading	140	140	\$305	\$220,477,498	\$3,734,810	0.00%	0.01%
326220	Rubber and Plastics Hoses and Belting Manufacturing	90	90	\$196	\$222,030,797	\$3,761,122	0.00%	0.01%
326291	Rubber Product Manufacturing for Mechanical Use	153	153	\$333	\$254,295,991	\$4,307,683	0.00%	0.01%
326299	All Other Rubber Product Manufacturing	291	291	\$634	\$481,285,766	\$8,152,809	0.00%	0.01%
327	Nonmetallic Mineral Product Manufacturing	6,308	6,308	\$13,920	\$9,998,012,804	\$171,530,222	0.00%	0.01%
327110	Pottery, Ceramics, and Plumbing Fixture Manufacturing	448	448	\$978	\$267,360,823	\$4,205,607	0.00%	0.02%
327120	Clay Building Material and Refractories Manufacturing	181	181	\$394	\$395,235,836	\$6,217,092	0.00%	0.01%
327211	Flat Glass Manufacturing	57	57	\$124	\$62,267,200	\$1,762,971	0.00%	0.01%
327212	Other Pressed and Blown Glass and Glassware Manufacturing	325	325	\$710	\$207,207,815	\$5,866,673	0.00%	0.01%
327213	Glass Container Manufacturing	20	20	\$44	\$24,117,972	\$682,852	0.00%	0.01%
327215	Glass Product Manufacturing Made of Purchased Glass	653	653	\$1,424	\$654,768,471	\$18,538,454	0.00%	0.01%
327310	Cement Manufacturing	49	49	\$109	\$127,333,263	\$1,872,236	0.00%	0.01%
327320	Ready-Mix Concrete Manufacturing	1,234	1,234	\$2,798	\$3,586,065,405	\$52,727,481	0.00%	0.01%
327331	Concrete Block and Brick Manufacturing	225	225	\$512	\$486,482,538	\$7,152,965	0.00%	0.01%
327332	Concrete Pipe Manufacturing	49	49	\$107	\$87,336,057	\$1,284,140	0.00%	0.01%
327390	Other Concrete Product Manufacturing	958	958	\$2,106	\$1,369,068,605	\$20,130,012	0.00%	0.01%
327410	Lime Manufacturing	12	12	\$28	\$31,125,544	\$582,325	0.00%	0.00%
327420	Gypsum Product Manufacturing	91	91	\$198	\$175,091,880	\$3,275,780	0.00%	0.01%
327910	Abrasive Product Manufacturing	147	147	\$320	\$292,134,504	\$5,465,521	0.00%	0.01%
327991	Cut Stone and Stone Product Manufacturing	1,541	1,541	\$3,369	\$1,586,363,191	\$29,679,144	0.00%	0.01%

**Table VI-26: Screening Analysis for Very Small Entities (Fewer than 20 Employees) Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate
(Exclusive of Cost Savings, 2022 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
327992	Ground or Treated Mineral and Earth Manufacturing	64	64	\$139	\$132,189,310	\$2,473,119	0.00%	0.01%
327993	Mineral Wool Manufacturing	87	87	\$192	\$179,411,030	\$3,356,587	0.00%	0.01%
327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing	167	167	\$368	\$334,453,360	\$6,257,262	0.00%	0.01%
331	Primary Metal Manufacturing	1,533	1,533	\$3,349	\$3,755,440,016	\$101,522,155	0.00%	0.00%
331110	Iron and Steel Mills and Ferroalloy Manufacturing	174	174	\$379	\$444,969,193	\$5,523,246	0.00%	0.01%
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	70	70	\$152	\$105,590,702	\$2,198,042	0.00%	0.01%
331221	Rolled Steel Shape Manufacturing	77	77	\$168	\$270,241,311	\$5,625,511	0.00%	0.00%
331222	Steel Wire Drawing	87	87	\$189	\$164,181,203	\$3,417,698	0.00%	0.01%
331313	Alumina Refining and Primary Aluminum Production	19	19	\$41	\$26,820,959	\$662,211	0.00%	0.01%
331314	Secondary Smelting and Alloying of Aluminum	20	20	\$44	\$204,216,733	\$5,042,126	0.00%	0.00%
331315	Aluminum Sheet, Plate, and Foil Manufacturing	30	30	\$65	\$45,959,515	\$1,112,738	0.00%	0.01%
331318	Other Aluminum Rolling, Drawing, and Extruding	76	76	\$166	\$150,948,962	\$3,726,941	0.00%	0.00%
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	64	64	\$139	\$384,069,065	\$7,995,020	0.00%	0.00%
331420	Copper Rolling, Drawing, Extruding, and Alloying	41	41	\$89	\$219,847,551	\$4,576,483	0.00%	0.00%
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	142	142	\$311	\$341,819,219	\$7,115,521	0.00%	0.00%
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	82	82	\$185	\$433,295,001	\$9,019,738	0.00%	0.00%
331511	Iron Foundries	101	101	\$220	\$193,712,363	\$9,149,375	0.00%	0.00%
331512	Steel Investment Foundries	24	24	\$52	\$35,707,136	\$1,686,511	0.00%	0.00%
331513	Steel Foundries (except Investment)	73	73	\$161	\$141,887,422	\$6,701,592	0.00%	0.00%
331523	Nonferrous Metal Die-Casting Foundries	167	167	\$364	\$243,374,270	\$11,494,994	0.00%	0.00%
331524	Aluminum Foundries (except Die-Casting)	146	146	\$318	\$185,143,921	\$8,744,672	0.00%	0.00%
331529	Other Nonferrous Metal Foundries (except Die-Casting)	140	140	\$305	\$163,655,489	\$7,729,736	0.00%	0.00%
339	Miscellaneous Manufacturing	19,598	19,598	\$289,676	\$14,784,871,603	\$775,436,649	0.00%	0.04%
339112	Surgical and Medical Instrument Manufacturing	689	689	\$10,161	\$1,133,808,267	\$83,135,152	0.00%	0.01%
339113	Surgical Appliance and Supplies Manufacturing	1,138	1,138	\$16,945	\$1,842,494,560	\$135,098,737	0.00%	0.01%
339114	Dental Equipment and Supplies Manufacturing	447	447	\$6,592	\$343,167,920	\$25,162,382	0.00%	0.03%
339115	Ophthalmic Goods Manufacturing	240	240	\$3,539	\$250,178,784	\$18,344,064	0.00%	0.02%
339116	Dental Laboratories	4,792	4,792	\$70,730	\$1,857,933,643	\$136,230,790	0.00%	0.05%
339910	Jewelry and Silverware Manufacturing	1,795	1,795	\$26,502	\$1,309,295,696	\$52,815,940	0.00%	0.05%
339920	Sporting and Athletic Goods Manufacturing	1,278	1,278	\$18,877	\$1,101,462,640	\$44,432,121	0.00%	0.04%
339930	Doll, Toy, and Game Manufacturing	442	442	\$6,519	\$404,576,662	\$16,320,299	0.00%	0.04%
339940	Office Supplies (except Paper) Manufacturing	320	320	\$4,852	\$265,785,648	\$10,721,580	0.00%	0.05%
339950	Sign Manufacturing	4,918	4,918	\$72,721	\$3,271,628,483	\$131,974,874	0.00%	0.06%

**Table VI-26: Screening Analysis for Very Small Entities (Fewer than 20 Employees) Affected by the Revisions to the HCS With Costs Calculated Using a 7 Percent Discount Rate
(Exclusive of Cost Savings, 2022 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
339991	Gasket, Packing, and Sealing Device Manufacturing	269	269	\$3,967	\$474,333,716	\$19,134,242	0.00%	0.02%
339992	Musical Instrument Manufacturing	495	495	\$7,300	\$281,190,846	\$11,343,014	0.00%	0.06%
339993	Fastener, Button, Needle, and Pin Manufacturing	71	71	\$1,047	\$50,089,383	\$2,020,566	0.00%	0.05%
339994	Broom, Brush, and Mop Manufacturing	90	90	\$1,357	\$120,163,350	\$4,847,293	0.00%	0.03%
339995	Burial Casket Manufacturing	59	59	\$885	\$47,059,450	\$1,898,341	0.00%	0.05%
339999	All Other Miscellaneous Manufacturing	2,555	2,555	\$37,681	\$2,031,702,555	\$81,957,255	0.00%	0.05%
42	Wholesale Trade	210,300	40,603	\$89,724	\$743,595,128,838	\$17,807,705,446	0.00%	0.00%
423	Merchant Wholesalers, Durable Goods	132,271	11,738	\$25,876	\$397,195,318,323	\$9,087,240,922	0.00%	0.00%
423450	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers	7,146	7,146	\$15,636	\$14,318,982,233	\$355,470,176	0.00%	0.00%
423840	Industrial Supplies Merchant Wholesalers	4,592	4,592	\$10,240	\$13,802,474,015	\$425,848,648	0.00%	0.00%
424	Merchant Wholesalers, Nondurable Goods	78,029	28,865	\$63,848	\$346,399,810,515	\$8,720,464,524	0.00%	0.00%
424210	Drugs and Druggists' Sundries Merchant Wholesalers	5,903	5,903	\$12,934	\$22,650,320,243	\$786,018,235	0.00%	0.00%
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	1,630	1,630	\$3,656	\$9,538,190,909	\$291,312,157	0.00%	0.00%
424690	Other Chemical and Allied Products Merchant Wholesalers	4,725	4,725	\$10,514	\$22,653,633,421	\$691,879,505	0.00%	0.00%
424710	Petroleum Bulk Stations and Terminals	1,226	1,226	\$2,811	\$22,113,348,900	\$213,354,357	0.00%	0.00%
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	1,319	1,319	\$2,907	\$30,382,540,215	\$293,137,298	0.00%	0.00%
424910	Farm Supplies Merchant Wholesalers	3,952	3,952	\$8,787	\$17,787,338,503	\$482,570,874	0.00%	0.00%
424950	Paint, Varnish, and Supplies Merchant Wholesalers	758	758	\$1,768	\$1,850,425,514	\$42,983,204	0.00%	0.00%
424990	Other Miscellaneous Nondurable Goods Merchant Wholesalers	9,352	9,352	\$20,469	\$17,105,834,948	\$397,348,391	0.00%	0.01%
Total		5,395,869	83,952	\$1,167,549	\$4,989,404,703,505	\$190,373,831,916	0.00%	0.03%

Source: U.S. DOL, OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis-Health (Document ID 0481).

Note: "Affected" firms are based on the maximum number affected by any one provision of the rule.

(B) Statement of the need for, and objectives of, the rule.

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 about 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. For further discussion on the need for this revision to the HCS, see Section IV., Need and Support for the Revised Hazard Communication Standard, earlier in this preamble.

(C) The response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments.

No comments were filed by the Chief Counsel for Advocacy of the SBA in response to the proposed rule.

(D) A statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments.

Significant issues raised by public comments in relation to the PEA were addressed earlier in this FEA, within discussion of the preliminary cost analysis and revisions (if any) to the preliminary cost analysis in response to public comments.

(E) A description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available.

As shown above in Table VI-2, OSHA estimates that 114,585 establishments within 106,017 private (business) firms/enterprises defined as small by the SBA will be affected by the final rule.

As shown above in Table VI-3, OSHA estimates that 84,754 very small establishments (fewer than 20 employees) within 83,952 private (business) firms/enterprises identified as very small will be affected by the final rule.

(F) A description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record.

This final standard revises the HCS by, among other things, updating the criteria for classification of certain chemical and physical hazards, simplifying the requirements for providing updated labels and labels for small containers, strengthening the awareness of hazard information related to the contents of SDSs, and modernizing definitions. The preamble to the final standard provides a comprehensive description of, and further detail regarding, the compliance requirements of the rulemaking.

Small business enterprises in Mining, Quarrying, and Oil and Gas Extraction, Manufacturing, and Wholesale Trade who import, produce, distribute, or otherwise come into contact with hazardous chemicals will be subject to the requirements of the final standard. For details on the affected NAICS industries and the number of affected small

business enterprises (firms), see Section VI.C., Profile of Affected Industries, Establishments, and Employees in this FEA.

All affected establishments must have a written hazard communication program explaining how the establishment meets the criteria of the standard with respect to labeling, SDSs, and worker information and training as discussed under paragraph (e) of the standard.

Chemical manufacturers and importers must evaluate chemicals produced in their workplaces or imported by them to classify the chemicals in accordance with the standard. For each chemical, the chemical manufacturer or importer must 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. A description of the types of entities subject to the new and revised requirements, and the types of professional skills necessary for compliance with the requirements, is presented in the relevant sections of this economic analysis; the corresponding unit time burdens are summarized below. These costs would apply only to those businesses not already in compliance with the revisions.

Costs associated with chemical reclassifications and related revisions to safety data sheets and labels; Health and Safety Specialist, fully loaded hourly wage of \$61.18:

- Medium establishments (100-499 employees): an average of 1.5 hours per SDS,
- Small establishments (1-99 employees): an average of 2.1 hours per SDS.

Costs associated with revisions to appendix language on precautionary statements and other mandatory language; Health and Safety Specialist:

- Medium establishments (100-499 employees): an average of 0.5 hours per SDS,
- Small establishments (1-99 employees): an average of 0.7 hours per SDS.

Costs associated with management familiarization with the revisions to the HCS;

Health and Safety Specialist:

- Medium directly affected establishments (20-499 employees): an average of 4.0 hours per establishment,
- Medium indirectly affected establishments (20-499 employees): an average of 1.0 hours per establishment,
- Small directly affected establishments (1-19 employees): an average of 1.0 hours per establishment,
- Small indirectly affected establishments (1-19 employees): an average of 0.25 hours per establishment.

Training costs associated with the revisions to the HCS; Mining, Quarrying, and Oil and Gas Extraction, and Manufacturing Sectors, per affected firm:

- 2.5 hours, Health and Safety Specialist, fully loaded hourly wage of \$61.18;
- 0.2 hours, Logistics Personnel, fully loaded hourly wage of \$60.37;
- 0.2 hours, Production Worker, fully loaded hourly wage of \$31.09.

Cost savings associated with the released-for-shipment provision, small firms in fertilizer and paint manufacturing, and small wholesalers of related farm and paint supplies:

- Percentage loss avoided ranging from 0.009 percent to 0.025 percent, applied to average product value.

Cost savings associated with abbreviated labels on very small containers, small firms in six manufacturing industries within NAICS 325 – Chemical Manufacturing:

- Cost savings of \$0.058 per label for very small containers multiplied by the number of affected labels.

(G) A description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of the applicable statutes,

including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

As was the case with the 2012 HCS, OSHA in this final rule has published an implementation schedule (paragraph (j) Dates) that minimizes the impacts on small employers. The final rule requires that chemical manufacturers, importers, and distributors, and employers evaluating substances be in compliance with all modified provisions of the HCS no later than eighteen months after the effective date of the final rule (paragraph (j)(2)(i)) and that chemical manufacturers, importers, and distributors, and employers evaluating mixtures must be in compliance with all modified provisions of the HCS no later than thirty-six months after the effective date of the final rule (paragraph (j)(3)(i)). Finally the final rule requires that all employers, as necessary, update any alternative workplace labeling used under paragraph (f)(6) of this section, update the hazard communication program required by paragraph (h)(1), and provide any additional employee training in accordance with paragraph (h)(3) for newly identified physical hazard, or health hazards or other hazards covered under this section no later than twenty-four months after the effective date of the final rule for substances and forty-two months after the effective date for mixtures (paragraphs (j)(2)(ii) and (j)(3)(ii)).

Taking into consideration all of the information received from the public during the comment periods and in hearing testimony, as well as the results of the economic analysis that examine the effects of different compliance dates on the overall costs of compliance, OSHA believes the implementation schedule published in this final rule sets a proper balance between employee safety and the economic interests of small business enterprises.

VII. OMB Review Under the Paperwork Reduction Act of 1995

A. Overview

OSHA is publishing a final rule to revise the HCS, 29 CFR 1910.1200, which contains collections of information that are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 et seq., and OMB regulations at 5 CFR part 1320. This rule is revising and updating 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).

On February 16, 2021, OSHA published an NPRM (86 FR 9576) to modify the HCS to align with Rev. 7 (Document ID 0060), to address issues that arose during the implementation of the 2012 update to HCS, and to better align with other U.S. agencies and international trading partners, while improving the effectiveness of the standard. The NPRM proposed to revise the OMB-approved information collection requirements contained in the HCS. Specifically, OSHA proposed to (1) clarify that under paragraph (d)(1) the chemical manufacturer or importer must 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 allows chemical manufacturers, importers, and distributors to provide updated labels with each shipment instead of relabeling; and (5) add new provisions allowing more limited labeling for small containers in paragraph (f)(12). On February 16, 2021, the agency prepared and submitted to OMB an Information Collection Request (ICR) for the 2021 proposed rule for review in accordance with 44 U.S.C. 3507(d).

B. Solicitation of Comments

In accordance with the PRA (44 U.S.C. 3506(c)(2)), OSHA solicited public comments on the collection of information contained in the NPRM. OSHA encouraged commenters to submit their comments on the information collection requirements contained in the proposed rule under docket number OSHA-2019-0001, along with their comments on other parts of the proposed rule. In addition to generally soliciting comments on the collection of information requirements, the proposed rule indicated that OSHA and OMB were particularly interested in comments that addressed the following:

- Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information is useful;
- The accuracy of the OSHA's estimate of the burden (time and cost) of the proposed collection of information, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information to be collected; and
- Ways to minimize the compliance burden on regulated entities, including through the use of appropriate automated or other technological techniques for collecting and transmitting information.

On August 4, 2021, OMB issued a Notice of Action (NOA) stating, "Terms of the previous clearance remain in effect. Prior to publication of the final rule, the agency

should provide to OMB a summary of all comments received on the proposed information collection and identify any changes made in response to these comments” (see https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202102-1218-002).

The agency received numerous public comments in response to the NPRM during the initial comment period. In addition, OSHA held public hearings on the proposal from September 21-23, 2021, where the agency heard testimony from stakeholders (see Document ID 0423; 0424; 0425). Participants who filed notices of intention to appear at the hearing were permitted to submit additional evidence and data relevant to the proceedings for a period of 60 days following the hearing. The record remained open for the submission of final briefs, arguments, and summations until December 22, 2021. OSHA received additional post-hearing comments.

OSHA received one comment from Ameren specifically on the proposed ICR, which stated that they agree with the collection of information requirements listed in Table 1 – Collection of Information Requirements Being Revised in the Hazard Communication Standard in the NPRM, although they noted that “[t]his does not necessarily indicate that Ameren agrees with these as a change to the HCS” (Document ID 0309, p. 3).

The comments submitted in response to the rest of the proposed rule and the hearing proceedings resulted in modifications to the provisions containing collections of information. OSHA considered these responses and resulting modifications when preparing the revised ICR for the final rule. Summaries of comments received on the NPRM and OSHA’s responses are found in Sections VI., Final Economic Analysis and Regulatory Flexibility Analysis, and Section XIV., Summary and Explanation of the Final Rule, in this preamble.

OSHA submitted the final ICR concurrent with the publication of this final rule, containing the full analysis and description of the burden hours and costs associated with

the final rule, to OMB for approval. A copy of this ICR will be available to the public at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202002-1218-002 (this link will become active on the day following publication of this notice). At the conclusion of OMB's review, OSHA will publish a separate notice in the Federal Register to announce the results.

C. Summary of 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 (29 CFR 1910.1200).
- 2. Description of the ICR:* The final rule revises the currently approved Hazard Communication ICR and changes the existing collection of information requirements currently approved by OMB.
- 3. Brief Summary of the Information Collection Requirements:*

This final rule revises and clarifies the collection of information contained in the existing ICR. Specifically, OSHA is (1) modifying the language in paragraph (d)(1) to clarify what hazards are required to be classified; (2) adding language to paragraph (f)(1) providing that hazards identified and classified under subparagraph (d)(1)(ii) do not have to be addressed on labels of shipped containers; (3) revising paragraph (f)(5) by adding two new provisions related to bulk shipments of chemicals; (4) revising paragraph (f)(11) to include a provision that adds flexibility related to updating labels for products already released for shipment; (5) adding paragraph (f)(12) to provide new labeling requirements for small containers; (6) clarifying the language in paragraph (g)(2); and (10); and (7) adding language in paragraph (i) to include requirements for how concentrations and concentration ranges can be claimed as trade secrets on SDSs. See Table VII.1.

Table VII.1 – Collection of Information Requirements Being Revised in the Hazard Communication Standard

Section number and title	Currently approved collection of information requirements	Final Rule collection of information requirements
§1910.1200(d)(1) – Hazard classification.	§1910.1200(d)(1) requires chemical manufacturers and importers to evaluate and classify the chemicals produced in their workplaces or imported by them to classify the chemicals as prescribed in this section. Chemical manufacturers or importers are required to determine the applicable hazard classes, and category of each class that apply for each chemical being classified. Employers are only required to classify chemicals when they choose not to rely on the classification from the chemical manufacturer or importer for the chemical.	§1910.1200(d)(1) requires chemical manufacturers and importers to evaluate and classify chemicals produced in their workplaces or imported by them to classify the chemicals prescribed in this section. Chemical manufacturers or importers are required to determine the applicable hazard classes, and category of each class that apply for each chemical being classified. <i>OSHA is requiring that the hazard classification include any hazards associated with the chemical's intrinsic properties including: a change in the chemical's physical form and chemical reactions products from known or reasonably anticipated uses or applications.</i> Employers are only required to classify chemicals when they choose not to rely on the classification from the chemical manufacturer or importer to comply with <i>paragraph (d)(1)</i> .
§1910.1200(f)(1) – Labels on shipped containers.	§1910.1200(f)(1) requires chemical manufacturers, importers, or distributors to ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked. Hazards not otherwise classified (HNOC) do not require labeling. Labels, tags or container marks must have the appropriate label elements, which include: 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) requires chemical manufacturers, importers, or distributors to ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked. Hazards not otherwise classified (HNOC) <i>and hazards identified and classified under (d)(1)(ii)</i> do not require labeling. Labels, tags or container marks must have the appropriate label elements, which include: Product identifier; Signal word; Hazard statement(s); Pictogram(s); Precautionary statement(s); and, Name, U.S. address, and U.S. telephone number of the chemical manufacturer, importer, or other responsible party.
§1910.1200 (f)(5) – Transportation.	§1910.1200(f)(5) requires chemical manufacturers, importers, or distributors to label, tag or mark each container of hazardous chemicals	§1910.1200(f)(5) requires chemical manufacturers, importers, or distributors to label, tag, or mark each container of hazardous chemicals leaving the

	leaving the workplace as required by this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 5101 et seq.) and regulations issued under that Act by the Department of Transportation.	workplace as required by this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 5101 et seq.) and regulations issued under that Act by the Department of Transportation. <i>Bulk shipment labels for hazardous chemicals must be either on the immediate container, transmitted with the shipping papers or the bills of lading or, transmitted by-technological or electronic means (if agreed to by receiving entity) so that workers on the receiving end have immediate access in printed form,.</i> <i>Label pictograms that are specified under Appendix C.4 are not required when a pictogram is required by the Department of Transportation under Title 49 of the Code of Federal Regulations to be on a shipped container,.</i>
§1910.1200(f)(11) – Release for Shipment	§1910.1200(f)(11) – requires chemical manufacturers, importers, distributors, or employers to revise the labels for chemicals within six months of becoming aware of new hazard information for a chemical. This applies to labels on containers in the warehouse, recently shipped, Chemical that are not currently produced or imported, require updated labels prior to the chemical being shipped or introduced into the workplace again.	§1910.1200(f)(11) requires chemical manufacturers, importers, distributors, or employers to revise the labels for chemicals within six months of becoming aware of new hazard information for the chemical. <i>For chemicals released for shipment but still in a holding facility prior to future distribution, chemical manufacturers, importers, distributors, or employers can opt not to relabel those containers; but in that case they must either provide the updated label for each individual container with each shipment or, upon agreement of the receiving entity, transmit the labels by electronic or other technological means.</i> Chemicals that are not currently produced or imported, require updated labels prior to the chemical being shipped or introduced into the workplace again.
§1910.1200 (f)(12) – Small container labeling.	[none]	§1910.1200(f)(12) – <i>Small container labeling applies to situations where: chemical manufacturers, importers, or distributors demonstrating the use pull-</i>

		<i>out labels, fold-back labels, or tags containing the full label information required by (f)(1) of this section is not feasible.</i> <i>The following information is required for containers less than or equal to 100 ml capacity, : 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.</i> <i>The following information is required for containers less than or equal to 3 ml capacity, for chemical manufacturers, importers, or distributors demonstrating that any label interferes with the normal use of the container: the product identifier on the container (minimum information requirement with no label).</i> <i>(iv) The following information must be on the immediate outer package for all small containers covered by paragraph (f)(12)(ii) or (iii) of this section:: 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; A statement that the small container(s) inside must be stored in the immediate outer package bearing the complete label when not in use.</i>
§1910.1200(g)(2)	§1910.1200(g)(2) requires that chemical manufacturers or importers prepare the safety data sheet in English (but additional languages for SDSs are also allowed) The SDS must include at least section numbers and headings, and associated information under each heading, in the order listed under Appendix D.	§1910.1200(g)(2) requires that chemical manufacturers or importers ensure that <i>the safety data sheet</i> is in English (additional languages are also allowed). The SDS must include at least the section numbers and headings, and the information associated under each heading, in the order listed under Appendix D.
§1910.1200(g)(10)	§1910.1200(g)(10) - Safety data sheets may be kept in any form, including	§1910.1200(g)(10) - Safety data sheets may be kept in any form, including <i>as</i>

	operating procedures, and may be designed 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).	operating procedures, and may be <i>stored in such a way</i> 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).
§1910.1200(i)(1)	§1910.1200(i)(1) allows chemical manufacturers, importers, or employers to withhold the specific chemical identity, (e.g. the chemical name, other specific identification of a hazardous chemical), or the exact percentage (concentration) of the substance in a mixture, from the safety data sheet, if: a trade secret claim for withheld information can be supported; hazardous information, properties and effects of the chemical are disclosed on the safety data sheet; the safety data sheet indicates that the specific chemical identity and/or percentage of composition is being withheld as a trade secret; and, the specific chemical identity and percentage is made available to health professionals, employees, and designated representatives.	§1910.1200(i)(1) allows chemical manufacturers, importers, or employers to withhold specific chemical identity, (e.g. the chemical name, other specific identification of a hazardous chemical), or the exact percentage (concentration) <i>and/or concentration range</i> of the substance in a mixture, from <i>section 3</i> of the safety data sheet, if: trade secret claim for withheld information is supported; hazardous information, properties and effects of the chemical are disclosed on the safety data sheet; the safety data sheet indicates that the specific chemical identity and/or <i>concentration or concentration range</i> of composition is being withheld as a trade secret; <i>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. The full concentration ranges from 0.1% to 100% with subranges as narrow as 0.9% to as broad as 30%; the narrowest prescribed concentration range possible must used. . Two ranges can be combined if they do not fit into one range, and the range falls between the prescribed ranges in (A) – (G). Manufacturers may provide a range narrower than those prescribed in (i)(1)(v).</i> The specific chemical identity and <i>exact concentration or concentration range</i> is made available to health professionals, employees, and designated representatives.
§1910.1200(i)(2)	§1910.1200(i)(2) requires that when a treating physician or nurse has determined that a medical emergency exists the chemical manufacturer, importer, or employer must immediately disclose the specific	(i)(2) requires that when a treating <i>PLHCP</i> determines that a medical emergency exists the chemical manufacturer, importer, or employer must immediately disclose the specific necessary information such as chemical

	necessary information such as chemical identity or percentage composition of a trade secret chemical to the treating physician or nurse, regardless of trade secret claim. Chemical manufacturers, importers, or employers may require a written statement of need and confidentiality agreement, , as soon as circumstances permit.	identity or percentage composition of a trade secret chemical to that treating <i>PLHCP</i>, regardless of trade secret claims. Chemical manufacturers, importers, or employers may require a written statement of need and confidentiality agreement, , as soon as circumstances permit.
§1910.1200(i)(3)	§1910.1200(i)(3) sets out the requirements that chemical manufacturers, importers, or employers need to follow for non-emergency situations. This includes disclosure, upon request, of specific withheld information regarding the chemical identity or percentage composition, , to a health professional (i.e., physician, industrial hygienist, toxicologist, epidemiologist, or occupational health nurse) providing medical or other occupational health services to exposed employee(s), and to employees or designated representatives, if:	§1910.1200(i)(3) sets out the requirements that chemical manufacturers, importers, or employers need to follow in non-emergency situations. This includes disclosure, upon request of, a specific withheld information regarding the chemical identity or <i>exact concentration or concentration range</i>, to a health professional (<i>e.g. PLHCP</i>, industrial hygienist, toxicologist, or epidemiologist) providing medical or other occupational health services to exposed employee(s), and to employees or designated representatives, if:

1. *OMB Control Number*: 1218-0072
2. *Affected Public*: Business or other for-profit.
3. *Number of Respondents*: 5,580,906.
4. *Frequency of Responses*: Varies.
5. *Number of Responses*: 98,762,005.
6. *Average Time per Response*: Varies.
7. *Estimated Annual Total Burden Hours*: 7,206,569.
8. *Estimated Annual Total Cost (Operation and maintenance)*: \$ 69,207,596.

VIII. Federalism

OSHA reviewed this final rule according to the Executive Order on Federalism (E.O. 13132, 64 FR 43255, Aug. 10, 1999), which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States before taking actions that would restrict State policy options, and take such actions only when clear constitutional and statutory authority exists and the problem is of national scope. E.O. 13132 permits preemption of State law only as provided by Congress or where State law conflicts with Federal law. Federal agencies must limit preemption of State law to the minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated.

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 States that obtain Federal approval for such OSHA-approved occupational safety and health plans as “State Plans.” Occupational safety and health standards developed by State Plans 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 Plans are free to develop and enforce under State law their own occupational 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, this final rule limits State policy options in the same manner as every standard promulgated by OSHA. In States with OSHA-approved State Plans, this final rule does not significantly limit State policy options to adopt equally effective or 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 this final rule.

IX. State Plans

When Federal OSHA promulgates a new standard or more stringent amendment to an existing standard, OSHA-approved State Plans must either amend their standards to reflect the new standard or amendment or show OSHA 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). State Plans must adopt the Federal standard or complete their own standard within six months of the promulgation date of the final Federal rule.

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 seven states and territories have OSHA-approved occupational safety and health plans that cover State and local

government employees only: Connecticut, Illinois, Maine, Massachusetts, New Jersey, New York, and the Virgin Islands.

This final rule updates the HCS to conform with updates to the GHS, improve alignment with other U.S. agencies and international trading partners, and address certain implementation concerns. This rule will increase worker protection by improving the quality and consistency of information provided to employers and employees regarding chemical hazards and protective measures.

OSHA received one comment relevant to the relationship between State Plans and Federal OSHA from the California Department of Public Health/Hazard Evaluation System and Information Service (Cal/HESIS). Cal/HESIS proposed that State Plans such as California be allowed to require manufacturers that sell chemicals in their states or territories to classify chemicals as carcinogens or reproductive or developmental toxicants when the chemical is listed as such by a state or territory body (such as California's Prop 65 list) and disclose this information on SDSs (Document ID 0313, p. 8). OSHA disagrees with this suggestion. As the agency discussed regarding State Plan amendments to their hazard communication standards in the 2012 HCS "OSHA intends to closely scrutinize amendments to previously approved State hazard communication standards submitted under current or future State plans to ensure equal or greater effectiveness, including assurance that any additional requirements do not conflict with, or adversely affect, the effectiveness of the national application of OSHA's standard. OSHA must also determine in its review whether any State plan standard provisions that differ from the Federal provisions, when applicable to products distributed or used in interstate commerce, are "required by compelling local conditions and do not unduly burden interstate commerce." OSH Act section 18(c), 29 U.S.C. 667(c)." (77 FR 17687).

The key benefit in aligning the HCS with the GHS in 2012 was to provide a uniform and consistent method for classification and dissemination of the information on

the label and the SDS (77 FR 17605). Allowing states to develop their own classification criteria, which could lead to vastly different and potentially contradictory information on the labels, would diminish and eliminate significant portions of those benefits. In 2012 stakeholders agreed that a dual system would undermine the benefits of aligning with the GHS (77 FR 17583). OSHA also finds that if State Plans were allowed to require different elements on labels and SDSs from state to state that this could disrupt and unduly burden interstate commerce as it could mean that manufacturers would need to develop different labels and SDSs depending upon the state. Therefore, State Plans must adopt comparable provisions within six months of publication of the final rule.

X. Unfunded Mandates Reform Act

OSHA reviewed this final rule according to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 et seq., and E.O. 13132 (64 FR 43255, Aug. 10, 1999). As discussed above in Section VI., Final Economic Analysis and Regulatory Flexibility Analysis, OSHA has concluded that this final rule 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 above in Section IX., State Plans, 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).

For the reasons discussed above in Section VI., Final Economic Analysis and Regulatory Flexibility Analysis, the 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.

Therefore, for the purposes of the UMRA, OSHA certifies that this final rule 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.

XI. Protecting Children from Environmental Health and Safety Risks

E.O. 13045 (62 FR 19885, Apr. 23, 1997), 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 (now amended by E.O. 14094) (i.e., a rulemaking that has an annual effect on the economy of \$200 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).

OIRA has determined that this final rule is not significant under Section 3(f)(1) of E.O. 12866, as amended (see Section VI., Final Economic Analysis and Regulatory Flexibility Analysis) and that the environmental health and safety risks addressed through this final rule do not present a disproportionate risk to children as set forth in E.O. 13045.

XII. Environmental Impacts

OSHA has reviewed this final rule 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 DOL's NEPA procedures (29 CFR part 11). In the NPRM, OSHA preliminarily determined that the proposed regulatory changes would have no impact on air, water, or soil quality; plant or animal life; or the use of land or aspects of the external environment and thus would have no significant environmental impacts (86 FR 9687). No commenter challenged this determination. Based on its review of the final rule, OSHA has determined that the regulatory changes will have no impact on air, water, or soil quality; plant or animal life; the use of land; or aspects of the external environment and the final rule will therefore have no significant environmental impact.

XIII. Consultation and Coordination with Indian Tribal Governments

OSHA reviewed this final rule in accordance with E.O. 13175 (65 FR 67249, Nov. 6, 2000) and determined that it does not have tribal implications as defined in that order. The final rule will 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 (see E.O. 13175 § 1(a)).

XIV. Summary and Explanation of the Final Rule

This section of the preamble explains OSHA's changes to the HCS (29 CFR 1910.1200). OSHA proposed to align this update of the HCS with the GHS Rev. 7 (Document ID 0060), where appropriate. The agency had preliminarily decided to base most of the GHS alignment on Rev. 7 for several reasons, even though Rev. 8 was issued in July 2019 (Document ID 0065). First, OSHA had preliminarily determined that there were sufficient significant updates to the GHS to warrant the initiation of the rulemaking process and OSHA began its work to update the standard prior to the release of Rev. 8.

Second, the U.S.'s major trading partners (including Canada, Europe, and Australia) have or are preparing to align with Rev. 7 (Document ID 0172; Document ID 0168; Document ID 0176). While the proposal was largely based on Rev. 7, OSHA asked for comment on adopting some of the most consequential changes from Rev. 8 in the Issues and Options section (86 FR 9691-9694).

In addition, OSHA proposed several changes that were unrelated to alignment with the GHS but were intended to address specific issues that have arisen since the 2012 rulemaking to revise the HCS and to provide better alignment with international trading partners, without lowering the protections provided by the standard.

OSHA received numerous comments on which GHS revision to align with in this rulemaking and received overwhelming support from commenters for its proposal to update to Rev. 7⁵⁴ (See, e.g., Document ID 0293, p. 1; 0327, pp. 1-2; 0359, p. 7; 0339, p. 1; 0323, p. 1; 0281, Att. 2, p. 2; 0358, p. 2). The most prevalent reasons given for supporting the update to Rev. 7 were better alignment with international trading partners, especially Health Canada's HPR, and improvements in hazard communications such as updating and adding additional hazard classes with the updates to the GHS. Specifically, Givaudan and the Household & Commercial Products Association (HCPA) supported alignment with Rev. 7 in order to increase consistency between OSHA's HCS and Health Canada's HPR (Document ID 0293, p. 1; 0327, pp. 1-2). Similarly, Dow Chemical (Dow) supported alignment with Rev. 7 on the basis that OSHA's proposed update would improve alignment with major trading partners (Document ID 0359, p. 7). Hach and the Dangerous Goods Advisory Council (DGAC) also supported the update to Rev. 7 to better align with trading partners (Document ID 0323, p. 1; 0339, p. 1).

⁵⁴ Comments regarding specific adoption of particular provisions are discussed in the appropriate sections of the Summary and Explanation.

Only two commenters objected to OSHA's proposal to align with Rev. 7. Toby Threet stated that OSHA should not adopt Rev. 7 because the agency should strive to align as closely as possible with other countries in order to meet the goal of GHS harmonization and argued that OSHA has not shown that the majority of other countries have aligned with Rev. 7, both because (1) at the time OSHA issued the NPRM several countries were preparing to align with Rev. 7 but had not yet (Canada, Europe, Australia, and New Zealand) and (2) OSHA failed to consider whether this would align with other, potentially more major, trading partners (such as China, Russia, Brazil, and India) (Document ID 0279, pp. 1-2).

OSHA disagrees with this comment. As indicated in the NPRM, Canada, Europe, Australia, and New Zealand all announced their intention to update their regulations to Rev. 7 (86 FR 9694). The U.S.'s closest trading partner, Canada, updated the HPR to align with Rev. 7 on January 4, 2023 (see <https://www.canada.ca/en/health-canada/services/environmental-workplace-health/occupational-health-safety/workplace-hazardous-materials-information-system/amendments-hazardous-products-regulations.html>), and the European Union (EU) updated its Classification, Labelling, and Packaging (CLP) regulation in 2023 as well (see <https://echa.europa.eu/new-hazard-classes-2023>). OSHA works diligently with our UN partners through the UNSCEGHS to address stakeholder concerns regarding the timing of updates across U.S. international trading partners. However, given the lengthy and complex process of regulatory development, exact timelines are difficult to manage. Nevertheless, OSHA does not believe that there will be meaningful differences in timing of updates between the international trading partners as OSHA's compliance deadline will allow stakeholders extended time to comply with the updated standard. The compliance dates for the HCS are discussed in more detail in the Summary and Explanation for paragraph (j).

Additionally, Brazil and Russia are currently in the process of aligning with Rev. 7, further indicating that this is the correct revision for OSHA to align with. China is using the fourth version of the GHS and therefore is currently not aligned with OSHA's HCS. India has not yet implemented the GHS and does not participate at the UNSCEGHS. OSHA does not believe it is acceptable to postpone its rulemaking until all trading partners, particularly those that have never adopted the GHS, adopt Rev. 7 as this would result in OSHA not updating the HCS for an indefinite period of time, meanwhile depriving U.S. workers of these important protections. While OSHA strives to align with major trading partners that are similarly committed to maintaining a harmonized GHS system where possible, the agency's primary mission is to protect workers.

ASSP also stated that OSHA should not align with GHS Rev. 7. They suggested that the agency should align with Rev. 8 because it is a newer version (Document ID 0284, p. 1). ASSP went on to state that updating to Rev. 7 would result in OSHA continuing to play 'catch-up' since the European Union's Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulation is updated every two years. OSHA notes that currently Health Canada HPR and the EU CLP have updated to Rev. 7, so the agency does not agree that the United States is falling behind its trading partners (Document ID 0176; 0172).

Other commenters expressed concerns about deviating from a single version of the GHS, either due to incorporating elements of another revision or due to incorporating elements that differed from the GHS altogether. Several commenters noted that they disapproved of selectively adopting elements of Rev. 8, and two of these commenters noted that this was because selective adoption would cause misalignment with trading partners (Document ID 0323, p. 2; 0423, Tr. 105; 0359, p. 7; 0368, p. 11). However, Ameren noted that adopting specific provisions from Rev. 8 "could improve worker safety now in lieu of waiting until the next revision of the HCS" (Document ID 0309, p.

14). While OSHA strives to align with trading partners where possible, OSHA's primary mission is to protect workers. Therefore, OSHA has concluded that some elements of Rev. 8 improve the safety of workers and the clarity of information being communicated and is adopting those provisions instead of their Rev. 7 equivalent.

Other stakeholders indicated that OSHA should not include changes that are not included in the GHS. The International Carbon Black Association (ICBA) supported alignment with Rev. 7, but opposed adding the sections of the proposal, such as the requirement to classify hazards based on downstream use, that went beyond GHS obligations because they felt this would lead to misalignment with international trading partners (Document ID 0291, p. 6). ACC provided similar comments and stated that "we strongly urge OSHA to pull directly from the UN GHS wherever possible, while retaining flexibility for existing provisions that provide similar levels of protection" (Document ID 0347, p. 4). NAIMA supported aligning with the GHS, but noted that "[t]here are also proposals from OSHA that have nothing to do with the GHS but will create heavy and unprecedented burdens upon all industries subject to the HCS" and stated that they did not support such changes (Document ID 0338, p. 1). These commenters provided greater specificity about their opposition to specific proposals that differ from Rev. 7, and OSHA discusses these specific comments in detail in the corresponding sections in the Summary and Explanation below.

OSHA received several comments asking the agency to completely withdraw the proposal or repropose it with significant changes due to concerns about the proposed rule decreasing worker protections (Document ID 0305, p. 1; 0312, p. 7; 0322, Att. 1, p. 1; 0344, p. 4; 0350, p. 1; 0354, p. 1). OSHA disagrees with the conclusion that this rule will decrease worker protections; as the agency has stated, and as discussed throughout the Summary and Explanation below, it expects this update of the HCS to improve worker safety by incorporating new hazard classes and categories, improving and streamlining

precautionary statements, and providing additional clarification of existing regulatory requirements. Therefore, OSHA is moving forward with finalizing the update to the HCS in this rulemaking. To the extent these commenters raised concerns about worker safety with respect to specific provisions, those comments are addressed in their respective sections of the Summary and Explanation.

Finally, OSHA received a variety of non-substantive comments pointing out minor errors such as missing punctuation or European spelling differences. OSHA has updated the regulatory text to incorporate these minor changes where appropriate, but does not discuss non-substantive edits in the Summary and Explanation below.

A. Discussion of Incorporation by Reference

OSHA is updating the agency's incorporation by reference section, 29 CFR 1910.6, to include the national and international consensus standards listed below. Where OSHA has updated consensus standards, OSHA does not intend to require chemicals already classified using an earlier version of a consensus standard to be reclassified and has retained earlier versions of the consensus standards in the text of the standard where relevant to avoid suggesting retesting is necessary (for the U.N. Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, this is reflected in the use of a generic citation where either Rev. 4 or Rev. 6 is acceptable, and a specific citation to Rev. 6 where there is new material included and only Rev. 6 is acceptable to use). 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 had considered alternative ways to clarify this in the final regulatory text, for instance 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 invited comments on this topic (86 FR 9694). OSHA received one comment from Ameren on this issue (Document ID 0309, p. 14), which is

addressed in the Summary and Explanation for Appendix B. OSHA has decided to not make the change to the “DATES” section but rather to retain references to the older versions of the consensus standards where relevant and has clarified this matter in the relevant portions of the Summary and Explanation for Appendix B.

In the NPRM, OSHA requested comment on whether it should update all of the consensus standards and received no comments on that particular question. ASTM International (ASTM) submitted a comment indicating that they believe OSHA should, in the future, update all references to consensus standards in bulk through the *Federal Register*, as the Food and Drug Administration (FDA) does (Document ID 0307, pp. 2-3). OSHA has decided to only add or update the references that the agency proposed, rather than updating all existing references to consensus standards in the regulatory text and Appendix B, but will consider the approach suggested by ASTM in a future rulemaking. OSHA is finalizing the proposed references to the consensus standards as proposed with one exception: DOD pointed out that one of OSHA’s proposed citations to consensus standards was incorrect and OSHA has updated the reference throughout the final rule (Document ID 0299, p. 3).

OSHA is finalizing its decision to incorporate by reference the materials below. Each standard is available for purchase through the publication agencies listed below. The following standards appear in the amendatory text of this document and were previously approved for appendix B to § 1910.1200: ASTM D56-05; ASTM D3278-96, ASTM D3828-07a, ASTM D93-08, ASTM D86-07a, ASTM D240-02 (Reapproved 2007), ASTM D1078-05, ISO 1056:1996(E) ISO 1056-2:2005, ISO 13943:2000(E/F), NFPA 30B, UN ST/SG/AC.10/Rev.4.

- ADR 2019, European Agreement Concerning the International Carriage of Dangerous Goods by Road, Annex A, January 1, 2019.

This standard describes test methods, units of measurement, definitions, and

applicable standards and regulations for determining fluidity of liquids for classification purposes.

- United Nations: <https://shop.un.org/product/18246?v=22452>
- ASTM D 4359-90 (reapproved 2019), Standard Test Method for Determining Whether a Material is a Liquid or a Solid, Approved July 1, 2019.

This standard covers test methods used to determine whether a viscous material is a liquid or a solid for regulatory purposes and was developed under internationally recognized principles established in “Decision on Principles for the Development of International Standards, Guides and Recommendations” by the World Trade Organization Technical Barriers to Trade (TBT) Committee. The standard only addresses test methods for the specified purpose of determining state of a material and is not intended to address all safety concerns associated with use of the material being tested.

 - ASTM International: <https://astm.org/Standard/standards-and-publications.html>
- DIN 51794:2003-05, Determining the ignition temperature of petroleum products, May 2003.

This standard specifies test methods for determining the ignition temperature of flammable gases and liquids, as well as petroleum products and their mixtures at temperatures between 75 °C and 650 °C. The ignition temperature is a measurement of a flammable substance’s tendency to ignite when in contact with hot objects. The standard also provides guidance for classification purposes.

 - German Institute for Standardisation (DIN): <https://din.de/en/about-standards/buy-standards>
- IEC 60079-20-1, Explosive atmospheres – Part 20-1: Material characteristics for gas and vapor classification – Test methods and data, Edition 1.0, 2010-01

This standard describes test methods for measurement of the maximum experimental safe gaps of a gas- or vapor- air mixture under normal conditions of temperature and pressure in order to make a determination of appropriate safety equipment as well as describes test methods for use in the determination of auto-ignition temperature of a chemically pure vapor or gas. This standard also provides guidance for classifying gases and vapors for explosive potential.

- International Electrotechnical Commission (IEC):

<https://webstore.ansi.org/standards/iec/iec6007920ed2010>

- ISO 817:2014(E), Refrigerants – Designation and safety classification, Third Edition, 2014-04-15

This standard provides guidance for determining the lowest temperature a substance can spontaneously ignite under normal atmospheric conditions without an external source of ignition, such as a spark or flame. The standard also provides guidance for classification of these materials for safety purposes. The standard was developed under internationally recognized principles established in “Decision on Principles for the Development of International Standards, Guides and Recommendations” by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

- ISO: *<https://iso.org/store.html>*

- ISO 10156:2017(E), Gases and Gas Mixtures – Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Fourth Edition, 2017-07

This standard provides test methods for determining the flammability of a gas or gas mixture and determining whether a gas or gas mixture is more or less oxidizing than air under atmospheric conditions. The standard also provides guidance for classifying gases or gas mixtures and for determining the appropriate

selection of gas cylinder valve outlets. The standard was developed under internationally recognized principles established in “Decision on Principles for the Development of International Standards, Guides and Recommendations” by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

- International Organization for Standardization (ISO):

<https://iso.org/store.html>

- UN ST/SG/AC.10/11/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Sixth Revised Edition, copyright 2015

This standard provides test methods, classification procedures, and criteria for classification of explosives, self-reactive substances, organic peroxides, and other various hazards (e.g., flammability of aerosols, desensitized explosives, flammable solids, liquids, oxidizing solids and liquids, corrosive to metals).

- United Nations: *<https://unece.org/info/Transport/Dangerous-Goods/pub/2581>*

OSHA is making all documents available for review by the public in accordance with the agency’s policies regarding availability of documents. Copies of the standards are available for purchase from the issuing organizations at the addresses or through the other publisher contact information listed in § 1910.6 of the amendatory text in this document. In addition, 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. Discussion of Regulatory Text

(a) Purpose.

Paragraph (a)(1) of the HCS states that “[t]he 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.” In the 2012 HCS, paragraph (a)(1) explained that the requirements of the standard were intended to be consistent with Rev. 3. The NPRM proposed to change the reference from Rev. 3 to Rev. 7. As stated in the introduction to the Summary and Explanation, revisions included in this final rule primarily serve to align the HCS with Rev. 7, with the exception of selected provisions which either align with Rev. 8 or do not relate to the GHS. OSHA is therefore finalizing paragraph (a)(1) to update the reference to the GHS to “Revision 7,” replacing “Revision 3.” In addition, OSHA is inserting “primarily” before “Revision” because the agency is finalizing some of the proposed changes from Rev. 8.

(b) Scope and application.

Paragraph (b) of the HCS specifies the scope and application of the rule, including the chemicals that are (and are not) covered by the standard. This final rule modifies paragraph (b)(6)(x) of the 2012 HCS, which excludes nuisance particulates from coverage under the HCS under certain circumstances. Specifically, OSHA is modifying paragraph (b)(6)(x) to clarify that nuisance particulates are excluded from the scope of the standard when the chemical manufacturer or importer can establish they do not pose any physical hazard, health hazard, or other hazards covered under the HCS.

Paragraph (b)(6)(x) of the 2012 HCS stated that the standard does not apply to nuisance particulates “where the chemical manufacturer or importer can establish that they do not pose any physical or health hazard covered under this section.” However, this could be interpreted as excluding hazards not otherwise classified (HNOC), which is not OSHA’s intent. Therefore, in the NPRM OSHA proposed 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., HNOC) covered by the standard (86 FR 9696). This proposed change was intended to clarify that all hazards covered by the standard must be considered when evaluating nuisance particulates. OSHA's proposal did not alter the requirement, first adopted in 1994, that nuisance particulates are excluded if they pose no hazard.

OSHA received no comments specifically regarding the addition of HNOC to this provision. However, OSHA received comments regarding paragraph (b)(6)(x) as a whole (Document ID 0325, pp. 12-13; 0397, pp. 12-13; 0279, p. 13). USBSA et al. commented that OSHA's proposal to add "other hazards" to the existing text of paragraph (b)(6)(x) would "contravene the burden-of-proof provision of the Administrative Procedure Act, 5 U.S.C. § 556(d)"⁵⁵ (Document ID 0325, pp. 12-13; 0397, pp. 12-13). USBSA et al. argued that OSHA's proposed change would improperly place the burden of proof on manufacturers and importers to determine whether nuisance particulates present "other hazards" under the HCS, in order to meet the requirements of (b)(6)(x) for when nuisance particulates may be excluded from the scope of the HCS (Document ID 0325, p. 12).

Similarly, Toby Threet commented that paragraph (b)(6)(x) requires the manufacturer or importer to establish the absence of a hazard and suggested that OSHA should revise the paragraph to exclude nuisance particulates where the chemical manufacturer or importer can establish that they *are not classified* as a physical hazard, health hazard, or any other hazards covered under the HCS. According to Threet, "the requirement to 'establish' the absence of a hazard" suggests that OSHA is intending to mandate testing, which the HCS does not require (Document ID 0279, p. 13).

⁵⁵ The "burden of proof" provision to which USBSA et al. referred is located in 5 USC 556, which applies to federal agency hearings. See 5 USC 556(a). The provision states, in pertinent part, "Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 USC 556(d).

OSHA disagrees with these comments. First, both comments pertain to aspects of paragraph (b)(6)(x) that have been part of the HCS since 1994 and that OSHA's proposed change does not affect. Regardless, contrary to USBSA et al.'s contention, paragraph (b)(6)(x) does not improperly shift the burden of proof onto the chemical manufacturer or importer. As USBSA et al. recognized, courts considering similar language in other OSHA standards have rejected the same argument. They have done so based on the well-established principle that the party seeking to claim an exemption from a legal requirement bears the burden of demonstrating it applies. See *Triumph Constr. Corp. v. Sec'y of Labor*, 885 F.3d 95, 98 (2d Cir. 2018); *Harry C. Crooker & Sons v. OSHRC*, 537 F.3d 79, 86 (1st Cir. 2008). Paragraph (b)(6)(x) is such an exemption (see 59 FR 6154 (stating in promulgation the provision that "the burden of proof for this exemption belongs to the manufacturer or importer"))).

Likewise, contrary to Threet's assertion, paragraph (b)(6)(x) does not establish testing requirements or otherwise affect methods of classification under the HCS, as OSHA made clear when promulgating the provision in 1994 (59 FR 6126 ("The hazard evaluation process for nuisance particulates is not any different than for any other chemical.")). Therefore, the suggestion to change the words "do not pose" to "are not classified" is unnecessary and OSHA declines to adopt it. OSHA's addition of "other hazards" to this paragraph is merely clarifying that nuisance particulates also must not pose an HNOC. Because the revision will clarify OSHA's original intent and ensure that nuisance particulates posing a combustible dust hazard or an HNOC are properly addressed by the standard, OSHA is finalizing paragraph (b)(6)(x) as proposed.

OSHA received several additional comments that are related to paragraph (b), but that are outside the scope of this rulemaking. An anonymous submitter commented that they support the rule and stated that "all chemical labels should follow the same guidelines and get approved before being used [in] an...establishment or put on a shelf"

(Document ID 0296). OSHA interprets this comment as supporting its proposal, but to the extent that the commenter was suggesting that OSHA should apply the HCS to all chemicals in the United States or that it should approve the labels before they are placed on chemicals, these suggestions are outside the scope of this rule because they would involve fundamental changes to the HCS that OSHA has not proposed and in some cases does not have the authority to do.

NAIMA commented that the HCS should apply to all labels within the U.S. Specifically, NAIMA commented that OSHA should not cede labeling authority for products regulated by other agencies and should not allow states to create additional requirements for labelling or classification requirements (Document ID 0338, pp. 11-12). Both of these suggestions are outside the scope of this rulemaking as the agency did not propose anything related to these issues. Additionally, OSHA only has jurisdiction to address the occupational hazards posed by chemicals and, even in that sphere, is in some cases preempted from enforcing safety and health standards where other Federal agencies exercise statutory authority (see 29 USC 653(b)(1)). OSHA cannot mandate how other agencies address labeling issues under their jurisdiction, and it already exercises its authority over State Plans in order to ensure that no states create requirements that conflict with the HCS.

OSHA received several comments on pesticide labels and SDSs and consumer product labeling (e.g., Document ID 0275; 0343, pp. 3-4; 0331, pp. 2-3; 0407, p. 9; 0341; 0340, pp. 3-4). As discussed in the 2012 HCS, OSHA and EPA have worked together to provide guidance to the regulated communities on preparing labels and SDSs for pesticide products (77 FR 17696-17697). In addition, consumer product labeling is outside of OSHA's jurisdiction. Since OSHA did not propose to address these issues in the NPRM, these comments are out of scope for this rulemaking and the agency declines to take any of the requested actions.

(c) *Definitions.*

Paragraph (c) of the HCS provides definitions for terms used throughout the rest of the HCS. Paragraph (c) is designed to increase stakeholders' comprehension of requirements under the HCS and improve compliance with the standard. Many of the definitions in paragraph (c) align with the GHS, but some are unique to the HCS. For definitions that are specifically related to individual health and physical hazards please see Appendices A and B.

In the NPRM, OSHA proposed modifications to three existing definitions in paragraph (c), the addition of definitions for eight new terms, and the deletion of one definition. OSHA proposed modifications to: *exposure or exposed*, *hazardous chemical*, and *physical hazard*. The eight new terms proposed were: *bulk shipment*, *combustible dust*, *gas*, *immediate outer package*, *liquid*, *physician or other licensed health care professional (PLHCP)*, *released for shipment*, and *solid*. OSHA proposed to delete the definition of *pyrophoric gas*.

For the reasons discussed in the remainder of this section, OSHA is finalizing the definitions of *bulk shipment*, *exposure or exposed*, *gas*, *hazardous chemical*, *immediate outer package*, *physician or other licensed health care professional (PLHCP)*, *released for shipment*, and *solid* as proposed. In addition, OSHA is eliminating the definition of *pyrophoric gas* as proposed. The agency is finalizing the definitions of *combustible dust*, *liquid*, and *physical hazard* with changes from the NPRM based on comments the agency received. These definitions are discussed below in alphabetical order.

Bulk shipment. OSHA proposed adding a definition of the term *bulk shipment* to the standard. The proposed definition stated that *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). This definition clarifies paragraph (f)(5)(ii), which OSHA proposed in the NPRM to explain that labels

for bulk shipments need not be placed on the immediate container but may instead 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. The proposed definition also distinguishes OSHA's bulk shipment requirements from the DOT's Pipeline and Hazardous Materials Safety Administration (PHMSA) requirements for bulk packaging (49 CFR Parts 100-185).

OSHA received multiple comments on this proposed definition. The Fragrance Creators Association (FCA) requested clarification as to whether the proposed definition of *bulk shipment* would encompass intermediate bulk containers (IBCs). An IBC is "a rigid or flexible portable packaging, other than a cylinder or portable tank, which is designed for mechanical handling" (49 CFR 171.8), typically holding 110-350 gallons (Document ID 0345, p.5). According to FCA, these IBCs are commonly placed into inventory as-is, and therefore should be labeled to ensure employee health and safety (Document ID 0345, pp. 5-6). OSHA intends the definition of "bulk shipment" to apply only when the mode of transportation is the immediate container, such as a tanker truck, rail car, or intermodal container. Therefore, IBCs do not fall within OSHA's definition of a bulk shipment.

DGAC, Interested Parties for Hazardous Materials Transportation (IPHMT), NACD, and NPGA suggested that OSHA should adopt DOT's definition of "bulk packaging" (Document ID 0339, pp. 1-2; 0423, Tr. 62; 0336, pp. 3-4; 0329, pp. 2-3; 0423, Tr. 124; 0465, pp. 2-3; 0364, pp. 6-7; 0423, Tr. 229). DOT defines "bulk packaging" as: "a packaging, other than a vessel or a barge, including a transport vehicle or freight container, in which hazardous materials are loaded with no intermediate form of containment. A Large Packaging in which hazardous materials are loaded with an intermediate form of containment, such as one or more articles or inner packagings, is also a bulk packaging. Additionally, a bulk packaging has:

- (1) A maximum capacity greater than 450 L (119 gallons) as a receptacle for a liquid;
- (2) A maximum net mass greater than 400 kg (882 pounds) and a maximum capacity greater than 450 L (119 gallons) as a receptacle for a solid; or
- (3) A water capacity greater than 454 kg (1000 pounds) as a receptacle for a gas as defined in § 173.115 of this subchapter.” 49 CFR 171.8.

NACD expressed concern that OSHA’s proposed definition of “bulk shipment” would conflict with DOT’s definition of “bulk packaging” (Document ID 0329, pp. 2-3; 0465, pp. 2-3; 0423, Tr. 124). DGAC stated that the definition of *bulk shipment* “should be similar or identical to those contained in the DOT regulations in Section 171 of the Hazardous Materials Regulations...[because] many of the packaging described as bulk are used for international movement of hazardous materials, but they’re also used as a containment system in manufacturing. So to have different definitions would create problems” (Document ID 0423, Tr. 62). NPGA and IPHMT suggested that OSHA incorporate the DOT definition, on the basis that incorporation would provide clarity on requirements for bulk shipments where both HCS and DOT’s Hazardous Materials Regulations (HMR) requirements apply; would offer uniformity in the training and education of workers on the types of containers and the required information to be displayed for bulk shipments; and would allow for updates to the definition of *bulk shipment* without requiring revision to the HCS (Document ID 0336, pp. 3-4; 0364, pp. 6-7). They also noted that the definition of *bulk shipment* needed to be “clear between the agencies” in order to codify the joint DOT and OSHA policy from a 2016 guidance document regarding labeling of bulk chemical shipments (Document ID 0244).

OSHA disagrees with these comments. The agency intends for its definition of *bulk shipment* to differ from DOT’s definition of bulk packaging, as DOT’s definition would not adequately support OSHA’s requirements in HCS paragraph (f)(5)(ii). OSHA’s use of the term *bulk shipment* solely refers to situations where the mode of

transportation is also the immediate container, while DOT's definition for *bulk packaging* encompasses a broader range of forms of packaging, including those with an intermediate form of containment such as 55-gallon drums or super sacks (flexible intermediate bulk containers) which can hold over a ton of material. OSHA only intends to create an exception in (f)(5)(ii) for shipments that do not have intermediate forms of packaging. Thus, adopting the DOT definition would not align with OSHA's intent and would provide less information to workers. The guidance created with DOT in 2016 does not conflict with this interpretation and a single definition is not required in order to codify it, as suggested by NPGA and IPHMT. That guidance uses the terms *bulk shipment* and *bulk packaging* correctly to refer to each agency's separate definitions and does not use the terms interchangeably. Therefore, OSHA is declining to adopt the suggestion that the agency incorporate or otherwise align with the DOT definition for *bulk packaging* and is finalizing the definition of *bulk shipment* as proposed.

Combustible dust. OSHA proposed adding a definition of the term *combustible dust* to the HCS. In the 2012 update to the HCS, OSHA included combustible dust under the definition of hazardous chemical, but did not provide a separate definition of the term. At that time, OSHA did not include a definition of *combustible dust* because the agency was considering a separate combustible dust rulemaking, OSHA had already begun work at the GHS on a definition for *combustible dust*, and the UNSCEGHS was also considering combustible dust classification and communication issues (see 77 FR at 17705). Additionally, OSHA explained that it had previously provided considerable guidance on the nature and definition of combustible dust in a variety of materials, including OSHA's Hazard Communication Guidance for Combustible Dusts (77 FR 17704). Since the 2012 rulemaking, however, OSHA has not promulgated a combustible dust standard and the UNSCEGHS has adopted a definition for *combustible dust*.

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” (Document ID 0060). In the NPRM, OSHA preliminarily determined that the definition developed in the GHS was consistent with existing OSHA guidance on combustible dust hazards and proposed adopting this definition (86 FR 9697; Document ID 0190; 0255). In addition, OSHA has other standards that use the term *combustible dust* but do not define the term (e.g., Grain Handling Facilities, 29 CFR 1910.272). In the NPRM, OSHA preliminarily determined that the proposed definition was consistent with uses of the term in other standards (86 FR 9696). While OSHA still believes the final definition to be consistent with other standards’ use of the term, the agency wishes to clarify its position should inconsistencies arise or become evident. Where the term *combustible dust* is used but not defined in another standard, and where OSHA has guidance specific to that standard, that guidance, rather than the HCS definition, is the relevant interpretive source.

OSHA received comments from ACC, API, and DGAC supporting the proposed addition of a *combustible dust* definition consistent with Rev. 7 (Document ID 0347, pp. 26-27; 0316, p. 2; 0339, p. 1). The agency also received several critical comments. First, several commenters believed that the proposed definition for *combustible dust* was confusing, ambiguous, and too broad (Document ID 0287, pp. 2-4; 0325, pp. 3-4; 0329, p. 3; 0369, Att. 2, pp. 2-3). For example, the Vinyl Institute found the proposed text “is ambiguous and confusing, is provided without context, appears to be inconsistent with accepted scientific practice and OSHA guidance, and may conflict with the existing HCS classification for flammable solids” (Document ID 0369, p. 2).

Several commenters stated that they or their member companies are accustomed to relying on National Fire Protection Association (NFPA) standards to provide a clear and well-defined definition of combustible dust, including testing procedures, and would

prefer for OSHA to adopt or align with NFPA’s definition. PLASTICS stated that OSHA has, in the past, referenced NFPA standards that define *combustible dust* as “[a] finely divided combustible particulate solid that presents a flash-fire hazard or explosion hazard when suspended in air or the process-specific oxidizing medium over a range of concentrations.” PLASTICS argued that this definition “clearly state[s] it is necessary to perform testing to determine if a material is a combustible dust and specify the design and energy levels of the igniters to be used” (Document ID 0314, p. 15). NACD noted that OSHA’s proposed definition is broader than the NFPA definition and that chemical distributors who import products “need to be able to provide their foreign suppliers with clear parameters and test methods so they can objectively determine whether or not their material is a combustible dust” (Document ID 0329, p. 3). The American Forest & Paper Association (AF&PA) and the American Wood Council (AWC) jointly submitted a comment that their members “have comfortably relied on the well-established, harmonized definition of that term contained in the NFPA combustible dust standards, which specifies the tests to be performed on the material” (Document ID 0287, pp. 3-4). AF&PA, AWC and PLASTICS also commented that while the GHS references the ISO/IEC 80079-20-2 standard for combustible dust, the GHS definition, and therefore also the proposed HCS definition, for *combustible dust* are inconsistent with the current ISO/IEC and NFPA standards (Document ID 0287, pp. 3-4; 0314, pp. 15-16). PLASTICS further commented that the benefits of harmonization with the GHS on the definition of *combustible dust* would be limited since combustible dust is not a classified hazard in the GHS and is only recognized under Canada’s Workplace Hazardous Materials Information System (WHMIS) (Document ID 0314, p. 16).

Several of these commenters requested that OSHA either align its proposed definition with NFPA’s definition or finalize the HCS without adding a definition for

combustible dust, effectively allowing employers to continue using the NFPA definition (Document ID 0314, pp. 15-16; 0369, p. 3; 0287, pp. 3-4).

OSHA disagrees with commenters' suggestion to adopt the NFPA definition in lieu of the agency's proposed definition for *combustible dust*. OSHA acknowledges that the wording in the GHS is not precisely the same as the definition in the ISO/IEC testing method consensus standard or the NFPA definition. However, the ISO/IEC method was the starting point for the definition in the GHS and the UN Subcommittee modified it to ensure that it was compatible with other consensus standards and would cover various conditions under which a dust could deflagrate. Similarly, OSHA proposed a broad definition with the intention of providing classifiers with a general understanding of the intrinsic properties of the category described. This definition, along with others in paragraph (c), is not intended to provide the detailed descriptions and/or test methods required to classify materials, which are instead provided through guidance materials and consensus standards. This is consistent with other hazards included in the HCS and GHS, for which the HCS and GHS provide a general definition and also provide further criteria or guidance on how to determine if a chemical exhibits this hazard.

Additionally, the NFPA definition indicates that specific tests would be required to determine explosibility. Adopting the NFPA definition in its entirety would be contrary to the general HCS principle that the standard does not require the label and SDS preparer to conduct testing. OSHA is aware that NFPA standards address combustible dust hazards in NFPA 652 as well as other NFPA consensus standards and believes that the agency's proposed definition of *combustible dust* is compatible with NFPA standards, even though it does not replicate them. Classifiers can therefore continue to rely on the NFPA standards to determine whether a material is a combustible dust.

Several stakeholders also provided comments on specific terms used in OSHA's proposed definition which differ from the terms used by NFPA. AF&PA and AWC commented that "catch fire" is undefined and could be conflated with "ignition" (Document ID 0287, pp. 3-4). PLASTICS also stated that OSHA's phrase "catch fire" is unclear, in part because it suggests that ignition energy levels are irrelevant, whereas NFPA standards use and define the term "flash-fire" instead (Document ID 0314, pp. 15-16). The Vinyl Institute commented that "catch fire" could be interpreted as meaning ignition or resulting in a self-sustaining propagation, which could be confused with flammable solid (Document ID 0369, Att. 2, pp. 2-3). USBSA et al. similarly commented that the use of the phrase "catch fire" in OSHA's definition of *combustible dust* would cause an overlap between the proposed category of combustible dust and the existing category of flammable solids (Category B.7 in Appendix B). As a result of this overlap, a substance might be classified as a combustible dust because of a flammability hazard (rather than because of an explosion hazard) and also classified as a flammable solid for the same reason (Document ID 0325, pp. 3-4; 0425, Tr. 15). USBSA et al. concluded that OSHA should adopt criteria that permit manufacturers to distinguish between the categories of "combustible dust" and "flammable solids" (Document ID 0325, p. 4).

OSHA agrees with the comments that the phrase "catch fire" is insufficiently clear. Accordingly, OSHA has eliminated the phrases "are liable to catch fire" and "on ignition" and replaced "catch fire" with "pose a flash-fire hazard," similar to NFPA standards 652 and 654 (Document ID 0433; 0457). However, OSHA disagrees that the definition will cause confusion between the category of combustible dust and the separate category of flammable solids, which have very specific classification criteria and clear test methods for determining flammability. To the extent that there is overlap between the classifications, this is because flammable solids are one type of combustible dust. Even so, it is important to identify both hazards because they can occur under different

conditions. For further discussion on flammable solids, please see the Summary and Explanation for Appendix B.7.

USBSA et al. also commented on the word “explode,” stating that it “is inaccurate and misleading” (Document ID 0325, p. 4). USBSA et al. noted that, of the elements needed for an explosion (fuel, ignition source, oxygen, dispersion of dust particles in sufficient quantity and concentration, and confinement of the dust cloud), several were missing from the proposed definition. USBSA et al. stated that without confinement as a criterion, the proper term is “deflagrate” instead of “explode.” USBSA et al. went on to state that OSHA should include the NFPA confinement and particle size criteria of less than 500 microns in the HCS definition of *combustible dust* (Document ID 0325, pp. 4-6; 0425, Tr. 15-17).

OSHA agrees that “explode” was not sufficiently clear in the proposed definition. In order to provide clarity and consistency with the NFPA definition of *combustible dust*, as commenters requested, OSHA has replaced the term “explode” with “explosion hazard” which refers to when solid particulates are dispersed in air or an oxidizing media. It is the oxidizing media that is especially important for the explosion hazard to be present (Document ID 0433; 0457). Additionally, deflagration is a type of explosion hazard, as indicated by the NFPA definition of explosion hazard, and therefore OSHA believes that it is more appropriate to use the broader term “explosion hazard” here, rather than USBSA et al.’s suggested “deflagration.” Also, to be consistent with the NFPA definition and the term “explosion hazard” OSHA is making a corresponding change of the term “particle” to “particulate” in the HCS definition of *combustible dust*.

OSHA disagrees, however, with USBSA et al.’s suggestion to include criteria for confinement and particle size because these criteria are not appropriate to OSHA’s purpose in providing the definition of *combustible dust*. While OSHA agrees that certain conditions must apply before a combustible dust explosion can occur, OSHA does not

believe the confinement and particle size criteria should be part of the HCS definition, which OSHA has written to include intrinsic properties of combustible dusts but not the conditions required for their ignition. OSHA has taken a similar approach to defining other physical hazards in the HCS. For example, the definition of flammable liquids (Appendix B.6) includes the flash point, which is an intrinsic property of a material. For a flammable liquid to ignite, several conditions, such as vapor layer and source of ignition, are needed, but these are not properties of the material that render it intrinsically flammable and are therefore excluded from OSHA's definition. Such conditions are important to evaluating the risk of ignition in handling and use, but not to identifying whether a liquid is itself flammable. Similarly, in the case of combustible dust, confinement is a condition wholly external to the material itself, and the particle size of the material does not determine whether it can ignite (even though it is relevant, together with other factors including the confinement area, to the likelihood of ignition). Therefore, OSHA has chosen not to add confinement and particle size to the HCS definition of *combustible dust*.

ACC recommended that OSHA place "measurable parameters around the definition or specify that it is ideally meant for organic and metal dusts" (Document ID 0347, p. 26). OSHA has determined that it is neither necessary to add more specific parameters to the definition of *combustible dust* nor helpful to limit it as ACC proposes. OSHA and NFPA have both provided guidance documents that outline how to determine if a dust is combustible as well as lists of materials that are commonly considered combustible. Moreover, combustible dust hazards are not limited to organic and metal dusts, so to limit the definition as ACC suggests would potentially result in some chemicals that pose combustible dust hazards not being labeled as such.

Dow commented that the agency should make a clear distinction between the definition of *combustible dust* and the phrase "explosible dust" as it is used in Appendix

C.4.31 (Document ID 0359, p. 5). OSHA intends these terms to be interchangeable and uses both terms in its own guidance products. For further discussion on this issue please see the Summary and Explanation for Appendix C.4.31.

USBSA et al. also asked OSHA to clarify that the definition of *combustible dust* is for hazard communication purposes only and is not for other regulatory purposes. As OSHA stated earlier, the proposed definition is sufficiently broad to be consistent with uses of the term in other standards (86 FR 9696) and would not be the primary source for interpreting those existing standards when the agency has guidance specific to those standards.

The Edison Electric Institute (EEI) asked OSHA to include a statement addressed to its compliance officers in the preamble of this rule acknowledging that a product labeled as posing a combustible dust hazard may not necessarily be combustible in a particular workplace (Document ID 0360, pp. 7-8). As EEI points out, OSHA has repeatedly stated that the determination of a hazard for classification purposes does not necessarily indicate risk in any particular workplace. However, OSHA addresses compliance issues and instructions to its compliance officers in other documents and therefore will not use the preamble of this rule to address this issue.

For the reasons discussed above, OSHA is finalizing the definition of *combustible dust* as proposed with the following modifications: the phrases “liable to catch fire” and “ignition” are replaced with “pose a flash-fire hazard”; the term “explode” is replaced with “explosion hazard”; and the term “particles” is changed to “particulates.” The final version defines *combustible dust* as “finely divided solid particulates of a substance or mixture that pose a flash-fire hazard or explosion hazard when dispersed in air or other oxidizing media.” While these modifications represent departures from the GHS definition, the agency believes the definition as finalized best effectuates the purpose of the HCS by remaining consistent with the intent of the GHS definition while addressing

the Vinyl Institute and others' concerns, discussed above, that OSHA's original definition was confusing, ambiguous, and overly broad (Document ID 0287, pp. 2-4; 0325, pp. 3-4; 0329, p. 3; 0369, Att. 2, pp. 2-3).

Exposure or exposed. OSHA proposed revising the definition of *exposure or exposed*. The definition in the 2012 HCS provided, 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. In the NPRM, OSHA proposed revising the definition to mean that 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 received no comments on this proposed revision, and is therefore finalizing the definition of *exposure or exposed* as proposed.

Gas, liquid, and solid. OSHA proposed to include three new definitions for the terms *gas*, *liquid*, and *solid*. The agency proposed including these terms to align with Rev. 7 (Document ID 0060). Although not included in the GHS definitions of these terms, OSHA also proposed adding the temperature in equivalent degrees Fahrenheit and pressure in equivalent pounds per square inch (PSI) to the new HCS definitions of *gas* and *liquid* because those measurements are more commonly used in the U.S.

OSHA proposed defining *gas* and *liquid* to be consistent with Rev. 7. Furthermore, in accordance with Rev. 7, OSHA proposed including, as part of the definition of *liquid*, that a viscous substance or mixture for which a specific melting point could not be determined "shall be subjected to ASTM 4359-90 ... 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)..." Finally, OSHA proposed adopting the GHS definition of *solid* as a substance or mixture not meeting the definitions of liquid or gas.

The agency proposed to include these definitions to improve clarity and ensure consistency in hazard communication and classification both domestically and internationally. The agency believes that defining these terms in the standard will clarify provisions under Appendices B and D for classification of hazardous chemicals and preparation of SDSs. OSHA indicated in the proposal that it did not anticipate that these new definitions would impact other existing standards for construction or general industry. OSHA requested comments on its proposal to include these definitions in this update.

OSHA received multiple comments on the specific proposed definitions for *gas*, *liquid* and *solid*. NIOSH supported the definitions, indicating that aligning with the GHS definitions would provide transparent, consistent, and clear language that is universally understood and would facilitate hazard communication and inform risk management decisions across multiple scenarios (Document ID 0456, Att. 2, p. 2). API, Michele Sullivan, and DGAC also supported aligning the definitions with the GHS (Document ID 0316, p. 2; 0339, p. 1; 0366, p. 2; 0423, Tr. 62). Ameren supported the new definitions and noted that OSHA should consistently implement these and other definitions in the NPRM in all affected OSHA standards (Document ID 0309, p. 15). OSHA discusses the impact of this final rule on other OSHA standards further below.

Since no commenters objected to the proposed definition of *gas*, OSHA is finalizing it as proposed.

OSHA received two comments that were critical of the definition of *liquid*. Specifically, PLASTICS and Toby Threet both commented that the phrase “shall be subjected to” in the proposed definition seemed to indicate OSHA was requiring testing even though the HCS has never required testing to comply with the standard (Document ID 0314, p. 16; 0279, p. 14).

OSHA agrees with these commenters that the proposed language implies a testing requirement and needs clarification. Since it was first promulgated in 1983, the HCS has required that manufacturers, importers, distributors, and employers evaluate the chemical hazards in the workplace and communicate those hazards to workers, but has not required testing in order to meet the provisions of the standard (48 FR 53280, 53290). The HCS specifies in paragraph (d)(2) that there is no requirement to test a chemical for hazard classification purposes. Moreover, the GHS specifically states, in Chapter 1.3.2.4.1, that it “does not include requirements for testing substances or mixtures” (Document ID 0060, p. 19).

To clarify OSHA’s intention on testing for this provision, Threet recommended removing the phrase “shall be subjected to” from the definition and to state instead that either of the cited testing methods “can establish whether a viscous substance or mixture is a liquid if a specific melting point cannot be determined” (Document ID 0279, p. 14). OSHA agrees that these revisions are more consistent with the agency’s intent and is amending the definition of *liquid* to include these revisions. Additionally, OSHA did not provide the PSI conversion for the first time the value 101.3 kPa is used. OSHA is inserting 14.69 PSI with 101.3 kPa in parentheses in the midsection of the definition so that it reads: “...which is not completely gaseous at 68°F (20°C) and at a standard pressure of 14.69 PSI (101.3 kPa)...” Accordingly, this final rule defines a *liquid* as shown in the amendatory text of this final rule.

Finally, OSHA received one additional comment on the definition of *solid* beyond the supportive comments noted above. PLASTICS suggested revising the proposed definition to recognize plasma as an additional state of matter. PLASTICS noted that plasma is “a generally accepted state of matter generated in certain lighting and has both cutting and arc welding applications” (Document ID 0314, pp. 16-17).

OSHA does not believe that revising the proposed definition of *solid* would serve OSHA's purpose in adding the term, which was to clarify the HCS and align with the GHS (86 FR 9697). The GHS and the HCS do not define or use the term plasma. The terms in paragraph (c) include those that are relevant to the GHS and the HCS, are needed for comprehension of provisions within the standard, and improve global harmonization (77 FR 17697). Since the term plasma is not defined in the GHS, is not referenced in the GHS definitions of *gas*, *liquid*, or *solid*, and is not related to any physical hazard covered under the HCS, the agency declines to revise the proposed definition of *solid* to recognize plasma as a state of matter. OSHA notes that, insofar as the physical properties of the material noted by PLASTICS as "plasma" in lighting, cutting, and arc welding meet the criteria of one of these definitions, they would be covered under the relevant hazard classes.

For the reasons discussed above, OSHA is finalizing the definitions of *gas* and *solid* as proposed and is revising the term *liquid* to incorporate the changes suggested by commenters.

Hazardous chemical. OSHA proposed updating the definition of *hazardous chemical* to delete a reference to pyrophoric gas because OSHA proposed classifying pyrophoric gas as a physical hazard in the flammable gas hazard class (see discussion in the Summary and Explanation for Appendix B.2). OSHA received one comment, from Ameren, stating that the revised definition is acceptable (Document ID 0309, p. 15). No commenter opposed the revision. The agency is therefore finalizing the definition of *hazardous chemical* as proposed.

Immediate outer package. OSHA proposed to add a definition for *immediate outer package*. In this final rule, paragraph (f)(12) (discussed in more detail in the Summary and Explanation for paragraph (f)) relaxes labeling requirements for small containers, but still requires 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.

OSHA received several comments in support of the proposed definition. Both Ameren and SAAMI supported the definition as proposed and SAAMI commended the agency for providing better harmonization with DOT (Document ID 0309, p. 15; 0294, p. 3; 0412, p. 2). DGAC supported the proposed definition as it provides clarity to the regulation and should enhance compliance with the standard (Document ID 0339, p. 1). No commenter opposed the proposed definition. OSHA is therefore finalizing the definition of *immediate outer package* as proposed.

Physical hazard. OSHA proposed to update the definition of *physical hazard*. The proposed definition also explicitly stated that “[t]he criteria for determining whether a chemical is classified as a physical hazard are detailed in Appendix B”. The proposal included two substantive changes to the previous definition: (1) it moved the reference to aerosols out of the parenthetical following the word “flammable”; and (2) it added a reference to desensitized explosives. These proposed revisions reflect the new hazard classes proposed for aerosols and desensitized explosives in Appendix B to align with Rev. 7 (see the Summary and Explanation for Appendix B). OSHA received one comment, from Ameren, indicating the revised definition is acceptable (Document ID 0309, p. 15). No commenter opposed the revised definition. Therefore OSHA is finalizing the definition of *physical hazard* as proposed with two minor technical amendments: OSHA is changing the contents of the parentheticals following “flammable” and “oxidizers” to read “...flammable (gases, liquids, or solids)...” and “...oxidizers (gases, liquids, or solids)...” for grammatical consistency with each other.

Physician or other licensed health care professional (PLHCP). OSHA proposed adding a definition of *physician or other licensed health care professional (PLHCP)* to

the standard. The new definition is necessary in light of OSHA’s proposal to replace the phrase “physician and nurse” in paragraph (i) 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 also discussed in the Summary and Explanation for paragraph (i). 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. One commenter, Ameren, indicated that the definition is appropriate because it is already used in other OSHA standards and reduces confusion with other OSHA standards (Document ID 0309, p. 15). No commenter opposed the proposed definition. OSHA is therefore finalizing the definition of *physician or other licensed health care professional (PLHCP)* as proposed.

Pyrophoric gas. OSHA proposed deleting the definition for *pyrophoric gas* from paragraph (c) in conjunction with its proposals to delete the reference to pyrophoric gas from the HCS definition of *hazardous chemical* and add the definition of *pyrophoric gas* to Appendix B.2, discussed earlier in this section of the Summary and Explanation. OSHA received one comment from Ameren indicating the change was acceptable (Document ID 0309, p. 15). No commenter opposed the change. OSHA is therefore deleting the definition of *pyrophoric gas* from paragraph (c).

Released for shipment. OSHA proposed 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 proposed for use in paragraphs (f)(1) and (f)(11) related to updating labels when new hazard information becomes available. This definition is similar, but not identical to, the definition used by the 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 has stored it in an area

where finished products are ordinarily held for shipment.” OSHA did not propose to include chemicals that are stored in an area where finished products are usually held but have not been packaged and labeled in the HCS 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 requested comments on whether the proposed definition is appropriate for application to the HCS. In addition, OSHA was interested in understanding whether the slight differences between OSHA’s and EPA’s definitions would pose any compliance issues for entities dealing with both OSHA and EPA labeling requirements.

OSHA received several comments on the proposed definition of *released for shipment*. SOCMA supported the proposed definition (Document ID 0447, p. 3). The Vinyl Institute also supported the definition, commenting that it reflects the realities of manufacturing operations by recognizing the occurrence of delayed or returned manufactured shipments (Document ID 0369, Att. 2, pp. 8-9).

A few other commenters were concerned that the proposed definition would cause confusion. Tom Murphy commented that workers may misunderstand the intention of the proposed definition; for example, the proposed language could be interpreted by workers as meaning products that had passed quality control testing, were correctly packaged for shipment, were “approved for presentation to the customers,” and were ready to move into inventory (Document ID 0277, p. 2). Murphy suggested that “packaged for shipment” may be a better term and would reduce misinterpretation by workers (Document ID 0277, p. 2). ACC similarly commented that *released for shipment* might be misunderstood to mean that the package “has met the business need or logistics criteria” and is ready for shipment, and suggested that OSHA adopt “packaged for shipment” or “labeled for shipment” instead (Document ID 0347, p. 9).

NACD recommended that OSHA reconsider including this definition, which they commented could create confusion and uncertainty as to whether the label must state “released for shipment.” Similar to other commenters, NACD noted that many products may be packaged and labeled but are still awaiting a final quality control check, third-party testing, or customer approval (Document ID 0329, p. 3; 0465, p. 3).

OSHA has decided not to adopt these suggestions for several reasons. First, the suggested changes would misalign the agency and EPA’s terms. Specifically, under EPA’s regulation, *released for shipment* is defined as product or stock that is packaged and labeled in a manner in which it will be distributed or sold, and the producer or distributor must provide the pesticide label to the receiver before or at the time of distribution (40 CFR Part 152.3). Many of the regulated entities who are affected by OSHA’s proposal to add a definition of *released for shipment* are also required to comply with EPA’s regulations, and OSHA does not want to cause confusion for parties who must comply with both, so OSHA finds that the proposed changes are not necessary and would be contrary to OSHA’s purpose for including this definition.

Moreover, OSHA disagrees that the definition will result in confusion. In response to NACD’s comments, OSHA does not intend for the manufacturer, importer, or distributor to include the phrase “released for shipment” on the label. The definition is only provided in paragraph (c) to help classifiers and other stakeholders understand the meaning of paragraph (f)(11). Furthermore, as is discussed in the Summary and Explanation for paragraphs (f)(1) and (f)(11), OSHA is eliminating the proposed requirement for the released for shipment date to be included on the label. Therefore, it is unnecessary for manufacturers to use the date of manufacture as a stand in for that term, as suggested by NACD. OSHA believes this clarification that the phrase “released for shipment” is not intended to be printed on the label (or anywhere on the package) may also relieve commenters’ concerns that the phrase “released for shipment” will be

confused with readiness for shipment in a business or logistical sense by individuals working in facilities where packages are stored for shipment.

Toby Threet commented that the “date of labeling and the date of release for shipment are the same thing, under OSHA’s definition” (Document ID 0279, p. 15). Since the agency is eliminating the proposed requirement to include the released for shipment date on the label, no such confusion should arise from the definition that OSHA proposed for *released for shipment*.

After considering the comments and testimony submitted, OSHA has determined that the definition for *released for shipment* should be retained in the final rule and should use the term “released” in order to align with EPA’s definition of *released for shipment* in its Pesticide Registration and Classification Procedures regulation, 40 CFR 152.3. Therefore, OSHA is finalizing the definition of *released for shipment* as proposed.

OSHA also received a few comments not related to any specific proposed definition. API commented that in general “any definitions used should align with the GHS” (Document ID 0316, p. 2). API stated that if a GHS definition is not available then the term should not be used. Alternatively, they suggested that if OSHA uses a term that is not taken directly from the GHS, then OSHA should “be transparent that the definition has not yet been harmonized in GHS and could change once harmonized” (Document ID 0316, p. 2). OSHA disagrees that only terms from the GHS should be used in the HCS. The OSHA HCS regulatory framework existed well before the GHS. While OSHA has aligned with the hazard classes of the GHS and most provisions in the annexes of the GHS that apply to occupational situations, the HCS includes additional provisions to inform and protect workers while providing a consistent framework for businesses regulated under the HCS. In addition, OSHA has been clear in both the NPRM and this final rule about the extent to which each definition aligns with the GHS.

OSHA also received a comment from PRINTING United Alliance (PRINTING) requesting the addition of a definition for “injurious corrosive material” (Document ID 0357, pp. 4-5). This is a term that appears in OSHA’s Medical Services and First Aid standard at 29 CFR 1910.151(c), not in the HCS. PRINTING expressed difficulty ascertaining which chemicals are “injurious corrosive materials” that require provision of eye wash or flushing stations pursuant to 29 CFR 1910.151(c) and asked OSHA to add a definition to the HCS similar to that used by Michigan Occupational Safety & Health Administration (MIOSHA) in a guidance document related to eyewash facilities (Document ID 0357, pp. 4-5). However, the HCS is not an appropriate location for a definition of “injurious corrosive material” because that term is not used in the HCS. Therefore, the agency will not be including this definition in the update to the HCS.

OSHA also received a comment from IMA-NA stating that OSHA should “align any definition of nanomaterials in the HCS to the EPA’s definition” (Document ID 0363, pp. 5-6). While OSHA has addressed particle characteristics, including particle size, in the context of Section 9 of the SDS in Appendix D (see Summary and Explanation for Appendix D), the agency has not proposed to add a definition of nanomaterials to the HCS and finds this comment to be outside the scope of this rulemaking.

Finally, as indicated above, OSHA received one general comment on the potential impact of several of the new or revised definitions on other standards. While Ameren commented that the definitions are generally acceptable, they also commented that they believed these new and revised definitions would impact other OSHA standards, contrary to OSHA’s assertion, and that OSHA needed to ensure that for several of the new and revised definitions they were consistently implemented in other OSHA standards. Specifically, they cited potential impacts on 29 CFR 1910.120, Hazardous waste operations and emergency response, and 29 CFR 1926.1101, Asbestos. However, Ameren did not provide any specifics as to how these two standards might be impacted.

Many of the terms that OSHA is adding or updating in this final rule are not used in the standards referenced by Ameren. Of the terms Ameren cited, only *gas* and *liquid* are used in 29 CFR 1910.120 and 29 CFR 1926.1101. In both standards, the terms are used in a very different way in contexts that make clear what is meant by the term *gas* or *liquid*. For instance, the term *gas* is used to modify the word meter (1910.120 (c)(6)(ii)) and used in reference to gas leakage in chemical protective suits (1910.120 (g)(4)(iii)). OSHA is not convinced that there will be any confusion on what is meant by the terms *gas* or *liquid* in these cases.

As stated above in the discussion under the *combustible dust* definition, while OSHA indicated in the proposal that it did not anticipate that these new definitions would conflict with or otherwise impact other existing standards for construction or general industry, the agency notes that where the same term is used but not defined in another standard, and where OSHA has guidance specific to that standard, that guidance, rather than the HCS definition, is the relevant interpretive source.

(d) Hazard classification.

Paragraph (d)(1) of the HCS outlines the requirements for chemical manufacturers and importers to evaluate the hazards of chemicals that are in the workplace or being imported to determine the hazard classes, and where appropriate, the category of each class that apply to the chemical being classified.

In the NPRM, OSHA proposed two changes to paragraph (d)(1). OSHA proposed 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* (emphasis added to indicate the proposed new language). The intent of the language that OSHA proposed was to simply reiterate the scope language currently in paragraph (b)(2) and OSHA's longstanding

position that hazard classification must cover hazards associated with normal conditions of use and foreseeable emergencies. As OSHA explained in its compliance directive for the HCS (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 proposed 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 believed adding this language to be necessary because there had been some confusion about whether chemical reactions that occur during normal conditions of use must be considered during classification and whether this information should be placed on the label and/or the SDS. This issue has arisen, 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. The intent of this proposed new language was to ensure that manufacturers and importers understood what information should be on the label (hazards associated with the chemical as shipped, including changes in physical form) versus what belonged on the SDS (all hazard information including information on hazards created through downstream use), and OSHA accordingly proposed a change in paragraph (f)(1) as well to reflect the new language in (d)(1). In addition, the proposed new language better aligns with international trading partners' label requirements under REACH and WHMIS and provides consistency on where this information is located so workers can easily find the information.

OSHA received several comments agreeing on the need for clarification about the requirements related to classification of hazards resulting from downstream uses.

NABTU agreed that OSHA's clarification on the hazards covered under (d)(1) would

help workers find information more quickly and minimize mistakes, as well as aid in training, because it would improve consistency in the location of information (Document ID 0425, Tr. 37). Additionally, NABTU provided several examples where hazards created by chemical reactions as part of the intended use of the product were not being conveyed consistently and, in some cases, not at all (see, e.g., Document ID 0450, Att. 2, p. 5). NABTU provided safety data sheets for spray foams, epoxies, and cement where a chemical reaction occurs in downstream workplaces following the manufacturer's instructions. The information on the SDSs for these chemicals does not differentiate the hazards of the original chemical versus the hazards the worker might be exposed to through prescribed use of the product (see, e.g., Document ID 0450, Att. 2, p. 5). Additionally, California's Department of Industrial Relations, Division of Occupational Safety and Health (Cal/OSHA) provided the example of a hair smoothing product used in professional hair salons where the intended use of the product created different hazards due to chemical reactions (formation of formaldehyde during use which caused various adverse health effects) than the hazards associated with the original chemical. In this case, these hazards were not identified on either the label or the SDS (Document ID 0451, pp. 3-4). Without this information, downstream users are unaware of the potential exposures and therefore do not have the information necessary to adequately protect themselves. NIOSH also supported the change and said that it would be helpful for worker safety and health (Document ID 0281, Att.1, p. 6).

However, OSHA also received numerous comments indicating that OSHA's proposed language could be misunderstood and cause confusion on what would be required under paragraph (d)(1). Many of these commenters opposed inclusion of the proposed language as written. Based on the comments received, as explained further below, OSHA is modifying the proposed language to more clearly articulate OSHA's intent for the scope of this requirement as well as to better distinguish between hazards

associated with the chemical as shipped and hazards associated with downstream use. Specifically, OSHA is deleting the phrase “under normal conditions of use and foreseeable emergencies.” The agency is adding at the end of (d)(1) the phrase “The hazard classification shall include any hazards associated with the chemical’s intrinsic properties including:” and then adding two subparagraphs, (d)(1)(i) and (d)(1)(ii).⁵⁶ New paragraph (d)(1)(i) reads, “a change in the chemical’s physical form and;” and new paragraph (d)(1)(ii) reads, “chemical reaction products associated with known or reasonably anticipated uses or applications.” OSHA is also changing the language in paragraph (f)(1) to clarify that hazards identified and classified under new paragraph (d)(1)(ii) will not be required to appear on a product’s label (see the Summary and Explanation for paragraph (f)(1)). Changes in Appendix D clarify that hazards identified and classified under both paragraphs (d)(1)(i) and (d)(1)(ii) must be included in Section 2 of the product’s SDS. As stated above, OSHA considers the language, as finalized, to be a rephrasing of the language proposed in the NPRM to more clearly articulate OSHA’s intent and not a substantive change from what OSHA originally intended in the NPRM or the preexisting requirement to incorporate downstream uses. The rest of the section therefore still relies on previous guidance and statements OSHA made regarding “normal conditions of use and foreseeable emergencies” to support the language OSHA is finalizing in this rule.

In the following discussion, OSHA addresses the comments received on paragraph (d)(1), separated by theme.

I. Arguments that the HCS has historically not required manufacturers to classify chemicals due to hazards related to downstream use,

⁵⁶ Throughout this section and in the regulatory text, OSHA refers to the “intrinsic” properties of chemicals. OSHA considers this to be synonymous with “inherent” properties, a term used by some commenters and in the original HCS.

Several stakeholders commented that the HCS historically has not required manufacturers to classify hazards based on downstream reactions (Document ID 0318, pp. 3-4; 0325, pp. 7-15; 0326, p. 3; 0337, p. 2; 0314, pp. 4-5; 0348, p. 2; 0356, p. 7; 0369, p. 4). For example, ACC stated, “[n]ot only is OSHA’s approach incompatible with the current language of the HCS, it is not supported in the text or regulatory history of the HCS” (Document ID 0347, p. 3). ACC quoted OSHA’s preamble from the 2012 update, where OSHA stated that manufacturers and importers have greater knowledge and expertise with regards to the composition of the chemicals they make or import than do downstream employers and are usually in the best position to assess the intrinsic hazards associated with them, whereas downstream employers are usually in the best position to determine the risk arising from the use of the chemical in their workplaces (Document ID 0347, p. 3). ACC also quoted OSHA’s compliance directive, where OSHA acknowledges that downstream users who alter the product become the manufacturer and become the responsible party, so would need to consider all the known or intended uses of the products when classifying for hazards. ACC commented that OSHA has not identified any guidance documents that would support the agency’s interpretation of (d)(1) (Document ID 0347, pp. 2-3). Additionally, PLASTICS indicated that OSHA has not historically required manufacturers to classify the hazards of by-products produced during downstream use of a chemical. PLASTICS provided several examples dating back to 2004 indicating that OSHA did not intend to have the byproducts included in the hazard determination process or that the downstream employer was responsible for the hazard determination process for byproducts. PLASTICS also indicated that OSHA has been unclear and that various guidance documents have appeared to be inconsistent in their discussion of the scope of the hazard classification process (Document ID 0314, Att. 1, pp. 4-9).

NAIMA suggested that OSHA should address the hazard classification revision in a separate rulemaking, and request information from the regulated community. NAIMA viewed the proposed changes as OSHA's attempt to impose new burdens and regulatory changes in the guise of harmonizing the HCS with the GHS (Document ID 0338, p. 9).

OSHA disagrees that the HCS has not historically required manufacturers to identify hazards related to downstream uses of the chemical they produce or provided any guidance to this effect. While ACC is correct that OSHA, in the preamble to the 2012 HCS, distinguished between the relative knowledge of manufacturers and downstream employers, ACC neglected to include in their comment the paragraph immediately following the one it quoted. That paragraph states: "OSHA's approach in promulgating the HCS reflects this reality. It places the duty to ascertain and disclose chemical hazards on manufacturers and importers, so that downstream users can use this information to avoid harmful exposures to chemical hazards. But because manufacturers and importers will often have less information about the particular exposures of downstream users, their hazard assessment and communication obligations are imposed only for *all normal conditions of use of their chemicals and foreseeable emergencies* associated with those chemicals" (emphasis added) (77 FR 17601-02). Additionally, during the 2012 rulemaking, in paragraph (a)(1) OSHA changed the language to specify that the purpose of the HCS is to ensure classification of hazards, rather than merely assessment or evaluation of them, further indicating that the language in the scope section regarding normal conditions of use and foreseeable emergencies was intended to apply to the classification process, not just assessment of hazards more broadly (77 FR 17693). Thus, the 2012 HCS did, in fact, contemplate that manufacturers would classify their chemicals for hazards associated with these types of downstream uses.

This concept has been part of the HCS since the beginning. As indicated in the preamble to the 1983 HCS, stakeholders raised concerns then regarding responsibility for

providing information on MSDSs (now referred to as SDSs) that only the downstream employer could know. In response, OSHA agreed that “[t]he chemical manufacturer or importer, in making hazard determinations, should evaluate and communicate information concerning all the potential hazards associated with a chemical, whereas the employer may supplement this information by instructing employees on the specific nature and degree of hazard they are likely to encounter in their particular exposure situations” (48 FR 53296). The preamble of the 1983 HCS went on to explicitly state “[t]herefore, the chemical manufacturer must provide thorough hazard information, which would be applicable to a full range of reasonably foreseeable exposure situations, rather than limiting the information on the basis of presumed use. The downstream employer will then be assured of having the information reasonably necessary to make informed choices for control measures” (48 FR 53307). When OSHA updated the HCS in 2012, it replaced the hazard determination process with the hazard classification process and indicated that hazard classification was “very similar to the process of hazard determination that is currently in the HCS, with the exception of determining the degree of hazard where appropriate” (58 FR 17698).

Another example of OSHA’s longstanding view that manufacturers must consider downstream hazards is found in a 1994 LOI regarding normal conditions of use for wood products. The LOI stated that wood and wood products are exempt from the hazard communication standard as articles “if the only hazard presented from use of the product is flammability or combustibility, which are hazards that are well-known among users of wood products. However, it may not be generally known among users that inhalation of certain types of wood dust or chemicals used to treat wood can present a serious lung disease hazard. For this reason, OSHA has always required under the hazard communication standard that distributors of wood products provide MSDS to employers whose employees may be exposed to these inhalation hazards” (available at

<https://www.osha.gov/laws-regs/standardinterpretations/1994-12-05>). As in 1994, OSHA does not intend that every possible downstream use be accounted for, only those that are known or can be reasonably anticipated. This policy was reiterated in a 2016 LOI which stated that manufacturers “must make a reasonable effort to obtain reliable information to determine how their product(s) or by-product(s) may expose workers under normal conditions of use or in foreseeable emergencies. A manufacturer’s or importer’s hazard classification must anticipate the full range of downstream uses of its products and account for any hazardous by-products that are known to be present and may be formed” (available at <https://www.osha.gov/laws-regs/standardinterpretations/2016-05-20>). The LOI went on to state that manufacturers are not required to contact every downstream workplace to obtain this information, but a reasonable effort should be made.

Finally, contrary to ACC’s and PLASTICS’ assertions, OSHA guidance documents have included in the hazard determination step that “[a]ll possible physical or health hazards that might be associated with a chemical’s use must be considered,” including in OSHA’s 2007 Guidance For Hazard Determination (available at <https://www.osha.gov/hazcom/ghd053107>). This concept was carried forward into the 2015 HCS compliance directive which also indicates that manufacturers must consider downstream uses of their chemicals when classifying. For example, the directive, which provides in-depth guidance on how to apply the criteria for classification, explains that a HNOC means an adverse physical or health effect that is not covered under one of the existing hazard classes in the standard. The directive then explains that: “The term physical effect generally refers to a material impairment of health or functional capacity caused by the intrinsic hazard(s) of a particular chemical in normal conditions of use or foreseeable emergencies” (Document ID 0007, pp. 19-20). These statements in combination make clear that OSHA expected the hazards of downstream uses to be

accounted for in the classification process. Additionally, what PLASTICS identified as inconsistency in OSHA's guidance actually represents its misinterpretation of the level of knowledge that can be expected from a manufacturer, importer, or distributor in two different scenarios: one where the chemical in question is used downstream to manufacture other chemicals and the other where the chemical is used by end-users. However, the confusion that PLASTICS points to is exactly why OSHA has decided to clarify in this final rule the scope of this existing obligation.

Additionally, OSHA has enforced the HCS in accordance with this understanding of the obligations to label for downstream hazards, which further reinforces the longstanding nature of this requirement. For instance, in 2011 and 2012 OSHA cited a number of manufacturers under the HCS for failing to communicate the hazards of formaldehyde exposure to salons, stylists, and consumers using hair products containing that chemical (see <https://www.osha.gov/hair-salons/government-response>).

As indicated above, OSHA has determined that the language it originally proposed to add to paragraph (d)(1), which would have stated that 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, is insufficiently precise, and is therefore adopting revised language in this final rule. The final language provides that hazard classification "shall include any hazards associated with the chemical's intrinsic properties including: (i) a change in the chemical's physical form and; (ii) chemical reaction products associated with known or reasonably anticipated uses or applications." This language in the final rule ties a responsible party's classification obligations to what the manufacturer, importer, or distributor knows or can reasonably anticipate and avoids the concerns that several commenters raised that the language was too vague (see, e.g., Document ID 0368, pp. 3-4; 0402, p. 1; 0283, p. 13; 0461, pp. 2-3; 0315, pp. 3-4; 0313, p. 3). Stakeholders should be familiar with the term

“reasonably anticipated” because OSHA has used similar language in multiple standards, guidance products, and LOIs, including the bloodborne pathogens standard (29 CFR 1910.1030), the respirable crystalline silica standard (29 CFR 1910.1053), and the hazardous waste operations and emergency response standard (29 CFR 1910.120). Moreover, this term is commonly used by other agencies as well; for example, the National Toxicology Program (NTP) uses “reasonably anticipated” as a classification for carcinogens (reasonably anticipated to be a human carcinogen) (86 FR 72988). EPA’s TSCA regulations (40 CFR 723.250) also use the term “reasonably anticipated” in their scoping language: “Reasonably anticipated means that a knowledgeable person would expect a given physical or chemical composition or characteristic to occur based on such factors as the nature of the precursors used to manufacture the polymer, the type of reaction, the type of manufacturing process, the products produced in polymerization, the intended uses of the substance, or associated use conditions (40 CFR 723.250).”

II. Arguments that classification should be based on inherent or intrinsic hazards.

OSHA received multiple comments from a variety of stakeholders stating that hazard classification is based on the intrinsic or inherent properties of the chemical and the proposed changes in paragraph (d)(1) go beyond the meaning of intrinsic or inherent properties (Document ID 0303, p. 1; 0347, pp. 2-3; 0322, p. 14; 0424, Tr. 116, 117, 138, 195, 205; 0366, p. 3; 0323, pp. 2-5; 0214, pp. 1-15).

OSHA agrees that the intention of the hazard communication standard is to provide information based on the intrinsic or inherent hazards of the chemical that are presented in the workplace and that are not tied to the level of exposure to the chemical, but disagrees that the change in paragraph (d)(1), either as proposed or as finalized here, goes beyond the meaning of intrinsic or inherent hazards. In final paragraph (d)(1), OSHA has made explicit that hazard classification under the HCS should be based on the intrinsic properties of the chemical to which workers are exposed. As finalized, paragraph

(d)(1) also identifies two examples of intrinsic properties: changes in the chemical's physical form and chemical reaction products associated with known or reasonably anticipated uses or applications. Label and SDS preparers must consider both when classifying the chemicals they produce, import, or distribute. These examples are consistent with OSHA's longstanding interpretation of intrinsic properties or hazards.

To clarify the meaning of intrinsic hazards, OSHA provided several examples in guidance issued in 2015 and 2016 regarding what the agency would consider non-intrinsic hazards (Document ID 0007, p. 20; 0008, p. 385). For instance, the agency explained that hazards due to scalds caused by exposure to chemicals at high temperatures and slips and falls caused by treading on a solid chemical shaped in a rounded form or spilled liquids are not physical effects caused by the chemical's intrinsic properties under the HCS. Any substance that is heated to high temperatures can cause a scald, and any spilled liquids could be a slip hazard. Intrinsic hazards are hazards that are derived from the essential nature or character of the substance, reaction product, or mixture, which would not simply be true of any substance under those conditions. Even prior to adopting the GHS in 2012, OSHA had identified intrinsic hazards as the basis for identification and hazard determination for the information on the labels, SDSs, and worker training. OSHA is not deviating from this approach. How a chemical will behave when its physical form changes and what chemical reaction products form when it is used downstream are based on the properties that are intrinsic to that chemical and would not be true of simply any substance under those circumstances, and thus fall within OSHA's conception of what constitutes an intrinsic hazard.

Michele Sullivan suggested that the agency should instead take a two-pronged approach to address the issue of inherent hazards and require 1) classification of chemicals as shipped, with hazard class and category and 2) inclusion of hazards or warnings, rather than classification, for chemical products with directions for downstream

use, such as kits (Document ID 0366, p. 3). OSHA does not agree with this approach because it incorrectly applies the idea of intrinsic hazards as a more limited concept, and the agency believes that the language “known or reasonably anticipated uses or applications” cabins the breadth of the language in (d)(1)(ii) so that it is feasible for manufacturers, importers, and distributors to classify in accordance with the requirements.

As noted above, to address these concerns, OSHA is updating the regulatory text to include the term “intrinsic” in (d)(1) to clarify that the hazard information required is based on classification of hazards related to the intrinsic properties of the chemicals workers are exposed to. The agency believes that this clarifies OSHA’s intent that the hazard be of an intrinsic nature and that it considers hazards from both changes in the chemical’s physical form and chemical reaction products associated with downstream use to be related to intrinsic properties.

III. Arguments that the proposed revision to (d)(1) would shift the burden from downstream users to the originating manufacturer (or upstream).

Several commenters expressed concern that OSHA’s proposed changes to paragraph (d)(1) would improperly shift the responsibility for determining and classifying chemical hazards from downstream users, such as manufacturers and employers that process chemicals, to the original manufacturer of the chemical (Document ID 0314, p. 2; 0323, p. 3; 0326, pp. 4-5; 0337, p. 2; 0347, p. 2; 0423, Tr. 134; 0348, pp. 1-2; 0404, pp. 3-4; 0361, p. 1; 0362, pp. 2-3; 0329, p. 8; 0287, p. 6). For example, ACMA noted that “. . . unlike the PSM standard where the responsibility for the analysis is properly placed on the employer operating the covered process, OSHA’s proposal would shift that obligation upstream to each of the multiple chemical manufacturers or importers who supplied a reactant in the downstream chemical reaction” (Document ID 0318, p. 9). The Vinyl Institute noted that “[a] broad expansion of the scope of the hazard classification of the

upstream supplier to reflect the hazards of downstream chemical reactions and the products of those reactions (including “foreseeable emergencies”) would be inappropriate. It would shift the responsibility from where it belongs (on the downstream manufacturer) to an upstream supplier who generally has not specified the chemicals to be used in the downstream reaction, has not designed the process chemistry, has not designed the process equipment in which the reaction occurs, has no control over the operation of the process and has no idea what other chemicals in the facility might be involved in what might be a foreseeable emergency from the perspective of the downstream manufacturer-employer” (Document ID 0369, p. 5). NACD stated that determining downstream hazards is outside the scope of responsibilities for a distributor or producer under the standard and that it is downstream employers who, under the HCS, bear the responsibility to conduct hazard assessments that apply to their own workplaces. NACD also commented that any chemical that can be mixed with a wide range of other chemicals could have an exponentially long and unknown list of hazards that “result from a chemical reaction” and that such hazards cannot reasonably be documented by an upstream user (Document ID 0465, p. 4). The Council of Chemical Association Executives (CCAE) provided similar comments (Document ID 0469, p. 2). Dow stated that the concept of classifying reaction products is overly broad and expands OSHA’s existing requirement for manufacturers to assess chemical hazards of the product as manufactured and shipped (Document ID 0359, p. 2).

OSHA disagrees that the proposed new language in paragraph (d)(1) shifts any burden from the downstream user to the manufacturer. First, as explained above, the revisions to paragraph (d)(1) clarify the existing requirements for hazard classification and do not create new requirements. Regardless, the intent of the new language is not to require manufacturers, distributors, or importers to predict how downstream employees will be exposed to a chemical or to anticipate every conceivable way the chemical could

be used, but rather to classify the chemical for hazards that arise through known or reasonably anticipated uses, thereby providing downstream users with sufficient information to perform a hazard assessment specific to their own workplace and how employees use the chemical there. As described above, OSHA has revised the language in this final rule to better reflect this intent. OSHA agrees that downstream users still must assess whether the specific processes they use will cause hazards in the workplace and is only adding this language to clarify that if the upstream manufacturer, distributor, or importer is aware of hazardous chemical reactions with the known or reasonably anticipated uses of its product it must include hazard classifications for those hazards.

IV. Arguments that the proposed change to (d)(1) would be infeasible or overly burdensome to manufacturers as it would require knowledge of all the downstream uses to classify correctly.

Many comments indicated that it would be infeasible or extremely burdensome for manufacturers, distributors, and importers of chemicals to learn all downstream uses of products and correctly classify them accordingly (Document ID 0291, pp. 5-6; 0303, p. 2; 0314, p. 10; 0315, p. 3; 0316, pp. 3-4; 0317, pp. 2-3; 0318, pp. 4-5; 0319, pp. 1-2; 0323, p. 3; 0324, p. 2; 0327, p. 7; 0347, Att. 1, pp. 2-4; 0468, pp. 1, 3; 0348, p. 2; 0356, pp. 7-9; 0357, pp. 1-3; 0359, p. 2; 0363, pp. 3-4; 0366, p. 3; 0367, p. 4; 0329, p. 2; 0369, p. 6). For example, Worksafe stated that “[b]oth ‘normal conditions of use’ and ‘foreseeable emergencies’ are largely unknowable by producers” (Document ID 0354, p. 4). HCPA also stated that it is not practical to list every potential hazard of the cleaning product which could interact with any number of unknown soils when used by downstream consumers (Document ID 0327, pp. 7-8; 0424, Tr. 15-17).

NAIMA asserted that under the proposed new language, the upstream chemical manufacturer or supplier would be responsible for performing a chemical process hazard analysis and hazard classification for each downstream chemical reaction and the reaction

products of that downstream chemical reaction conducted by a downstream customer or manufacturer. NAIMA stated that downstream reactions typically involve at least two chemicals, and often mixtures, that would require multiple manufacturers' suppliers to provide redundant and overlapping chemical process hazard analysis and hazard classification to all of these downstream manufacturers. They also noted this same requirement would also apply upstream to the suppliers' suppliers, and "the real world problem with such astounding overreach is it is unlikely that any manufacturers will take the risk of such a convoluted and impossible evaluation" (Document ID 0338, p. 10).

Dow also stated that proposed changes implied that the manufacturer and SDS preparer are responsible for knowing all foreseeable downstream uses of the substance, including chemical reactions and resulting chemicals generated, that could occur in the downstream supply chain with that substance. Dow suggested that to require this level of knowledge would present a significant compliance challenge for chemical manufacturers because manufacturers cannot reasonably know all possible resulting chemical reactions and uses by downstream users and the hazards they may create. Dow further explained that the hazards created by manufacturing and the resulting chemical reactions are the responsibility of the manufacturer performing that manufacturing, as they are the experts in the product and the chemistry they are performing (Document ID 0359, pp. 1-2).

NACD commented that its members do business in different markets, which makes it difficult for them to ascertain every type of downstream use that could be considered normal conditions of use. NACD stated that it is impractical for a manufacturer or distributor to know all possible uses, hazards, or potential reactions associated with downstream customers, and manufacturers should be only responsible for communicating the hazards present in the form of the chemical as sold (Document ID 0329, p. 8; 0423, Tr. 128-130; 0465, p. 4).

Innovative Chemical Technologies (ICT) stated that a chemical producer cannot adequately guess all possibilities and then analyze those scenarios for hazards to include on the SDS because a reaction results in one or more new chemical substances, which may be more or less hazardous than the reactants. ICT expressed concern that compliance with the proposed revision would require chemical producers to essentially do a portion of a process hazard analysis (PHA) for reaction products, focused on customer sites that it does not own or control (Document ID 0324, p. 2). ACMA and PLASTICS submitted similar comments (Document ID 0314, Att. 1, p. 12; 0318, p. 8). OSHA notes that ACMA also asserted in their comment that the proposed language in paragraph (d)(1) is economically infeasible but did not provide financial data to corroborate the assertion. As explained in Section VI.G., Economic Feasibility and Impacts, OSHA has determined based on the record evidence that the requirements of this final rule are economically feasible.

After reviewing the concerns expressed in the numerous comment submissions on this provision, OSHA concludes that the agency's intention was not clear as written and was therefore misinterpreted. OSHA did not intend for an upstream supplier or manufacturer to identify every conceivable use or process in which a downstream user might apply the chemical and to classify these potential hazards of chemicals downstream. OSHA's intent was to ensure classification only for those downstream uses where the manufacturer knows or could reasonably anticipate how the chemical will be used and where that use creates a hazard that needs to be communicated in the workplace. The record demonstrates that manufacturers have basic information on how their chemicals will be used by downstream users and markets to those uses. For instance, many chemical manufacturers have product stewardship programs to address these very issues (Document ID 0443, p.1; 0330, p.1). However, the agency is also aware that product research and new uses will continue to be developed and that some chemicals

have so many uses it would be difficult to anticipate them all. Therefore, the agency finds it would be unreasonable to expect manufacturers to predict and account for every possible use downstream. For example chemicals, such as toluene, that are often used as starting materials for manufacturing other chemicals, would likely have too many possible uses for the upstream chemical manufacturer to know or reasonably anticipate the ways that it could be combined with other chemicals. OSHA would not expect manufacturers of toluene, for instance, to classify hazards of the products that use toluene as a starting material in the manufacture of a downstream user's products. However, manufacturers of toluene would still need to ensure that the SDS had the appropriate information in Section 10 on stability and reactivity that would help those downstream manufacturers consider the risks of their specific processes.

Therefore, as explained above, OSHA has modified the language to better reflect the agency's intent that hazard classification should encompass hazards present during downstream uses or applications that are known or reasonably anticipated by the manufacturer, importer, or distributor, such as the intended use for which the substance is manufactured.

Moreover, OSHA received comments describing situations where not only would it be feasible for manufacturers to include hazard information regarding known or reasonably anticipated uses or applications, it would also greatly improve worker safety. Cal/OSHA provided several examples of uses of materials that manufacturers should have been aware of but did not include on the SDS (Document ID 0322, pp. 13-14; 0375, pp. 13-14). One such use was an aerosol degreaser used in automotive repair facilities that was linked to cases of neuropathy in automotive repair technicians. Cal/OSHA stated that it was standard practice in the industry for the technicians who were assigned the dirtiest jobs in an automotive repair facility to use between six and 10 cans of degreasing solvent products in just one day (Document ID 0322, pp. 13-14; 0375, pp. 13-14). The

agency finds that this example shows the utility of the new language in paragraph (d)(1) because not only does it illustrate the intrinsic hazard presented by the product, but demonstrates that this type of use would be “reasonably anticipated” to a manufacturer familiar with the automotive repair industry, given Cal/OSHA’s findings that this was a pervasive practice in that industry.

Cal/OSHA also provided an example of workers in hair salons being exposed to excessive amounts of formaldehyde formed as a reaction product to hair straightening products used in the salons (Document ID 0451, Att. 1, pp. 3-4). Cal/OSHA had submitted this as an example of their concerns that the proposed language “normal conditions of use” would “open the door for producers – without sufficient downstream information – to *not* disclose a chemical based on the assumption that under ‘normal conditions of use,’ no health-hazardous exposures would occur,” concerns which Worksafe echoed in their comments (Document ID 0451, p. 2; 0354, p. 1). However, OSHA finds just the opposite, particularly with respect to the revised language that the agency is adopting in this final rule. Since the conditions described by Cal/OSHA are apparently commonplace in the salon industry, the formaldehyde hazard would result from a “known or reasonably anticipated use” for a manufacturer or distributor familiar with that industry and would therefore be encompassed by paragraph (d)(1). OSHA believes that clarifying hazard classification requirements under paragraph (d)(1) will ensure that manufacturers, distributors, and employers understand how to meet their obligation to disclose this information to workers and that workers will be better protected.

Additionally, OSHA received examples of product stewardship programs and SDSs that demonstrate companies are aware of and able to determine the uses of their products, which further underscores the feasibility and utility of requiring them to identify known or reasonably anticipated uses. NIOSH also indicated that both individual

manufacturers and coalitions have product stewardship programs, which allow sharing of information related to product uses, and cited ACC's "Responsible Care" program as an example. NIOSH described these programs as a "great tool" for hazard communication (Document ID 0423, Tr. 39; 0456, Att. 2, p. 2). ACC, in its post hearing comments, also discussed at length the various ways that some of their members engaged with downstream users to ensure safety information was thoroughly provided, including on-site training, customer notification letters, surveys and questionnaires, and indicating additional information on the SDS regarding typical reactions (Document ID 0468, p. 5). NABTU also provided examples of SDSs and product stewardship programs that account for downstream uses of chemicals (Document ID 0450, Att. 7).

In conclusion, OSHA agrees with commenters that it would not be possible for every manufacturer, importer, and distributor to be aware of every single use or application of its products, and the agency is not requiring these entities to do the kind of intensive investigations that many of the commenters described as infeasible. Additionally, regulated parties will not immediately be aware of all uses when new products are developed or when there are trade secret issues with downstream users. Similarly, OSHA would not expect a manufacturer to know every use of feedstocks (raw materials used to make other chemical products), starting materials or commodity chemicals, solvents, reactants, or chemical intermediates where there could be thousands of uses or the substances are used in downstream manufacturing to produce new chemical products. However, the agency concludes that manufacturers must make a good faith effort to provide downstream users with sufficient information about hazards associated with known or reasonably anticipated uses of the chemical in question. As discussed above, OSHA is finalizing language to make this clear, and to tie the classification obligation to either the manufacturer, importer, or distributor's own knowledge or facts that the manufacturer or importer can reasonably be expected to know.

V. Arguments that it would be impossible to correctly classify uses due to downstream manufacturers' trade secret/CBI issues.

Several commenters suggested that full classification might not be possible in situations where downstream users may not share usage information due to confidential business information (CBI) or trade secret concerns (see, e.g., Document ID 0291, pp. 5-6; 0324, p. 2; 0326, p. 4; 0337, pp. 2-3; 0348, p. 4; 0363, p. 4; 0367, p. 4; 0369, p. 5; 0347, p. 2; 0468, p. 3). OSHA would not consider a manufacturer or supplier to know or be able to reasonably anticipate a downstream use if the downstream user uses the chemical in a proprietary process, producing derivatives that are trade secrets. Therefore, this situation would not trigger the classification requirements under paragraph (d)(1).

VI. Arguments that this would lead to duplicative classification.

ICBA and others expressed concern about how OSHA's proposed new language in paragraph (d)(1) would apply to chemicals like carbon black, which are typically sold in bulk quantities for use in a multitude of different downstream products. ICBA noted that because those downstream products also contain various other substances, all of the upstream manufacturers of the ingredient substances would have to "independently and duplicatively classify[] downstream products," which would be inefficient and could lead to "divergent hazard classifications of the same product" (Document ID 0291, p. 6; 0318, p. 2-9; 0348, pp. 1-4; 0461, pp. 1-2). ICBA stated that "the downstream user is in the best position to classify its own product." Similarly, NAIMA stated that "It is unclear how manufacturer-suppliers and manufacturer-users would resolve a situation in which multiple suppliers of reactants used in a particular downstream chemical reaction are required to perform a hazard classification for that reaction and reach different conclusions, which seems likely for any chemical with broad uses" (Document ID 0338, p. 3).

OSHA agrees that manufacturers of chemicals are responsible for the classification of their own chemical products. As discussed above, OSHA's intent in adding clarifying language to paragraph (d)(1) was not to require upstream manufacturers to engage in hazard analyses with respect to products created downstream, but rather to ensure that upstream manufacturers provide sufficient hazard information about their own products so that downstream users have the information they need to conduct their own hazard analyses and/or take other appropriate action. This will not result in duplicative or divergent classification because the manufacturers, importers, and distributors will not be required to do hazard classification unless they know or could reasonably anticipate the uses with sufficient information to classify the hazard. ICBA and NAIMA's concerns about duplicative classification rest on the assumption that the responsible party will be required to learn the processes of every downstream user and perform hazard classification for each process, but as OSHA has clarified above, that is not the case. Additionally, this change would not decrease the quality of information provided to workers. On the contrary, as indicated in the 1983 HCS, when manufacturers provide thorough hazard information, applicable to a full range of reasonably foreseeable uses, downstream manufacturers and employers will have the information necessary to make informed choices for control measures without limiting the downstream manufacturer from providing additional information as warranted (48 FR 53307).

VII. Arguments that the information is already covered under other specific sections of the SDS.

The clarifying changes OSHA is making to paragraph (d)(1) also clarify the requirements of Section 2 of the SDS because that section requires the presentation of hazard information for chemicals. Accordingly, several commenters provided comments relevant to paragraph (d)(1) as it relates to the SDS. Several stakeholders commented that the information OSHA proposed to clarify is required in section 2 of the SDS is already

covered in other sections of the SDS (Document ID 0303, p. 2; 0347, p. 2; 0468, Att. 2, p. 12; 0361, p. 1; 0329, pp. 7-8; 0356, p. 6; 0467, p. 4). Tom Murphy commented that there are limits to the concept of “foreseeable” in the context of an emergency and that the information is better covered under paragraph (h) *Employee information and training* and placed under section 10(c) of the SDS (Document ID 0277, p. 3). The American Welding Society (AWS) commented that “current requirements are adequate to ensure that manufacturers continue to warn about the general nature of the anticipated physical and health hazards arising out of product use, as appropriate, in Sections 2, 8, 10 and 11 of the product Safety Data Sheet” (Document ID 0303, p. 2), while ACC commented that “the requirement is unnecessary as these hazards are already identified in sections 5, 9, and 10 of the SDS. Anything beyond that is unrealistic and entirely speculative” (Document ID 0467, Att. 2, p. 14). ILMA commented that this information should be in section 11 and section 15 (Document ID 0356, p. 6). The Archer-Daniels-Midland Company (ADM) and PLASTICS stated that this information should be in other sections without further explanation (Document ID 0361, p. 1; 0467, p. 11).

As OSHA discussed in the 2012 update to the HCS, the standardization of the SDS format improves the effectiveness of the SDS by providing a format that makes it easier for users to find information (77 FR 17596). Additionally, the information commonly wanted and used by employees, and of the greatest interest for emergency responders is presented early in the SDS while more complex or technical information is presented later (58 FR 17596). While it is true that similar, but not identical, information may be contained in multiple sections of the SDS and used for different purposes and potentially by different readers of the SDS, the changes to paragraph (d)(1) specifically require Section 2 to contain information on hazards resulting from a change in the chemical’s physical form and from chemical reaction products when they are known or can be reasonably anticipated. Although there does exist some overlap between Section 2

and Section 10, Section 2 provides workers with necessary, easily understandable health and safety information, whereas Section 10 provides health and safety professionals information on when and how to design safety systems to protect workers. Similarly, Section 5 of the SDS provides information on fire-fighting measures which are specific to types of hazards related to fire; Section 8 provides information on exposure controls and personal protection but does not indicate the actual hazards associated with the chemicals; Section 11 provides information on stability and reactivity of a chemical which is used primarily by medical professionals, occupational health and safety professionals, and toxicologists (Document ID 0060, p. 394); and Section 15, which is a non-mandatory section, permits additional information on regulatory requirements. Therefore, Section 2 is the appropriate location for information about actual hazards and the specific hazard classifications that workers can easily access. For more detailed discussion on the various sections of the SDS, please see the Summary and Explanation for Appendix D.

VIII. Arguments that the proposed paragraph (d)(1) does not align with the GHS or international trading partners.

Several stakeholders commented that the language proposed in the NPRM does not align with international trading partners, or the GHS (Document ID 0314, pp. 12-13; 0326, p. 3; 0338, p. 2; 0348, p. 3; 0362, p. 1; 0369, pp. 5-7; 0366, p. 1; 0347, pp. 4-5; 0468, Att. 2, p. 12). AWS stated that the GHS uses the term “hazard classification” to indicate only intrinsic properties of substances (or mixtures). AWS said these hazardous properties are based on the hazards exhibited in the form substances (or mixtures) are purchased, shipped, and received in commerce, not from subsequent use in the workplace. AWS urged OSHA to “not deviate from the principles of classification based upon intrinsic hazards and be consistent with the reasoned approach taken by the authors of the GHS” (Document ID 0303, p. 2). Hach made the same point (Document ID 0323,

pp. 4-5). Similarly, NACD commented that since the proposed requirements in the SDS are not included in the GHS, the proposal would make OSHA's requirements more divergent from the global system rather than aligning with it (Document 0465, p. 5). ACC stated that "the requirement is not part of the GHS, so rather than facilitating alignment, the change would have the opposite effect of making the U.S. rules even more divergent from the global system" (Document ID 0468, Att. 2, p. 12). The Vinyl Institute commented that the language proposed in the 2021 NPRM was in contrast to language in the EU CLP citing Article 5: "The information shall relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used" (Document ID 0369, pp. 6-7).

Contrary to commenters' arguments, the GHS does not specify that it only applies to chemicals in their shipped form or in commerce; it states that it applies to all hazardous chemicals across stages in their life cycles (Document ID 0060, p. 5). As explained above, OSHA believes commenters have conflated the idea of intrinsic or inherent hazards with hazards of a chemical as shipped. Additionally, OSHA opined on the development and implementation of the GHS in the 2012 rulemaking to update the HCS. As discussed there, in developing the GHS, it was recognized that countries' regulatory authorities would need to have the discretion to address national circumstances in ways that are suited to the regulatory perspective of the country. Thus, authorities such as OSHA are free to make determinations about scope and application issues while still being harmonized with the primary provisions of the GHS (58 FR 17695). Therefore, OSHA disagrees with the commenters' premise that any difference between the HCS and the GHS means that OSHA is improperly deviating from the GHS or from its trading partners.

In any event, OSHA interprets the EU CLP differently than the Vinyl Institute and finds the changes to paragraph (d)(1) actually align with similar provisions in other

jurisdictions since the CLP guidance quoted by the Vinyl Institute explicitly requires consideration of “reasonably expected use” during the classification process (Document ID 0256, p. 55).

Additionally, since a number of other countries separately regulate hazards of chemicals as shipped and chemicals in the workplace, OSHA is improving alignment of labels with other countries that may only regulate hazards of chemicals as shipped by clearly stating that hazards related to downstream use only need to be on the SDS.

Therefore, the agency believes that the inclusion of this language actually strengthens trading relations because it better aligns the HCS with international jurisdictional requirements for labeling and workplace hazard communication.

IX. Arguments that proposed paragraph (d)(1) will result in expansion of tort liability for manufacturers.

Several commenters stated that the proposed changes to paragraph (d) would expand tort liability for manufacturers (Document ID 0314, p. 12; 0326, p. 4; 0366, p. 3; 0369, p. 4). Hach commented that “expanded legal obligation to perform hazard classifications at the downstream levels creates more opportunities for inadequate hazard communication,” which could cause plaintiffs’ attorneys to pursue claims against upstream manufacturers (Document ID 0323, p. 5). NACD and CCAE stated that because of liability concerns with attempting to determine all downstream uses and chemical reactivity hazards, the proposed change will result in several pages of “legalese” to indemnify the entity on the SDS, which will not enhance worker safety. Consequently, they stated, manufacturers and distributors should be responsible for communicating the hazards of the material in the form sold only (Document ID 0329, p. 8; 0423, Tr. 128 -130; 0465, pp. 4-5; 0469, p. 3).

However, no commenter provided specific examples of case law or other evidence to support their contentions that the proposed language to update paragraph (d)

would result in an expansion of tort liability. Moreover, the OSH Act expressly provides that nothing in the statute shall supersede, or in any manner affect, workers' compensation laws or other common law or statutory rights, duties, or liabilities related to employment-related injuries, illnesses, or fatalities (29 USC 653(b)(4)). Therefore, OSHA finds no merit to arguments that adoption of the proposed changes to paragraph (d) would expand tort liability.

X. Arguments that the proposed paragraph (d)(1) will result in software issues.

Both ACC and NACD commented that computer systems used by most larger companies to generate SDSs are automated using existing formulations based on current rules and companies would incur a significant burden to update the systems (Document ID 0347, Att. 1, p. 8; 0329, p. 5). NACD reasoned that, because many chemical manufacturers and distributors rely on the services of outside software companies to prepare SDSs, adopting the proposed changes in the SDS would create complications for manufacturers and distributors. NACD indicated that this change would require product-by-product evaluation of hazards, "which is contrary to the basic principles of the GHS" and which would cause problems because much of the software used by manufacturers relies on GHS classifications and data from the EU (Document ID 0465, p. 5).

OSHA is not convinced that the changes to paragraph (d)(1) will lead to significant burdens for industry. First, as to NACD's assertion that there are no data sources for downstream reactions, SDS preparers can use the same sources as they do for classification of other chemicals as well as information from the manufacturer. Additionally, if it were true that software companies could not respond to updates to the GHS and changes in classification procedures, then neither OSHA nor other countries would ever be able to make regulatory changes to maintain alignment with the GHS (see Section VI., Final Economic Analysis and Regulatory Flexibility Analysis). In fact, NACD did not contend that there are technological barriers to creating compliant

software, only that existing software is not currently configured to meet these requirements. Finally, because the new language simply clarifies that classifiers must include hazards associated with known or reasonably anticipated uses, these hazards are most likely already classified elsewhere, such as the example discussed above where formaldehyde was generated as a by-product during use of hair straightening products (Document ID 0451, pp. 2-8). Accordingly, OSHA finds that software-related concerns do not pose an obstacle to adopting the new language in paragraph (d)(1).

XI. Arguments that the inclusion of the proposed language could be misinterpreted as including “articles”.

Some commenters believed that inclusion of the originally proposed language, “normal conditions of use” and/or “foreseeable emergencies,” could be misinterpreted as including “articles,” which are generally exempted from the HCS (Document ID 0339, p. 2; 0332, pp. 1-2, 4; 0358, p. 2; 0369, pp. 3-4). The Portable Rechargeable Battery Association (PRBA) suggested that the proposed language demonstrated “OSHA’s intention to expand the purview of the HCS to include certain products that have previously been exempted as articles” (Document ID 0332, p. 4). The Vinyl Institute commented that “it would be inappropriate to consider changes in physical form through destruction or recycling to be a normal condition of use that would change the classification of a product as an article. Under such an unprecedented approach, OSHA would disqualify almost every current article from continuing to be treated as an article” (Document ID 0369, pp. 3-4). The Vinyl Institute indicated this concern was prompted by OSHA’s classification requirement with respect to downstream changes in physical form under normal conditions of use such as: “(a) Reduction in particle size from combustible solids to combustible dust, (b) Reduction in particle size from non-respirable to respirable, (c) solid substances becoming corrosive or irritant when moistened or in contact with moist skin or mucous membranes” (Document ID 0369, pp. 3-4). Similarly,

AF&PA and AWC's joint comment stated that destruction and demolition of wood products could be considered "normal conditions of use" (Document ID 0287, pp. 5-6).

OSHA did not and does not intend the change in paragraph (d)(1) to affect the definition of "article" or change the exemption status of any product. The HCS defines "article" as "a manufactured item . . . which is formed to a specific shape or design during manufacture . . . which under normal conditions of use does not release more than very small quantities . . . of a hazardous chemical . . . and does not pose a physical hazard or health risk to employees" (29 CFR 1910.1200(c)). Nothing in paragraph (d)(1) affects this definition. Moreover, to the extent the commenters were concerned about the originally proposed language "normal conditions of use and foreseeable emergencies," that language, as explained above, has been revised and does not appear in the final rule.

XII. Arguments that proposed paragraph (d)(1) will result in over-warning or warning fatigue for downstream chemical users.

Several commenters suggested that the proposed changes in paragraph (d)(1) would lead to confusion and complexity of the SDS that could lead to "over-warning" or "warning fatigue" as workers could be receiving multiple warnings on the same chemical, or irrelevant hazard information potentially turning the SDS into a "novel." They argued this could lead to workers being overloaded or overwhelmed with hazard information that may be too confusing to discern the real hazards they would be potentially exposed to (Document ID 0314, p. 10; 0318, p. 6; 0319, p. 2; 0337, p. 2; 0343, pp. 2-3; 0356, p. 8; 0369, p. 6; 0468, Att. 2, p. 12; 0348, p. 4; 0444, p. 3; 0361, p. 1; 0362, p. 7; 0329, p. 8). Many of these comments are related to chemicals that are produced in bulk quantities and intended to be ingredients in various downstream chemical products. For example, NACD indicated that "[a]ny chemical that can be mixed with a wide range of other chemicals could have an exponentially long and unknown list of hazards that 'result from a chemical reaction'" (Document ID 0329, p. 8).

OSHA disagrees that the changes to paragraph (d)(1) create any problem with warning fatigue. First, as explained above, manufacturers need not classify hazards for every conceivable future use, just those that are known or reasonably anticipated. Second, the SDS and the product label serve two different purposes. As provided for in paragraph (f)(1) of this final rule, hazards associated with known or reasonably anticipated uses do not need to be included on a product's label. Such hazards must be included in Section 2 of the SDS, but this is appropriate because the SDS is meant to have more comprehensive information available to workers who need or desire more details about the product. OSHA is not dictating how this information is presented in Section 2 of the SDS. SDS preparers have discretion to present the information in an organized fashion to prevent confusion for the downstream user.

XIII. Additional comments.

OSHA received additional comments that did not fit neatly within any of the above categories. ACC stated its belief "that OSHA has conflated two separate obligations under the Hazard Communication Standard – the scope of the HCS with respect to an employer's workplace, and the scope of the hazard classification (known as the 'hazard determination' prior to HCS 2012" (Document ID 0468, p. 2). ILMA and PLASTICS made similar comments (Document ID 0314, pp. 2-3; 0356, p. 6). OSHA believes that these concerns arose from the agency's proposed use in paragraph (d)(1) of the terms "normal conditions of use" and "foreseeable emergency," which both appear in paragraph (b)(2) of the HCS, which describes the scope of the entire standard. Because the use of those terms in paragraph (d)(1) created significant misinterpretations, OSHA has changed the regulatory language for this final rule, as explained above.

Several commenters also argued that the examples OSHA provided were insufficient to support the broad nature of the proposed language in paragraph (d)(1) (Document ID 0325, pp. 8-13; 0323, p. 4; 0316, pp. 3-5, 0362, pp. 2-3). For example,

Hach claimed that the examples OSHA provided were unique situations and did not warrant the “proposed over broadening of the classification scope” (Document ID 0323, p. 4).

OSHA disagrees with commenters who suggest that there is insufficient evidence presented to support the requirement. While OSHA provided several examples in the NPRM, other commenters, such as Cal/OSHA and NABTU (as discussed above), have also provided additional examples of situations where manufacturers should have reasonably anticipated downstream hazards but failed to warn of these hazards and workers were harmed.

SAAMI was concerned that the proposed language in paragraph (d)(1) would impose additional requirements on explosives since these types of materials can be used for demolition or destruction as a normal condition of use and that the classification as an explosive and the resulting hazard communication is sufficient to alert users to the potentialities (Document ID 0412, p. 3). OSHA believes that the classification of explosives already accounts for many of the hazards that would be associated with demolition or destruction because the hazard is still explosiveness regardless of whether that risk is in transport or during actual use of the explosives. However, the HCS covers all health and physical hazards and there are some circumstances of downstream use that need to be accounted for during the classification process, such as if the explosive itself creates a toxic atmosphere when used.

The National Association of Printing Ink Manufacturers (NAPIM) suggested that OSHA should define the term “reaction” for paragraph (d)(1) because some members of the regulated community may not understand what OSHA intends it to mean in this context (Document ID 0317, p. 2). OSHA does not believe this is necessary. First, the term “reaction” is used in multiple ways throughout the HCS depending on the context of the requirement. For example, in Appendix A it is used to describe health effects (e.g.,

Table A.4.2) while in Appendix B the term “chemical reaction” is part of the definition for explosives (see B.1.1.1). Thus, OSHA believes that providing a single definition of “reaction” for the whole standard could create confusion. OSHA also does not believe the term “chemical reaction” needs a definition because it is common knowledge for SDS preparers that “chemical reaction” refers to a change of the chemical structure versus a mere change in the physical form of a substance.

Several commenters indicated that the proposed language would only be reasonable if it were limited to uses specified or directed by the upstream supplier and that OSHA should ensure that paragraph (d)(1) only applies to a narrow range of downstream reactions (see, e.g., Document ID 0316, p. 4; 0362, p. 3; 0404, p. 3; 0367, p. 5; 0315, p. 3, 0359, p. 1-2). For example, HCPA agreed that “the chemical reactions should be included in the hazard assessment in cases when multiple chemicals are sold together with the intention that they’d be mixed together before use.” However, HCPA stated that the proposed changes in paragraph (d)(1) constitute agency overreach, giving the example of concentrated cleaning products that downstream customers dilute with water and the inability of the manufacturer to know every type of a soil a cleaning product might be used on (Document ID 0327, pp. 7-9; 0424, Tr. 15-17). They recommended that the mixing of two or more chemicals be considered in classification only when the label directs the user to use the chemical in such a manner and excludes products where the label directs users to only mix with water (Document ID 0327, p. 7). Similarly, Dow suggested that the proposed paragraph be revised to state that the manufacturer need only provide product chemical reaction hazard assessment based on its intent and the knowledge of a chemical reaction that will occur during the downstream use of its product as manufactured and sold (Document ID 0359, pp. 1-2).

OSHA disagrees with these comments for several reasons. First, OSHA would not expect any additional hazard classifications simply for diluting a more concentrated

chemical with water because, as HCPA noted, such an action would only reduce the chemical's hazards, not increase them. Second, under the finalized language in paragraph (d)(1), manufacturers of cleaning products need only classify hazards associated with known or reasonably anticipated uses of the products, not every potential type of soil that a downstream customer might clean. OSHA believes that "known and reasonably anticipated uses", rather than only uses that are explicitly directed by the product's label, is the appropriate requirement to provide sufficient information to downstream employers and workers.

Two commenters suggested that OSHA should rescind the proposed text and address unique situations of hazard identification and downstream uses affecting the scope of HCS in a letter of interpretation rather than updating the standard (Document ID 0323, p. 5; 0368, p. 3). OSHA disagrees. The regulatory text is the first and primary place the regulated community turns to understand its obligations under the HCS. The agency is exercising its statutory authority to promulgate and revise safety and health standards through notice-and-comment rulemaking. OSHA has provided an opportunity for stakeholders to comment on the proposed regulatory text changes, reviewed and considered all of the comments, and made changes to the regulatory text, where appropriate, based on the record as whole. By making this change in the regulatory text, OSHA intends to ensure all regulated parties are aware of this requirement and alleviate confusion on this point. Addressing this issue in letters of interpretation would not achieve the full extent of that goal.

XIV. Suggested Edits/Proposed New Language.

OSHA also received several recommendations for changing the proposed text for paragraph (d)(1), in addition to those discussed above. PLASTICS and Vinyl Institute recommended that OSHA state detailed and narrow conditions under which classification of downstream reactions would be required. Their recommendations for such conditions

included where the manufacturer specifies the uses, provides all of the chemicals, and specifies the complete process and process conditions. Additionally, they recommended adding that the classification is only contingent on the downstream users following the specified processes (Document ID 0314, pp. 14-15; 0369, pp. 7-8). A joint comment from RISE and CropLife also provided recommendations for new text that would limit the classification requirement to only “approved” uses (Document ID 0343, p. 3). RISE and CropLife explained that their proposed revision “narrows the scope of the hazard classification and provides clarity so the provision can be more readily implemented without over classification of the chemical hazards” (Document ID 0343, p. 3).

ACC submitted proposed new text for paragraph (d)(1): “In the case of a hazardous product for which instructions for use, provided at the time of the sale or importation, require its combination with one or more products, mixtures, materials or substances resulting in the creation of one or more new materials or substances that present one or more new or more severe hazards not already identified on the safety data sheet of the hazardous product, the safety data sheet must also provide the following information elements, in respect of each new material or substance and clearly indicate that they pertain to that new material or substance: (a) the nature of the new or more severe hazard; and (b) the content of the applicable specific information elements set out in Appendix D to § 1910.1200 - SAFETY DATA SHEETS (Sections 4-11)” (Document ID 0347, Att. 1, p. 8). ACC stated that while their preference was for OSHA to remove the proposed language entirely, if the agency was unwilling to remove the language, then OSHA should consider utilizing their draft text as it was modeled after a similar Canadian provision (Document ID 0347, Att. 1, p. 9).

OSHA appreciates these stakeholders providing thoughtful proposals for new language, but the agency finds that the suggested changes do not represent the original intent which OSHA’s proposal sought to clarify. The commenters’ suggested changes

would narrow the current obligations of the HCS (thereby reducing protections for workers) and, in some cases, would introduce new ambiguity. PLASTICS' and Vinyl Institute's suggested edits, while appearing to give clarity to what they perceived OSHA's intent to be, contain qualifications that would actually narrow the scope of the HCS and the classification requirements. Similarly, in the language suggested by RISE and CropLife, requiring classification only for uses specified on the label would not only narrow the scope of the HCS but might incentivize manufacturers to minimize the information provided to downstream users to limit the need for classification. OSHA also does not believe that ACC's language is less ambiguous. It would require the manufacturer to decide if or when a hazard is more severe than a hazard already identified or whether it is identified on the SDS. This also defeats the purpose of having the hazards in one section upfront on the SDS to ensure that the workers are aware of all of the potential hazards without having to read the entire SDS. Accordingly, OSHA declines to adopt the suggestions.

XV. Out of Scope comments.

OSHA received two comments on paragraph (d) that are out of scope for this rulemaking. First, Cal/HESIS recommended that OSHA add a new paragraph (d)(4) which would provide a source for authoritative lists for chemical classifications (Document ID 0313, p. 4). This comment is out of scope for this rulemaking, as OSHA did not propose a change related to this issue. In addition, OSHA notes that this is already addressed in the non-mandatory Appendix F of the HCS. Second, Cal/OSHA, Worksafe, and the National Council for Occupational Safety and Health (National COSH) commented that OSHA should include in paragraph (d)(2) the "single study rule" (Document ID 0322, p. 2; 0354, p. 1; 0407, p. 12). This comment, too, is out of scope because OSHA did not propose a change related to this issue. OSHA notes that the extent of its incorporation of the single positive study is explained in the preamble to the 2012

HCS (77 FR 17708) and is discussed further in the Summary and Explanation for Appendix A.0.3.5 of this final rule.

To summarize, for the reasons discussed above, OSHA is finalizing different language than what was proposed in the NPRM to better clarify the extent of the obligations of manufacturers, importers, and distributors and to better distinguish the requirements for hazard classifications that must appear on the label and those that appear only in the SDS. OSHA is not finalizing the proposed phrase “under normal conditions of use and foreseeable emergencies,” but is adding language providing that hazard classification shall include hazards associated with the chemical’s intrinsic properties, including “(i) A change in the chemical’s physical form and; (ii) chemical reaction products associated with known or reasonably anticipated uses or applications.” As discussed above, OSHA believes that stakeholders should be familiar with the terms “known” and “reasonably anticipated” as OSHA has used these terms in multiple standards, guidance products, and LOIs. The agency finds that this language captures the intent of the original language from 1983 and the intent of the proposal while minimizing ambiguity. Finally, this clarification will ensure that workers have the information necessary to protect themselves from the hazards posed by chemicals to which they are occupationally exposed.

(e) Written hazard communication program.

Paragraph (e) of the HCS provides specific requirements for chemical manufacturers, importers, distributors, or employers to develop, implement, and maintain a written hazard communication program. Paragraph (e)(4) requires employers to make their written hazard communication program available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director of NIOSH.

The final rule contains one change to correct a reference in paragraph (e)(4) that erroneously referred to 29 CFR § 1910.20 instead of 29 CFR § 1910.1020 when

specifying when and how employers must make the written hazard communication program available. OSHA's Access to Employee Exposure and Medical Records standard was originally located at § 1910.20, but was renumbered to § 1910.1020 in 1996 (61 FR 31429), resulting in the incorrect reference OSHA is now correcting. In the NPRM, OSHA proposed this minor editorial correction after finding 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 (OSHA's Access to Employee Exposure and Medical Records standard). OSHA proposed to fix this error. At the time the NPRM was published, the error was reflected only in the print version of the CFR and the eCFR (www.ecfr.gov) was correct, but at the time of this final rule, the eCFR is also incorrect.

No stakeholders objected to the correction of the reference. However, OSHA received one comment suggesting that a different standard should be referenced to explain when and how employers must make written hazard communication programs available. The U.S. Department of Defense, Force Safety and Occupational Health (DOD) asserted that § 1910.1020 "is not a relevant reference for the hazard communication program" because it "likely will not contain specific employee exposure information" (Document ID 0299, p. 2). They suggested that OSHA cite to § 1910.120(l)(1)(i) (the Hazardous Waste Operations and Emergency Response (HAZWOPER) standard) instead and included proposed language to implement their suggestion. They also suggested adding a provision stating that the employer may limit employee requests for copies of SDSs to chemicals that the requesting employee was personally potentially exposed to (Document ID 0299, p. 2).

OSHA disagrees with DOD's suggestion that § 1910.1020 is not relevant and that § 1910.120 should be referenced instead. Rather, § 1910.1020 is the appropriate reference here. Paragraph (e) of the hazard communication standard has referenced OSHA's

Access to Employee Exposure and Medical Records standard since 1983. Section 1910.1020(c)(5) states that an “employee exposure record” means a record containing any of several kinds of information including a safety data sheet indicating a material may pose a hazard to human health (§ 1910.1020(c)(5)(iii)) and a chemical inventory or any other record that reveals the identity of a toxic substance or harmful physical agent and where and when it is used (§ 1910.1020(c)(5)(iv)). Paragraph (e)(1)(i) of the HCS (§ 1910.1200) requires that the written hazard communication program contain a list of the hazardous chemicals known to be present using a product identifier that is referenced on the appropriate safety data sheet. Thus, the information a written hazard communication program is required to contain classifies the program as an employee exposure record within the meaning of § 1910.1020. Section 1910.1020 also contains specific access requirements, including the requirement to assure that employees are provided with records in a reasonable time, location, and manner and the requirement that employers assume the costs of records provision to employees and their representatives. Therefore, citing to § 1910.1020 for requirements pertaining to an employer’s written hazard communication program is appropriate regardless of whether the program contains any specific employees’ exposure information.

On the other hand, § 1910.120(l)(1), which addresses the requirements for an emergency response plan under the HAZWOPER standard, is intended to cover only procedures for emergency response situations, does not reference exposure information, lacks the detailed access procedures included in § 1910.1020, and is not intended to cover all workplaces with hazardous chemicals. As such, it is less relevant to records access pertaining to routine and regular employee exposures than § 1910.1020.

OSHA also disagrees with DOD’s suggestion that the agency amend paragraph (e)(4) to include a statement that an employer need only provide copies of a chemical’s SDS to an employee if the employee was potentially exposed to that chemical. This

suggestion is beyond the scope of this rulemaking because OSHA only proposed a typographical revision to this section and did not propose any changes to the substance of paragraph (e)(4). OSHA notes that the HCS does not require employers to provide copies of SDSs to employees, only immediate access. Where an SDS constitutes an exposure record under 29 CFR 1910.1020(c)(5), then 1910.1020's requirement to allow employee access (which includes the opportunity to examine and copy) would apply.

For the reasons discussed above, OSHA has determined that § 1910.1020(e) is appropriate to reference for access requirements pertaining to written exposure control plans under HCS, rather than § 1910.120(l)(1). In the final rule, the agency has corrected the technical error and retained the reference to § 1910.1020.

(f) Labels and other forms of warning.

Paragraph (f) of the HCS provides requirements for labeling. In the NPRM, OSHA proposed to modify paragraphs (f)(1), (f)(5), and (f)(11), and also proposed a new paragraph (f)(12).

Paragraph (f)(1) of the HCS, *Labels on shipped containers*, specifies what information is required on shipped containers of hazardous chemicals and also provides that hazards not otherwise classified (HNOCs) do not have to be addressed on these containers. OSHA proposed 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 believed this information was not appropriate on containers because it might confuse users about the immediate hazards associated with the chemical in the container. However, because OSHA believed information on hazards resulting from a reaction with other chemicals under normal conditions of use *is* important for downstream users, the agency did not propose 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 proposed to add the word “distributor” to the third sentence of paragraph (f)(1) to make it consistent with the first sentence.

OSHA did not receive comments on inclusion of “distributor” in this paragraph, so the agency is finalizing that addition as proposed. OSHA received several comments on the proposal that “hazards resulting from a reaction with other chemicals under normal conditions of use” be exempt from inclusion on shipping labels. Michele Sullivan agreed with OSHA that including this information on the label could be confusing and potentially misleading, stating that including downstream hazards on the container could cause confusion with DOT requirements (Document ID 0366, p. 3). However, Cal/OSHA and Worksafe expressed concern that exempting this type of information from the label would withhold important information on chemical reactivity and hazards from workers throughout the supply chain (Document ID 0322, pp. 2-3, 15-16; 0424, Tr. 166-168, 193-195; 0354, p. 5). Cal/OSHA also took issue with using the term “under normal conditions of use” as the trigger for the labeling exemption, contending that it is unrealistic to expect chemical producers to be able to accurately identify such situations. Cal/OSHA stated that chemical manufacturers would need to rely on assumptions about downstream uses and if a manufacturer relied on incorrect assumptions, this could result in essential chemical hazard information being withheld (Document ID 0322, pp. 13-14).

OSHA disagrees with the assertion that not requiring this information on the shipping label would allow manufacturers to withhold important hazard information from workers. As explained in the NPRM, information about downstream hazards is required to appear in Section 2 (Hazard(s) Identification) of the SDS, which must be readily available to workers using the product. Additionally, omitting hazard information created from later chemical reactions from the label properly places the label’s emphasis on the hazards associated with the chemical in the container, while

minimizing the potential for over-warning, which could mask the hazards to which workers are exposed. However, as discussed in the Summary and Explanation for paragraph (d), OSHA received many comments expressing uncertainty about what the agency meant by the term “under normal conditions of use.” Accordingly, in this final rule, OSHA has revised paragraph (d)(1) to remove the “under normal conditions of use” language and replace it with language that more clearly describes obligations for classification. Correspondingly, in paragraph (f)(1), this final rule removes the reference to “under normal conditions of use” and replaces it with a direct reference to paragraph (d)(1)(ii). As finalized, this change to paragraph (f)(1) maintains the proposed exemption but ensures consistency and minimizes confusion about which hazards are required on both the label and the SDS and which hazards are required solely on the SDS.

Hach commented that OSHA should update (f)(1)(vi) to be consistent with the proposed changes in Appendix D to specify that the address and phone number of the responsible party should be the U.S. address and phone number (Document ID 0323, p. 11). OSHA is specifying that the address and telephone number of the chemical manufacturer, importer, or other responsible party required in Section 1 of the SDS, Identification, must be United States domestic, in order to minimize confusion on this point. As OSHA discussed in the NPRM, this change is not a new requirement, but clarifies the previously existing requirements of Appendix D, which requires that the name, address, and telephone number of the responsible party, such as the chemical manufacturer or importer, be listed on the SDS (86 FR 9722). OSHA explained in a 2016 LOI that when chemicals are imported into the United States, the importer (defined by the HCS as being the first business with employees in the United States to receive hazardous chemicals produced in other countries for distribution in the United States) is the responsible party for purposes of compliance with the HCS and is required to use a

U.S. address and U.S. phone number on the SDS (Document ID 0090). For the same reasons that OSHA is making this change in Appendix D (see the Summary and Explanation for Appendix D), OSHA agrees that the change should be made here as well. Therefore, this final rule revises (f)(1)(vi) to include “U.S.” before “address” and “telephone number.”

OSHA also proposed to add a new paragraph, (f)(1)(vii), that would introduce a requirement that the label include the date a chemical is released for shipment. The agency proposed 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. The agency believed that providing the date a chemical is released for shipment on the label would allow manufacturers and distributors to more easily determine their obligations under paragraph (f)(11) when new hazard information becomes available.

OSHA received numerous comments on this proposal. NAIMA supported the inclusion of a date for release for shipment on the basis that including such a date aligns with OSHA’s other proposed changes related to chemicals that have been released for shipment (Document ID 0338, p. 7). Tom Murphy commented that including a date on the label could benefit workers but suggested that OSHA change the title “Release for Shipment” to “Packaged for Shipment” to better reflect the intent of (f)(1) (Document ID 0277, p. 2). Many commenters, however, objected to or had concerns about the requirement of adding the release for shipment date on the label. Some raised practical objections, such as inadequate space on the label and lack of clarity about what the proper date would be (Document ID 0361, pp. 1-2; 0362, pp. 3-4). Many others questioned the need for such a requirement since manufacturers already track the date of manufacturing through various means such as lot numbers or manufacturing dates (Document ID 0327, p. 4; 0359, p. 3; 0323, pp. 8-9; 0315, pp. 1-2; 0321, p. 1; 0333, p. 1; 0339, p. 2; 0340, pp. 4-5; 0348, p. 2; 0349 p. 1; 0423, Tr. 103, 195-196, 210-216; 0424, Tr. 21). For example,

Epson America, Inc. (Epson) commented that the proposed requirement was “not necessary and meaningless” and that the proposal did not make clear which date to use (Document ID 0288, p. 1). NPGA, Dow, and Hach also commented that a required date on the label would add unnecessary burdens and create confusion (Document ID 0364, pp. 1-2; 0359, pp. 3-4; 0323, pp. 8-9). IMA-NA suggested that such a date would not bear a connection to when the container was actually ready to ship (Document ID 0363, p. 8). Michele Sullivan commented that requiring the date on the label was contrary to international harmonization because the GHS does not have such a requirement (Document ID 0366, p. 4). Similarly, Hach observed that other international partners (e.g., Canada) do not require the date of release for shipment on the labels (Document ID 0323, pp. 8-9).

Some commenters indicated that OSHA underestimated the burden of this requirement since either manufacturers would need to modify their processes or the new requirement would preclude the use of pre-existing labels, which save manufacturers time and cost (Document ID 0290, p. 1; 0315, pp. 1-2; 0358; p. 2; 0324, pp. 2-3, 7; 0359, pp. 3-4; 0323, pp. 8-9; 0424, Tr. 21; 0425, Tr. 73; 0368, p. 6). Others questioned whether the proposal would create issues with labeling requirements imposed by other agencies. For example, ILMA commented that some of their members are also regulated by FDA and the use of a ship date as opposed to a batch code may violate FDA regulations (Document ID 0444, p. 6). Several commenters commented that the addition of this date on the label could create confusion with very little benefit. AmeriGas stated that a “released for shipment” date could lead to confusion with DOT requalification dates (Document ID 0423, Tr. 210-216), and SAAMI suggested that there could be confusion with expiration dates (Document ID 0421, p. 2).

In addition, HCPA, ACC, and others recommended that OSHA allow manufacturers and importers to use their own methods to track their inventory throughout

distribution rather than require an additional date on the label (Document ID 0301, p. 1; 0315, pp. 1-2; 0327, p. 5; 0324, pp. 3, 7; 0423, Tr. 103). A comment jointly submitted by the Compressed Gas Association (CGA) and the Gases & Welding Distributors Association (GAWDA) recommended that the date be optional to provide manufacturers flexibility, especially those that reuse containers and inspect labels regularly (Document ID 0310, pp. 1-2).

OSHA appreciates the various views and comments submitted by stakeholders. The agency finds compelling the arguments that the date a chemical was released for shipment is not needed on labels because this information is already available through other means and that the addition of the date could cause confusion for downstream users due to other (non-HCS) date requirements on the label. Since OSHA indicated in the NPRM that the primary reason to include the “release for shipment” date was to aid manufacturers and distributors in complying with (f)(11), the agency finds it relevant that manufacturers and distributors believe they already have adequate means to track their inventory (86 FR 9698). OSHA therefore concludes it is unnecessary to require dates be included on the label and is not including this proposed requirement in the final rule.

Paragraph (f)(5) specifies label requirements that apply to the transport of hazardous chemicals from workplace to workplace. In the NPRM, OSHA proposed to add the heading “Transportation” to this paragraph. The agency received no comments on the proposed new paragraph heading, so is finalizing the heading “Transportation” as proposed. In addition, OSHA is making one technical correction to (f)(5)(i). The citation for the requirements of the Hazardous Materials Transportation Act has been changed from 49 U.S.C. 1801 et seq. to 49 U.S.C. 5101 et seq. OSHA has updated the reference.

Finally, OSHA proposed to add two new subparagraphs to (f)(5) that specify requirements related to the transportation of hazardous chemicals. OSHA proposed to add a new paragraph (f)(5)(ii) to address the transportation of bulk shipments of hazardous

chemicals (i.e., in tanker trucks, rail cars, or intermodal containers). 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 by other technological or electronic means so that the information is immediately available in print to workers on the receiving end of the shipment.

OSHA received numerous comments on this proposed provision. Several comments supported the proposed paragraph. ILMA indicated that the option of using either physical or technological means to transmit the information was beneficial (Document ID 0365, p. 12). ADM supported the proposed language, finding it to be in full agreement with pre-existing OSHA guidance and industry practice (Document ID 0361, p. 2). Similarly, FCA supported the addition of paragraph (f)(5)(ii) as long as the term *bulk shipment* is not expanded to encompass intermediate containers (Document ID 0345, pp. 5-6). OSHA notes that the regulatory text narrowly defines *bulk shipment* to include only tanker trucks, rail cars, and intermodal containers.

NAIMA, Hugo Hidalgo, and Ameren also supported the proposed new paragraph, stating it provided needed clarity (Document ID 0297, pp. 2-3; 0309, pp. 11, 16; 0338, p. 7). National Refrigerants, Inc. (NRI) supported the addition of (f)(5)(ii) but requested that OSHA permit sending the label electronically just once for multiple shipments with the same materials (Document ID 0326, p. 7). Similarly, NACD and a comment submitted jointly by the Association of American Railroads (AAR) and the American Short Line and Regional Railroad Association (ASLRRA) stated that there need only be one electronic transmission of a label if multiple shipments are made of the same material (Document ID 0329, pp. 3-4; 0351, pp. 2-4; 0465, pp. 3-4). OSHA disagrees with these suggested changes since sending the label just once would not provide the label to the receiver of each shipment at the time of delivery. The intent of (f)(5)(ii) is to ensure the label is immediately available to the person receiving the shipment while recognizing

advances in technology that allow manufacturers or suppliers alternate methods of ensuring a hard copy is available.

While IPHMT and NPGA also supported the addition of (f)(5)(ii), they requested that OSHA revise the paragraph to read as follows: “It is permissible for the label for bulk packaging of hazardous chemicals to be on the container in a manner that does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 et seq.) [now 49 U.S.C. 5105 et seq.] and regulations issued under that Act by the Department of Transportation, or to 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 the shipment.” These commenters stated that their proposed language would clarify that OSHA does not intend to prohibit markings required by DOT (Document ID 0336, p. 2; 0364, pp. 5-6). OSHA does not agree that this change is needed, since (f)(5)(i) already provides that labeling used to comply with the HCS must not conflict with the Hazardous Materials Transportation Act (49 U.S.C. 1801 et seq.) [now 49 U.S.C. 5101 et seq.] and regulations issued under that Act by DOT.

Toby Threet also supported, in general, the provision for sending electronic labels, with a minor edit to clarify that it is not the worker who should be in printed form (Document ID 0279, p. 3). OSHA is not convinced that the language as proposed is truly ambiguous and in need of clarification.

Dow requested a slight change to the proposed text to allow for greater latitude for where to affix the label on the bulk shipping container, suggesting OSHA change “may be on the immediate container” to “may be attached or affixed to the immediate container” (Document ID 0359, p. 2). DGAC expressed similar support for revisions that would allow for flexibility of label placement (Document ID 0339, p. 2). OSHA disagrees that this language is necessary or adds any additional flexibility. OSHA already

allows flexibility in its definition of label in paragraph (c). The definition notes that labels may be affixed to, printed on, or attached to the immediate container (or outside packaging). Therefore, OSHA is maintaining the language as proposed.

NACD and others questioned the need for a label on a bulk shipping container, suggesting that since the DOT placard and SDS are already required, the end user will have the necessary safety and health information without a label (Document ID 0329, pp. 3-4; 0315, p. 2). OSHA disagrees with this assertion. OSHA does not require the SDS to accompany the actual shipment of the chemical and therefore it may not be immediately available upon delivery (although it must be readily accessible to employees). Also, the DOT placard does not include the full range of hazards covered by the HCS.

Additionally, Idemitsu Lubricants America Corporation (ILA) suggested that a hard copy of the label was not necessary since the storage container on the receiving side should already be appropriately labeled (Document ID 0315, p. 2). OSHA disagrees, since the person who is unloading the material from the bulk shipment may not have immediate access to the storage vessel and its label.

NIOSH commented that proposed (f)(5)(ii) was practical and would not result in additional risk to the worker. However, NIOSH recommended that OSHA have a mechanism to verify that the label information is transmitted (Document ID 0281, Att. 2, p. 4). OSHA agrees that some sort of acknowledgement or acceptance of this information from the end user is important to ensure that the information is appropriately received. Therefore, in this final rule OSHA is revising the proposed language to include that if the label is transmitted in a means other than a label on the bulk shipment container or in printed form, the recipient of the shipment must agree to receive the labels by an alternate method. OSHA is also revising the word “may” to “must” in the first sentence of (f)(5)(ii) to clarify that the label preparer must choose one of the options provided in the paragraph.

Both Cal/OSHA and Worksafe objected to permitting shippers to send labeling information electronically, expressing concern that this method could leave workers who handle containers during shipment unaware of their contents and leave emergency responders unaware of the presence of hazardous materials and unable to respond safely to an emergency that occurs during shipment (Document ID 0322, pp. 2, 14-15; 0375, pp. 2, 14-15; 0354, p. 5). DOT has jurisdiction over hazardous chemicals while they are in transport and has provided alternate methods to ensure the safety of people transporting hazardous materials via packaging and labeling as well as to ensure that emergency responders are aware of the hazards in case of an emergency. The HCS, in contrast, is concerned with chemical hazards in the workplace after transport has concluded. The purpose of providing the HCS label either on the bulk shipping container or with the bill of lading is to ensure that the downstream recipient has the information immediately upon delivery. This long-standing requirement ensures that the recipient has the information immediately while not posing any potential conflicts with the placarding required by DOT.

Steven Wodka expressed concern that permitting electronic transmission of labels will result in workers on the receiving end of the shipment not having necessary hazard information quickly enough. Wodka stated that warning labels should appear at the point of danger where they would be most effectively seen, and that permitting electronic transmission of labels will lead to a delay between the bulk shipment's arrival at the customer's plant and the placement of the appropriate label, even at the most OSHA-compliant workplaces (Document ID 0312, pp. 2-5). As noted above, to further address the concern that labels should be immediately available at the point of danger, OSHA is revising the proposed language of (f)(5)(ii) to include a requirement that the recipient of a shipment must agree to receive labels electronically. OSHA believes that the proposed regulatory language requiring that labels be "immediately available to workers in printed

form on the receiving end of shipment,” coupled with the new language in the final version requiring recipients to consent to electronic delivery of labels, addresses the delay concerns.

If a manufacturer, importer, or distributor uses electronic transmission of product labels for bulk shipments, they must ensure the recipient chooses to “opt-in” to accept the electronic transmission. A downstream user/recipient may choose to “opt-out” of an electronic distribution system from a manufacturer, importer, or distributor at any time. If a downstream user/recipient does opt out, the manufacturer, importer, or distributor must then ensure a product label is on each bulk shipment in accordance with paragraph (f)(1) or provide a hard copy of the product label with shipping papers or bills of lading. As a note, this provision does not change the existing obligations of the downstream employer to ensure that any chemical container in the workplace is labeled in accordance with paragraph (f)(6) before any worker uses the chemical. A tanker truck or railroad tank car may be labeled in accordance with paragraph (f)(7) when considered a stationary process container.

In sum, OSHA is finalizing paragraph (f)(5)(ii) with revisions to clarify that the label may be electronically transmitted only with agreement from the receiving end. Electronic transmission of product labels for bulk shipment may be accomplished in numerous ways through various electronic platforms including computer systems, facsimile, or bar or QR code, as long as the product label is immediately available in printed form on the receiving end of the shipment.

As discussed in the NPRM, under the 2012 HCS, Appendix C paragraph C.2.3.3 provides that where a pictogram required by 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, since 2012, DOT has updated

its regulations to indicate that it does not consider the HCS pictogram to conflict with the DOT pictogram, and based on this, OSHA no longer believes that having both pictograms will create confusion for workers handling the chemical (49 CFR 172.401). Accordingly, in the NPRM OSHA proposed to: (1) delete the language currently in paragraph C.2.3.3 from Appendix C and (2) add new paragraph (f)(5)(iii) to provide that where a DOT pictogram appears on 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 2012 standard, the flame pictogram on the OSHA-compliant label would be prohibited because the DOT label would contain the equivalent pictogram. The proposed change 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.

OSHA received several comments relevant to this proposed change. ILMA supported harmonizing the HCS with DOT because it will “reduc[e] confusion regarding hazards, not only for workers but for the businesses that must juggle two different labeling rules” (Document ID 0356, p. 12). IPHMT commented that the proposed regulatory language did not make it sufficiently clear that adding the HCS pictogram was permissible but optional, rather than required. They requested the agency amend the proposed language to clarify that the addition of the HCS pictogram with the DOT pictogram is permissible but not required (Document ID 0336, p. 3). OSHA disagrees that additional language is needed; the proposed regulatory text states clearly that the HCS pictogram “is not required on the label.” NPGA and IPHMT also commented that

the agency had not made a compelling case that no confusion would ensue if both pictograms were required and this might affect emergency responders' response (Document ID 0336, p. 3; 0364, p. 6). However, these commenters did not provide any evidence that there would be or has been confusion due to two distinctly different pictograms. OSHA notes that the DOT placard is larger than and separate from the OSHA-compliant label, enabling emergency responders to distinguish between the two types of labels. Moreover, these commenters provided no reason for OSHA to disagree with DOT's conclusion, based on that agency's experience and expertise, that confusion should not arise from inclusion of both pictograms.

SOCMA supported the proposed change, stating that "DOT has updated its regulations to indicate that it does not consider the HCS pictogram to conflict or cause confusion with the DOT pictogram for the same identified hazard. This provision simply harmonizes labeling regulations between OSHA and DOT while simplifying the dual labeling requirements for regulated entities" (Document ID 0367, p. 5).

DOD asked OSHA to clarify whether the HCS pictogram is permitted or required once the container reaches its destination (Document ID 0299, p. 2). OSHA intends that if the immediate container bears a DOT pictogram, the same pictogram does not need to also be on the HCS label, as long as the DOT pictogram is not removed or defaced. The end user would not need to add the corresponding HCS pictogram.

NACD suggested alternate language to distinguish between DOT terminology for "marking" a shipping container and OSHA terminology for "labeling" hazardous chemicals. They suggested that OSHA remove two references to "the label" from proposed (f)(5)(iii) (Document ID 0329, p. 4). OSHA partially agrees that the use of the term "the label" for both DOT requirements and OSHA requirements may be confusing because DOT sometimes uses the term marking rather than labeling. However, the use of the term "on the label" to reference OSHA labeling is appropriate. Therefore, OSHA is

removing the first reference to “the label” from the text of (f)(5)(iii); the text as finalized reads, “Where a pictogram required by the Department of Transportation under Title 49 of the Code of Federal Regulations appears on a shipped container, the pictogram specified in Appendix C.4 of this section for the same hazard is not required on the label.”

NACD also suggested that OSHA require that the pictogram(s), hazard statement(s) and signal word(s) be in the same field of view as the DOT’s hazard class symbol, so workers could view all hazard information at once, in order for the HCS pictogram to not be required (Document ID 0329, p. 4). OSHA disagrees with this suggestion. The DOT markings are used for different purposes and the size and location may be dictated in such a way that it would not be feasible to have them in the same field of view. Therefore, the agency is finalizing (f)(5)(iii) as proposed with the exception of removing the phrase “the label for” where it referred to DOT requirements.

In the 2012 HCS, paragraph (f)(11) 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 is shipped. Therefore, in the NPRM OSHA proposed 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 chemical manufacturer or importer must provide the updated label for each individual container with each shipment. The purpose of these changes 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 (see 86 FR 9699). 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 (86 FR 9699).

In addition to the compliance difficulties noted by manufacturers, OSHA is aware that the act of relabeling (or in some cases repackaging) 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 workplace hazards such as the potential for chemical exposures.

OSHA has previously recognized the complexities involved with relabeling existing stock of hazardous chemicals. Following promulgation of the 2012 HCS, the HCS compliance directive (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 those deadlines, employers were required to ensure that each container was labeled with an HCS 2012-compliant label prior to shipping. OSHA used this enforcement policy as a basis for the proposed revisions to paragraph (f)(11). OSHA sought commenters' input 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 received numerous comments on this proposed provision. A comment jointly submitted by the Fertilizer Institute (TFI) and the Agricultural Retailers Association (ARA) supported the proposal and stated that it would reduce their burden without impacting the hazard information (Document ID 0340, pp. 4-5). Tom Murphy supported the provision but indicated it could be clearer if the agency changed the term "release for shipment" to "packaged for shipment" (Document ID 0277, p. 2). NIOSH, NAIMA and Ameren also expressed support, noting that the provision would allow manufacturers with long distribution cycles the opportunity to send updated labels with the shipment while avoiding unnecessary risk to workers (Document ID 0281, Att. 2, p. 4; 0338, p. 7; 0309, p. 11). NIOSH recommended that clear responsibility be established to ensure labels accompany shipment. OSHA agrees; it is the responsibility of the originator to ensure updated labels accompany the shipment.

Some commenters expressed confusion about what the proposed provision would require; in particular, they appeared to interpret the proposed provision as mandatory rather than optional. API and Michele Sullivan urged OSHA to make the proposed

provision optional, as it would not be relevant to many supply chain operations (Document ID 0316, pp. 4-5; 0366, p. 4). NAPIM appeared to read the proposed provision as requiring manufacturers to place an updated label on each container that had already been prepared for shipment (Document ID 0317, p. 2). NPGA and a comment jointly submitted by CGA and GAWDA stated that the proposed provision would be inappropriate for manufacturers of cylinder gas products and urged the agency not to include it in the final rule (Document ID 0310, p. 2; 0385, p. 2; 0364, p. 4). OSHA notes that the proposed provision was intended to be optional and is revising the language in the final version to clarify that manufacturers have the option to adopt the provision's alternate labeling procedures but are not required to do so. Manufacturers, distributors and importers can always follow the requirements for updating labels as laid out in the first part of (f)(11). OSHA is also revising the title of paragraph (f)(11) from "Release for Shipment" to "Label Updates" to better reflect the true purpose of this provision: providing requirements for updating information on labels. This change is similar to a suggestion submitted by Toby Threet, that OSHA should revise the title "to something more representative of the entire paragraph, such as 'Revision of Labels'" (Document ID 0279, p. 5).

Some commenters conditioned support for the changes on OSHA eliminating or adjusting the correlating proposed requirement to add the date of "release for shipment" on the label (Document ID 0327, p. 5; 0347, Att. 1, pp. 9-11; 0361, p. 1). As discussed above, OSHA has decided not to adopt its proposed requirement to include the "release for shipment" date on the label in this final rule.

Other commenters, while supporting this provision in principle, did not support shipping the updated label with the shipment. Several commented that doing so would inappropriately place the burden on the downstream user to update the label on site. For example, the Medical Device Transport Council (MDTC) strongly supported the relief

from relabeling that (f)(11) would afford but did not support placing the burden on subsequent distributors and customers to apply the updated labels to the containers (Document ID 0358, pp. 2-3). Likewise, DGAC commented that it does not support this provision as it places the burden on subsequent distributors and their customers (Document ID 0339, p. 3). Similarly, others including Dow commented that shipping unaffixed labels could create issues with safety and raise liability issues, and that there would be no way to ensure that relabeling would even take place (Document ID 0349, p. 1; 0359, pp. 2-3; 0368, pp. 5-6). The agency believes that the commenters are exaggerating the nature of any additional burden on downstream users. The purpose of the accommodation proposed in (f)(11) is to avoid the burdens and hazards that can come with relabeling containers in a specific, narrow set of circumstances, while still providing the up-to-date information to downstream users. If upstream manufacturers are concerned about liability, they can opt not to take advantage of this optional accommodation and instead update the label at the point of shipment.

Other commenters requested flexibility on how and when to send the labels downstream, such as sending them electronically and/or in advance of the shipment, or suggested it is not necessary to send updated labels at all since the downstream user already has the information on the SDS (Document ID 0279, p. 5; 0297, pp. 5-7; 0319, p. 2; 0327, p. 5; 0345, pp. 4-5; 0349, p. 1; 0368, pp. 5-6). ACI indicated that new processes would need to be put in place to provide the updated label (Document ID 0319, p. 2). However, it is important to ensure that downstream users have the most up-to-date information at the time the hazardous chemical is received. Allowing the label to be sent separately from the shipment or relying on the SDS would fail to ensure that the downstream user has the updated label with each container. OSHA again notes that this provision is optional, so if a manufacturer does not have a mechanism to provide the

updated label with the shipment or is concerned about liability, they can relabel each container prior to shipment.

Several commenters stated that they found the term *released for shipment* to be confusing (Document ID 0329, p. 4; 0465, p. 4; 0324, p. 3). OSHA is adding a definition of *released for shipment* in the final rule (see the Summary and Explanation discussion for paragraph (c)).

Cal/OSHA opposed the proposed update, characterizing it as an “additional delay in relabeling” that would “expose[] workers throughout the supply chain to undisclosed chemical hazards” (Document ID 0322, p. 15). OSHA disagrees that the proposed provision will cause a delay in downstream workers receiving the correct label information because it would require updated labels to be sent together with every shipped container. In providing this accommodation OSHA is providing flexibility to manufacturers in a way that minimizes potential hazards to upstream workers who could be exposed to hazards due to relabeling while still providing the updated label information with the shipped product within the required timeframe.

Finally, several commenters requested clarification about aspects of the proposed provision. NRI asked whether this accommodation applies to any container filled, sealed, and labeled by the manufacturer before the expiration of the six-month deadline (Document ID 0326, p. 6). The answer is yes. NRI also asked whether the provision would apply to labels on a chemical’s immediate container as well as labels on immediate outer packages holding small containers (Document ID 0326, p. 6). This answer is also yes: this accommodation would apply to containers within an immediate outer package, as long as the immediate outer package is already released for shipment.

The Vinyl Institute asked whether the exception applies when the immediate container is filled and labeled, but the immediate container has not yet been placed in its kit or outer container, palletized, and/or shrink wrapped (Document ID 0369, pp. 8-9).

PLASTICS supported the proposed provision but suggested a supplemental statement to state that: “The ‘released for shipment’ criterion would be satisfied if the immediate container were filled, sealed, and labeled by the deadline even if the immediate container (1) has not yet been placed in its kit or outer container, palletized, and/or shrink wrapped, or (2) the product is on a temporary QA hold and is subsequently cleared for distribution” (Document ID 0314, p. 19). In the Vinyl Institute’s question and in PLASTICS’ suggestion, it appears that the immediate containers still would need to be packaged for shipment, so they would not meet the definition of *released for shipment* discussed previously in the Summary and Explanation for paragraph (c), and the exception would not apply.

IMA-NA asked OSHA to implement staggered timelines for label updates based on the severity of the hazard, indicating that a Class 1 hazard should have a short timeline and a Class 2B hazard could wait as much as twelve months for new labeling (Document ID 0363, p. 8). This comment is out of scope for this rulemaking since OSHA did not propose to change the basic schedule for updating labels after learning of new hazard information. In addition, the agency believes downstream users must have the updated information available on the immediate container as quickly as possible regardless of the severity of the hazard.

For the reasons discussed above, OSHA is modifying the proposed text for (f)(11) to make clear that for chemicals that have been released for shipment and are awaiting further distribution, the chemical manufacturer, importer, or distributor has the option not to relabel after learning significant new hazard information. However, if they choose to take that option, they must produce updated labels for each container and send those labels with the shipment for the downstream users.

Finally, OSHA proposed a new paragraph, (f)(12), to address small container labeling. The 2012 HCS required that all shipped containers be labeled with the

information specified in paragraph (f)(1). Many stakeholders have told OSHA that they have difficulty 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 (86 FR 9699). In response to these concerns, through LOIs and the HCS compliance directive, 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 (see 86 FR 9699). This 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. In the NPRM, OSHA proposed to incorporate this practical accommodation into the standard in new paragraph (f)(12).

OSHA proposed that all of the new 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 paragraphs (f)(12)(ii)(A)-(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. 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 provision states that if a container meets the conditions of (f)(12)(iii) and no label is required, the container must bear, at minimum,

the product identifier. For example, the product identifier (e.g., chemical name, code number or batch 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 provision 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 intended these proposed changes to provide chemical manufacturers, importers and distributors with flexibility in labeling small containers. The proposal was consistent with the small packaging examples provided in the GHS Annex 7: *Examples of Arrangements of the GHS Label Elements* (Document ID 0197, pp. 431-436), and would result in better alignment with Health Canada's HPR small capacity container requirements (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 requested comments on the feasibility of the proposed small container labeling provisions as well as whether the proposed changes would improve safe handling and storage for chemicals in small containers.

OSHA received numerous comments on proposed paragraph (f)(12). Most commenters supported adoption of (f)(12) (Document ID 0281, Att. 1, p. 4; 0309, p. 16;

0316, p. 6; 0323, pp. 6-8; 0329, pp. 5-6; 0338, pp. 7; 0339, pp. 3-4; 0345, p. 3; 0346, pp. 1-2; 0347, Att. 1, pp. 12-13; 0349, p. 1; 0359, p. 4; 0361, pp. 2-3; 0366, p. 4; 0367, p. 3). FCA described proposed (f)(12) as a “substantial improvement” and “strongly urge[d]” adoption of the provision (Document ID 0345, p. 3). The Flavor and Extract Manufacturers Association agreed that trying to include all the information required on a full-sized label on small packages is infeasible and voiced support for the flexibility that (f)(12) would provide (Document ID 0346, pp. 1-2). NAIMA called proposed (f)(12) a “common sense” solution (Document ID 0338, p. 7). While API noted that the addition of proposed paragraph (f)(12) to the HCS would likely impact laboratory samples, they indicated no concerns about adding it (Document ID 0316, p. 6).

Other commenters, while supporting this accommodation, had additional recommendations. ACC voiced general support for adding paragraph (f)(12) but recommended that the agency expand full relief to any container below 100 ml, eliminating the need for separate provisions for 3 ml and 100 ml (Document ID 0347, Att. 1, pp. 12-13; 0406, Att. 1, pp. 12-13). OSHA disagrees with this recommendation. The information on the immediate container is essential for worker safety and most containers, except for the very smallest, have enough room on the immediate container (either attached directly or with the use of tags or pull-out labels) to provide at least minimal information.

NACD and Loren Lowy recommended that the small package label also reference the SDS (Document ID 0329, pp. 5-6; 0333, p. 1; 0465, pp. 4-5). OSHA does not believe this is necessary. Workers should already be trained on the hazards they are exposed to and have ready access to the SDSs. Space on small containers is at a premium and including unnecessary references to the SDS might detract from the hazard information. However, NACD or others can add this statement if they deem it appropriate.

NIOSH recommended that outer packages be “water resistant” (Document ID 0281, Att. 1, p. 4). While OSHA believes “water resistant” packaging might be beneficial, this suggestion is beyond the scope of this rulemaking because OSHA did not propose any new requirements related to the durability of labels.

Hach supported the small package labeling provision but suggested that OSHA eliminate the requirement to include a U.S. phone number, stating that this takes up valuable label space and reduces harmonization with trading partners such as Canada and Mexico (Document ID 0323, pp. 6-8). OSHA disagrees with this suggestion. The phone number should be maintained on the label since this provides the worker with immediate access to where they can seek additional information if the SDS is not in the immediate vicinity.

Givaudan, PLASTICS, the Vinyl Institute, and ACA suggested that OSHA eliminate the need to show infeasibility while ICT requested that OSHA explain what the agency means by “demonstrating that it is not feasible” (Document ID 0293, p. 1; 0314, pp. 17-18; 0369, p. 9; 0324, p. 4; 0368, pp. 7-9). Michele Sullivan also noted that neither Canada nor the GHS requires proof of infeasibility (Document ID 0366, p. 4). OSHA maintains that requiring a showing of infeasibility is appropriate. It is imperative that, wherever possible, workers have the full label information on the immediate container to ensure safe use at all times. If this is demonstrated to be not feasible (for example, due to space considerations or extraordinary economic considerations), then OSHA has provided a way to minimize these impacts while still providing valuable information to workers. The label provides a concise, immediate, and conspicuous visual reminder of chemical hazards at the site where the chemical is used; reducing this information where it is feasible to provide the entire label would reduce protections for the downstream user of the chemicals. Relatedly, Ameren commented that prior approval should not be required for using the abbreviated labels (Document ID 0309, p. 12). To clarify, new

paragraph (f)(12) would not require prior approval, only that the company must demonstrate that the full label was infeasible.

HCPA's comment supported the agency's efforts, but requested that OSHA follow the approach of Canada, which does not require entire label elements on the outer package (Document ID 0327, pp. 5-6). OSHA believes that not having this information on the immediate outer package would be a reduction in protections that the HCS currently affords and removing this information would not provide any benefits other than aligning with Canada. While OSHA strives to align with Canada where possible, OSHA's primary mission is to protect workers. OSHA believes providing the full label on the immediate outer package is appropriate and provides the workers downstream with the information they need.

While not endorsing or disagreeing with the proposal, Epson asked if OSHA would offer the same exemptions as the EU CLP regulation which provides exemption for containers not exceeding 125 ml (Document ID 0288, p. 1). OSHA has chosen to provide labeling flexibility for containers of 100 ml or less because OSHA believes that the information on the immediate container is essential and the chemicals even in very small containers can be extremely hazardous. OSHA's determination to place the cut-off at 100 ml also aligns with Canada's small container labeling requirements and therefore serves the important purpose of consistency with our largest trading partner. Hach asked for the 3 ml limit for very small containers to be raised to 5 ml and provided photos in comments and testimony to demonstrate their concerns (Document ID 0323, pp. 6-8; 0425, Tr. 83-84). OSHA believes, however, that 3 ml is the appropriate cut-off for a total exemption of hazard information. This cut-off is consistent with Canada's requirements for small container labeling, and while Hach provided pictures of small containers of less than 5 ml, there is no indication that a label would interfere with the use of the product.

PLASTICS expressed concern about a “mixed kit” scenario, where an outer package would contain smaller containers of varying sizes or where some containers in a kit do not contain hazardous materials and would not be covered by the HCS, and proposed alternate regulatory language that would accommodate this type of situation (Document ID 0314, pp. 18-19). PLASTICS also requested that OSHA permit downstream users to relabel containers in such a scenario. While OSHA acknowledges that a “mixed kit” scenario might pose challenges in applying this accommodation, OSHA does not believe that the appropriate response is to move the responsibility of labeling the immediate container to the downstream users. This would require each downstream user to open each kit and figure out which container would need to be relabeled, creating the potential for mislabeling. OSHA already provides multiple flexibilities, including the use of attached tags which can be applied to the immediate outer container for the full information. Rev. 8 shows several different options on how to label “kits” in Annex 7 (example 10 - scenario A and B) (Document ID 0065, pp. 451-457).

Toby Threet suggested regulatory text changes for proposed paragraph (f)(12). Threet stated that any container less than or equal to 3 ml capacity is automatically also less than or equal to 100 ml capacity and label preparers cannot comply with both paragraphs (f)(12)(ii) and (f)(12)(iii); therefore, OSHA should modify paragraph (f)(12)(ii) to add a lower limit of “greater than 3 ml” (Document ID 0279, pp. 25-26). OSHA does not believe that this change is appropriate because paragraphs (f)(12)(ii) and (f)(12)(iii) have separate conditions that trigger their applicability; thus, there is no conflict between the two provisions. Threet also requested that OSHA exclude situations where the immediate outer container might itself present a hazard, such as if it became contaminated with radiation (Document ID 0279, p. 26). In such a situation, the downstream user would have an obligation to ensure appropriate labeling under

paragraph (f)(9); the agency does not believe it would be beneficial to complicate the regulatory text here.

OSHA received one additional comment that was beyond the scope of proposed changes related to paragraph (f). PLASTICS submitted a comment relating specifically to (f)(6)(iii) that recommends using color-coded charts to replace labels at workstations where solvents present an issue with label integrity (Document ID 0357, pp. 3-4). This comment is out of scope because it does not relate to any changes proposed in the NPRM. OSHA notes that this issue has already been addressed in the 2015 HCS compliance directive (Document ID 0007).

For the reasons discussed above, OSHA is finalizing paragraph (f)(12) of the rule as proposed.

PLASTICS and Vinyl Institute also asked OSHA to address the difficulties associated with creating labels to meet the requirements of multiple jurisdictions with inconsistent requirements even though the manufacturer “does not know where the product will be shipped at the time it is packaged and labeled” (Document ID 0314, Att. 1, p. 20; 0369, Att. 2, p. 10). PLASTICS and Vinyl Institute did not provide any specific suggestions regarding how OSHA should address this issue. The HCS has always differed in some respects from other jurisdictions that adopt the GHS, and the GHS anticipates that countries will adopt the GHS with slight variation, so OSHA does not believe this is a new issue presented by the updates in this rulemaking. OSHA does not have control over the requirements of other jurisdictions, but notes that many of the changes in this final rule are designed to better align with other jurisdictions to avoid issues with inconsistent requirements.

OSHA received two additional comments that are pertinent to paragraph (f), but that are out of scope for this rulemaking. PLASTICS requested that the agency codify the guidance in an LOI from November 23, 2015, that provides an exception for containers

that are shipped to destinations outside of the U.S. and sent directly overseas with no anticipated exposures to downstream U.S. workers (Document ID 0314, Att. 1, p. 20).

Vinyl Institute also identified this as a change that was missing from the proposals in the NPRM (Document ID 0369, Att. 2, p. 10). OSHA did not propose to codify this LOI in the NPRM, therefore this comment is outside the scope of this rulemaking and the agency declines to take the requested action.

(g) Safety data sheets.

Paragraph (g) specifies the requirements for chemical manufacturers and importers to obtain or develop an SDS for each hazardous chemical in the workplace. 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 for employees who are exposed to a hazardous chemical, industrial hygienists, safety professionals, emergency responders, health care professionals, and other interested parties. This final rule revises paragraphs (g)(2), which identifies what information must be included on an SDS, and (g)(10), which addresses the form and storage of SDSs, and corrects erroneous references to material safety data sheets in (g)(7).

The first sentence of paragraph (g)(2) previously stated 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 proposed to revise paragraph (g)(2) by removing the reference to preparing the SDS. The sentence as proposed reads “The chemical manufacturer or importer shall ensure that the safety data sheet is in English...”. This is a technical clarification intended to ensure consistency with paragraph (g)(1). OSHA also changed the wording in the parenthetical at the end of paragraph (g)(2) from “§

1910.1200–Safety Data Sheets” to “to this section.” OSHA received no comments on these proposed revision to (g)(2); therefore, OSHA is finalizing (g)(2) as proposed.

OSHA also proposed a change to paragraph (g)(10) to allow SDSs to be stored, rather than designed, in a way that covers groups of hazardous chemicals in a work area. When the HCS was first promulgated in 1983, paragraph (g)(10) permitted employers to design SDSs to cover groups of hazardous chemicals in a work area where it may have been more appropriate to address the hazards of a process rather than addressing the hazards of each chemical individually (48 FR 53337).

In 2012, OSHA changed the SDS provisions of the HCS to require a standardized 16-section format, which improved hazard communication by ensuring users could quickly find relevant information (see 77 FR 17596-98). The standardized format requires each SDS to address a single hazardous chemical rather than groups of hazardous chemicals. Therefore, OSHA has proposed 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. As OSHA explained in the NPRM, the proposed change would allow employers flexibility in how they keep SDSs in the workplace while also ensuring that the required SDS format is maintained (86 FR 9700). The agency requested comments regarding whether the proposed revision would require stakeholders to make any significant changes to their current practices (86 FR 9688).

Several commenters expressed support for this proposed revision. NAIMA supported the proposed revision, as SDSs must currently follow a standard format (Document ID 0338, p. 8). NACD similarly observed that the proposed revision “makes sense as the HCS requires SDSs to use a standard format” and further noted that it would not require any major changes to chemical distribution operations (Document ID 0329, p. 6). Ameren also noted that the proposed revision would not require significant changes to its current practices (Document ID 0309, p. 12). In addition, NIOSH stated that it is

unaware of any changes to current practices that will be required by the proposed revision (Document ID 0281, p. 4; 0423, Tr. 19). OSHA received no comments or testimony objecting to the proposed revision to (g)(10).

Several commenters requested clarification regarding the proposed change to paragraph (g)(10). API asked for “further clarification about the storing language” (Document ID 0316, p. 9). ACC asked if the revision would allow electronic storage of SDSs, or merely allow employers to group the SDSs together (Document ID 0347, p. 12). Dow also asked for clarification on electronic storage, stating that they “do not foresee an impact as long as OSHA can confirm that this change will still allow for on-site back-up storage of SDS’s while also allowing employers to provide electronic access to employees” (Document ID 0359, p. 4).

In response to API’s request for clarification, OSHA notes that the general intent of the change to (g)(10), as discussed in the NPRM and reiterated above, is to allow the individual 16-section SDSs required by the 2012 HCS to be stored in a way that covers groups of hazardous chemicals in a work area (86 FR 9700). Because the HCS now requires an individual SDS for each chemical, however, employers can no longer “design” SDSs that cover groups of hazardous chemicals. Following publication of the final rule, OSHA will issue guidance materials and respond to inquiries on any aspects of the HCS for which stakeholders request information or clarification.

In response to questions regarding electronic storage, OSHA notes that paragraph (g)(8) of the HCS, which requires the employer to maintain copies of the required SDSs for each hazardous chemical and make sure that they are readily accessible to employees when they are in their work areas, specifically permits electronic access to SDSs provided that such access poses no barriers to immediate employee access. OSHA elaborated on this in the preamble to the 2012 HCS (77 FR 17729). OSHA’s revision to (g)(10) does not change the requirements of (g)(8); the HCS still allows employers to provide SDSs

via electronic access as long as employees have immediate access to the SDSs and employers are able to immediately provide copies of SDSs to medical personnel.

For the reasons discussed above, OSHA is finalizing paragraph (g)(10) as proposed.

Additionally, OSHA is also correcting references to material safety data sheets in (g)(7)(i), (iii), and (iv) which it identified after the NPRM. In this final rule, OSHA is updating those references to reflect the change to the terminology safety data sheets in the 2012 HCS.

Finally, OSHA received one out-of-scope comment regarding paragraph (g)(4). TFI and ARA jointly commented that (g)(4) permits agricultural retailers to create a single SDS for all custom fertilizer blends of the same hazard classification, and asked OSHA to include a statement in the preamble adopting this interpretation (Document ID 0340, pp. 4-6).

Paragraph (g)(4) allows chemical importers, manufacturers and retailers to prepare a single SDS where complex mixtures have similar hazards and contents (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture). Where a single SDS is used for similar mixtures or in cases of batch-to-batch variability, concentration ranges of ingredients may be used. If the composition differences are small, and the hazard(s) remain the same, concentration ranges may be used for multiple, similar products; however, separate SDSs are required for blends containing distinct ingredients. TFI and ARA's comment is beyond the scope of this rulemaking because OSHA did not propose any revisions to paragraph (g)(4). In addition, as TFI and ARA noted in their comment, OSHA has previously addressed this question in a letter of interpretation requested by TFI. As stated in that letter, OSHA cannot provide a blanket approval because the agency does not approve or endorse SDSs (available at <https://www.osha.gov/laws-regs/standardinterpretations/2016-02-25>.)

(i) Trade secrets.

Paragraph (i) of the HCS 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.

In the NPRM, OSHA proposed several changes to paragraph (i). First, OSHA proposed to allow manufacturers, importers, and employers to withhold a chemical's concentration range as a trade secret, which had not previously been permitted, and to add language specifying that it is Section 3 of the SDS from which trade secret information may be withheld. Second, OSHA proposed to require 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. These changes were proposed to align with Canada's WHMIS, allowing manufacturers, importers, and employers the ability to use the same SDS for both U.S. and Canadian workplaces. The proposed ranges are the same as those required by Canada (Document ID 0172). Third, OSHA proposed to replace the phrase "physician and nurse" in paragraph (i) with the term *Physician or other licensed health care professional (PLHCP)*, defined 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.

OSHA requested comments on the proposed changes to paragraph (i), including information on stakeholders' experiences with developing SDSs using the prescribed concentration ranges for compliance with Canada's WHMIS and any concerns they might have about using concentration ranges on the SDS. OSHA also requested comments on whether the proposed ranges would provide sufficient information for

downstream manufacturers to conduct hazard classifications and whether the proposed ranges would be too wide to provide sufficient information to protect workers.

Additionally, OSHA requested comments specific to proposed new paragraph (i)(1)(v), which would require use of the narrowest applicable concentration range, but in cases where the concentration range to be withheld falls between 0.1 percent and 30 percent and does not fit entirely into one of the prescribed concentration ranges, would permit use of a single range created by the combination of two applicable consecutive ranges instead, provided that the combined concentration range does not include any range that falls entirely outside the actual concentration range in which the ingredient is present. OSHA requested comments on this proposal and on two alternatives to the proposed provision: a more lenient version, allowing combinations among all ranges up to 100 percent concentration, and a more restrictive version, such as allowing combinations only for the ranges up to 10 percent concentration.

Several commenters expressed general support for OSHA's proposal to allow actual concentration ranges to be withheld as a trade secret and to require the use of prescribed concentration ranges (Document ID 0316, p. 28; 0323, p. 9; 0329, p. 6; 0359, p. 4; 0361, pp. 2-3; 0363, pp. 6-7; 0368, p. 12; 0425, Tr. 75-78). IMA-NA supported the trade secret protections in the NPRM, stating that the proposed revisions would provide necessary flexibility in the use of concentration ranges for mixtures omitted from SDS disclosures and protect sensitive information (Document ID 0363, pp. 6-7). NACD commented that the prescription of ranges would improve accuracy of companies' hazard assessments and reporting by introducing a standardized set of ranges and reducing "guesswork" in the selection of an appropriate range and would ease compliance with OSHA's PSM standard and the EPA's Risk Management Program, (Document ID 0329, p. 6; 0423, Tr. 178-179). Dow also supported the use of prescribed ranges to protect trade secrets, stating that OSHA's proposal "strikes a fair balance between disclosure of

information and worker protection” (Document ID 0359, p. 4). NABTU strongly supported the proposed requirement of mandatory concentration ranges (Document ID 0334, p. 4; 0425, Tr. 24-25).

Several commenters, including industrial entities or associations such as Hach, NACD, Dow, and ACA, additionally supported the specific ranges OSHA proposed, which align with those already in use by Health Canada (Document ID 0323, p. 9; 0329, p. 8; 0359, p. 4; 0368, p. 12). ACA noted that some ACA members already use the ranges prescribed by Canada and have found that the ranges provide adequate information to downstream users (Document ID 0368, p. 12).

OSHA also received comments critical of its proposal. Some stakeholders argued that the proposed requirement would weaken protections for CBI relative to the provisions of the 2012 HCS. Among these, most suggested that OSHA should make the use of prescribed concentration ranges optional for entities claiming the actual concentration range as a trade secret (Document ID 0319, p. 2; 0321, pp. 2-3; 0327, p. 6; 0343, p. 3; 0356, p. 4; 0343, p. 3; 0347, pp. 13-14; 0366, p. 6; 0367, p. 3; 0369, p. 9; 0374, p. 2; 0424, Tr. 13; 0447, pp. 4-5), while FCA favored maintaining the existing trade secret provisions (Document ID 0345, p. 4). Several stated that the specific ranges OSHA proposed would be too narrow to adequately protect CBI (Document ID 0324, p. 4; 0345, p. 4; 0366, p. 6; 0367, p. 3; 0369, p. 9; 0468, pp. 3-4), or could be confusing because some of the ranges overlap one another (Document ID 0345, p. 4) or cross some hazard classification thresholds (Document ID 0347, p. 14; 0349, pp. 1-2; 0366, p. 6). Michele Sullivan commented that ranges which cross hazard classification thresholds “could also cause a conflict with the EU CLP requirements” (Document ID 0366, p. 6).

A few commenters stated that requiring the use of prescribed ranges would be expensive and time-consuming for companies who would need to program changes to their SDSs for use in the U.S. if claiming actual concentration range as a trade secret

(Document ID 0343, p. 3; 0347, pp. 13-14); NAIMA, on the other hand, commented that it “is not aware of any economic implications associated with including the prescribed concentration ranges so long as they are not so narrow as to effectively annul the Trade Secret” (Document ID 0338, p. 8). Others argued that workers are adequately protected under the standard’s existing provision allowing medical professionals to obtain chemical composition from the chemical manufacturer, importer, or employer in an emergency, in addition to the standard’s existing provisions for OSHA and certain others to obtain it in some non-emergency situations (Document ID 0366, p. 6; 0356, p. 4; 0337, p. 2; 0349, pp. 1-2). APA commented that the previously existing HCS provisions for trade secrets and medical personnel access to information are appropriate because errors in judgment may occur if emergency responders opt to rely on information from a prescribed range instead of contacting the manufacturer to get an exact percentage (Document ID 0337, p. 2).

While most commenters who expressed concern about protection of CBI or the potential costs of compliance did not give further information, examples, or analysis to support their position, a few provided additional explanation. ILMA noted that, because their products are often customized, a requirement to provide concentration range information could compromise CBI for their customers as well as themselves, and that legal protections of CBI may be lost once a trade secret is revealed through non-illicit means (Document ID 0356 p. 4; 0424, Tr. 120-121). ACC stated that the concentration of a substance within a mixture could possibly be determined “for example, if the classification limit is close to one of the concentration cutoffs” (Document ID 0347, p. 14). In their post-hearing comments, ACC provided a hypothetical example: “If there are 2-3 components in a solution one at 95% and two at 2 and 3 %, the 1 to 5% range could just be a few competitor tests away from getting it right... [A] wide range protects more” (Document ID 0468, pp. 7-8). NAIMA’s post-hearing comment stated that “For mixtures,

any [range] less than 10 percent would be too narrow.” NAIMA also stated that the following ranges “have been identified as . . . sufficient to protect trade secrets: a) 7 to 13%; b) 10 to 30%; c) 15 to 40%; d) 30 to 60%; e) 45 to 70%; f) 60 to 80%; g) 65 to 85%; h) 80 to 100%; and 0-10%” (Document ID 0461, p. 1).

Some commenters suggested that companies should be allowed to design ranges appropriate to their CBI or other business needs (Document ID 0319, p. 2; 0324, p. 4; 0345, p. 4; 0363, p. 6; 0366, p. 6; 0425, Tr. 24-25). For example, ICT commented that OSHA should permit mixture manufacturers/importers to prepare SDSs with concentration ranges that sufficiently protect their trade secrets (Document ID 0324, p. 4) and FCA requested that manufacturers be allowed to utilize ranges customary within their industry (Document ID 0345, p. 4). In addition, several commenters suggested that OSHA should allow companies to select ranges narrower than those OSHA proposed (Document ID 0299, pp. 2-3; 0309, pp. 13-16; 0321, p. 2; 0334, pp. 3-4; 0349, p. 1; 0359, p. 4; 0368, p. 12; 0425, Tr. 24-25, 35-36, 117-118; 0464, p. 6). Dow noted that Health Canada’s latest proposed revision to their HPR codifies a similar allowance for smaller ranges that fit within the prescribed ranges, so that adoption of a similar provision by OSHA would maintain alignment with Canada (Document ID 0359, p. 4).⁵⁷ Industrial Health and Safety Consultants (IHSC) suggested that the issue of over-classification (i.e., cases in which use of a prescribed range could result in classifying a substance in an additional and/or higher hazard category) could be alleviated by allowing the use of concentration ranges narrower than those proposed (Document ID 0349, pp. 1-2). PLASTICS asked whether a classifier would be required to classify a product to reflect the most severe category into which the highest point of a range selected to represent batch variability would fall (Document ID 0314, p. 21).

⁵⁷ Health Canada published the update to their HPR in December 2022. Their final rule includes the allowance for narrower ranges. Canada Gazette, Part II, Volume 157, Number 1.

NABTU supported permitting manufacturers and importers to use their own concentration ranges if they are narrower than the prescribed ranges (Document ID 0425, Tr. 24-25; see also Document ID 0334, p. 4; 0424, Tr. 35-36, 0464, p. 6).

NIOSH testified at the public hearing that “non-mandatory use of the prescribed concentration ranges... could weaken protection of workers by downplaying the contribution of the chemical in question to the hazards of the product” (Document ID 0423, Tr. 20) and that the prescribed concentration ranges “will allow handlers of the materials better protections and better hazard communication, as well as emergency responders potentially dealing with a substance and having to access that information readily” (Document ID 0423, Tr. 31-32). NIOSH also commented that allowing manufacturers to use their own concentration ranges could result in ranges so broad as to be nearly useless, providing the example of an SDS that listed a concentration range from one-half of one percent to 50 percent (Document ID 0281, p. 6; 0423, Tr. 30-31, 47-48). NABTU echoed this concern, stating in post-hearing comments, “[t]he wide concentration ranges manufacturers are currently listing on their SDSs make it more difficult to determine if the use of a given product is likely to result in exposures above or below levels considered to be safe” (Document ID 0464, p. 6).

After considering all comments received on the agency’s proposed requirement to use prescribed ranges which align with those in use by Health Canada, OSHA has decided to finalize the requirement to utilize prescribed concentration ranges when claiming exact concentration as proposed, with the exception that OSHA is adding a new paragraph (i)(1)(vi). This new provision allows the use of narrower ranges than those prescribed in (i)(1)(iv) and (i)(1)(v), meaning that the range must be fully within the bounds of a prescribed range listed in (i)(1)(iv) or fully within the bounds of a combination of ranges allowed by (i)(1)(v). OSHA’s responses to the concerns received regarding proposed paragraph (i) are given below.

First, OSHA is not persuaded that requiring the use of prescribed ranges, or the specific ranges the agency proposed, would significantly compromise CBI. The trade secret provisions of the HCS do not rely only on withholding of concentration information in order to protect CBI, but also allow the manufacturer or supplier to claim the chemical identity as CBI (paragraph (i)(1)). In addition, OSHA does not require listing the chemical's generic chemical identity or alternative name (e.g., "Alcohol" for propanol vs. "Component 1"), which provides additional CBI protection. And, while several commenters opined that required use of the ranges OSHA proposed could compromise CBI, none provided persuasive information, argument, or analysis to support their concerns or preferred alternative. While NAIMA provided alternate ranges for OSHA's consideration in post-hearing comments, which they said, "have been identified as . . . sufficient to protect trade secrets," this statement is not supported by the source NAIMA cites. That source is a document summarizing the thirteen prescribed concentration ranges included in Canada's 2015 update to the HPR for use in protecting trade secrets. These ranges include the ranges (a) 0.1 to 1 percent; (b) 0.5 to 1.5 percent; and (c) 1 to 5 percent, which are not included in the set of ranges NAIMA gave when citing the summary document. They do not include the range 0-10 percent, which was included in NAIMA's post-hearing comment citing the document. NAIMA's statement that the ranges it listed "have been identified" as protective of CBI therefore does not accurately reflect the content of the source it cited; rather, that source refers to the prescribed ranges that Canada adopted and that OSHA proposed in the NPRM (Document ID 0461, p. 2).

Furthermore, OSHA's proposed ranges have been in use by entities trading in Canada since 1988 (previously under WHMIS 1988 and then reinstated under the HPR in 2018), yet no commenter provided a real-world example of CBI compromised due to the use of Canada's prescribed ranges. Notably, ACA stated that some of its members

already use the ranges prescribed by Canada and have found they provide adequate information to downstream users (Document ID 0368, p. 12); ACA did not report that using the prescribed ranges compromised any of their members' trade secrets. NACD commented that individuals involved in the commercial and sales aspects of chemical distribution "reported no concerns that the prescribed ranges would inadvertently disclose trade secret information" (Document ID 0329, p. 6; 0423, Tr. 178-179). API stated it had no concerns with the proposed change (Document ID 0316, pp. 10, 28). And, as previously noted, OSHA received comments from several industrial entities or associations including Hach, NACD, Dow, and ACA, specifically supporting the requirement to use the ranges used by Health Canada (Document ID 0323, p. 9; 0329, p. 8; 0359, p. 4; 0368, p. 12).

After consideration of the comments received on possible compromise of CBI, OSHA finds that these commenters have not adequately supported their position that the proposed requirement to use prescribed concentration ranges would significantly compromise CBI. OSHA is also not persuaded that paragraph (i) should include broader ranges than those proposed or allow companies flexibility to design ranges broader than those proposed. Creating broader ranges would be less informative to workers and other downstream users, and would negate the benefit of consistency with Canada's system. However, OSHA notes in response to PLASTICS that classifiers would be required to classify a substance according to the most severe hazard associated with the range they select, and agrees with comments that allowing the use of narrower concentration ranges than those prescribed would alleviate some of the classification concerns raised by stakeholders without compromising the information provided to workers and other users. Therefore, OSHA is adding a new paragraph (i)(1)(vi) which states that the SDS preparer may provide a range narrower than those prescribed in (i)(1)(iv) or (i)(1)(v). This means that the range selected must be fully contained within the range or combination of ranges

required under (i)(1)(iv) and (i)(1)(v), inclusive of the boundaries of such ranges. For example, when the ingredient's concentration range in the mixture is 0.9 to 2 percent and that range is claimed as CBI, paragraph (i) as proposed would have required the manufacturer or supplier to give the range 0.5 to 5 percent (a combination of the prescribed ranges 0.5 to 1.5 percent and 1 to 5 percent). The revision to the proposed text allows the manufacturer or supplier to disclose a narrower range such as 0.5 to 2 percent, or 0.9 to 5 percent, or 0.5 to 2.5 percent. If a manufacturer or supplier finds that the concentration range they intend to claim as a trade secret is below a certain hazard classification/category threshold but using a prescribed range (or allowable combination of prescribed ranges) would trigger other requirements (e.g., shipping, storage) which would not have been triggered by the actual concentration range, they may use a narrower range or combination of ranges to avoid this issue. The allowance for the use of narrower concentration ranges that fall within the prescribed ranges aligns with Canada's WHMIS (Document ID 0172).

OSHA also disagrees with commenters who stated that requiring the use of prescribed concentration ranges would provide no benefit to workers beyond the existing provisions pertaining to medical emergency situations, which allow medical professionals to obtain chemical composition from the chemical manufacturer, importer, or employer in the event of a medical emergency. OSHA has determined that providing ready access to information about the concentration range of hazardous substances to workers and other users is also essential to the purposes of the HCS when such ranges are claimed as trade secrets. Workers have a right to know, and to be able to readily access, information about the nature and extent of their occupational exposures to hazardous substances for their own information, records, and use—for example, in the event that health concerns arise that may be work-related. In addition, OSHA believes that emergency responders will benefit from ready access to the prescribed concentration range of a hazardous

substance, particularly in cases where it may not be possible to achieve immediate contact with the producer. Furthermore, the use of prescribed ranges will help employers and other users to appropriately assess risk in the workplace, even before an emergency arises. This requirement provides information to help manage risk proactively.

Some commenters objected that OSHA's proposed changes to paragraph (i) would not sufficiently inform workers regarding hazardous materials in the workplace (Document ID 0268; 0299, pp. 2-3; 0341, pp. 38-39; 0354, p. 1, 0354, p. 6, 0356, p. 6). National COSH and Worksafe jointly commented that the proposal would increase uncertainty for workers as well as for regulators, employers, worker representatives and other decision-makers (Document ID 0354). In contrast, NABTU found the proposed approach to be an acceptable alternative to the current standard as the prescribed concentration ranges "would at least provide some information [about] concentration in every instance of the trade secret claim" (Document ID 0425, Tr. 24-25). NIOSH stated that the proposed change would not increase risk to workers provided that the trade secret exemption is applied only in limited and specific situations, and that complete information on hazardous properties, special handling requirements, and necessary PPE is provided on the SDS (Document ID 0281, p. 4; 0423, Tr. 19-20).

OSHA disagrees with comments that the proposed revisions to paragraph (i) would lessen protections and/or information for workers. Under paragraph (i), there are three types of information that manufacturers can claim as a trade secret: the name of a chemical, the exact percentage of a chemical's concentration in a mixture, and/or a concentration range. In the 2012 HCS, OSHA allowed manufacturers to completely withhold the name and/or the exact percentage; manufacturers who withheld a chemical's exact percentage were not required to list a concentration range in its place. Under this final rule, manufacturers may no longer completely withhold the exact percentage; they

must now provide a concentration range in its place. This change will result in additional information available to workers.

The Work Health and Survival Project (WHSP) and an anonymous commenter suggested that OSHA should adopt the trade secret policies of Australia's Work Health and Safety (WHS) regulation, in which the identities of chemicals presenting moderate hazards may be withheld as trade secrets on the SDS and disclosed using a generic name (Document ID 0341, pp. 38-39; 0268). A different anonymous commenter, who claimed to have experience with companies that make insufficiently supported trade secret claims as a pretext for withholding the identity or percentage of hazardous ingredients, opined that OSHA's proposal to allow the concentration range to be withheld as a trade secret would make it more difficult for downstream users to conduct hazard classifications, and that "the inappropriate claiming of trade secret status should be addressed before companies are allowed to also claim the range as a trade secret" (Document ID 0308, p. 1). They suggested that the HCS should not allow "chemical ingredients of public knowledge or of general knowledge in an industry" to be claimed as a trade secret.

OSHA did not propose to require the use of a generic name when the identity of chemicals presenting moderate hazards are withheld as trade secrets or to disallow trade secret protection for generally known chemical components. These suggestions are therefore out of scope for this rulemaking. For OSHA to consider these changes they would need to be addressed in a future rulemaking. Furthermore, OSHA does not agree that the proposal to allow concentration ranges to be withheld as a trade secret must not be finalized until the possibility that some manufacturers may be using the trade secret provisions inappropriately is eliminated. OSHA believes that potential misuse of trade secret protections is best addressed through enforcement.

Several commenters gave input on the proposed rules for combining ranges, including responses to the question OSHA posed in the NPRM as to whether it should

allow more expansive combination of the prescribed ranges. NAIMA and Ameren supported combination of all ranges listed (Document ID 0309, p. 13; 0338, p. 8; 0423, Tr. 162-163). Ameren cited “potential cost savings by OSHA allowing combinations among all ranges” (Document ID 0309, p. 13).

DOD opposed allowance for combinations of all prescribed ranges, arguing that the benefits to be gained by requiring use of prescribed ranges would be negated by allowing combination of an unlimited number of concentration ranges. DOD recommended instead that OSHA should “allow no more than 2 prescribed concentration ranges, below 20%, to be combined as this would still provide actionable information for managers and safety professionals to protect worker health” and that the use of any concentration range greater than 20% (or combined concentration ranges greater than 20%) should require some form of special exemption (Document ID 0299, pp. 2-3).

OSHA agrees with DOD that allowing employers to combine prescribed ranges from (i)(1)(iv)(A) through (M) would prevent important information from reaching employees and health and safety professionals. However, OSHA does not agree that limiting concentration ranges to no greater than 20% will materially improve the effectiveness of the standard over the concentration ranges OSHA proposed. Most of the concentration ranges OSHA proposed to adopt in paragraph (i)(1)(iv) are 25% or less, with the exception of paragraph (i)(1)(iv)(I) (concentrations between 30% and 60%). The largest range that could be created through combining ranges is 23% (for concentrations of 7% to 30%). As explained above, the ranges chosen have been in use by entities trading in Canada since 1988 and OSHA finds no evidence in the record, or in DOD’s comment, demonstrating that these ranges are insufficient to effectively inform workers and downstream users of chemical hazards. In addition, altering the concentration ranges would negate the benefit of consistency with Canada’s system. Therefore, OSHA is not adopting DOD’s suggestion.

PLASTICS asked OSHA to clarify what is required if the actual concentration range straddles two prescribed ranges, in two situations. First, PLASTICS stated that the proposal “does not clearly convey the options available if the exact range falls between 0.1% and 30% and does not fit entirely into one of the prescribed ranges.” Second, PLASTICS asked for clarification on what should be done if the actual concentration range straddles two prescribed ranges and it exceeds 30%. PLASTICS proposed the following revision to address these situations: “[w]hen the concentration or concentration range for an ingredient is withheld as a trade secret, the SDS must list the narrowest prescribed concentration range(s) in § 1910.1200(i)(1)(iv) which include(s) the actual concentration or concentration range for that ingredient” (Document ID 0314, p. 21; see also 0423, Tr. 142-143).

OSHA disagrees with PLASTICS’ suggestion. First, OSHA believes proposed paragraph (i)(1)(v) does clearly specify what a manufacturer must do when the exact range falls between 0.1 and 30 percent but does not fit entirely into one of the prescribed ranges (A) through (G). In that case, the manufacturer must combine two consecutive ranges between (A) and (G) and may supply the resulting range in place of selecting a single prescribed range to represent the concentration range on the SDS.

Regarding PLASTICS’ question as to what should be done when a concentration range above 30 percent cannot be captured by the use of a single prescribed range, OSHA believes in such a circumstance it would be inappropriate for a manufacturer to withhold the concentration range from the SDS. In the hypothetical case where representing a manufacturer’s batch would require a combination of ranges above 30 percent, the resulting range would generally be too wide to provide meaningful information to workers, and permitting such combinations would bring the HCS out of alignment with Canada. Therefore, OSHA is not adopting PLASTICS’ proposed revision. OSHA notes

that manufacturers would still, in such cases, have the option of withholding the chemical identity in order to protect trade secret information.

ADM similarly suggested that OSHA revise paragraph (i) “to clarify that any of the prescriptive concentration ranges be allowed, if accurate” (Document ID 0361, p. 3). OSHA notes that ADM’s requested change would contradict, rather than clarify, the agency’s intent. Manufacturers must use the narrowest range possible that includes the true concentration range, so that workers will have access to the most precise information possible under a system of prescribed ranges which align with Health Canada’s requirements.

For the reasons discussed above, OSHA is finalizing the rules for combination of prescribed ranges as proposed, with the exception that OSHA has added paragraph (i)(1)(vi) to allow use of narrower ranges, and narrower combinations of ranges, than those described in (i)(1)(iv) and (i)(1)(v) respectively.

PLASTICS also suggested revising (i)(1) to state that the chemical manufacturer, importer, or employer may withhold the chemical identity and/or concentration or concentration range of a hazardous chemical “*substance... from Section 3 (as well as every other section)* of the safety data sheet...” (emphasis added to indicate PLASTICS’ suggested additions to (i)(1)) (Document ID 0314, p. 20). PLASTICS opined that the reference to Section 3 in paragraph (i)(1) “could imply that it must still be included elsewhere” on the SDS.

OSHA does not believe that PLASTICS’ suggested text is necessary or appropriate. OSHA intended the instructions contained in paragraph (i)(1) to pertain to how to treat chemical trade secrets for Section 3 of the SDS. This is evident in OSHA’s HCS Compliance Directive, which specifies that if a trade secret is claimed, the SDS must indicate that the identity and/or concentration of the chemical is claimed as a trade secret in Section 3 (Document ID 0007, pp. 76-77). OSHA proposed to add “in Section

3” to paragraph (i)(1) to ensure that its intent for the directions contained in paragraph (i)(1) to apply specifically to the SDS Section 3 is clear. However, OSHA did not intend for this clarification to imply that a manufacturer who withholds the identity of a hazardous chemical from Section 3 in accordance with paragraph (i) must provide the name of that chemical in other sections, such as in conjunction with its OSHA Permissible Exposure Limit (PEL) or American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) (if applicable) in Section 8. Rather, the identifier provided for that chemical in Section 3 should be used consistently throughout the SDS. This is also conveyed by the directive, which indicates that the identifier used in Section 3 and Section 8 must be the same if there is a PEL or TLV associated with the constituent. In addition to the requirement to use a single identifier for a hazardous chemical throughout the SDS, OSHA notes that in other sections where a manufacturer may make specific claims about a chemical constituent’s health effects and provides supporting evidence for those claims (e.g., Section 11, Toxicological information) the manufacturer must provide sufficient information regarding the chemical identity for others to assess these claims.

Furthermore, OSHA notes that PLASTICS does not explain the addition of “substance” in its suggested text. The agency finds that adding “substance” in the place indicated does not improve on the original text and is not making this change to the regulatory text.

Toby Threet was concerned that if a range is broader than OSHA’s specified “‘trade secret’ ranges, but... not being withheld as a trade secret... an Agency inspector [may] misunderstand and issue a citation, believing that these broad ranges did not comply with paragraphs (i)(1)(iv) and (i)(1)(v).” Threet requested “clarification from OSHA that the provisions of paragraphs (i)(1)(iv) and (i)(1)(v) apply only to concentration ranges that are withheld as a trade secret, not to actual concentration ranges

that are disclosed in the SDS. Thus, if the actual concentration range is broader than the ranges stated in paragraph (i), and is disclosed, this does not constitute noncompliance with paragraph (i)” (Document ID 0279, p. 7). OSHA does not believe this to be an issue because paragraphs (i)(1)(iv)-(v) unambiguously apply only to trade secret claims and paragraph (i)(1)(iii) requires the SDS to indicate when the specific chemical identity and/or percentage concentration or concentration range of composition is being withheld as a trade secret. Moreover, OSHA expects that its inspectors will be adequately trained in the proper application of the standard’s requirements. Therefore, OSHA does not believe there will be any confusion on this point and is not adopting Threet’s suggestion.

As explained in the Summary and Explanation for paragraph (c), OSHA proposed in the NPRM to add a definition of *Physician or other licensed health care professional (PLHCP)* to the standard, defined 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. Correspondingly, OSHA proposed to replace the phrase “physician and nurse” in paragraph (i) with “PLHCP” to be consistent with other OSHA standards that use the term PLHCP and to better reflect current medical practices. No commenter objected to this revision.

In their comments and at the public hearing, PLASTICS requested guidance on what measures an employer may take prior to disclosing a trade secret in the event of a medical emergency to verify it would be disclosed to an appropriate individual (Document ID 0314, p. 21; 0423, Tr.142-143). Paragraph (i)(2) specifies that where a treating PLHCP determines that a medical emergency exists and the chemical identity and/or specific percentage concentration of a hazardous chemical is needed for emergency or first-aid treatment, the chemical manufacturer, importer, or employer must immediately disclose the specific chemical identity or percentage composition of a trade

secret chemical to that treating PLHCP, regardless of whether a written statement of need or a confidentiality agreement exists. However, 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), as soon as circumstances allow. The confidentiality agreement authorized by paragraph (i)(3)(iv) provides remedies to ensure CBI is protected.

Finally, PLASTICS and Michele Sullivan expressed concern that the use of “or” in paragraph (i)(1) could suggest that either the identity or the concentration of an ingredient may be withheld as CBI, but not both. (Document ID 0314, pp. 20-21; 0366, p. 5). OSHA’s intent is that both chemical identity and the exact percentage (or the concentration range) may be claimed as a trade secret. To clarify this, and to be consistent with similar language in paragraph (i)(1)(iii), OSHA has revised paragraph (i)(1) in the final rule to state that the manufacturer, importer, or employer may withhold the specific chemical identity *and/or* the exact percentage (concentration) or concentration range of the chemical for which a trade secret is claimed.

(j) Dates.

Paragraph (j) of the HCS specifies the dates by which compliance with the updated provisions of the HCS is required. This final rule modifies the previous dates in paragraph (j), which pertained to implementation of the 2012 update to the HCS and have all passed. As explained below, OSHA has modified the compliance dates in the final rule from those proposed in the NPRM to address stakeholders’ concerns that the proposed dates did not provide sufficient time for chemical manufacturers, importers, and distributors to comply.

In the NPRM, OSHA proposed a two-year tiered compliance period. First, OSHA proposed that the final rule would become effective 60 days after the publication date (paragraph (j)(1)). The agency then proposed two staggered compliance dates: chemical

manufacturers, importers, and distributors evaluating substances would be required to comply with all modified provisions of the HCS no later than one year after the effective date (paragraph (j)(2)) and chemical manufacturers, importers, and distributors evaluating mixtures would need to comply no later than two years after the effective date (paragraph (j)(3)) (86 FR 9701).

OSHA received numerous comments on the proposed dates in paragraph (j), including requests for extension of compliance dates; comments related to the proposed differentiation between compliance dates for substances and mixtures; and requests for clarification.

Two commenters stated that they believed the proposed compliance dates were adequate (Document IDs 0309, p. 17; 0360, p. 9). Many commenters, however, requested more time to comply with the proposed changes to the HCS. Suggestions included extension of compliance dates ranging from an additional six months to two years for substances and six months to three years for mixtures (see, e.g., Document ID 0347, pp. 14-16; 0423, Tr. 106; 0327, pp. 2-3; 0329, pp. 9-10; 0343, p. 4; 0349, pp. 2-3; 0338, pp. 5; 0461, pp. 3-5; 0368, p. 10; 0323, p. 10; 0367, p. 6; 0447, p. 6; 0291, pp. 2-4; 0356, p. 11; 0339, p. 4; 0316, p. 11; 0364, p. 3; 0283, p. 6). Commenters based these recommendations on a number of considerations related to the difficulty of updating labels and SDSs. For example, ACC stated that a significant number of the proposed changes to the HCS would either require updating a large number of SDSs, such as the requirement to list particle characteristics, or would require extensive time to implement properly due to the need to purchase new software, test and approve changes to software, and update precautionary statements on SDSs (Document ID 0347, pp. 15-17). NAIMA noted additional reasons that updating labels and SDSs would be time-consuming, including the time required to replace language or change color on a product label;

review the changes for quality, accuracy, and compliance with all regulatory requirements; and redesign the labels (Document ID 0338, pp. 4-5; 0461, pp. 3-5).

Several commenters expressed support for OSHA's proposed tiered approach which provided a later compliance date for chemical manufacturers, importers, and distributors responsible for evaluating mixtures than for those evaluating substances (See, e.g., Document ID 0323, p. 10; 0327, p. 2; 0356, p. 10; 0366, p. 6; 0367, p. 6; 0447, p. 6; 0347, p. 14; 0287, p. 12; 0309, p. 17; 0316, p. 11). However, some commenters expressed concern that the compliance windows were too short because downstream users might not receive key information from upstream manufacturers, importers, or distributors in time to comply with the requirement to update SDSs or labels (See, e.g., Document ID 0327, pp. 2-3; 0329, p. 10; 0356, p. 10; 0317, p. 2; 0314, pp. 22-23; 0338, pp. 3-5; 0323, p. 10; 0287, p. 11; 0362, pp. 4-5). The National Association of Manufacturers (NAM) noted that many downstream manufacturers, importers, or distributors may not know whether there are any updates in classification coming from upstream (Document ID 0362, pp. 4-5). Hach echoed this concern, stating that this issue had previously caused problems with OSHA's 2012 update to the HCS (Document ID 0323, p. 10). Hach suggested that OSHA extend the compliance deadline for chemical manufacturers of mixtures to two years beyond the compliance date for substances (Document ID 0323, p. 10).

For similar reasons, some commenters recommended adding an additional tier for chemical manufacturers who combine multiple mixtures since they will be reliant on upstream manufacturers, importers, or distributors for new information, which may come at the end of the compliance period for the mixture tier (Document ID 0317, p. 2; 0362, pp. 4-5; 0326, p. 8). NAM and NRI recommended that in this potential third tier OSHA should explicitly state that such companies are allowed three months to update SDSs and six months to update labels from the date the companies receive new information from

upstream suppliers (Document ID 0362, p. 5; 0326, p. 8). NACD proposed a slightly different change to the tiered compliance dates and requested that OSHA adopt a staggered implementation timeline based on role in the supply chain, where the original chemical producer would have 18 months to comply, and the next segment of the supply chain (typically chemical distributors) would have an additional year (Document ID 0329, pp. 9-10).

As the following discussion explains, OSHA believes that the proposed compliance dates will be adequate for implementation of most of the HCS revisions included in this final rule. However, OSHA is adopting a modest extension to the proposed compliance dates to account for the possibility that some of the issues cited by stakeholders could present a significant challenge to meeting the proposed timeline.

As discussed further in Section VI., Final Economic Analysis and Regulatory Flexibility Analysis, OSHA has analyzed the time, effort, and cost of the changes in this rule and has concluded that most of the revisions will require only limited changes to 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 (Appendix C and Appendix D). As also noted in that section, chemical manufacturers and importers periodically review, revise, and update the electronic templates they use to create SDSs and labels when new information becomes available, changes are made to the product, or new products are introduced to the market, allowing many chemical manufacturers and importers to phase in any required revisions to their labels and SDSs in accordance with the normal cycle of updating these items. The arguments raised by commenters were accounted for in that analysis. Therefore, the agency estimates that the revisions it is finalizing will, for the most part, be possible to work into the normal cycle of SDS and label updates.

Although OSHA believes that the proposed one- to two-year tiered compliance dates will accommodate implementation of most revisions included in this final rule, the agency also recognizes that some of the changes to the HCS in this update will result in major changes to classifications, and that some of the changes to Appendix C and Appendix D may result in significant changes to some labels or SDSs, which could pose difficulties for some stakeholders to meet the compliance dates originally proposed. Therefore, OSHA is extending the compliance date for chemical manufacturers, importers, and distributors evaluating substances to be 18 months after the publication date and the compliance date for mixtures to be 36 months after the publication date. OSHA is amending the designation of the compliance date for substances to be paragraph (j)(2)(i) and is amending the designation of the compliance date for mixtures to be paragraph (j)(3)(i) in order to accommodate the addition of paragraphs (j)(2)(ii) and (j)(3)(ii), discussed later in this section. OSHA is not further differentiating the compliance timeline between manufacturers of mixtures from substances and manufacturers of mixtures from mixtures, as some commenters suggested. Nor is OSHA adopting a staggered implementation timeline based on role in the supply chain, as NACD suggested. OSHA is concerned that adding such additional tiers could potentially create a very long compliance timeline, leaving workers along the supply chain with uneven protections and undermining the purpose of the HCS, which is to have a single harmonized system. As the agency explained in finalizing the 2012 HCS, although some overlap between the current requirements and the new ones is inevitable during the phase-in period, “hazard communication during this transition period will be confusing and less effective” (77 FR 17739). OSHA seeks to limit this effect by ensuring that the transition is completed in a timely fashion.

OSHA has determined that the changes in this final rule can be implemented within the timeframes set for compliance. OSHA believes that the extended dates and

tiered approach based on substances and mixtures will alleviate the vast majority of compliance issues. However, OSHA recommends that manufacturers of mixtures and downstream clients who use their products for further processing and/or manufacture of other mixtures work together to ensure that all parties have sufficient time to comply with this standard. OSHA believes, as it did in 2012, that “[t]hese types of issues are generally addressed by the market, and the needs of a manufacturer’s customers” (77 FR 17739). In addition, where particular circumstances warrant special consideration (such as where a downstream user has not received the necessary information despite its best efforts), OSHA retains enforcement discretion to address those situations as appropriate.

Hach and ACA also requested an unlimited sell-through period for products labeled prior to the compliance deadlines to prevent waste and unnecessary compliance burden (Document IDs 0323, p. 10; 0368, p. 10). Hach noted that “[e]xisting label stock would cover thousands of products. Without an unlimited sell-through these existing stocks would need to be disposed of and manufactured products would need to be relabeled” (Document ID 0323, p. 10). While OSHA is not specifically providing unlimited time to use already-created labels on existing stock, the agency is finalizing an update to paragraph (f)(11) which allows manufacturers, importers, and distributors to not relabel chemicals that have been released for shipment and are awaiting distribution, which will reduce the need to dispose of existing label stock and eliminate relabeling for those products. See the Summary and Explanation for paragraph (f) for further discussion of the update to paragraph (f)(11).

Several commenters recommended that the compliance dates should align with other countries (Document ID 0279, p. 2; 0327, p. 2; 0347, p. 15; 0359, p. 5). In particular, HCPA, Dow, and ACC recommended that OSHA coordinate compliance dates with Health Canada’s WHMIS update (Document ID 0347, p. 15; 0327, p. 2). OSHA notes that Health Canada has already published their update to the HPR and they are now

aligned with Rev. 7 (see <https://www.canada.ca/en/health-canada/services/environmental-workplace-health/occupational-health-safety/workplace-hazardous-materials-information-system/amendments-hazardous-products-regulations.html>) with a compliance date of December 14, 2025. The agency will, however, work with Canada to address stakeholder concerns regarding the timing of updates and related compliance dates as OSHA has done with other cross-cutting issues. Additionally, OSHA notes that chemical manufacturers have the option to coordinate their compliance with Canada and OSHA's updated requirements by coming into compliance with whichever country's compliance dates occur first.

OSHA also received requests for clarification related to the proposed compliance deadlines. ICBA, NRI, AF&PA and AWC, and ILMA stated that the terms "evaluating substances" and "evaluating mixtures" in proposed paragraphs (j)(2) and (j)(3) were unclear (Document ID 0291, pp. 2-4; 0356, p. 10; 0326, pp. 7-9; 0287, p. 10). ICBA noted that if OSHA meant the term "evaluating" to refer only to the task of hazard classification, the proposed regulation is unclear as to when manufacturers, importers, or distributors must comply with other new or revised requirements in this final rule, particularly those that normally occur after a determination of a hazard classification, as no other compliance dates were provided (Document ID 0291, p. 3). ICBA, ILMA, and AF&PA and AWC sought to clarify which provisions of the final rule have a compliance deadline of 60 days, one year, and two years after the effective date of the final rule (Document ID 0291, p. 3; 0356, p. 10; 0287, p. 10). Relatedly, ASSP raised concerns about the sufficiency of the compliance periods for training requirements specifically, and recommended that OSHA implement a transition period to allow employers adequate time to retrain workers (Document ID 0284, p. 2).

OSHA intends that the terms "evaluating substances" and "evaluating mixtures" include hazard evaluations and updates to classification, labeling, and SDSs required to

comply with the revisions in this final rule. These changes are to be completed by 18 months from the effective date for substances (paragraph (j)(2)(i)) and by 36 months from the effective date for mixtures (paragraph (j)(3)(i)). Because this final rule contains only limited revisions of the hazard classification rules, the agency does not anticipate that most employers will need to complete additional requirements that follow from changes to hazard classification, namely, updating any alternative workplace labeling used under paragraph (f)(6), updating the hazard communication program required by paragraph (h)(1), and providing any additional employee training in accordance with paragraph (h)(3) for newly identified hazards. However, recognizing that some employers will need to complete these requirements, OSHA is adding new paragraphs (j)(2)(ii) and (j)(3)(ii) to the final rule. Those paragraphs provide an additional six months after the compliance dates to complete any necessary updates to alternative workplace labeling, updates to the hazard communication program, and additional employee training for newly identified physical or health hazards resulting from evaluation of substances and mixtures (that is, 24 months after the effective date for substances and 42 months after the effective date for mixtures).

None of the provisions revised in this final rule have an immediate compliance deadline on the effective date of the final rule (i.e., 60 days after the date of publication of the final rule). To further clarify how employers can comply with the HCS through the implementation phase of the final rule, OSHA is adding a new paragraph (j)(4), which provides that chemical manufacturers, importers, distributors, and employers may comply with either §1910.1200 revised as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], or the previous version of this standard, or both during the transition period.

In conclusion, for the reasons discussed above, OSHA is finalizing paragraph (j) with the following modifications: chemical manufacturers, importers, and distributors

evaluating substances are required to comply with all modified provisions of the HCS no later than 18 months after the effective date (paragraph (j)(2)(i)) and those entities evaluating mixtures must comply with all modified provisions no later than 36 months after the effective date (paragraph (j)(3)(i)); new paragraphs (j)(2)(ii) and (j)(3)(ii) require employers to update any alternative workplace labeling under paragraph (f)(6), update the hazard communication program required by paragraph (h)(1), and provide any additional employee training in accordance with paragraph (h)(3) for newly identified hazards no later than 24 months following the effective date for substances and 42 months following the effective date for mixtures; and new paragraph (j)(4) provides that chemical manufacturers, importers, distributors, and employers may comply with either the previous version of this standard, the version finalized in this rule, or both during the transition period. The revised paragraph (j) will replace the regulatory text previously included in paragraph (j).

C. Appendix A

Appendix A addresses the health hazards covered by the HCS, including classification criteria consistent with the GHS.

OSHA proposed to update Appendix A in several respects. The agency's finalized changes to Appendix A, its review of the comments and testimony received on the proposed changes to Appendix A, and OSHA's response to these comments and testimony 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.

At the time that OSHA's NPRM was published, OSHA provided a redline strikeout version of Appendix A, which reflected all of OSHA's proposed revisions, in the docket and on the OSHA website (Document ID 0222, pp. 39-115) so that interested parties could view all of the proposed changes in context. OSHA will update this

document to show the changes being made in this final rule and strongly encourages stakeholders to review that document in conjunction with the discussion of the revisions, as the discussion provided in this final rule's Summary and Explanation does not fully describe all of the non-substantive or editorial changes OSHA is making in Appendix A. Stakeholders can examine the redline strikeout of the regulatory text (changes from 2012 HCS to this final) at OSHA's HCS webpage (<https://www.osha.gov/dsg/hazcom/>) to view all of the changes to the 2012 HCS made in this final rule.

OSHA received comments broadly supporting its proposed revisions to Appendix A. (NAIMA stated that it "supports the extensive changes to Appendix A because the classification is clarified in a positive manner and not changed... NAIMA agrees [with OSHA] that proposed amendments will bring greater clarity" (Document ID 0338, p. 7). ILMA stated, "ILMA and its members are generally supportive of OSHA's proposed changes to Appendix A. While largely editorial, these changes better synchronize the Hazard Communication Standard with the GHS and, with respect to ease of international trade, such synchronization to those other jurisdictions, which are adopting more recent versions of the GHS, assist ILMA members who do business internationally" (Document ID 0404, Att. 2, p. 1). ILMA further requested that OSHA publish guides to assist the regulated community with classification, particularly smaller companies who may not use subscriptions to database-driven hazard communication software and who may not understand how to incorporate non-animal testing results in their classifications of mixture products (Document ID 0404, Att. 2, p. 2). OSHA anticipates updating some of the existing hazard communication standard guidance products, such as the Hazard Classification guidance (Document ID 0008), and also anticipates developing new products to assist the regulated community in complying with the updated standard.

OSHA's proposed revisions to Appendix A are reviewed in detail below, together with a review of the comments and testimony received on each proposed revision and discussion of the provisions adopted in the final rule.

I. General Classification Considerations (Appendix A.0).

In paragraph A.0.1, OSHA proposed to add a note from paragraph 1.3.3.1.3 of Rev. 7 (Document ID 0060, p. 21), 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 came to believe that this note adds clarity and is useful for aligning with the GHS, so proposed to add this note as paragraph A.0.1.3. OSHA's intent in proposing this provision was to clarify that manufacturers and importers must consider the hazards of all classified components when classifying chemicals, which the agency believed would help ensure accurate classification of chemicals and therefore improve protections for workers.

OSHA received one comment regarding its proposed addition (Document ID 0316, pp. 11-12). API supported the proposed revision, noting that the proposed language aligns with the UN GHS and prior OSHA guidance (Document ID 0316, pp. 11-12). OSHA did not receive any comments objecting to the proposed addition of the note from Paragraph 1.3.3.1.3 of Rev. 7; therefore, the agency has finalized the addition of this provision in new paragraph A.0.1.3.

Cal/OSHA, Cal/HESIS, Worksafe and National COSH submitted suggestions that OSHA should modify paragraph A.0.3.5 to require a single positive study to determine the hazard classification (Document ID 0322, Att. 1, p. 9; 0313, p. 5; 0354, p. 1; 0407, p.

12). Cal/OSHA stated that “[r]equiring disclosure of the findings of a single positive study that reports ‘statistically and biologically significant positive results’ is important for a number of reasons.” They noted that this single positive study rule would (1) represent the highest possible standard of evidence in establishing causation in health studies, (2) address the issue that scientific standards of evidence can bias health effects studies toward false negative results, (3) remove the economic incentive for a manufacturer, importer or classifier not to classify based on a single study, and (4) reduce “information asymmetries” between producers and downstream buyers (Document ID 0322, Att. 1, pp. 9-12).

OSHA did not propose any changes to A.0.3.5, therefore, these comments are out of scope for this rulemaking. Additionally, OSHA discussed its decision to remove the across-the-board “one-study” approach in the 2012 update to the HCS. The agency explained that the hazard evaluation process in the HCS goes beyond simply identifying one study and was preferable because it includes a complete evaluation of all of the information available when determining what information to transmit to users of the chemical, although the one-study approach was still included in some criteria in the 2012 HCS (77 FR 17708).

OSHA also proposed to modify the introduction of paragraph A.0.4.1, which previously characterized the process of mixture classification provided in A.0.4.1(a) through (c) as “recommended,” to instead characterize the specified process as mandatory. OSHA did not receive any comments objecting to the proposed revision. Therefore, the agency has finalized the introduction of paragraph A.0.4.1 to state that, except as provided in A.0.4.2, the process of mixture classification is based on the specified sequence of steps in A.0.4.1(a) through (c).

John Baker submitted a comment expressing support for the existing language of paragraph A.0.4.3.2, which specifies that, 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 must be classified accordingly, in light of the unique hazards posed by nanoscale particles. Baker noted that “[t]his is important because the health (and to some extent, physical) hazard posed by nanoscale particles is related to the large number of particles rather than their aggregate weight percentage in the mixture” (Document ID 0302). OSHA did not propose to alter paragraph A.0.4.3.2, therefore, it is unchanged in the final rule.

II. Acute toxicity (Appendix A.1).

In paragraph A.1.1, OSHA proposed 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 previous definition referred 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 four hours. This change was proposed to align with Rev. 7 (Document ID 0060, p. 115; 0131).

Cal/OSHA commented that the *acute toxicity* definition needed more clarity. Specifically, they noted that a “serious health effect” is not synonymous with death (i.e., lethality) and that OSHA contradicted itself in A.1.2.1 if it intended “serious health effect” to mean death (Document ID 0322, Att. 2, p. 1). Cal/OSHA also commented that “acute toxicity has to do with the timing of health effects, not their nature; therefore, it is not appropriate to use the term ‘serious’ to qualify ‘health effects’”, and that “there are many forms of acute toxicity that do not lead to death,” ranging from mild (e.g., skin irritation) to serious (e.g., eye damage) to deadly (e.g., pulmonary edema) (Document ID 0322, Att. 2, pp. 1-2). Finally, they noted that non-lethal health effects are covered by their respective sections in Appendix A and that the introductory material for acute toxicity should make this clear.

OSHA agrees with Cal/OSHA that the general term “acute” refers to timing, rather than severity, of effects. In the proposed language, the term “acute” refers to health effects “occurring after a single or short-term oral, dermal, or inhalation exposure to a substance or mixture.” However, as Cal/OSHA observed, non-lethal health effects are covered by their respective sections in Appendix A, and thus the inclusion of “serious adverse health effects (i.e., lethality)” is a necessary component of the definition to indicate to regulated parties that within the HCS framework the classification of acute toxicity is only used when the effects are sufficiently severe in order to avoid duplicative classifications or unnecessary confusion between hazard classifications.

Furthermore, the phrase “serious adverse health effects (i.e., lethality)” in the proposed definition is not intended to imply that OSHA considers serious adverse health effects to be, in general, synonymous with death. Rather, this phrase is taken from the GHS and is intended to signify that the endpoint of the toxicological test methods used to classify for “acute toxicity” is the death of animals in the test population. The definition’s reference to lethality is intended to distinguish between hazards that meet the classification criteria established for “acute toxicity,” utilizing toxicological test methods with an endpoint of lethality, from hazards which are acute in nature, but which should be classified under other sections in Appendix A because the available information does not indicate lethality. The phrase does not represent a determination by OSHA that other health effects are not serious in the sense of being “material” for the purposes of the OSH Act.

Finally, OSHA disagrees with Cal/OSHA that the new text added to A.1.2.1 contradicts the agency’s use of “lethality” in the proposed definition of “acute toxicity.” Although some *in vivo* methods include indicators such as “significant clinical signs of toxicity” to approximate LD₅₀/LC₅₀ values, these methods are using the clinical signs of toxicity to indirectly determine the acute toxicity estimate (ATE) which is nevertheless

intended to characterize the lethality of a toxic substance. Therefore, OSHA maintains that its revisions to A.1.2.1 do not contradict its use of the term “lethality” to characterize the endpoint used to classify a hazard under “acute toxicity.” OSHA therefore declines to adopt the recommendations made by Cal/OSHA regarding the definition of *acute toxicity*.

John Baker commented that the modified definition is “vague as to the dimension of time” and recommended that OSHA amend the proposed definition of acute toxicity to refer to serious health effects (i.e., lethality) 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” (Document ID 0302). However, OSHA notes that the references to time in the acute toxicity definition were purposely removed so that the definition would be more general and neutral with respect to test guidelines (86 FR 9705). Since the HCS is test method neutral, OSHA believes that the definitions in the HCS should not include timeframes as listed in specific test guidelines. Therefore, OSHA has retained the proposed modifications in the acute toxicity definition to exclude timeframes in the final rule.

For the reasons discussed above, OSHA is finalizing the definition of *acute toxicity* in paragraph A.1.1 as proposed.

OSHA also proposed to revise the classification criteria for substances in A.1.2.1 to indicate that “[w]hile some *in vivo* methods determine LD₅₀/LC₅₀ 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 was proposed to align with classification criteria in the Rev. 7 (Document ID 0060, p. 115; 0131).

The Physicians Committee for Responsible Medicine (PCRM) supported this revision and recommended that OSHA include the Collaborative Acute Toxicity Modeling Suite (CATMoS) for screening chemicals for acute oral toxicity, which can be

used to predict GHS classification (Document ID 0295, p. 2). As the HCS is test method neutral and, as stated in A.0.2.2, test guidelines that have been scientifically validated are acceptable, OSHA has not included a specific reference to CATMoS in paragraph A.1.2.1 in the final rule. However, the agency will consider including information about CATMoS in one of its guidance products, as it may be helpful to classifiers. API also supported the proposed revision, noting its alignment with the GHS (Document ID 0316, p. 15). Therefore, OSHA has finalized the classification criteria for substances in A.1.2.1 as proposed.

OSHA also proposed slight revisions to Table A.1.1 to align with Rev. 7 (Document ID 0060, p. 115; 0131). The GHS presents the ATE range in Table A.1.1 using the term “ATE” to express the range, while the 2012 HCS uses the term “and.” OSHA proposed to change the “and” in the ATE ranges to “ATE” to align with Rev. 7. The proposed modification was not to change the classification criteria itself, but as OSHA explained in the NPRM, would be more technically accurate and consistent with the way the table is expressed in the European Chemicals Agency’s Guidance on the Application of the CLP Criteria: Guidance to Regulation (EC) No 1272/2008 on classification, labelling, and packaging of substances and mixtures (Document ID 0256, pp. 237-238).

Michele Sullivan suggested that the format used in the 2012 HCS Table A.1.1 should be retained, as it is familiar to small businesses, businesses, and stakeholders operating in the U.S. According to Sullivan, the “focus of the USA OSHA HCS should be to express technically correct values in a format easy to understand for USA stakeholders, not to be consistent with formatting in EU regulations” (Document ID 0366, p. 7).

Tom Murphy commented that “the information to be conveyed in [Table A.1.1] is in the format ‘>5 ATE ≤ 50.’ The placement of the acronym in the format of the proposed

rule makes the information difficult to comprehend at a glance, and this opportunity for a systemic failure is easily addressed: please consider changing the format of the table entries to either ' $5 < ATE \leq 50$ ' or ' $ATE > 5$ and $ATE \leq 50$ '" (Document ID 0277, p. 1).

OSHA believes that the proposed format, in addition to aligning with Rev. 7 and the EU's CLP regulation, is also more technically correct than the format used in the 2012 Table A.1.1. The ATE values define the hazard categories for acute toxicity. For example, if a gas has an ATE of less than or equal to 100, then it should be classified as Category 1. The format used in the 2012 version of the standard included just the number " ≤ 100 " under the Category 1 column, while the proposed Table A.1.1 includes " $ATE \leq 100$ ". OSHA believes that the proposed format displays the criteria in a more technically accurate way, and that classifiers will understand the information presented in this format. As such, OSHA has retained the modifications to Table A.1.1 in the final rule. While Tom Murphy's suggested change is technically equivalent to OSHA's proposal, it is not evident that Murphy's notation would be significantly easier to understand "at a glance" nor would it be consistent with the GHS or other international partners. Therefore, OSHA is not adopting the suggestion.

OSHA is also making a correction to the heading of Table A.1.1 in the final rule. The heading of Table 3.1.1 in Rev. 7 states, "Acute toxicity estimate (ATE) values and criteria for acute toxicity hazard categories." OSHA inadvertently left out the change to the heading in the NPRM and is making the editorial correction in this final rule to maintain alignment with the GHS.

OSHA proposed to include a new sentence at the end of paragraph A.1.2.3 to clarify that data from both animal tests and human studies should be considered in evaluating acute toxicity. The proposed text stated that "[i]n 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 (Document ID 0131, p. 116) and OSHA proposed adding this sentence to align with Rev. 7. OSHA did not receive any comments pertaining to the proposed revision. Therefore, the agency is finalizing paragraph A.1.2.3 as proposed.

OSHA proposed a new paragraph A.1.2.4 which corresponds to Chapter 3.1 (paragraph 3.1.2.6.5) in Rev. 7 (Document ID 0060, p. 117). The agency proposed this paragraph and its subparagraphs to require the classifier to consider whether the chemical is corrosive to the respiratory tract if data are available that indicate that the mechanism of toxicity was corrosivity of the substance or mixture. The proposed paragraph was also to clarify that the hazard *corrosive to the respiratory tract* is covered under the HCS.

As OSHA explained in the NPRM, the agency did not explicitly include the *corrosive to the respiratory tract* hazard in the HCS in 2012 but explained in its guidance, OSHA 3844: *Hazard Communication: Hazard Classification Guidance for Manufacturers, Importers, and Employers*, that this hazard should be considered during classification (Document ID 0008, p. 48). 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 indicate acute inhalation toxicity with corrosion of the respiratory tract and the effect does not lead to lethality, then the guidance explains that the hazard may be addressed in the Specific Target Organ Toxicity (STOT) hazard classes included in Appendices A.8 and A.9 of the HCS. OSHA proposed to include these clarifications in paragraphs A.1.2.4.1 and A.1.2.4.2, and to change the “may”

language from the guidance to “must” language to ensure that *corrosive to the respiratory tract* is appropriately considered during the classification process.

OSHA received several comments on proposed paragraph A.1.2.4. NIOSH supported OSHA’s proposed addition of paragraph A.1.2.4, noting that it “adds information to help protect workers’ safety and health,” is in line with the intent of the original 1983 HCS, and facilitates the design and implementation of protective measures appropriate to the hazard (Document ID 0281, Att. 2, p. 5). ILMA also supported the addition of proposed paragraph A.1.2.4, noting that it would assure appropriate consideration of hazards corrosive to the respiratory tract during the classification process (Document ID 0356, Att. 1, p. 5). ICT agreed that the addition of A.1.2.4 “clarifies that some lethal inhalation effects are not due to systemic poisoning but are due to local destruction of respiratory tissue” (Document ID 0324, p. 5).

ICT also requested clarification on when the statement would be applicable. Both ICT and an anonymous commenter asked whether OSHA intended the “Corrosive to the respiratory tract” hazard statement for use instead of, or in addition to, the existing hazard statements (e.g., “Fatal if inhaled”) related to acute toxicity by the inhalation route (Document ID 0265; 0324, p. 5).

ACC asked OSHA to clarify the proposed text in paragraphs A.1.2.4.1 and A.1.2.4.2. ACC indicated that “in many cases, suppliers may choose to warn for corrosion to the respiratory tract simply based on a substance being corrosive to eyes and skin,” and that “without knowledge as to whether this effect leads to lethality, it is not clear how suppliers should classify.” ACC further stated that it is unclear what OSHA’s intent is in referring to the regulatory text for STOT classifications and questioned what the agency meant by the term “addressed” in A.1.2.4.2 (Document ID 0347, p. 16). In answer to these requests for clarification, OSHA has modified the proposed language. The following discussion explains the general classification process and how label

preparers are to apply a hazard statement for corrosion of the respiratory tract based on the final text. To further clarify how corrosive effect to the respiratory tract should be addressed, OSHA is adding a note to each of the relevant tables in Appendix C.

When classifying for corrosive to the respiratory tract the classifier should take a tiered approach. If the classifier has data to indicate the chemical is corrosive to the respiratory tract and the effect leads to lethality, then the label should contain the hazard statement “Corrosive to the respiratory tract” and the corrosion pictogram in addition to the prescribed acute toxicity hazard statement(s) and other label and SDS elements. If the classifier has data that indicate the chemical is corrosive to the respiratory tract but does not lead to lethality, then the chemical should be classified using the criteria as provided under STOT single exposure (STOT-SE). The label should then include the hazard statement “Corrosive to the respiratory tract if inhaled.” This hazard statement should be used instead of a more general STOT-SE hazard statement for the respiratory tract (e.g., “Causes damage to respiratory tract if inhaled”) and unlike the corresponding statement for acute toxicity, this hazard statement includes “if inhaled” because A.8.2.1.2 requires the relevant route(s) of exposure by which the classified substance produces damage to be identified. Additionally, OSHA is requiring the use of the more specific corrosion pictogram instead of the more general health pictogram when this hazard is addressed under STOT. However, if there are other target organ hazards, the current STOT hazard statement and pictogram should be used to communicate those hazards, in addition to the required hazard statement and pictogram for corrosive to the respiratory tract.

Finally, in response to ACC’s comment on classifiers’ current practices, OSHA is modifying the proposed language to state that if the classifier does not have direct data on corrosivity to the respiratory tract (and would therefore not classify the chemical under STOT-SE) but the chemical is classified under either skin corrosion/irritation or serious eye damage/eye irritation, the classifier must consider the available data (including skin

and/or eye data) to determine whether the chemical may be corrosive to the respiratory tract if inhaled. If they determine that it may be corrosive to the respiratory tract, they must include the hazard statement corrosive to the respiratory tract along with the already required hazard statement (e.g., causes severe skin burns and eye damage) and pictogram (e.g., corrosion) to ensure that the respiratory corrosion hazard is communicated to downstream users. This is intended to ensure workers have complete hazard information when handling a substance or mixture that may cause corrosion to the respiratory tract in order to avoid gases, vapors, or mists that may be generated under certain conditions (e.g., accidental spill) even if the substance or mixture is not intended for such an exposure route.

As OSHA indicated in proposed paragraph A.1.2.4, the corrosive to the respiratory tract classification is intended to be used, when appropriate, in addition to the inhalation toxicity classification and the hazard statement “corrosive to the respiratory tract” would be used in addition to the hazard statements for acute toxicity. To clarify this provision, OSHA has modified proposed paragraph A.1.2.4.1 to state, “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 in addition to the appropriate acute toxicity pictogram and hazard statement, the chemical must be labeled with the hazard statement ‘corrosive to the respiratory tract’ and the corrosion pictogram.” OSHA anticipates providing additional guidance on the “Corrosive to the respiratory tract” hazard statement following publication of the final rule.

Cal/OSHA commented that paragraph A.1.2.4.1, as written in the NPRM, would not adequately warn workers and emergency responders, reasoning that when inhalation of a corrosive chemical substance “leads to lethality,” that information should be communicated on the label, not just on the SDS (in some cases “Fatal if inhaled” would appear on the SDS) (Document ID 0451, Att. 1, p. 2). Cal/OSHA suggested alternative

language for A.1.2.4.1 to require that, if the classifier determines a chemical is corrosive to the respiratory tract and data are available that indicate that the effect leads to lethality, then the chemical must be labeled with either the hazard statement, “This chemical is corrosive to the respiratory tract and can cause death if inhaled” or “This chemical is corrosive to the respiratory tract and can be fatal if inhaled” (Document ID 0451, Att. 1, p. 2).

Because the hazard statement “Corrosive to the respiratory tract” would supplement, rather than replace, the appropriate acute toxicity pictogram and hazard statement, OSHA disagrees with Cal/OSHA that the proposed supplemental hazard statement “Corrosive to the respiratory tract” should be modified from the GHS statement when the data indicate lethality. The acute toxicity statements already indicate lethality when appropriate. For example, a chemical that is acute inhalation toxicity Category 1 and is corrosive to the respiratory tract will carry the skull and crossbones pictogram and the hazard statement “Fatal if inhaled” in addition to the “Corrosive to the respiratory tract” statement.

An anonymous commenter asked whether hazard categories are being established for “Corrosive to the respiratory tract” and, if so, how the categories will be defined, how mixtures should be classified that contain component(s) deemed “Corrosive to the respiratory tract,” and if cut-off values would be established. They also noted that this hazard statement does not appear in Appendix C of the proposed standard and asked what signal word, pictogram, and precautionary statements should appear on the SDS and label when the “Corrosive to the respiratory tract” hazard statement is used (Document ID 0265).

As explained above, the “corrosive to the respiratory tract” hazard is not a distinct hazard class. Therefore, no hazard categories will be established for it. Classification of mixtures would follow the same principles as for other health hazards. If there are no data

for the mixture as a whole, mixtures that contain component(s) deemed corrosive to the respiratory tract should be classified as acutely toxic, STOT-SE, skin corrosion/irritation, or eye damage/irritation and carry the appropriate pictogram(s), signal word, hazard statement(s) and precautionary statement(s) on the label and SDS based on the hazard class and category. The SDS and label for the mixture will also contain the hazard statement “Corrosive to the respiratory tract” (for acute toxicity, skin corrosion/irritation, or eye damage/irritation) or “Corrosive to the respiratory tract, if inhaled” (for STOT-SE). As discussed above and in the Summary and Explanation for Appendix C, OSHA agrees that the hazard statements for corrosion to the respiratory tract should be included in Appendix C along with the other label element information and has included it there in the final rule. The Summary and Explanation for Appendix C includes further discussion of the label element requirements associated with corrosion to the respiratory tract.

ACC expressed concern about the impact of this proposal on GHS harmonization, stating that “[t]he introduction of a new Acute Toxicity and Specific target organ toxicity (single exposure) (STOT SE) classification for corrosion to the respiratory tract will cause a number of significant classification differences between jurisdictions and confusion among manufacturers and importers” and argued that the information could be accurately represented in Section 11 of the SDS. They noted the EU as an example which “includes supplementary EUH [European Union hazard] phrases, but does not require the use of an entirely separate classification” (Document ID 0347, p. 16).

Furthermore, ACC stated that STOT classifications are not appropriate for classifying respiratory corrosion. According to ACC, STOT repeat exposure (STOT-RE) is not appropriate because respiratory corrosion is an acute effect; STOT-SE Category 1 or Category 2 are also not appropriate because respiratory corrosion is not a systemic effect; and STOT-SE Category 3 is not appropriate because it only refers to respiratory irritation (Document ID 0347, p. 17). VelocityEHS similarly opined that corrosion to the

respiratory tract does not fit the criteria under STOT because “damage from corrosivity/causticity is not usually tied to a specific organ, but damages multiple tissues (skin, eyes, mucus membranes). Corrosive/caustic substances damage whatever tissue they come into contact with, and therefore do not meet the definition of being target organ specific” (Document ID 0320, p. 2).

OSHA disagrees with ACC and VelocityEHS’ position that STOT criteria should not be used for corrosion to the respiratory tract. Specifically, OSHA disagrees with ACC’s position that STOT-SE Category 1 and Category 2 cover only systemic effects and are therefore not the appropriate hazard classes and categories to address the corrosion of the respiratory tract hazard. The GHS recognized that local effects are also covered under STOT in Rev. 2, published in 2007. Prior to Rev. 2, the hazard class chapter was entitled “Specific Target Organ/Systemic Toxicity.” In Rev. 2, the UNSCECHS agreed to replace the term “Specific target organ/systemic toxicity” and all its related terms with “Specific target organ toxicity” on the understanding that, according to paragraphs 3.8.1.1 and 3.9.1.1 of the GHS, “all significant health effects that impair function (both reversible and irreversible, immediate and/or delayed) are regarded to be “target organ toxicity”, irrespective of the toxic effects being local or not” (ST/SG/AC.10/C.4/22, available at <https://unece.org/DAM/trans/doc/2006/ac10c4/ST-SG-AC10-C4-22e.pdf>, p. 6). Corrosion to the respiratory tract fits the meaning of “Specific target organ toxicity” as explained by the UNSCECHS.

Similarly, OSHA disagrees with VelocityEHS’s reasoning that the occurrence of corrosion in multiple organs (e.g., skin, eye, mucus membranes) excludes classification for a respiratory tract STOT. Under STOT-SE in the HCS (A.8.1.4), classifiers should take into consideration both changes in a single organ or biological system and generalized changes of a less severe nature involving several organs.

However, OSHA agrees with ACC that since respiratory tract corrosion is an acute effect, STOT RE is not an appropriate hazard class for corrosion of the respiratory tract. OSHA is therefore removing the reference to A.9 from A.1.2.4.2. OSHA also agrees that corrosion of the respiratory tract would not be appropriately classified as STOT-SE Category 3 because it would not meet the criteria in A.8.2.2. The language in A.1.2.4.2 is a general reference that corrosive to the respiratory tract should be classified under STOT and therefore no regulatory text change is necessary to exclude STOT Category 3. Additionally, to make this clear, OSHA has not included a note regarding corrosive to the respiratory tract in Appendix C under the table for STOT-SE Category 3. For the reasons explained above, OSHA maintains that STOT-SE Category 1 and Category 2 should be used for classifying corrosive to the respiratory tract hazards when the data meet the criteria and indicate the effect does not lead to lethality.

OSHA disagrees with ACC's comment that the use of STOT criteria would cause significant classification differences between jurisdictions, including diverging from the EU's approach to classification. OSHA notes that ACC may have misunderstood OSHA's intent regarding corrosive to the respiratory tract since paragraph A.1.2.4 incorporates additional hazard phrases but does not create an entirely separate classification, which is also, as ACC noted, how the EU treats corrosion of the respiratory tract. However, OSHA has made changes to the approach so that the label and SDS would be more consistent with other jurisdictions, including the EU. First, OSHA has updated the label elements under STOT-SE for consistency so the hazard statement and pictogram on the label (and SDS) would be equivalent to the EU. Additionally, OSHA has updated its approach to include the hazard statement "Corrosive to the respiratory tract" under Appendices A.2 and A.3 when there are insufficient data to support classification under STOT. This is similar to the EU approach where if a chemical is corrosive and the chemical may be inhaled then the EUH071 "Corrosive to the

Respiratory Tract” hazard phrase must be used. Furthermore, OSHA disagrees with ACC that information on corrosivity to the respiratory tract can be sufficiently covered in Section 11 of the SDS, as Section 11 is not typically used to convey important toxicity information to workers at a level of generality appropriate to a lay reader, but rather to safety and health experts at a more detailed level.

VelocityEHS further commented that labeling elements present for corrosive to the respiratory tract versus acute toxicity and STOT could be confusing or misleading to a worker since the pictogram for corrosion is different. To illustrate this issue, VelocityEHS provided an example indicating that if a chemical is corrosive to the respiratory tract, but the effect does not lead to lethality, corrosion still occurs and is likely corrosive to the skin and eye. In that case, they noted that providing the health hazard pictogram to represent the STOT along with the corrosion pictogram could be misleading and confusing as to why the health hazard pictogram was included (Document ID 0320, p. 3)

VelocityEHS suggested alternate criteria for evaluating corrosive to the respiratory tract when it does not lead to lethality, including modified text for paragraph A.1.2.4 and its subparagraphs that lays out a tiered approach for classifying chemicals as corrosive to the respiratory tract. They suggested first classifying chemicals as corrosive to the respiratory tract under the skin or eye hazard classes, and then if not classified under either of these hazard classes, classifying under STOT-SE. VelocityEHS provided additional text for Appendices A.2 (Skin Corrosion/Irritation) and A.3 (Serious Eye Damage/Eye Irritation) including classification guidance and label elements for corrosive to the respiratory tract (Document ID 0320, pp. 2-7).

OSHA agrees with VelocityEHS that Appendices A.2 and A.3 are relevant for corrosive to the respiratory tract and has updated the text of A.1.2.4.2 accordingly, but disagrees with VelocityEHS’s suggestion that they should be the primary hazard classes

that should address corrosive to the respiratory tract. As discussed above, OSHA believes that STOT-SE criteria are appropriate when the data indicate corrosion to the respiratory tract and indicate non-lethality; therefore, Appendix A.8 (STOT-SE) is appropriate. However, the agency recognizes that in many cases the data may be insufficient to justify a STOT-SE classification and therefore it would be appropriate to include corrosive to the respiratory tract based on data used for either skin corrosion/irritation classification or serious eye damage/eye irritation classification.

OSHA also disagrees with VelocityEHS that workers will find the label elements for acute toxicity confusing or misleading when used alongside label elements for corrosion of the respiratory tract. OSHA understands that workers may be already familiar with the corrosion pictogram because of skin and eye corrosion, and with effective training, the combination of the corrosion pictogram and the skull and bones pictogram for acute toxicity will helpfully and accurately convey the level of severity of the hazard and thus are helpful to include together. However, OSHA does believe that more targeted hazard communication is warranted for STOT SE and, as explained above, is adding a new hazard statement “Corrosive to the respiratory tract, if inhaled” and requiring the use of the corrosivity pictogram instead of the health pictogram. Workers will also need to be trained on the corrosive to respiratory tract hazard and that they may see the corrosion pictogram in addition to the skull and crossbones, but OSHA believes that with the training required under the HCS these modifications will ultimately provide better information and will not be confusing.

However, OSHA also notes that in Appendix C, the agency gives direction on the label elements and in particular has added a new paragraph in this rulemaking (C.3.2.4) to make clear that if multiple hazards require the same pictogram only one pictogram should appear on the label (see discussion in Appendix C). Additionally, Appendix C provides flexibilities under C.2 (Hazard statements) and C.4 (Precautionary statements)

indicating that the label preparer can omit statements if they can show that a statement is inappropriate or that modified statements improve readability. Lastly, the label preparer can provide supplemental information to the label (or SDS) as long as the information does not contradict or cast doubt on the required information. With all of these flexibilities, OSHA believes SDS and label preparers will be able to minimize any confusion that VelocityEHS suggests will exist.

Following the discussion above, OSHA is finalizing the new paragraph A.1.2.4 which provides that if the classifier has data indicating that there is acute inhalation toxicity, based on lethality data, with corrosion of the respiratory tract, then the substance or mixture should be labeled with the additional hazard statement “Corrosive to the respiratory tract” and the corrosion pictogram. OSHA is retaining the provision that if the classifier has data that indicates corrosion of the respiratory tract and the effect does not lead to lethality, then the hazard must be addressed in the STOT-SE (A.8) hazard class, with the modified hazard statement and corrosion pictogram in lieu of the usual STOT-SE requirements. If there are insufficient data to classify the hazard as STOT, and the classifier determines based on relevant skin and/or eye data that the chemical may cause corrosion of the respiratory tract, then the hazard statement “Corrosive to the respiratory tract” must be used in A.2 and/or A.3, as appropriate. As described further in the summary and explanation for Appendix C, OSHA has also added notes to the relevant sections in Appendix C to further clarify this issue. However, OSHA is removing the reference to STOT-RE (A.9) from paragraph A.1.2.4.2. Additionally, OSHA intends to update its Hazard Classification guidance document (Document ID 0008) following the publication of the final rule and anticipates adding further guidance for “Corrosive to the respiratory tract.”

Paragraph A.1.3.6.1 explains how to classify a mixture when there are data for all of the ingredients in the mixture. Cal/OSHA commented on paragraph A.1.3.6.1 that the

units that are used in the ATE formula are unclear and suggested that OSHA provide more explanation and an example using each of the applicable units (Document ID 0322, Att. 2, p. 3). OSHA did not propose a change to the ATE formula in A.1.3.6.1 and therefore this comment is outside the scope of this rulemaking. However, Table A.1.1, Acute toxicity estimate (ATE) values and criteria for acute toxicity hazard categories, provides the units that should be used to calculate the ATE by route of exposure. Additionally, OSHA provides guidance on classification of acute toxicity and examples using the ATE formula in its Hazard Classification guidance document (Document ID 0008, pp. 33-35).

In Figure A.1.1 and paragraph A.1.3.6.2.2, OSHA proposed to correct the cross-reference from A.1.3.6.2.3 to A.1.3.6.2.4. OSHA did not receive any comments pertaining to this proposed revision and is therefore finalizing the corrections to Figure A.1.1 and paragraph A.1.3.6.2.2 as proposed.

OSHA also proposed 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 one percent, paragraph A.1.3.6.2.3 previously required a statement that “X” percent of a mixture consists of ingredient(s) of unknown toxicity on the label and SDS. OSHA proposed to revise this paragraph to require a statement that “X” percent of the mixture consists of ingredient(s) of unknown *acute (oral/dermal/inhalation)* toxicity on the label and SDS in such cases (emphasis added), thus indicating that the percentage of unknown acute toxicity must be differentiated by route of exposure. Given that it is possible to have unknown ingredients for more than one relevant route of exposure (e.g., oral, dermal, inhalation), OSHA reasoned that differentiating the statement by route would be helpful to chemical users. This proposed change aligns with paragraph 3.1.3.6.2.2 in Rev. 7 (Document ID 0060, p. 121). OSHA also proposed to delete the second paragraph in A.1.3.6.2.3 because it is duplicative of the first paragraph.

ILA supported the proposed revision in A.1.3.6.2.3, stating that the change “adds value to the label and provides valuable information to the end user” (Document ID 0315, p. 3). However, ILA also commented that more clarity is needed surrounding when the statement should be used, and that it may be difficult for users to understand when the statement of unknown toxicity is required on a label. Specifically, they asked “[s]hould the statement be used when the material is classified as Acute Oral/Dermal/Inhalation without testing AND contains components greater than 1% with unknown toxicity? OR if the intention is to place this statement on labels when no testing data is available, the material does not have an acute oral/dermal/inhalation classification but contains components greater than 1% with unknown toxicity?” (Document ID 0315, p. 3).

OSHA’s proposed changes to A.1.3.6.2.3 do not affect when the statement of unknown acute toxicity is required. As clarified in OSHA’s classification guidance (Document ID 0008, p. 42), the unknown acute toxicity statement is required on the label and the SDS where the chemical mixture is already classified as acutely toxic for a particular route of exposure, and there are one or more other “relevant ingredients” of unknown acute toxicity for that particular route. In the event that an ingredient with unknown acute toxicity is used in a mixture at a concentration $\geq$ one percent, and the mixture as whole has not been tested, the mixture cannot be attributed a definitive acute toxicity estimate. In this situation, the mixture is classified based on the known ingredients only. A statement that X percent of the mixture consists of ingredient(s) of unknown acute toxicity (oral, dermal/inhalation) is required on the label and SDS in such cases. Conversely, if a mixture as a whole has been tested but is not classified based on this testing, then no statement is required regardless of ingredients (Document ID 0008, p. 42). OSHA anticipates updating this guidance following the publication of the final rule and including a discussion of this provision.

An anonymous commenter submitted a question pertaining to paragraphs A.1.3.6.2.3, C.3.3, and Appendix D of the proposed HCS, which require a statement of the concentration of ingredients of unknown acute toxicity to appear in Section 2 of the SDS and on the label: “[c]onsider the case of a mixture in which the exact concentration(s) of hazardous component(s) are withheld as trade secrets and reported as prescribed concentration range(s) (pursuant to paragraph (i)(1)(iv)) in Section 3 of the SDS. In Section 2 of the SDS and on the label, is it acceptable to report the percentage of ingredient(s) of unknown acute toxicity as a range corresponding to one of the prescribed ranges, or must the exact percentage be reported?” (Document ID 0266). OSHA has addressed this comment below in the Summary and Explanation for Appendix D.

OSHA received an anonymous comment that referred to the “split entry concept” and the agency’s 2013 LOI (available at <https://www.osha.gov/laws-regs/standardinterpretations/2013-04-02>), which describes “split entry” as a concept used in the EU that allows for a modified GHS classification in certain situations, such as when particle size in laboratory tests differs from the particle size expected in workplace exposures (Document ID 0270). The commenter asked OSHA to clarify in the HCS how SDS providers should classify “substances that are acutely toxic by inhalation that are not respirable in the form in which they are supplied” (Document ID 0270).

OSHA did not propose to address this issue in the NPRM, therefore, the request for clarification in the HCS is outside the scope of this rulemaking. However, OSHA notes that the 2013 LOI states that the HCS 2012 classification process does not support the use of the split entry concept. The agency will consider addressing this issue in updated guidance to clarify that the use of “split entry” is still not allowed under the standard.

After reviewing these comments, OSHA is finalizing the proposed changes to paragraph A.1.3.6.2.3.

III. Skin Corrosion/Irritation and Serious Eye Damage/Eye Irritation (Appendices A.2 and A.3).

OSHA proposed revisions to the sections on skin corrosion/irritation and serious eye damage/irritation (Appendices A.2 and A.3), which correspond to Chapters 3.2 and 3.3 in the GHS, respectively. As OSHA explained in the NPRM (86 FR 9703), the UNSCEGHS, in its 16th Session (December 2008), 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 (Document ID 0093). 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. However, the working group completed its efforts to clarify the skin corrosion/irritation and serious eye damage/eye irritation chapters prior to publication of the NPRM. The work was approved by the UNSCEGHS in 2012 (Document ID 0212). Accordingly, in 2021, OSHA proposed to revise Appendices A.2 and A.3 to incorporate all the modifications to the GHS skin corrosion/irritation and serious eye damage/eye irritation chapters agreed to by the UNSCEGHS up to and including Rev. 7. The agency reasoned that this would ensure that OSHA's HCS remains aligned with the GHS.

OSHA proposed substantial revisions to Appendix A.2 (Skin Corrosion/Irritation) that reflect the final changes the UNSCEGHS adopted through Rev. 7. However, Rev. 8, published in July 2019 (Document ID 0065, pp. 129-145), 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. Table 3.2.1 from Rev. 8 updated the tiered approach for classification, including an elevation in acceptance of *in vitro* data to tier 2 of the approach. The updated tiered approach also included 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 updated the background information to provide additional guidance for how to use non-animal test data to classify chemicals.

In Section XV., Issues and Options Considered, in the NPRM, OSHA requested comments from the regulated community to determine if the agency should adopt Chapter 3.2 from Rev. 8 with all of the revisions to the classification scheme. The agency noted that adoption would greatly benefit classification for new chemicals where no existing data currently exists. It also explained that 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.

OSHA received several comments that favored including updates from Rev. 8 in the revised HCS. ILMA supported the inclusion of Rev. 8's tiered approach in Appendix A.2 and indicated that their members would benefit from the inclusion of data from non-animal testing protocols, although they also noted that changes in criteria for skin and eye irritation would present the biggest compliance challenge to ILMA members and would require ILMA members to spend more time reviewing the updated criteria to assure that all available data are considered (Document ID 0356, pp. 5-6). PCRM also supported incorporating in Appendix A.2 "all revisions to the classification scheme for skin corrosion/irritation" from Rev. 8 (Document ID 0295, p. 1). ACC thanked OSHA "for taking into consideration the additional flexibility that the inclusion of Chapter 3.2 (specifically Table 3.2.1) provides" and expressed support for the use of non-animal test methods for classification purposes (Document ID 0347, p. 6). PETA, HCPA, and

NAIMA also expressed support for OSHA expanding the use of non-animal testing (Document ID 0282, p. 1; 0327, p. 8; 0338, p. 7).

NIOSH supported adoption of a tiered approach to classification of chemicals for skin irritation and corrosion (Document ID 0281, Att. 2, p. 5). NIOSH also recommended that OSHA consider the NIOSH Current Intelligence Bulletin 61: A Strategy for Assigning New NIOSH Skin Notations as a resource (NIOSH [2017]. A strategy for assigning new NIOSH skin notations. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2009-147). NIOSH stated that the proposed expansion of the use of nonanimal test methods in evaluating skin corrosion/irritation from Rev. 8 “would elevate the use of *in vitro* methods in the tiered approach to the classification of chemicals under Appendix A.2 Skin Corrosion/Irritation... [and] would be beneficial if systemic effects of the chemical in question have been ruled out. *In vitro* methods predictive of *in vivo* outcomes continue to improve but may not accurately predict systemic response [Stueckle and Roberts 2019]” (Document ID 0281, Att. 2, p. 5).

A few commenters expressed concerns with adopting Rev. 8. Michele Sullivan commented that it was good planning for OSHA to consider adopting Rev. 8, but expressed concern that the regulatory text was not provided (Document ID 0366, p. 2). API similarly requested that OSHA provide the exact regulatory language (Document ID 0316, p. 31). In response to these stakeholder concerns regarding the regulatory text, OSHA notes that the NPRM provided the updated criteria from Rev. 8 which describes the classification criteria as well as the full text of the GHS purple book for Rev. 8 (Document ID 0065, pp. 129-136). OSHA believes that this provided ample notice for interested parties. No commenter expressed specific concerns about the GHS classification criteria provided in the docket.

OSHA agrees with commenters that including the updates in Rev. 8 to the skin corrosion/irritation chapter would benefit classification and has revised Appendix A.2 in the final rule to align with the updates in Rev. 8. The agency is not including any revisions regarding Category 3 because the agency did not adopt Category 3 in 2012, which is primarily for consumer products, and commenters agreed this decision was appropriate (77 FR 17709). OSHA did not receive any comments suggesting that the agency should adopt Category 3 in this final rule and is not including it in this update. OSHA has also not included the guidance material in Rev. 8.

OSHA will take NIOSH's concern regarding systemic effects into account when updating its classification guidance. The agency also acknowledges ILMA's concern regarding the additional time required to review the updated criteria. However, OSHA reiterates that the agency is not changing the HCS classification criteria. The updates from Rev. 8 provide additional guidance for how to use non-animal test data to classify new chemicals. Inclusion of these updates in the HCS does not require a re-evaluation of chemicals already classified because the overall tiered approach for evaluating existing data has been retained (86 FR 9692). However, OSHA has taken ILMA's suggestion and extended the compliance deadlines from the timelines in the NPRM (see Summary and Explanation for paragraph (j)).

In the NPRM, OSHA's proposed text for Appendix A.2 was based on Rev. 7, so the agency's decision, based on the comments it received, to align with Rev. 8 necessarily entails changes from the proposed text. Thus, many of the sections discussed below are now numbered differently or may be rephrased. Additionally, several new sections have been added. These changes are discussed below in the order in which they appear in Appendix A.2.

In Appendix A.2, skin corrosion/irritation, Paragraph A.2.1.1 provides updated definitions of skin corrosion and skin irritation, and those definitions are the same in Rev.

7 and Rev. 8. Cal/OSHA suggested that OSHA should clarify the revised definitions in paragraph A.2.1.1 since the time references were removed from the definition (Document ID 0322, Att. 2, pp. 3-4). As discussed below, OSHA proposed to modify the HCS health hazard definitions to make the definitions more general and to remove the references to the test guidelines. OSHA believes these revisions provide clearer and more concise definitions and a clear differentiation between the “definitions” section and “general considerations” section. Therefore, OSHA has retained the revised definitions of skin corrosion and skin irritation in the final rule. However, in response to Cal/OSHA’s comments, OSHA has modified the final definitions of skin corrosion and skin irritation to include the word “initial” to clarify the time parameters. The updated definitions in the final rule read, “*Skin corrosion* refers to the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis occurring after initial exposure to a substance or mixture” and “*Skin irritation* refers to the production of reversible damage to the skin occurring after initial exposure to a substance or mixture.” Additionally, OSHA has included information about the time parameters in A.2.2.2.1.1, A.2.2.2.2.1, and A.2.2.2.2.2. For skin corrosion in A.2.2.2.1.1, the agency is adding the word “initial.” For skin irritation in A.2.2.2.2.1, OSHA is including the text “following its application for up to 4 hours” and in A.2.2.2.2.2 is adding the text “when after the first application” to indicate that these provisions refer to a one-time exposure.

OSHA originally proposed that new paragraph A.2.1.2 would clarify the sequence in which data should be evaluated when classifying for skin corrosion/irritation using a tiered evaluation approach. However, since OSHA is now aligning Appendix A.2 with Rev. 8, it is finalizing language based on Rev. 8’s language in 3.2.1.2, which clarifies that all available and relevant information must be considered when conducting classifications. It also indicates that all classifications must be based on data generated using internationally validated and accepted methods. OSHA believes that the content of

its original proposal for A.2.1.2 is adequately clarified in Figure A.2.1 and is not necessary to include in A.2.1.2. Also to align with Rev. 8, OSHA is adding paragraph A.2.1.3, which was not in the text of the proposed rule, to provide information on the tiered approach to classification of skin corrosion/irritation hazards.

OSHA proposed to revise paragraph A.2.2 to present the information in a clearer, more logical fashion but did not propose to change the classification criteria. The text OSHA originally included in the NPRM for this paragraph was based on Rev. 7, but because the agency has decided to align it with Rev. 8, the language and numbering has changed since the proposal. Paragraph A.2.2 contains more information on when to use sub-categories 1A, 1B, and 1C. New paragraphs A.2.2.1 and A.2.2.2 provide information on classification based on standard human data and animal test data, respectively. Paragraph A.2.2.2.1 and subparagraphs A.2.2.2.1.1 and A.2.2.2.1.2, as well as Table A.2.1, provide classification information and criteria for skin corrosion. Skin irritation information and criteria are included in paragraph A.2.2.2.2.

ACC commented that OSHA should retain flexibility in classification and “avoid an overly prescriptive inclusion of Table 3.2.1” of Rev. 8. ACC did not explain what it might consider an “overly prescriptive inclusion of Table 3.2.1” to be. Since ACC expressed general support of updating Appendix A.2 to expand the use of non-animal test methods as outlined in Rev. 8 and praised “the additional flexibility that the inclusion of Chapter 3.2 (specifically Table 3.2.1) provides” in their comments, and since OSHA has not added any requirements for testing or requirements to re-evaluate chemicals already classified, the agency believes its approach to incorporating Rev. 8 changes into Table A.2.1 (which is drawn from Table 3.2.1) would not likely be “overly prescriptive” in ACC’s view (Document ID 0347, p. 6).

Tom Murphy commented on paragraph A.2.2.2.1 (now A.2.2.2.2.1), suggesting that OSHA consider a change from the proposed text “A substance is irritant to skin

when it produces reversible damage to the skin following its application for up to 4 hours” to “A substance is an irritant to the skin when it produces reversible damage to the skin within 4 hours of the initial application” (Document ID 0277, p. 1). Murphy reasoned that an improper reading of the proposed wording could lead a reader to misunderstand that the application is constantly applied (rather than applied once and allowed to remain) for up to four hours while observing the subject for reversible damage.

The language in paragraph A.2.2.2.1 (now A.2.2.2.2.1), “for up to 4 hours,” is consistent with the language used in the GHS and was taken from the Organisation for Economic Co-operation and Development (OECD) test guidelines, which are widely recognized and accepted around the world. Classifiers are already familiar with the language and the associated test guideline. Therefore, OSHA is maintaining this provision as proposed in the final rule. However, as discussed above, OSHA has updated the definition of skin irritation in A.2.1.1 to include the word initial and paragraph A.2.2.2.1 (now A.2.2.2.2.2) with the additional phrase “when after the first application” for classification for skin irritation (category 2), which should provide the requested clarity.

OSHA also received comments on paragraph A.2.2.2.4 (now A.2.2.2.2.4), which discusses the variability of animal irritant responses within a test. Cal/OSHA commented that the text in the paragraph is not clear (Document ID 0322, Att. 2, p. 4). They asked what OSHA meant by the word “might,” and if the manufacturer or importer is required to act on this information or not. They also inquired about the meaning of a “very elevated mean score,” how “other responses” fulfill this criterion, and how this increases “the sensitivity of the classification system.” In response to Cal/OSHA’s comments, OSHA modified the text in the third sentence of paragraph A.2.2.2.2.4 from “might” to “should” to clarify that manufacturers should designate a substance as an irritant when at

least one of three test animals show a very elevated mean score according to the test method used throughout the study, including lesions persisting at the end of an observation period of normally 14 days. OSHA also modified the text in the fourth sentence, from “could” to “should” to indicate that other irritant responses should also fulfill the same criterion. OSHA notes that the agency did not propose to modify this paragraph, which is in the 2012 HCS as A.2.2.2.2, but the agency believes adopting this change is consistent with the changes made throughout Appendix A to provide clarity. With regard to Cal/OSHA’s questions about other language in A.2.2.2.4, OSHA has provided detailed guidance on classification which discusses each hazard class. In particular, OSHA has provided numerous examples for skin corrosion and irritation classification scenarios which provide detailed rationale on applying the classification principles (Document ID 0008, pp. 69-85) and therefore does not believe that the intention of the text is unclear to regulated parties, but will review the guidance to determine if additional material should be added to clarify the terms addressed by Cal/OSHA.

Table A.2.2 provides the classification criteria for skin irritation Category 2. Cal/OSHA asked why the classification criteria indicate that a chemical should be deemed a skin irritant if the criteria are met in Table A.2.2 in at least two animals, rather than one (Document ID 0322, Att. 2, p. 4). OSHA notes that the HCS skin irritation classification criteria align with the current criteria used for classification of skin irritation in the GHS reference tests where irritant responses are present in two of three tested animals. Regardless, to the extent Cal/OSHA seeks a modification in the criteria in Table A.2.2, such changes were not proposed in the NPRM and thus would be beyond the scope of this rulemaking.

As previously explained, OSHA is introducing changes to the final rule which align with Rev. 8. To that end OSHA has added additional paragraphs to Appendix A.2 in

the final rule. New paragraph A.2.2.3 provides information on classification based on *in vitro/ex vivo* data. New paragraph A.2.2.4 provides information on classification based on other existing skin data in animals. New paragraph A.2.2.5 includes information on classification based on chemical properties. New paragraph A.2.2.6 includes information on classification based on non-test methods. New paragraph A.2.2.7 outlines the approach to evaluation of information that should be considered. In addition, Figure A.2.1 was updated to make it consistent with the text and to show the tiered evaluation process.

PCRM supported adding these sections, specifically highlighting the revised Figure 3.2.1 and Sections 3.2.2.3, Classification based on *in vitro/ex vivo* data, and 3.2.2.6, Classification based on non-test methods (Document ID 0295, pp. 1-2).

Cal/OSHA commented that the phrase “buffering capacity” in paragraph A.2.3.5 is used inconsistently in paragraph A.2.3.5, and is not defined in the chapter, nor is the term “acid/alkaline reserve” (Document ID 0322, Att. 2, p. 5). Due to the changes made to align with Rev. 8, the content Cal/OSHA is referring to is now in A.2.2.5. OSHA intends to update some of its existing compliance assistance products following the publication of the final rule and anticipates providing further guidance on acid/alkaline reserve (buffering capacity).

Paragraph A.2.3 (proposed as A.2.4) provides information on classification criteria for mixtures. OSHA had proposed changes to align with Rev. 7, including changes to proposed A.2.4.1.1 and A.2.4.1.2. As with the other classification criteria in A.2, in this final rule OSHA is aligning this section with Rev. 8 instead. Therefore, OSHA is updating A.2.3.1.1 (proposed as A.2.4.1.1) and A.2.3.1.3 (proposed as A.2.4.1.2) and adding a new paragraph A.2.3.1.2. In the new A.2.3.1.1, OSHA is including language stating that the tiered approach specified in Figure A.2.1 must be taken into account when evaluating mixtures. New paragraph A.2.3.1.2 provides

information on using *in vitro/ex vivo* data and limitations regarding applicability domains. The new A.2.3.1.3 is also included to indicate that if there are no other data on the mixture besides pH, and the pH is extreme ($\text{pH} \leq 2$ or $\text{pH} \geq 11.5$), 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 this needs to be confirmed by other data.

OSHA also proposed 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 was to align with the note to Table 3.2.3 in Rev. 7 (Document ID 0060, p. 133), in order to provide information OSHA believes will be useful for classifiers. OSHA received no comments on this proposed note, and is finalizing it as proposed except to remove the phrase “data are available and” to align with Rev. 8 as discussed previously (Document ID 0065, p. 136).

ACC suggested that OSHA consider adding Tables 3.2.6 and 3.2.7 from the GHS to either the standard or an updated guidance document (Document ID 0347, p. 6). OSHA anticipates updating some of its guidance products following the publication of the final rule and providing relevant guidance, including the content of Tables 3.2.6, Skin corrosion criteria for *in vitro/ex vivo* methods, and 3.2.7, Skin irritation criteria for *in vitro* methods from Rev. 8, as well as references to NIOSH’s Current Intelligence Bulletin and/or other relevant NIOSH guidance.

For the reasons discussed above, OSHA is finalizing Appendix A.2 to align with Rev. 8 in several respects, including the changes to numbering and wording, and the additional paragraphs described above.

In Appendix A.3, OSHA proposed updates to align with Rev. 7. API supported these changes and noted that they were in alignment with the GHS (Document ID 0316, p. 19).

OSHA proposed 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 proposed revision was to 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. OSHA received no comments on this change, and is finalizing it as proposed.

The changes OSHA proposed 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 proposed revisions rearrange the presentation of the information and include additional headings to provide a clearer, more logical sequence. All of the proposed changes were to conform with Rev. 7 (Document ID 0060, pp. 139-145).

OSHA proposed a new paragraph A.3.2 to provide a summary of the classification criteria for substances that is provided in Tables A.3.1 and A.3.2. Paragraph A.3.2.3 of the 2012 HCS (now renumbered as A.3.2.1.3) provided that if there is pronounced variability among animal responses, that information “may be taken into account” when determining the classification. Worksafe and Cal/OSHA commented that the language in the 2012 HCS would allow producers to withhold evidence of a serious health effect in toxicological studies if the effect occurs among a range of other effects (Document ID 0354, p. 4; 0322, Att. 1, p. 3). While Worksafe and Cal/OSHA incorrectly suggest that this is a new problem with the language, since the word “may” was already in the 2012 HCS, OSHA agrees with these comments and has concluded that making a change would be consistent with the editorial and clarifying nature of the edits OSHA

proposed for A.3.2 and A.3.3 and the broader goal of this update to Appendix A to clarify which elements are mandatory. The agency has therefore revised proposed paragraph A.3.2.1.3 in the final rule to indicate that the provision is mandatory and that information on pronounced variability “must” be taken into account when making classification decisions.

OSHA received a comment from Cal/OSHA asking why two out of three test animals are required for category 1(b) while only one positive test is required in (a). Additionally, they stated the text in the table is unclear about the meaning of irreversible effects (Document ID 0322, p. 5). While OSHA proposed to modify the title and added a footnote to Table A.3.1, OSHA did not propose to modify the actual criteria and they remain consistent with the GHS. Therefore, this comment is outside the scope of this rulemaking.

OSHA proposed a new paragraph A.3.3.6 (now A.3.2.2.6 in the final rule) as a reorganization of the 2012 HCS paragraphs A.3.3.3 and A.3.3.4. Proposed paragraph A.3.3.6 (now A.3.2.2.6) was to provide guidance on using the tiered approach and making weight-of-evidence decisions, and also to indicate OSHA’s preference for not conducting new animal tests. OSHA received no comments on proposed paragraph A.3.3.6 (now A.3.2.2.6), and is therefore finalizing it as proposed.

OSHA proposed to modify Figure A.3.1 to align with the tiered evaluation scheme in Figure 3.3.1 of Rev. 7 (Document ID 0060, p. 142). Under OSHA's proposed revisions, Figure A.3.1, “Tiered Evaluation for serious eye damage and eye irritation” (previously titled “Evaluation strategy for serious eye damage and eye irritation” in the 2012 HCS), would remain largely the same. However, as in Figure A.2.1, OSHA proposed 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 proposed 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 also proposed modifications to the footnotes of Figure A.3.1 to reflect the most recent test methods. Specifically:

- OSHA proposed to include two additional sentences in footnote c (previously footnote (3)) 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.
- OSHA proposed to include OECD Test Guideline 460 (Fluorescein leakage (FL)) in footnote d (previously footnote (4)) as an additional example of an internationally accepted, scientifically validated test method for identifying eye corrosives and severe irritants. OSHA also proposed 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.
- OSHA proposed to revise footnote f (previously footnote (6)) 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 proposed to remove the last two sentences at the end of footnote f and add a new sentence indicating that negative results from applicable scientifically validated *in vitro* tests are considered in the total weight of evidence evaluation.

PCRM supported updating the footnotes for Figure A.3.1 (Document ID 0295, p. 2). OSHA received no other comments on the changes to Figure A.3.1 and is therefore finalizing them as proposed.

In proposed paragraph A.3.4 (now A.3.3 in the final rule), OSHA proposed several minor editorial changes to ensure consistency in the terminology used. For example, OSHA proposed to use the term “serious eye damage” (rather than “eye

corrosion”) throughout the text to reflect the name of the hazard class. OSHA received no comments on these revisions and is therefore finalizing them as proposed.

For the reasons discussed above, OSHA is finalizing the entirety of A.3 as proposed, except for changing “may” to “must” in A.3.2.3 and renumbering some of the paragraphs to better align with the GHS.

IV. Respiratory or Skin Sensitization (Appendix A.4).

OSHA proposed a small number of primarily editorial changes in Appendix A.4, Respiratory or Skin Sensitization. It received no comments on those changes, but did receive an out of scope comment on this section.

Cal/OSHA commented that in paragraph A.4.2.1.3.1, “[t]he proposal requires disclosure of chemical asthmagens that cause respiratory sensitization, but does not require disclosure of chemicals that produce bronchospasm without a sensitization (immune) effect, also known as reactive airway dysfunction syndrome (RADS), or acute-onset, irritant induced asthma (IIA)” (Document ID 0322, Att. 1, pp. 17-18). Cal/OSHA therefore recommended adding a category 1C to this hazard class (Document ID 0322, Att. 2, p. 6). OSHA notes that the agency did not propose to modify paragraph A.4.2.1.3.1, therefore, Cal/OSHA’s proposal is outside the scope of this rulemaking. Additionally, as stated above, OSHA has provided considerable guidance on each hazard category under its Hazard Classification guidance (Document ID 0008). In this case, OSHA’s classification guidance covers organ dysfunction, such as RADS, under the hazard classes STOT-SE and STOT-RE (Document ID 0008, pp. 192, 213).

V. Germ Cell Mutagenicity (Appendix A.5).

As discussed below, OSHA proposed to add a definition for germ cell mutagenicity in A.5.1.1. Because of this new paragraph, OSHA also proposed adjusting the subsequent numbering of existing paragraphs in A.5.1. OSHA received no comments on these changes and is finalizing them as proposed.

In A.5.4, *Examples of scientifically validated test methods*, paragraph A.5.4.2, OSHA proposed 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. The proposed change was to align with Rev. 7 (Document ID 0060, p. 163) and to ensure that hazard classifications are being conducted with the most current scientific principles. OSHA received no comments on this revision and is therefore finalizing it as proposed.

Toby Threet stated that Figure A.5.1 “should not place all human epidemiological studies on an equal footing. Sometimes an epidemiological study, by itself, is not sufficient to establish that a chemical is a known human germ cell mutagen” and proposed modified text (Document ID 0279, p 16). OSHA did not propose to modify Figure A.5.1; therefore, the proposed revision is out of scope for this rulemaking and OSHA declines to change the text as requested.

VI. Carcinogenicity (Appendix A.6).

Paragraph A.6.4.2 indicates that when OSHA has identified a chemical as a carcinogen in 29 CFR part 1910, Subpart Z, Toxic and Hazardous Substances, that chemical must be classified as a carcinogen for purposes of the HCS (for instance, the respirable crystalline silica standard references the HCS and silica being a carcinogen in 29 CFR 1910.1053(j)(1)). OSHA proposed to strike the specific citation to 29 CFR part 1910, Subpart Z, Toxic and Hazardous Substances, and replace it with the text “this section subpart.” Toby Threet and the Vinyl Institute stated that the proposed text was unclear, and the Vinyl Institute commented that the reason for the revision was vague (Document ID 0279, p. 17; 0369, p. 10). OSHA included the text “section subpart” in error in the NPRM. The proposed text should have replaced the citation to 29 CFR part 1910, Subpart Z, Toxic and Hazardous Substances with the text “this subpart.” However, OSHA agrees with these comments and is retaining the original text for clarity.

Cal/HESIS, Cal/OSHA, Worksafe, National COSH, and Steve Wodka

commented that manufacturers should be required to classify chemicals as carcinogens and provide carcinogenicity information when the chemical is listed as a carcinogen by authoritative organizations. Cal/HESIS specified these should include “the NTP, the IARC, the EPA, and OSHA when OSHA has included cancer as a health hazard to be considered by classifiers for the chemical under 29 CFR part 1910, Subpart Z, Toxic and Hazardous Substances” (Document ID 0313, pp. 6-7). Some of these commenters provided suggested text for paragraph A.6.4 (Document ID 0313, pp. 6-7; 0312, p. 6; 0322, Att. 1, pp. 5-7; 0354, pp. 5-6; 0407, p. 15). OSHA did not propose to modify the paragraphs that Cal/HESIS proposed revisions to (except to use the term “of this subpart” in A.6.4, which is unrelated to this issue). Therefore, the suggested revisions are out of scope for this rulemaking and OSHA declines to make those changes. Furthermore, OSHA provides ample guidance in both Appendix F, which includes a table on how to classify carcinogens based on NTP and the International Agency for Research on Cancer (IARC) classifications, and Appendix C of the compliance directive (Document ID 0007, p. 103) which OSHA anticipates updating after issuing this final rule.

Cal/HESIS also commented that OSHA should “allow State Plan States such as California to require manufacturers that sell chemicals in their states or territories to classify chemicals as carcinogens or as having reproductive toxicity or developmental toxicity when the chemicals are listed by a state- or territory-specific body... as carcinogens or as reproductive or developmental toxicants” (Document ID 0313, p. 8). This issue is outside the scope of this rulemaking as OSHA proposed nothing related to this issue in the NPRM. However, OSHA notes that it has already addressed the issue of labeling of hazardous chemicals in its 1997 approval of the California State Standard on Hazard Communication Incorporating Proposition 65 (Prop 65) (62 FR 31159).

VII. Reproductive Toxicity (Appendix A.7).

In Appendix A.7, OSHA proposed to revise the “effects on or via lactation” hazard category classification criteria in Figure A.7.1(b) to align with OSHA’s Hazard Classification guidance (Document 0008, p. 172). During the development of the Hazard Classification guidance document, it became apparent to OSHA that there were issues with regard to the classification criteria in Figure A.7.1(b). The hazard category for effects on or via lactation captures two separate effects: (1) substances that can interfere with lactation and (2) substances and their metabolites that may be transmitted through breast milk to children in amounts sufficient to cause concern for the health of the breastfeeding child. However, the criteria in effect at that time did not adequately distinguish between these two separate effects. OSHA therefore proposed to delete the text “hazardous to breastfed babies” in the second sentence in Figure A.7.1(b), which was not grammatical and excluded the effects on lactation. OSHA also proposed to modify the third sentence in the figure to read: “Classification for effects via lactation shall be assigned on the basis of:” in order to avoid confusion on how to apply the criteria for effects on lactation. These proposed changes would not affect the classification of substances or mixtures as reproductive toxicants. OSHA received no comments on this revision and is therefore finalizing it as proposed.

OSHA also proposed 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 proposed a correction to the top left heading from “ingredients classified as” to “ingredient classified as.” OSHA explained in the NPRM that the use of the word “ingredients” in this context could be confusing, as it could suggest that the additivity principle should be applied. Therefore, OSHA proposed this change for clarity. These

proposed modifications in Appendix A.7 were to align with Rev. 7 (Document ID 0060, pp. 185-187). OSHA received one comment from PCRM in support of the addition of OECD TG 443, and no comments objecting to its addition. OSHA is therefore finalizing these changes as proposed.

Cal/HESIS commented that OSHA should add a requirement that manufacturers refer to authoritative organizations when classifying chemicals that have reproductive toxicity as follows: “Manufacturers classifying chemicals shall treat the following source as establishing that a substance is a reproductive or developmental toxicant for hazard communication purposes in lieu of applying the criteria described herein: 1. Reproductive or developmental toxicants identified in the Monographs on the Potential Human Reproductive and Developmental Effects, National Toxicology Program, Office of Health Assessment and Translation” (Document ID 0313, p. 6). OSHA did not propose any modifications to the classification criteria in Appendix A.7 related to authoritative organizations when classifying chemicals that have reproductive toxicity, therefore, Cal/HESIS’s comment is therefore outside the scope of this rulemaking and OSHA declines to accept their proposal.

VIII. Specific Target Organ Toxicity Single Exposure (Appendix A.8).

In addition to non-substantive changes in A.8.1.6 and A.8.2.1.7.3, OSHA proposed adding new paragraph A.8.3.4.6 to include the concept of “relevant ingredient” when classifying mixtures containing Category 3 ingredients using the additivity approach. Under the 2012 HCS, the additivity principle was introduced in paragraph A.8.3.4.5. However, a “relevant ingredient” for this procedure had not been established. OSHA therefore proposed paragraph A.8.3.4.6 to 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 $\geq$ one percent (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 < one percent is still relevant when classifying the mixture for respiratory tract irritation or narcotic effects. This proposed paragraph would align with Rev. 7 (Document ID 0060, p. 198). OSHA received no comments on these revisions and is finalizing them as proposed.

OSHA received a comment from Toby Threet arguing that in Tables A.8.1, A.9.1, A.9.2, and paragraph A.8.3.4.6, the use of the words “gas,” “vapor,” and “mist” as three distinct categories is scientifically incorrect and that either “gas” and “vapor” are synonymous or “vapor” and “mist” are synonymous, depending on OSHA’s intended meaning of “vapor.” Threet suggested that OSHA modify these sections to only have two categories (Document ID 0279, p. 17). OSHA notes that the agency did not propose to modify the use of these three terms in Tables A.8.1, A.9.1, or A.9.2 or how those terms are used more generally in the HCS, and A.8.3.4.6, while new, reflects that underlying concept. Therefore, such changes would be out of scope for this rulemaking. OSHA notes that its Hazard Classification guidance provides substantial guidance and examples regarding how to apply the hazard criteria to vapors, mists, and gases (Document ID 0008, pp. 189-226).

IX. Specific Target Organ Toxicity Repeated Or Prolonged Exposure (Appendix A.9).

OSHA made a few changes to Appendix A.9 that are discussed below in the section on broader changes made throughout Appendix A. OSHA received one comment on Appendix A.9 unrelated to its proposed changes. Cal/HESIS commented that OSHA should add the following requirement: “For chemicals that affect the nervous system, manufacturers shall treat the following sources as establishing that a substance is a neurotoxicant for hazard communication purposes in lieu of applying the criteria described herein: 1. Agency for Toxic Substances and Disease Registry (ATSDR), Health Effects of Toxic Substances and Carcinogens, Nervous System. 2. Chemicals for which a reference dose or concentration has been developed based on neurotoxicity in the United

States Environmental Protection Agency's Integrated Risk Information System database (searching for "Organ/System affected: Nervous")" (Document ID 0313, pp. 7-8). While OSHA agrees that these sources are relevant and the classifiers can rely on this information for classification purposes, OSHA did not propose to modify the classification criteria in Appendix A.9 to include a requirement that manufacturers refer to authoritative organizations when classifying chemicals that have specific target organ toxicity, therefore, it is outside the scope of this rulemaking to modify Appendix A.9 as suggested by Cal/HESIS.

X. Aspiration Hazard (Appendix A.10).

OSHA proposed changes to Appendix A.10 to clarify the classification criteria for mixtures when data are available for all ingredients or only for some ingredients and to align with Rev. 7 (Document ID 0060, p. 213). OSHA proposed 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, OSHA proposed a new heading, "Category 1," as new paragraph A.10.3.3.2. and proposed paragraphs A.10.3.3.2.1 and A.10.3.3.2.2 to clarify that the principle of additivity applies in Appendix A.10. OSHA did not propose any substantive changes to the classification criteria. ILMA commented in support of the changes in A.10.3.3, stating that the clarifications provided "will assist ILMA members (many of whom compound and market low-viscosity petroleum product mixtures) in properly classifying their products for aspiration toxicity" (Document ID 0356, p. 6). OSHA received no objections to the changes and is finalizing them as proposed.

XI. Changes to Definitions and Terminology, Clarification of Mandatory Requirements, and Corrections.

(A) Definitions.

OSHA proposed to update Appendix A to include changes to the health hazard definitions to reflect those adopted in Rev. 7 (Document ID 0060; 0131). In the time since OSHA revised the HCS in 2012, the UNSCEGHS revised all of the health hazard definitions in the GHS. 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 proposed to adopt all the revised health hazard definitions from Rev. 7 in Appendix A, as well as corresponding changes to text throughout the appendix. For example, in some cases OSHA proposed to remove OECD test guidelines from definitions and to move them to paragraphs outlining classification criteria. OSHA has discussed in the respective sections above the definition changes that had substantive impacts on the rest of their hazard classifications and has made alterations to some of the proposed definitions. These health hazard definitions are the definitions that OSHA is finalizing in Appendix A:

- *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 initial exposure to a substance or mixture.
- *Skin irritation* refers to the production of reversible damage to the skin occurring after initial 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. 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.
- *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.
- *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.

- *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.
- *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.

NAIMA and API commented in support of the proposed modifications to the health hazard definitions (Document ID 0338, p. 7; 0316, p. 12). OSHA received comments on some of the specific definitions, which are addressed in their respective sections (including *acute toxicity*, *skin corrosion*, and *skin irritation* definitions) and the definitions listed above include any responsive modifications OSHA decided to make based on those comments. OSHA received no objections to the changes to the *serious eye damage*, *eye irritation*, *respiratory sensitization*, *skin sensitization*, *germ cell*

mutagenicity, carcinogenicity, reproductive toxicity, STOT-SE, and STOT-RE definitions, and is therefore finalizing these definitions as proposed.

(B) Terminology Issues.

The 2012 HCS was somewhat inconsistent in the way the terms “hazard category” and “toxicity category” were used throughout Appendix A. In some cases, the terms were used interchangeably, while in other instances the terms were intended to have different meanings. OSHA therefore proposed revisions to ensure that these terms are used appropriately and consistently. As such, OSHA proposed to delete the term “toxicity category” and replace it with “hazard category” in various places, including paragraphs A.0.5, A.1, A.3, A.8, A.9, and A.10. These proposed changes also align with Rev. 7 (Document ID 0060; 0084). OSHA received no comments on these changes and is finalizing them as proposed.

(A) Mandatory Language.

OSHA proposed to update a number of provisions in Appendix A to make it clear that those provisions are mandatory. For example, OSHA proposed to change the term “should” to “must” in paragraph A.3.4.3.3 (now paragraph A.3.3.3.3) to 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. OSHA received no comments on these changes and is finalizing them as proposed.

(B) Corrections.

OSHA proposed 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 of the 2012 HCS. OSHA therefore proposed 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 of the 2012 HCS. Thus, OSHA also proposed 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. OSHA received no comments on these changes and is finalizing them as proposed.

D. Appendix B

Appendix B addresses the physical hazards covered by the HCS, including classification criteria consistent with the GHS. OSHA proposed several substantive updates to Appendix B, including the addition of a new hazard class (desensitized explosives) and several new hazard categories (splitting Category 1 into 1A and 1B and further subdividing Category 1A into flammable gases, chemically unstable gases and pyrophoric gases in the Flammable Gases class, as well as nonflammable aerosols in the Aerosols class), revisions to the consensus standards and testing methods referenced in Appendix B, and clarifications based on implementation issues that arose from the 2012 HCS.

OSHA proposed to include the new hazard class and hazard categories because, since the HCS aligned with the GHS in 2012, new physical hazard classes or hazard categories have been added to Rev. 7 which better identify and communicate hazard information to downstream workers (Document ID 0060). OSHA proposed to adopt those additions to maintain alignment with the GHS. As explained in the NPRM and in the discussion to follow on individual classes within Appendix B, OSHA 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 by using more targeted hazard statements, precautionary statements, and pictograms.

In order to maintain alignment with Rev. 7 (Document ID 0060), OSHA also proposed several updates to references 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 proposed to update consensus standards and testing methods referenced in Appendix B in accordance with Rev. 7 to ensure that data considered for classification incorporate updated scientific principles. OSHA is not, however, implying that data obtained from the older methods would no longer be valid or that classifiers would need to retest or reclassify chemicals due to these updated methods. Third, OSHA proposed 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 changes, discussed further below, were proposed to align the HCS with the GHS while improving the classification and communication of hazards and maintaining or enhancing worker safety and health. As noted elsewhere in this preamble, OSHA has determined that primarily aligning the HCS with Rev. 7 will not only improve safety and health but will also ease compliance burdens for U.S. stakeholders that must also comply with international requirements for hazard classification and communication.

OSHA also proposed to make several changes to Appendix B to clarify compliance requirements. These changes arose from the agency's experience with implementing the HCS and are expected to maintain existing safety and health protections while easing or having no effect on the compliance burdens for regulated entities. They are described in more detail in the discussions below on individual classes within Appendix B.

Finally, OSHA provided a redline strike out version of Appendix B, which reflected all of OSHA's proposed revisions, in the docket and on the OSHA website to

allow interested parties to view all of the proposed changes in context (Document ID 0222). OSHA will update this document to show the changes being made in this final rule and strongly encourages stakeholders to review that document in conjunction with the discussion of the revisions, as the discussion provided in this final rule’s summary and explanation does not fully describe all of the non-substantive or editorial changes OSHA is making in Appendix B. Stakeholders can examine the redline strikeout of the regulatory text (changes from 2012 HCS to this final rule) at OSHA’s HCS webpage (<https://www.osha.gov/dsg/hazcom/>) to view all of the changes from the 2012 HCS made in this final rule.

I. Explosives (Appendix B.1).

OSHA proposed several minor amendments to Appendix B.1. First, OSHA proposed a clarification to the classification criteria for Division 1.6 explosives in B.1.2 (f). Under 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 (Document ID 0085, Att. 2, p. 4). Rev. 7 (Document ID 0060, p. 44) states that the criteria are met if the article (“item” in the HCS) “predominantly” contains extremely insensitive detonating chemicals. OSHA proposed to make the same change to paragraph B.1.2 (f) of Appendix B on the basis that changing the criteria from containing “only” extremely insensitive detonating chemicals to “predominantly” containing extremely insensitive detonating chemicals would be more technically accurate and better align with the guidance in test series 7 in the UN Manual of Tests and Criteria (Document ID 0151). It would also reduce confusion for chemical manufacturers or importers when classifying explosives. OSHA did not receive any comments on this change and is finalizing it as proposed.

OSHA also proposed to add two notes from the GHS (Document ID 0060, pp. 44-45) to Appendix B, paragraph B.1.3.1, that are related to the addition of the desensitized

explosives hazards class (Appendix B.17, newly added in this final rule and discussed later in this document). The first new note OSHA proposed to add (Note 2) provides an explanation that explosives for which explosive properties have been suppressed or reduced by being wetted with water or alcohols, diluted with other substances, or dissolved or suspended in water or other liquid substances must be classified as desensitized explosives.

The second new note OSHA proposed (Note 3) explains 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. OSHA proposed that 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).

OSHA received comments on proposed Note 2 from DOD. DOD stated that “The techniques cited in B.1.3.1...do not necessarily ‘suppress or reduce explosive properties’ as indicated within NOTE 2. Instead, those techniques simply result in sensitivity suppression or reduction by homogeneously dispersing certain concerning molecules amongst other inert molecules, which is why the resultant chemicals are known as ‘desensitized explosives’” (Document ID 0299, p. 3). DOD recommended that OSHA change the first sentence of Note 2 to read: “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 *or sensitivity*” (Document ID 0299, p. 3; emphasis added).

OSHA believes the language proposed in the NPRM captured the idea of a reduction of sensitivity in the phrase “suppress or reduce their explosive properties.” However, to ensure clarity, OSHA has added the term “sensitivity” at the end of the first sentence of Note 2 as DOD requested.

DOD additionally recommended that OSHA should address the concept of desensitizing an explosive by mixing it with an inert solid (e.g., silica) in Note 2 (Document ID 0299, p. 3). OSHA does not agree that this addition is necessary. The primary purpose of this note is to alert the classifier that a mixture may be a desensitized explosive and that they should consider this in their classification process. The note is not intended to give guidance on how to dilute an explosive to become desensitized or list every mechanism by which such desensitization can be achieved. OSHA notes that mixing explosives with solids is not excluded from this note because it includes the phrase “diluted with other substances.” Additionally, this wording matches the wording in Rev. 7, which is reflected in both this proposed note and proposed Section B.17, Desensitized Explosives. Furthermore, OSHA notes that the addition of solids to explosive chemicals is not an unequivocal abatement of the explosive hazard nor does it automatically create a desensitized explosive. Under certain circumstances such an addition would be a new mixture that may need to be reevaluated to determine whether it is an explosive or desensitized explosive. OSHA does not want to suggest that solids can in all cases be used to create a desensitized explosive. Thus, OSHA is not adding the suggested edits by DOD but anticipates providing additional information on this issue as it updates its classification guidance.

DOD provided two suggestions for Note 3. First, DOD noted that there is an error in OSHA’s citation of the is UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria and that it should be to UN ST/SG/AC.10/11/Rev.6 instead of UN ST/SG AC.10/30/Rev.6. Second, DOD recommended that OSHA add the

phrase “which are exempted from classification as explosives (based on a negative result in Test Series 6 in Part I, Section 16, of UN ST/SG/AC.10/11/Rev.6)” (Document ID 0299, pp. 3-4). OSHA agrees with both suggested revisions and notes that DOD’s second recommended change is in the Rev. 7 note which OSHA’s Note 3 was based on (Document ID 0060, p. 45, Note 2 under table 2.1.2). Therefore, OSHA is updating Note 3 as recommended by DOD.

OSHA received several comments from SAAMI. First, SAAMI commented that, similar to OSHA’s approach to changes from Rev. 8 of the GHS, OSHA should provide an option in the final rule for industry to change over to Rev. 9 for GHS chapter 2.1 (Document ID 0370, p. 2). However, unlike the changes in Rev. 8, OSHA did not propose or raise as an issue the potential to adopt Rev. 9 updates to chapter 2.1 in this final rule. OSHA does not believe there has been sufficient notice and comment to make such sweeping changes to this final rule. However, while OSHA is not making a finding in this rulemaking that this will be the case for every explosive, OSHA believes that under many circumstances following the Rev. 9 update to chapter 2.1 will result in full compliance with the requirements of the HCS, and manufacturers, importers, and distributors can determine whether in a given case following Rev. 9 would also comply with the HCS.

OSHA’s conclusion is based on several factors unique to explosives. First, OSHA notes that following Rev. 9 would meet the HCS requirement to not use updated classification criteria from subsequent GHS revisions. As illustrated by SAAMI’s comparison spreadsheet (Document ID 0294, Att. 2), which OSHA has reviewed and concluded is accurate, the same TDG classification criteria are used. The categories are simply called different names (e.g., Divisions 1.1-1.3 and 1.5 are now called 2A, Division 1.4 is called 2B or 2C) and are regrouped to better break down the classification into low, medium, and high hazards when outside of the packaging. A label preparer could follow

all of the classification instructions in Appendix B and simply call it a different category name as a result, which would not confuse workers because the category name is not used on labels.

Second, explosives have unique flexibility under Appendix C with regard to the language used on labels compared to other hazards and the labeling language in Rev. 9 is generally quite similar to the language used in Rev. 7. Specifically, in Appendix C, in the note under C.4.14, if a label preparer determines that an unpackaged or repackaged explosive corresponds to a hazard category other than Division 1.1, OSHA allows the use of the corresponding symbol (i.e., pictogram), signal word, and/or hazard statement. Since labels are attached to the immediate container, which would be exposed when explosives are unpackaged or repackaged, OSHA believes that it is often appropriate to use this flexibility on HCS labels for explosives. OSHA therefore believes that this provision, in combination with the usual flexibilities regarding hazard statements under C.2.2.1 and C.2.2.2, can allow the label preparer to determine, on a case-by-case basis, that the hazard statements in Chapter 2.1 of Rev. 9 are appropriate. Similarly, because deviations in precautionary statements between Rev. 7 and Rev. 9 are infrequent and usually small, OSHA believes that the labeling flexibility under C.2.4 would allow for the use of precautionary phrases from Rev. 9. OSHA would allow deviations in labeling language, for both hazard statements and precautionary statements, if the label preparer can show that based on their analysis of the explosive the label elements in Rev. 9 are more appropriate and therefore would be in full compliance with the HCS (see Appendix C, C.2.2.2 and renumbered C.2.4.9). The hazard statements, pictograms and signal words for explosives in Rev. 9 are all at least as protective as the Rev. 7 elements that OSHA proposed to include in the updated HCS, except for the low hazard explosives (Category 2C, which corresponds to explosive 1.4S in Rev. 7 and the HCS) where an exclamation mark pictogram is used instead of an exploding bomb (Document ID 0294, Att. 2). While

there is no general flexibility regarding pictograms in C.2.3, in Appendix C, Category 1.4S small arms and ammunition are specifically exempted from the requirement to include a pictogram, meaning that the pictogram requirements in the HCS and Rev. 9 are not in conflict.

Considering all of the flexibilities outlined above, OSHA concludes that a label preparer may, on a case-by-case basis, determine that using the label elements prescribed in Rev. 9 for labeling explosives would be in compliance with the HCS. OSHA also believes that this could help harmonize labeling since Rev. 9 categorization gives labelers a clearer path forward to an appropriate labeling scheme where explosives are removed from their original packaging and the use of alternate labeling elements are appropriate as allowed under the HCS. However, OSHA is not making a finding in this rulemaking that it will be appropriate to follow Rev. 9 in every case because this was not put through notice and comment and the agency has not, therefore, had the opportunity to consider every possibility that might cause a conflict between the HCS and Rev. 9. Label preparers who wish to follow Rev. 9 in a given situation must carefully consider whether doing so will comply with the HCS.

OSHA also received several comments regarding explosives that are out of scope for this rulemaking. SAAMI commented about potential confusion between the definitions of the term *article* in the HCS versus in DOT regulations as they applied to “explosive articles.” SAAMI noted that “in the HCS, ‘explosive articles’ are ‘items’ rather than ‘articles’ and are thus covered by the HCS” (Document ID 0294, p. 3). They expressed concern that the term “article” is used in DOT regulations, but has a different meaning than the term used in the HCS, which could cause confusion since DOT articles may not be OSHA articles. They suggested that OSHA should clarify the distinction “in the preamble of the final rule or in the HCS itself” (Document ID 0294, p. 3).

OSHA did not propose any updates to the definition of *article* in the NPRM, therefore this comment is out of scope for this rulemaking. Furthermore, since OSHA does not use the term “explosive article” in the HCS and has carefully delineated between “articles” and “items” as it pertains to explosives, the agency disagrees with SAAMI that the differences between the DOT and HCS terms will cause confusion. OSHA notes that in the 2012 update to the HCS, the agency was careful to explain the difference between the long-standing definition of *article* in the HCS and the term “item” when referring to explosives (77 FR 17722). OSHA will consider explaining, as suggested by SAAMI, the terminology in the updated guidance products it will produce following the promulgation of this final rule.

DOD also commented on the definition of *article* and argued that paragraph 1.3.2.1.1 of Rev. 7 creates confusion regarding whether explosives are covered by the HCS. They suggested clarifying that explosive and pyrotechnic items, as defined in paragraph B.1.1.1 of Appendix B, are within the definition of “chemical.” As stated above OSHA did not propose changes to the term “article” or “chemical”, therefore this comment is out of scope for this rulemaking. The agency also believes that under the regulatory text of the HCS it is clear that all explosives are covered under the HCS. However, OSHA will consider further clarifying that explosives are covered as it updates guidance products to reflect this final rule.

OSHA also received a comment from Daniel Nicponski of Albany Molecular, resubmitting his e-correspondence communication with OSHA regarding his concern that the calculation in B.1.3.4 is incorrect (Document ID 0304, p. 1). Because OSHA did not propose a change to this formula, this comment is out of scope for this rulemaking. However, the agency notes that this issue has been brought up in a variety of fora including an OSHA and DOT Public meeting, the UN Subcommittee of Experts on the Transport of Dangerous Goods (UNSCETDG) and the International Group of Experts on

the Explosion Risks of Unstable Substances (IGUS) meeting. These discussions are ongoing and may result in an update to the formula in a future revision of the GHS. If the GHS decides to update the formula, OSHA will consider updating the formula in B.1.3.4 in a subsequent rulemaking.

OSHA received a comment and supporting documents from Ben Barrett, a private citizen, providing information for the docket documents that identified potential inconsistencies and potential solutions for the classification of unintentionally energetic substances in the UN Manual of Tests and Criteria (Document ID 0463). These proposals are still under consideration by the UN Subcommittee of Experts on the Transport of Dangerous Goods and have yet to be incorporated into the manual. Similar to the discussion above, Barrett's comment is not related to a proposed change and is therefore out of scope for this rulemaking; however, if the Manual of Tests and Criteria is updated in the future, OSHA will consider incorporating by reference the updated version in a subsequent rulemaking.

II. Flammable Gases (Appendix B.2).

OSHA proposed several changes to the Flammable Gases hazard class (Appendix B.2). Most significantly, OSHA proposed 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, in alignment with changes made in Rev. 7 (Document ID 0060, p. 53) since OSHA updated the HCS in 2012. As explained in the NPRM, the proposed subcategories would provide downstream users with a better understanding of the severity of the hazards associated with the flammable gases in each category in order to take appropriate precautions or determine if a substitute chemical is less hazardous. Furthermore, OSHA noted that the proposed bifurcation (splitting flammable gases Category 1 into Category 1A and 1B) would not alter transportation requirements for flammable gases because all flammable gases categorized as either 1A

or 1B would still count as Category 1 flammable gases for the transportation classification and communication scheme.

Most comments that OSHA received on this change supported the proposal to subdivide Category 1 of the Flammable Gases hazard class. Commenters supported this change for a variety of reasons, including that it improves alignment with the GHS (Document ID 0316, pp. 21-22; 0366, p. 7), it will encourage the use of less harmful substances (Document ID 0298, p. 1), and it will facilitate the transition to low Global Warming Potential (GWP), lower flammability refrigerants which will fit into the new GHS Category 1B classification (Document ID 0355, pp. 1-2; 0311, pp. 1-2).

OSHA received one comment objecting to the proposal to split flammable gases into subcategories. NPGA noted that similar federal regulations, codes, and standards do not distinguish by categories of flammability and argued that this is because it is inconsequential and that employers, employees, or emergency responders do not apply different handling or safeguard protocols to ‘extremely flammable’ products compared to ‘flammable’ products. Additionally, they asserted that the agency’s discussion in the NPRM indicated an ambition to direct chemical choices for purposes they consider to be beyond the scope of the HCS. They asked the agency to consider eliminating distinctions in flammability and promulgate one flammability hazard statement for a single category of flammability (Document ID 0364, pp. 4-5).

OSHA disagrees with NPGA’s assertions. The agency notes that NPGA’s comments did not include any information to support their claim that distinctions among flammable products are inconsequential to the selection of handling procedures and safeguards. OSHA has good reason to believe that the two categories previously provided for flammable gases should be further refined, and in particular that splitting flammable gas Category 1 into Category 1A and Category 1B will better articulate the hazards of flammable gases to support appropriate hazard communication, identification, and

assessment of alternatives. Category 1 and Category 2 were based on the percentage of the gas in a mixture with air that is ignitable and on ranges of flammability in air. In practice, based on those criteria, almost all flammable gases (except ammonia and methyl bromide, which are treated separately) are classified as Category 1. Therefore, no distinctions were drawn between gases that exhibit a wide spectrum of flammable properties for hazard identification and communication purposes. The new subcategories of flammable gases provide greater information on the exact conditions under which the gas is flammable (i.e., flammability limit and its fundamental burning velocity) and how flammable the gas is. Therefore, under the proposed divisions downstream users will have the information necessary to determine whether an alternative product would be not only less flammable but also less likely to propagate, and thereby cause less risk to workers (86 FR 9707).

Furthermore, NPGA's claim that OSHA exceeded the scope and purpose of the HCS misstates OSHA's position. In the NPRM, OSHA noted that the subdivision of Category 1 flammable gases would facilitate users choosing a less flammable product where possible and gave an example where a non-ozone depleting refrigerant was less flammable than propane although they were both classified as Category 1. This example is consistent with the purpose of the HCS to ensure that chemicals are appropriately classified and information is transmitted to employers and workers to enable better choices for worker safety and health, such as choosing a chemical that is less flammable than an alternative. OSHA was not suggesting in the NPRM that it would prefer to see the non-ozone depleting chemical used because it would reduce ozone depletion, but rather because of its lower flammability. Therefore, OSHA disagrees with NPGA's objections and is finalizing the update to divide flammable gases into Category 1A and 1B as proposed.

Heating, Air-conditioning, & Refrigeration Distributors International (HARDI) asked OSHA to update its Process Safety Management standard (PSM), 29 CFR 1910.119, to reflect this change once this rule is finalized (Document ID 0355, p. 2). HARDI's comment is out of scope for this rulemaking, which pertains solely to updating the HCS. However, OSHA notes, as stated above, that both subdivisions of Category 1 flammable gases (1A and 1B) remain Category 1 flammable gases and therefore are covered by the PSM Standard.

When OSHA revised the HCS in 2012, pyrophoric gases were not classified under Rev. 3 (Document ID 0085). Therefore, to ensure that the 2012 update did not reduce protections and that the hazards of pyrophoric gases would continue to be covered and communicated following the alignment with the GHS, OSHA specifically added pyrophoric gases under the HCS. 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).

Since OSHA revised the HCS in 2012, the UNSCEGHS updated the criteria for flammable gases to include pyrophoric gases (Document ID 0086; 0060, p. 53). Rev. 7 reflects the decision from the UNSCEGHS that pyrophoric gases, as well as chemically unstable gases, should always be classified as Category 1A flammable gases because 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. In the NRPM, OSHA preliminarily agreed with this decision and proposed incorporating it into Appendix B.2.

OSHA also proposed to adjust the definitions in paragraph (c) related to pyrophoric gases to reflect this change in Appendix B.2. Further discussion of changes to the definition section can be found in the Summary and Explanation for paragraph (c).

OSHA had previously defined pyrophoric gas in paragraph (c) as “a chemical in a gaseous state that will ignite spontaneously in air at a temperature of 130 degrees F (54.4 degrees C) or below.” The GHS 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” (Document ID 0065, p. 51). This change was officially made in Rev. 8 of the GHS. OSHA proposed to align with the GHS use of the term “liable to ignite” to be more technically accurate, since some pyrophoric gases may have a delayed ignition time (see, e.g., Document ID 0065, p. 51, Note 4). OSHA also proposed to move the pyrophoric gas definition to Appendix B.2. OSHA anticipated that these proposed changes would have no significant impact on the scope of gases considered pyrophoric gases, and did not expect that chemical manufacturers or importers would need to reclassify chemicals due to these changes.

As noted above, OSHA also proposed adding a new subcategory for chemically unstable gases to the flammable gases hazard class to allow for more accurate communication of the hazards associated with those gases. OSHA proposed to adopt the Rev. 7 definition of a chemically unstable gas: “a flammable gas that is able to react explosively even in the absence of air or oxygen” (Document ID 0060, p. 53) in paragraph B.2.1. Consistent with Rev. 7, under proposed Table B.2.1, a Category 1A chemically unstable gas would be further sub-classified 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 (68 °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 (68 °F) and/or a pressure greater than 101.3 kPa (14.7 psi).”

As OSHA explained in the NPRM, a chemically unstable gas is a subcategory of flammable gases, and any chemical that meets the criteria for chemically unstable gas would have met the previous HCS definition of flammable gas. While these hazards were classified in flammable gases, the UNSCEGHS noted that these gases exhibit slightly different behaviors, 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 (Document ID 0250, p. 5). Because chemical manufacturers are currently classifying chemically unstable gases as flammable gases, OSHA did not propose a new hazard category for these gases. Instead, OSHA proposed the addition of chemically unstable gases as a separate category in the appendix for flammable gases (Appendix B.2) to improve the way the hazards of these gases are identified, evaluated, and communicated.

Rev. 7 (Document ID 0060, p. 53) also added three clarifying notes under Table 2.2.1 that were not included in Rev. 3 (Document ID 0085). The notes provide guidance on the classification of flammable gases under the new hazard categories. OSHA proposed to add these notes to the HCS following Table B.2.1 because they allow for better clarity and communication of hazards. Proposed Note 2 states “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.” Proposed Note 3 states “Spontaneous ignition for pyrophoric gases is not always immediate, and there may be a delay.” Proposed Note 4 states “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).”

Rev. 7, in Chapter 2.2.4.2, provides additional guidance on the classification of flammable gases, including the new hazard categories (Document ID 0060, p. 57). It includes updated references to consensus standards and test methods (i.e., ISO

10156:2017), 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), DIN 51794, and Part III of the UN Manual of Tests and Criteria). OSHA proposed to adopt these changes, 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 incorporate by reference the cited standards and test methods. To incorporate this guidance from the GHS Chapter 2.2.4.2, OSHA proposed edits to the already-existing paragraph B.2.3. (B.2.3.1, as proposed) and proposed similar language in new paragraphs B.2.3.2, B.2.3.3 and B.2.3.4. However, OSHA did not propose to require chemicals that were already classified using an earlier version of ISO 10156 to be reevaluated with the updated test method; the updated criteria would apply only to new chemicals or chemicals not already classified.

The revisions to B.2.3.1 proposed to update the consensus standards and testing methods that were previously referenced in that section. Proposed B.2.3.2 included guidance on the test methods to determine pyrophoricity. Proposed B.2.3.3 includes guidance regarding when testing should be considered for pyrophoric gases and how to classify flammable gas mixtures if testing has not been done. Proposed B.2.3.4 provides guidance on the test methods to determine chemical stability, including references to the most up-to-date editions.

OSHA received a few comments on the additions of pyrophoric gases and chemically unstable gases as subcategories to the flammable gases hazard class. API indicated they supported the proposed changes as they would align with the GHS (Document ID 0316, pp. 21-22). Cal/OSHA submitted several comments on OSHA’s proposed changes in Appendix B.2. pertaining to Notes 3 and 4 below Table 2.1 and proposed paragraph B.2.3.3.

First, Cal/OSHA observed that Note 3 “describes a uniquely hazardous property of pyrophoric gases; that is, their potential delay in ignition,” which in their view demonstrates the necessity of clear testing protocols and “erring on the side of classification and labelling to protect downstream users” (Document ID 0322, Att. 2, p. 7). Cal/OSHA requested that OSHA revise proposed Note 3, which states that spontaneous ignition is not always immediate, by removing “and there may be a delay” from the first sentence, and adding in a second sentence a discussion of the factors which influence the time it takes for pyrophoric gases to spontaneously ignite and by stipulating that a rigorous testing regime is required for all flammable gases that contain pyrophoric components in any amount. Cal/OSHA’s suggested text also states that “when experience or past practice indicates a higher degree of hazard [than indicated by testing], the classification must reflect that experience” (Document ID 0322, Att. 2, pp. 7-8).

Second, Cal/OSHA submitted comments on OSHA’s proposed paragraph B.2.3.3 and argued that it “gives undue discretion to producers at the expense of workers and downstream users” since it would allow producers to avoid classifying and labeling a flammable gas as pyrophoric “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” (Document ID 0322, Att. 1, p. 17). Finally, they asserted that the paragraph is inconsistent with Note 3 since OSHA in one place is providing manufacturers the discretion on when to test and in another place indicating caution because there is variability and cases where the pyrophoric effects may be delayed, which indicates pyrophoric gases are “uniquely hazardous.” Cal/OSHA commented that this introduces “ambiguities and unclear regulatory direction with regard to pyrophoric gases” and suggested deleting paragraph B.2.3.3 in its entirety (Document ID 0322, Att. 2, pp. 7-8).

Finally, Cal/OSHA requested that OSHA revise proposed Note 4, which states that a flammable gas mixture should be classified as a pyrophoric gas if data on its pyrophoricity is absent and it contains more than 1% (by volume) of pyrophoric component(s). Cal/OSHA suggested revising this note to state that “All flammable gases that contain 0.01% or more of a pyrophoric gas must be subjected to testing for pyrophoricity and classified accordingly.” They also suggested changing “should” to “must” and “1%” to “0.01%” in the existing sentence. Finally, they suggested adding a sentence indicating that “when experience or past practice indicates pyrophoricity with a lesser percentage, the classification must reflect that experience” (Document ID 0322, Att. 2, pp. 7-8).

OSHA disagrees with most of Cal/OSHA’s suggested changes. First, OSHA does not require testing under the HCS. This has been a long-standing position (48 FR 53291, 53336). Therefore, it would not be appropriate to add testing requirements or imply testing requirements under this hazard class. This does not negate the fact that SDS and label preparers must use all available data and relevant experience when classifying chemicals. But to the extent that Cal/OSHA’s suggested revisions to Notes 3 and 4 would mandate testing in order to comply with the HCS, they would be contrary to the approach taken in the HCS. Therefore, OSHA is not adopting them.

OSHA also does not see B.2.3.3 and Note 3 as creating inconsistencies or ambiguities in requirements for classification of pyrophoric gases. B.2.3.3 provides the requirements for classification and Note 3 provides some guidance on the potential properties of pyrophoric gases that SDS and label preparers need to be aware of. OSHA does not believe that either B.2.3.3 alone or these paragraphs in combination give manufacturers undue discretion but rather accounts for the inherent challenges of requiring classification without requiring testing. B.2.3.3’s statement that experience can be used to determine whether to apply the classification procedures for pyrophoric gases

does not mean that experience can override test data; if there are already test data available for these chemicals that indicate it is pyrophoric, the test data would be used over “experience” or “expert judgement.” B.2.3.3 also requires that the manufacturer classify the chemical if it contains 1 percent or greater of a pyrophoric gas in the absence of testing, which means the classifier only has discretion when a mixture contains less than 1.0 percent pyrophoric gas. OSHA therefore disagrees with Cal/OSHA’s request to delete paragraph B.2.3.3. OSHA also does not agree that 1% should be changed to 0.01% in Note 4. Cal/OSHA did not supply any additional information or data supporting why OSHA should deviate from the GHS text that was developed by the subject matter experts at the GHS subcommittee. However, OSHA will consider whether to include some of the discussion regarding variability of spontaneous ignition that Cal/OSHA suggested for Note 3 as recommendations when OSHA updates its classification guidance following promulgation of this final rule.

OSHA agrees with Cal/OSHA that the wording in Note 4 should include mandatory language instead of “should.” OSHA’s original intent was to update proposed GHS text where appropriate to make it mandatory, including Note 4.

For the reasons discussed above, OSHA is finalizing all of section B.2 as proposed, with the exception of changing “should” to the mandatory language “shall be” in Note 4.

III. Aerosols and Chemicals Under Pressure (Appendix B.3).

OSHA proposed to align with Rev. 7 (Document ID 0060, pp. 59-62) by expanding the existing Flammable Aerosols hazard class (Appendix B.3) to include non-flammable aerosols as well as flammable aerosols. Under Rev. 3 and the 2012 HCS, Chapter 2.3 and Appendix B.3, were each titled “Flammable Aerosols.” Under Rev. 3, the hazards presented by non-flammable aerosols were either not classified at all or were

classified in another health hazard class or physical hazard class (e.g., gases under pressure) (Document ID 0085).

As OSHA explained in the NPRM (86 FR 9708), the agency believes that most aerosols are classified as gases under pressure under Rev. 3 (and were classified accordingly under the HCS) because of the design criteria of the aerosols under DOT regulations (Document ID 0163). Under DOT regulations, aerosols are “any non-refillable receptacle containing a gas compressed, liquefied, or dissolved under pressure” and the highest permissible pressure is 180 psig at 130 °F in most cases (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 psig) or more, or which are liquefied or liquefied and refrigerated (see existing paragraph B.5.1). 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.

Since Rev. 3, the UNSCEGHS and the 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 (Document ID 0060, pp. 59-60). This hazard category now captures aerosols that (1) contain 1% or less flammable components (by mass); and (2) have a heat of combustion that is less than 20 kilojoules per gram (kJ/g).

As OSHA described in the NPRM, OSHA assessed the hazards associated with aerosol containers and compressed gas cylinders to consider the impacts of the proposed change and ensure that it would not compromise worker safety and health. A study conducted for OSHA by ERG, an OSHA contractor, evaluated how aerosol products and gases under pressure differ in terms of container characteristics, failure mechanisms, and previous incidents (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. The report also noted differences in failure mechanisms for pressurized cylinders versus aerosols, including 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 (Document ID 0009). This conclusion was also supported by data from OSHA's Fatality and Catastrophe Information Summary (FatCat) database, located at <https://www.osha.gov/pls/imis/accidentsearch.html>, which revealed 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 (86 FR 9709).

Following a review of the data and the ERG report, OSHA preliminarily determined that a new category for non-flammable aerosols is appropriate. Additionally, OSHA noted that 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).

OSHA proposed several other changes related to changes in the GHS including: updating the aerosol hazard class to include non-flammable aerosols (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 Rev. 7 to paragraph B.3.2 (now B.3.1.2) (Document ID 0060, p. 59). For example, OSHA proposed to revise Note 2 to B.3.2.1 (now B.3.1.2.1) 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 preliminarily concluded that aerosols (flammable and non-flammable) should not also be classified as gases under pressure in order to ensure that the appropriate hazard warnings are presented on aerosol containers.

OSHA also proposed to adopt Rev. 7 (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, was proposed to update hazard communication requirements to better reflect the true hazards of non-flammable aerosols. As further discussed below in the Summary and Explanation for Appendix C, OSHA reasoned that this would also result in changing the labeling for any such aerosols that are currently classified as compressed gases, including the pictogram and hazard statements, and would better differentiate between the hazards associated with compressed gases and the hazards associated with aerosols.

OSHA received several comments on the proposed changes to the aerosol hazard class. ACA, IHSC, and Seymour of Sycamore supported the inclusion of non-flammable aerosols (Document ID 0368, p. 9; 0349, p. 2; 0321, p. 2). HCPA also expressed support, noting that “Expanding the current ‘Flammable Aerosols’ hazard class to include all aerosol products not only makes logical sense but aligns with both the GHS Rev.7 and GHS Rev. 8” (Document ID 0327, pp. 8-9). Michele Sullivan commented that “The proposed changes to the Flammable Aerosols/Aerosols Chapter are particularly welcomed” because they re-align the HCS with the GHS. NIOSH agreed with OSHA that the addition of a new hazard class and several new hazard categories to Appendix B would improve worker safety through more specific descriptions of hazards (Document ID 0281, Att. 2, p. 5; 0423 pp. 22-23). ACC commented in support of changes to the aerosols category that more closely align with the GHS (Document ID 0347, p. 6).

Two commenters recommended that OSHA make the compressed gas cylinder pictogram optional (Document ID 0368, p. 9; 0321, p. 2). Seymour of Sycamore suggested allowing the optional use of the pressurized cylinder pictogram for both non-

flammable and flammable aerosols because “[t]he use of the pressurized cylinder icon provides information to the end user that the product is under pressure and the end user needs to be aware of conditions that could make the product unsafe if the product is exposed to those conditions” (Document ID 0321, p. 2). ACA similarly asked OSHA to make the use of the pressurized cylinder pictogram optional because aerosols are common in both consumer products and the workplace, even though they also noted “[i]n environments where workers have a more sophisticated understanding of pictograms, the symbol could lead to some confusion as to whether the product is a non-flammable aerosol or a gas under pressure” (Document ID 0368, pp. 9-10).

OSHA disagrees with these comments for several reasons. First, as OSHA indicated in the NPRM, the main reason for revising the aerosol chapter is to better differentiate the hazards of aerosols and compressed gases. As discussed above and in the NPRM, allowing the compressed gas cylinder to aerosols would lead to “over warning” on aerosols and could also dilute the message for compressed gases. In addition, allowing the optional use of compressed gas pictogram would introduce inconsistency between labels of similar products, and may confuse downstream users, which ACA noted even as it suggested allowing the pictogram. OSHA also notes that the hazard statement for nonflammable aerosols makes clear that the container is pressurized and therefore believes the hazard noted by Seymore of Sycamore is already accounted for appropriately. Therefore, OSHA will not allow the optional use of the compressed gas pictogram for aerosol products. However, aerosol cans that have already been released for shipment as of the compliance date of this final rule for labelling updates do not need to be relabeled and may bear the compressed gas pictogram.

Although OSHA proposed updates to the classification and labeling of aerosols to align with Rev. 7, the agency also noted in the NPRM that Rev. 8 contains several

significant additional changes in the aerosol chapter and requested comments on whether the agency should adopt two specific changes that appear in Rev. 8.

First, 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 (Document ID 0065, pp. 57-58). 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 in Appendix B. In the NPRM, OSHA preliminarily determined that there are no substantive differences between OSHA's current text and the text represented in the new Rev. 8 table, although they contain slightly different language.

Several commenters suggested that OSHA should adopt the updated language in Rev. 8 instead of Rev. 7 (Document ID 0316, p. 22; 0347, p. 6; 0327, p. 9; 0309, p. 14). ACC indicated updating to the Rev. 8 criteria table would maximize harmonization, thereby reducing the regulatory burden on their members (Document ID 0347, p. 6).

While HCPA supported aligning with Rev. 8, they asked OSHA to change proposed Table B.3.1 by deleting "Contains > 1% flammable components" from the Category 2 criteria to align with the table in Rev. 8. HCPA reasoned that the proposed version of Table B.3.1 could be misinterpreted to mean that an aerosol product Category 3 cannot contain one percent or more of flammable material by mass or have a heat of combustion equal to or greater than 20 kJ/g, which would conflict with the GHS's two different criteria for an aerosol product to be classified as a Category 3 aerosol (Document ID 0327, pp. 9-10).

OSHA disagrees with HCPA's comment. The first step in the decisions logics for aerosols in Rev. 7 and Rev. 8 clearly states that only if an aerosol has both less than one percent flammable component and less than 20 kJ/g can it directly go to category three. Only after it fails the subsequent criteria for Category 1 and 2 can it also become a

Category 3 aerosol (Document ID 0060, pp. 60-62; 0065, p. 59). OSHA has taken this into account by using the word “and” in Category 3 to indicate that the additional criterion applies to an aerosol that has either greater than one percent flammable components or ≥ 20 kJ/g. The proposed criterion for Category 3 was intended to encompass both scenarios as described by HCPA. Additionally, OSHA disagrees that the HCS table could be interpreted to mean that a Category 3 aerosol could not have greater than one percent flammable components because the language “Contains $>1\%$ flammable components, or the heat of combustion is ≥ 20 kJ/g” in Category 2 is linked to the other criteria with an “and”. Therefore the correct interpretation is that a chemical that does not meet all of the criteria of Category 2 is a Category 3 chemical, rather than that just having more than one percent flammable components or a heat combustion greater than or equal to 20 kJ/g indicates a chemical belongs in Category 2. Therefore, OSHA declines to make the modifications requested by HCPA. However, to avoid any potential confusion with the proposed layout, OSHA is making an editorial change to Category 3 by placing a (1) before the phrase “The chemical does not meet the criteria for Categories 1 and 2” and a (2) before the phrase “the chemical contains $< 1\%$ flammable components (by mass) and has a heat of combustion < 20 kJ.g.”

NIOSH expressed concern that incorporating the Rev. 8 changes might lower worker protections relative to the proposed paragraph B.3.1 in the HCS (Document ID 0281, Att. 2, p. 5). They noted that Table 2.3.1 in Rev. 8 allows certain aerosols with a heat of combustion ≥ 20 kJ/g to be classified in Category 3, while the proposed paragraph B.3.1, which aligns with Rev. 7, requires all aerosols with a heat of combustion ≥ 20 kJ/g to be classified in Category 1 or 2. Therefore, NIOSH reasoned, adoption of Rev. 8 provisions in Table B.3.1 might lower worker protections from aerosols which could be classified in Category 3 under the Rev. 8, but not the Rev. 7, decision logic.

OSHA agrees with NIOSH that there appears to be to an inconsistency between Category 2 and Category 3 as they are presented in Table 2.3.1 of Rev. 8. OSHA notes that the Table B.3.1 in the HCS is consistent with the decision logics provided in paragraph 2.3.4.1 of Rev. 7 (Document ID 0060, p. 60) and paragraph 2.3.1.4 of Rev. 8 (Document ID 0065, p. 59).

To avoid confusion and to harmonize with trading partners, such as Canada, which adopted Rev. 7, OSHA is finalizing changes to the aerosols hazard class to align with Rev. 7, as proposed. OSHA will review the criteria in Rev. 8 for aerosols at the UN subcommittee to ensure that it accurately reflects the original decision logics.

The second update to the classification and labeling of aerosols in Rev. 8 that OSHA requested comment on was the adoption of a new hazard category, chemicals under pressure, within the aerosols class (Document ID 0065, pp. 61-63). OSHA noted that these products function similarly to aerosol dispensers covered under DOT (49 CFR 173.115) but are packed in pressure receptacles (refillable and non-refillable) of up to 450 liters (86 FR 9693). Chemicals under pressure used for spray applications present hazards similar to those presented by aerosol dispensers. Therefore, the classification criteria and hazard information for the Rev. 8 hazard category of chemicals under pressure are the same as for aerosols. In the NPRM, OSHA recognized 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) (86 FR 9693).

OSHA requested comment on whether the agency should adopt the Rev. 8 hazard category and classification criteria for chemicals under pressure in the aerosol chapter. The agency received several comments supporting the addition of chemicals under pressure. Michele Sullivan was also generally supportive and noted that “[t]his new hazard category can be helpful to some stakeholders” but requested that OSHA stay as close as possible to the GHS text (Document ID 0366, p. 2). NIOSH supported the

addition of chemicals under pressure since it would improve worker safety and health by covering certain chemicals that might not be otherwise captured under the HCS (Document ID 0281, Att. 2, p. 5). Ameren and ACC also supported the addition of chemicals under pressure (Document ID 0309, p. 14; 0347, p. 6). HCPA supported the addition of chemicals under pressure to the HCS, but as a separate chapter from aerosols. They noted that there are differences between aerosols and chemicals under pressure such as the difference in size limitations. HCPA concluded that since aerosols and chemicals under pressure are independent hazard classes, “it would be logical for chemicals under pressure to be its own chapter... and separate from aerosols” (Document ID 0327, p. 9).

OSHA does not agree with HCPA that chemicals under pressure should be in its own chapter. The agency believes that adding these categories to the current chapter B.3 to keep the aerosols and chemicals under pressure hazard classifications in the same chapter is appropriate, since they are often similar chemicals in different receptacles, but is providing separate definitions, hazard criteria, and hazard communication elements to ensure that the differences between these two hazards are recognized. The agency expects that clearly separating the two categories with different definitions, criteria, and communication elements will avoid creating any confusion related to its inclusion in chapter B.3. Furthermore, including it in the aerosols chapter allows the HCS to remain aligned with the GHS and its numbering system.

For the reasons discussed above, OSHA is adding chemicals under pressure as a separate hazard classification in the HCS within the aerosols chapter. In adopting the chemical under pressure hazard classification, OSHA is following a similar structure to the GHS. OSHA is renaming B.3 “Aerosols and Chemicals Under Pressure” and adding a new B.3.2 “Chemicals under pressure”, including B.3.2.1 “Definition” and B.3.2.2 “Classification criteria.” OSHA is renumbering B.3.2 “Classification criteria (under Aerosols)” to B.3.1.2 to maintain consistency with the GHS. In finalizing the chemicals

under pressure hazard classification, OSHA is including all three categories as defined in Table 2.3.3 in Rev. 8 as well as the hazard communication elements in Table 2.3.4 in Rev. 8 (Document ID 0065, p. 62) in Appendix C.16. OSHA has also removed the word “aerosol” from B.3.3.2 to maintain alignment with the updates from Rev. 8 and to indicate that the formation calculation relates to both aerosols and chemicals under pressure.

For the reasons discussed above, OSHA is finalizing Appendix B.3 as Aerosols and Chemicals Under Pressure. In the aerosols section, the agency is aligning with Rev. 7 by including non-flammable aerosols as a category and making the necessary revisions associated with that change. The agency is not adopting Table 2.3.1 from Rev. 8. The agency is, however, adding chemicals under pressure to B.3 in alignment with Rev. 8.

OSHA received one out of scope comment on Appendix B.3. Toby Threet suggested that OSHA change the word “aerosol,” as used in the context of physical hazards, to “spray cans” in order to better differentiate between the meaning of aerosol in Appendix A and Appendix B (Document ID 0279, pp. 6-8). OSHA did not propose any changes to the definition or use of the term *aerosol* so this comment is out of scope; therefore, the agency is not making the suggested change. Furthermore, the agency does not believe that the inconsistency in how aerosol is used in Appendix A and Appendix B is an issue in practice. Over the past 10 years, while OSHA has published many letters of interpretation pertaining to requests for clarification of terms in the HCS, the usage of the term *aerosol* has not been raised as an issue, nor has OSHA seen issues pertaining to these definitions in classifications.

IV. Oxidizing Gases (Appendix B.4).

OSHA proposed to revise the note in B.4.1, and the text in B.4.3 “Additional classification considerations,” to clarify that the provisions are referring to the most recent version of the ISO 10156 standard. In the NPRM, OSHA explained that the

proposed change would provide more clarity on the definition and classification of oxidizing gases and lead to more accurate classification and improved communication and would also align with Rev. 7 (Document ID 0060, pp. 63-65). OSHA noted that it did not propose to require reclassification of chemicals already classified using an earlier version of ISO 10156, only that new chemicals or chemicals not already classified needed be classified according to the new ISO standard. OSHA did not receive any comments on this revision and is finalizing it as proposed.

V. Gases under pressure (Appendix B.5).

OSHA proposed to align the definition of gases under pressure in B.5.1 with Rev. 7 (Document ID 0060, p. 67) by adding a temperature of 20 degrees Celsius (68 degrees Fahrenheit) so that the full definition reads “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.” The proposed change was intended to clarify that the pressure of the receptacle is measured at standard conditions. OSHA also proposed to align with Rev. 7 by adding a note to Table B.5.1 to clarify that aerosols should not be classified as gases under pressure (Document ID 0060, p. 67). The proposed change was a consequence of OSHA’s proposal to add a new hazard category for non-flammable aerosols, as discussed previously. OSHA received one comment from HCPA indicating that they supported the proposed note under Table B.5.1 (Document ID 0327, p. 9). OSHA is therefore finalizing these changes as proposed.

VI. Flammable Liquids (Appendix B.6).

OSHA proposed to make several clarifying changes to the flammable liquid hazard class in Appendix B.6. First, OSHA proposed to add a reference to paragraph (a)(14) of the Flammable Liquids standard (29 CFR 1910.106), in paragraph B.6.3 in order to provide additional guidance about methods that can be used to determine flash point for storage purposes. 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 therefore proposed 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.⁵⁸ In addition, the proposed note would explain that if the chemical manufacturer, importer, or distributor used an alternative calculation (namely, the 10% distillation point method) to find the boiling point to determine the appropriate storage for flammable liquids, this must be clearly noted on the SDS (in sections 7 and 9) to alert downstream users. In the NPRM, OSHA explained that the agency did not intend for the updated HCS classification requirements for flammable liquids to impact the longstanding storage requirements under 29 CFR 1910.106. Manufacturers can still use the flexibilities under § 1910.106 for mixtures which do not have a constant boiling point

⁵⁸ The flammable liquids standard states “Boiling point shall mean the boiling point of a liquid at a pressure of 14.7 pounds per square inch absolute (p.s.i.a.) (760mm). Where an accurate boiling point is unavailable for the material in question, or for mixtures which do not have a constant boiling point, for purposes of this section the 10 percent point of a distillation performed in accordance with the Standard Method of Test for Distillation of Petroleum Products, ASTM D-86-62... may be used as the boiling point of the liquid.” 29 CFR 1910.106(a)(5).

when determining storage requirements. The proposed note was intended to ensure that the proper container size and type will be used for storing flammable liquids while still appropriately communicating all necessary information on the SDS. OSHA did not propose any changes to the classification criteria for flammable liquids under the HCS. OSHA also requested comments on whether a footnote like the one proposed for B.6.3 should 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. In the 2012 HCS, Appendix B.3 (formerly flammable aerosols) includes note 2 to the classification criteria, which previously indicated that “[f]lammable aerosols do not fall additionally within the scope of flammable gases, flammable liquids, or flammable solids.” The HCS contains a cross-referencing note in Appendix B.2 (flammable gases), but OSHA inadvertently omitted the statement in Appendix B.6. OSHA therefore proposed to add a note stating that aerosols should not be classified as flammable liquids following Table B.6.1, for consistency and to minimize confusion, in alignment with Rev. 7 (Document ID 0060, p. 71).

Several commenters expressed concerns about OSHA’s proposed addition of footnote 9 to Appendix B.6 (Document ID 0339, p. 3; 0316, p. 23; 0359, p. 5; 0347, p. 23). API indicated that they were concerned about this change not aligning with GHS (Document ID 0316, p. 23). DGAC stated that they did not support limiting the determination of the initial boiling point to just two ASTM standards because they believe it is not necessary to list how to determine it and they were concerned that OSHA was excluding the methods for determining initial boiling point in the HMR (Document ID 0339, p. 3). Similarly, IHSC commented that they did not support the addition to require the initial boiling point to be determined by methods in § 1910.106 and suggested that OSHA limit this requirement for mixtures that contain an ingredient (greater than 1

percent) with a boiling point less than 95 °F (Document ID 0349, p. 2). Dow commented that they disagreed with the proposal to determine the initial boiling point by methods in § 1910.106 because they believed this was a change to OSHA's position that it does not require testing (Document ID 0359, p. 5). ACC commented on the second half of the footnote specifically, requesting that OSHA remove the requirement to note an alternate calculation in Sections 7 and 9 of the SDS and asking why this was included as a proposal in the update (Document ID 0347, p. 23).

OSHA believes that several of these commenters may have misunderstood OSHA's proposed changes. Contrary to DGAC, IHSC, and Dow's assertion, OSHA did not intend to suggest that the boiling point could only be determined by the methods specified under OSHA's Flammable Liquids standard. First, 29 CFR 1910.106(a)(5) does not specify the means of determining the initial boiling point except "Where an accurate boiling point is unavailable for the material in question, or for mixtures which do not have a constant boiling point," so footnote 9 only addresses the calculation of boiling point when it is being used to determine a storage container and type and where the conditions in the flammable liquids standard are met. Second, while the language of footnote 9 is mandatory ("shall be determined by methods specified under § 1910.106(a)(5)"), the language in paragraph (a)(5) of the flammable liquids standard is permissive ("may be used as the boiling point of the liquid"). When read together it is clear that manufacturers, importers, and distributors can use other methods approved by the HCS to determine boiling point and the flammable liquids standard only adds another option for calculating boiling point under specified conditions. This was intended to ensure that the HCS is compatible with § 1910.106 and to clarify situations where using the initial boiling point for HCS classification would result in storage requirements that might differ from the requirements under § 1910.106.

This alternate calculation is solely allowed in determining the storage requirements for flammable liquids where an accurate boiling point is not available and practically speaking would only apply to Category 1 flammable liquid mixtures. For example, if a Category 1 flammable liquid had an initial boiling point of 80° F under the methods in the HCS, but using the 10 percent point of distillation accommodation for mixtures under § 1910.106(a)(5) resulted in a boiling point of 100°F, then for storage purposes under § 1910.106 it would be considered a Category 2 flammable liquid. The new footnote makes explicit that this second calculation is allowed to be used for determining storage requirements under the HCS, but the SDS preparer would need to add in Sections 7 and 9 of the SDS a note stating that an alternate calculation was used for determining storage requirements. For the example given above, an appropriate note would be “Initial boiling point 80 °F / estimated boiling point 100 °F (for storage purposes).” However, if a category 1 flammable liquid mixture had an initial boiling point of 80 °F under the HCS methods and the boiling point using the accommodation for mixtures under § 1910.106(a)(5) was 92 °F, then for storage purposes the flammable liquid mixture would still be a Category 1 flammable liquid and there would be no obligation to put in the additional note on the SDS. OSHA believes this clarification addresses the concerns raised by these commenters. However, to the extent that DGAC was commenting on the sentence “The initial boiling point shall be determined in accordance with ASTM D86-07a or ASTM D1078,” OSHA did not propose any changes to that section and has previously also limited the calculation of boiling point to these two ASTM standards, so that comment would be out of scope.

Additionally, nothing in the proposal should be read to require testing as Dow asserted. As with all of the references to testing standards in the HCS, OSHA is only stating what methods are acceptable for determining certain characteristics, not requiring the SDS or label preparer to do these kinds of testing themselves. As to ACC’s question

regarding why the calculation of initial boiling point should be included in Sections 7 and 9 of the SDS if an alternate calculation was used for storage purposes, OSHA proposed including that requirement to ensure clarity on what underlying information about the chemical was used so that users are able to apply that information accurately to their own workplace and ensure worker safety. OSHA therefore disagrees with ACC that this requirement should be removed. Finally, OSHA disagrees with API's assertion that this footnote is problematic because it is not aligned with the GHS. The alternate calculation is not used in the ultimate classification of flammable liquids under the HCS, therefore the HCS is in full alignment with the GHS. The addition of the footnote is supplemental information (as allowed by the GHS) and, as stated above, OSHA is including this requirement to ensure clarity about the underlying information.

Even so, these comments indicate that the proposed language may be confusing, so although OSHA is finalizing the proposed changes to B.6 (Flammable Liquids), the agency has updated the footnote for clarity. As finalized, Footnote 9 to Appendix B.6 reads: "To determine the appropriate flammable liquid storage container size and type, the boiling point shall be determined by § 1910.106(a)(5). 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 *and the classification for storage differs from the classification listed in Section 2 of the SDS.*" (Emphasis added to new text.)

OSHA received comments from ACA and Hach asking OSHA to add Note 2 from beneath Table 2.6.1 of Rev. 7 to the HCS (Document ID 0323, pp. 11-13; 0368, p. 12). That note states that liquids with a flash point of more than 35 °C and not more than 60 °C need not be classified as non-flammable liquids for some regulatory purposes, such as transport, if negative results have been obtained in the sustained combustibility test according to the sustained combustibility test L.2 of Part III, section 32 of the UNTDG, Manual of Tests and Criteria (Document ID 0060, p. 71). Hach commented that adding

this note to the HCS would relieve compliance burdens and customer confusion regarding the classification of certain liquids and suggested a slightly altered version of the note in order to align with DOT PHMSA's regulation under 49 CFR 173.120 (Document ID 0323, pp. 11-13). Hach's comment is out of scope for this rulemaking since the agency did not propose any changes relating to this aspect of liquids classification. Furthermore, this note was also part of Rev. 3 and OSHA opted not to incorporate Note 2 when promulgating the HCS in 2012 because it would reduce protections in workplaces, where conditions may vary highly when handling chemicals (e.g., heating chemicals above their flashpoint) (77 FR 17722).

VII. Flammable Solids (Appendix B.7).

OSHA proposed one change to Appendix B.7 (Flammable Solids): a new 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 Rev. 7 includes this note (Document ID 0060, p. 75). OSHA did not receive any comments relating specifically to the addition of the new note and is finalizing it as proposed.

OSHA received one comment pertaining to Appendix B.7. Toby Threet asserted that OSHA should not promulgate provisions for flammable solids until the agency has definitive criteria for "fire by friction" (Document ID 0279, pp. 18-20). OSHA notes that this hazard class was first promulgated in 2012 and OSHA did not propose to update the criteria for flammable solids. Therefore, Threet's comment is outside the scope of this rulemaking.

VIII. Self-Heating Chemicals (Appendix B.11).

OSHA proposed adding a note beneath Table B.11.1 to explain that classification of solid chemicals must be based on tests performed on the chemicals as presented. The note also provides an example indicating that if a 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 Rev. 3 (Document ID 0085, Att. 2, p. 84), 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 proposed to add the note to be consistent with the GHS and the way the HCS treats other physical hazards. OSHA did not receive any comments on the new note and is finalizing it as proposed.

IX. Chemicals Which, in Contact with Water, Emit Flammable Gases (Appendix B.12).

OSHA proposed to update the classification criteria for Category 3 of this hazard class in Table B.12.1. In Rev. 3 (Document ID 0085, Att. 2, p. 87) and in the 2012 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.

OSHA explained in the NPRM that this criterion does not accurately reflect the corresponding criteria in Test N.5 in Part III, sub-section 33.5.4.4.1 of the UN Manual of Tests and Criteria, which provides that the maximum rate of evolution of the flammable gas is *greater* than 1 liter per kilogram of chemical per hour (Document ID 0151, p. 379).

OSHA proposed 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 methods, aligning with Rev. 7 (Document ID 0060, p. 91). OSHA preliminarily determined this proposed change would not affect worker protections. OSHA did not receive any comments on this change and is finalizing it as proposed.

X. Oxidizing Solids (Appendix B.14).

OSHA proposed 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 Rev. 3 (Document ID 0085, Att. 2, p. 95), 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 (Document ID 0151, p. 382). This was reflected in the 2012 HCS, Appendix B.14. In the NPRM, OSHA explained that 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), which uses a reference mixture of calcium peroxide, has been added to Part III, sub-section 34.4.3 of the UN Manual of Tests and Criteria and the Recommendations on the Transport of Dangerous Goods Model Regulations (TDG MR) (Document ID 0151, p. 393; 0150, p. 100). Consistent with Rev. 7 (Document ID 0060, p. 97), OSHA proposed to allow oxidizing solids to be classified using either Test O.1 or Test O.3. The agency further noted that 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 proposed 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 (Document ID 0141). OSHA did not receive any comments on the addition of Test O.3 or on the update to this note and is therefore finalizing both as proposed (with a technical amendment to reorganize B.14.2 to better clarify which version of the Manual of Tests and Criteria is appropriate for Test O.1 and Test O.3).

OSHA received one comment on Appendix B.14 from Cal/OSHA opposing the language in B.14.3.3, which requires that, in the event of a difference between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgements based on known experience take precedence over test results. Cal/OSHA suggested revising B.14.3.3 to state that “experience demonstrating an oxidizing hazard shall take precedence over negative test results” (Document ID 0322, Att. 1, pp. 12-13). OSHA did not propose any changes to B.14.3.3 in the NPRM,

therefore this comment is outside the scope of this rulemaking. OSHA notes that Cal/OSHA's suggested language, while structured differently than B.14.3.3, presents the same requirement: producers must disclose oxidizing hazards for a chemical if the producer has experience that indicates those hazards, even if test results for the chemical are negative. Further discussion on the use of expert judgement in the classification process can be found in the Summary and Explanation for Section B.2 (flammable gases).

XI. Corrosive to Metals (Appendix B.16).

OSHA did not propose to make any changes to Appendix B.16, Corrosive to Metals. This is notable because OSHA preliminarily decided not to adopt a note that was added in Chapter 2.16 of Rev. 7, under Table 2.16.2, which states: "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" (Document ID 0060, p. 107). Chapter 1.4.10.5.5 contains, in relevant part, labeling provisions that state competent authorities can allow the corrosive to metals pictogram to be omitted from labels for "substances or mixtures which are in the finished state as packaged for consumer use" (Document ID 0060, p. 32). As was discussed in the NPRM, OSHA 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 (29 CFR 1910.1200 (b)(5)(v)) and therefore OSHA did not propose to adopt the note. OSHA did not receive any comments on this preliminary conclusion and is therefore finalizing its decision not to add the note to Appendix B.16.

OSHA received one out of scope comment on this hazard class. Toby Threet commented that OSHA should add copper to Table 16.1 (Document ID 0279, p. 22).

OSHA notes that since the agency did not propose adding copper to Table 16.1 or otherwise changing it, this comment is outside the scope of this rulemaking.

XII. Desensitized Explosives (Appendix B.17).

OSHA proposed to add a new physical hazard class for desensitized explosives to align with Rev. 7 (Document ID 0060, p. 109). Desensitized explosives are chemicals that are treated so that they are stabilized, or their explosive properties are reduced or suppressed. As OSHA discussed in the NPRM, 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 2012 HCS, OSHA acknowledged, consistent with Rev. 3 (Document ID 0085, Att. 6, p. 15), that these chemicals are considered explosives if the wetting agent is removed by including in Appendix C, C.4.14, 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. However, the hazard statement, signal word, pictogram and other precautionary statements required under the 2012 HCS C.4.14 primarily target 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 (Document ID 0206). In 2014, the UNSCEGHS concluded that a new hazard class was warranted for desensitized explosives in the GHS (Document ID 0087). Rev. 7 separately classified desensitized explosives with a full set of unique label elements (including the appropriate signal word, hazard statement, pictogram, and precautionary statements) (Document ID 0060, pp. 109-112). 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.

As discussed in the NPRM, OSHA reviewed the UNSCEGHS reports on desensitized explosives and 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 were covered under the scope of the 2012 HCS as explosives, OSHA preliminarily determined that 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 proposed to add the desensitized explosives hazard class to the HCS as Appendix B.17. As explained in the NPRM, OSHA intended the new Appendix B.17 to provide relevant definitions and general considerations, specify applicable classification criteria, and include information about additional classification considerations for this hazard class, as well as reference several sections from the UN Manual of Tests and Criteria that would be incorporated by reference. As with all hazard classes, Rev. 7 does not require testing and allows classifiers to use data reported in the literature that was generated using specified or equivalent test methods. Proposed Appendix C.4.30 included the proposed communication elements for desensitized explosives relevant to proposed Appendix B.17.

The proposed Appendix B.17 was based on Chapter 2.17 of Rev. 7 (Document ID 0060, p. 109-112). OSHA proposed to adopt most of the classification language on desensitized explosives from Chapter 2.17 to minimize deviations from the GHS. However, similar to the 2012 rulemaking, OSHA carefully reviewed each of the hazard classification criteria within the context of the HCS and proposed to modify some of the language. These edits included 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. OSHA also proposed adding a definition for “phlegmatized,” which is drawn from the TDG MR, in a footnote because many stakeholders may be unfamiliar with that term from the UN Recommendations.

OSHA did not propose to include portions of Chapter 2.17 that do not relate specifically to the method of classification for desensitized explosives, such as the text relating to hazard communication (which is in Appendix C) and the decision logics. OSHA may, however, use the decision logics in guidance materials.

OSHA received several comments on the proposed addition of Appendix B.17, all of which supported adopting the desensitized explosive hazard class. ACC, API, Michele Sullivan, and Dow expressed support for aligning the classification of desensitized explosives with the GHS and trading partners (Document ID 0347, p. 17; 0316, p. 23; 0366, p. 7; 0359, p. 5). API commented that “[d]esensitized explosives should be classified in accordance with GHS” (Document ID 0316, p. 23). Other than ensuring that the language is appropriate for OSHA’s jurisdiction and written in regulatory language, OSHA’s proposal follows the GHS classification criteria. For the reasons explained above, OSHA is finalizing Appendix B.17 as proposed with minor editorial changes. Stakeholders can examine the redline strikeout of the regulatory text (changes from 2012 HCS to this final) at OSHA’s HCS webpage (<https://www.osha.gov/dsg/hazcom/>) to view all of the changes to the 2012 HCS made in this final rule. Additionally, in the NPRM OSHA requested comments on whether the agency should, in the final rule, update all of the existing references to UN ST/SG/AC.10 (many of which are in Appendix B) to Rev.

6 or add Rev. 6 references to the existing Rev. 4 references such that they would be alternative options for compliance. OSHA only received one comment on this, which was from Ameren, and which supported adding the Rev. 6 references to allow for compliance alternatives (Document ID 0309, p. 14).

As discussed in the Summary and Explanation for Incorporation by Reference, OSHA has decided to retain the generic citation to ST/SG/AC.10 in all places where compliance with Rev. 4 or Rev. 6 is allowed, and has inserted specific citations to ST/SG/AC.10/11/Rev.6 where only Rev. 6 is allowed for compliance (for instance, in situations where new text was added to Rev. 6 and there was no comparable material in Rev. 4). For further discussion of that issue, see the Summary and Explanation for Incorporation by Reference.

OSHA also received one general comment on Appendix B from Cal/OSHA, noting that “In several places, referenced technical documents are out-of-date” and recommending that the most recent versions of document should be used “unless there is a specific reason not to, such as where an updated test method is less sensitive than the previous method, for example” (Document ID 0322, Att. 2, p. 14). Cal/OSHA did not provide further details on which references to technical documents it believed were out of date. OSHA is updating several references to technical documents in this rulemaking, which are discussed throughout the Summary and Explanation, and it concludes that it has updated all of the appropriate references.

E. Appendix C

Appendix C includes requirements and instructions for the allocation of label elements. Paragraph (f)(2) 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.

OSHA proposed several updates to Appendix C to improve communication of hazard information on labels. These changes were proposed in order to: (1) address labeling requirements for the new hazard classes and categories in Appendix B (physical hazards); (2) align the HCS with Rev. 7; and (3) improve alignment of the HCS with other federal agencies and Health Canada's labeling requirements in furtherance of the goals of the RCC.

As was discussed in OSHA's 2009 proposal 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. In the 2021 NPRM, OSHA proposed several changes based on new precautionary statements and instructions in Rev. 7. Additionally, since 2012, OSHA has continued to work with other Federal agencies on crosscutting labeling issues. Some updates to Appendix C were proposed to align with DOT labeling regulations. OSHA also proposed 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 signed in June 2018 (Document ID 0217), with the expectation of aligning efforts for international trade requirements between the two countries.

Overall, OSHA anticipated that the proposed changes to Appendix C would provide improved communication of hazard information and greater detail and clarity for downstream users, which would maintain or enhance the safety and health of workers. The agency also expected the updates would more consistently align the HCS with other Federal and international regulations, thereby easing compliance burdens for U.S. stakeholders that must also comply with those requirements.

The changes OSHA proposed to Appendix C and the changes OSHA is now finalizing are extensive. OSHA addresses the substantive changes in the discussion below, and in addition to the regulatory text below, OSHA will provide a redline strike-out version of the final text of Appendix C on the OSHA website (<https://www.osha.gov/dsg/hazcom/>), as it did for the NPRM. This version will reflect all of OSHA's revisions, including all non-substantive updates. This will allow interested parties to view all of the changes in context to aid in the implementation of the updated regulatory text. OSHA encourages stakeholders to use that document in conjunction with the discussion of the revisions below, as the discussion does not fully describe all of the non-substantive or editorial changes OSHA is making.

I. Sections C.1-C.3.

The instructions in the beginning of Appendix C (C.1-C.3) provide directions and information about the signal words, pictograms, hazard statements and precautionary statements required in C.4. OSHA proposed several changes to C.1-C.3.

First, OSHA proposed 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 would codify OSHA's agreement with Health Canada to permit the exclamation mark pictogram to be used for HNOCs. While OSHA does not require labeling for HNOC hazards, Health Canada requires a pictogram, signal word, hazard statements, and precautionary statements for HNOCs. 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 (Document ID 0103). Use of the exclamation mark pictogram would not be mandatory under the HCS. OSHA also added desensitized explosives under the flame pictogram in Figure C.1, and that change is discussed with the other changes related to desensitized explosives below (see discussion of revisions to C.4).

OSHA proposed several additional related changes. As discussed above under the Summary and Explanation for paragraph (f), OSHA proposed to move the existing text in paragraph C.2.3.3 from Appendix C to paragraph (f)(5)(iii) in the text of the standard, so that all of the instructions related to the transport of hazardous chemicals and DOT regulations are in one section of the HCS. OSHA also proposed to replace that text in C.2.3.3 with a new paragraph, 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. Additionally, because any pictogram may appear only once on a label, OSHA proposed 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 situations when the exclamation mark pictogram would be used for both an HNOC and for another hazard. OSHA requested comments on these proposed changes, particularly whether the agency should require the exclamation mark pictogram to be used for HNOCs.

OSHA received several comments supporting the proposal to include “HNOC (non-mandatory)” as a hazard identified by the exclamation point pictogram (Document ID 0349, p. 2; 0309, p. 17) and agreeing that use of the pictogram for HNOCs should not be mandatory (Document ID 0316, p. 25; 0347, p. 18; 0366, p. 7). OSHA received no comments objecting to these revisions to Figure C.1, C.2.3.3, and C.2.3.4 and is therefore finalizing them as proposed.

The remaining changes OSHA 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 proposed 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 also required 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 also proposed 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.

ACC and Michele Sullivan generally supported the addition of proposed paragraph C.2.4.7 because it adds flexibility (Document ID 0347, p. 18; 0366, p. 8). ACC, however, requested that OSHA remove the proposed requirement to use any variations in precautionary statements consistently on the label and SDS. According to ACC, most companies use SDS software that comes with the GHS precautionary phrases from the regulation already pre-loaded and ready for use; therefore, in their view, modifying the phrases in the SDS software in small ways to exactly match the text on the label would create a significant burden without enhancing worker protection (Document ID 0347, pp. 18-19). Michele Sullivan similarly stated that making small changes to precautionary statements that do not change their meaning requires significant time and money without improving worker protection or safety (Document ID 0366, p. 8).

OSHA disagrees with ACC's request. New paragraph C.2.4.7 is permissive, not mandatory, so label preparers can opt to rely on language provided in Appendix C and used by their existing software rather than expend additional time and resources to modify the statements if they do not find it beneficial. In addition, OSHA's

understanding is that the software used to create SDSs and labels can be updated, if necessary, to apply variations in precautionary statements consistently across both SDSs and labels in order to comply with the proposed requirement. OSHA has determined that variations should be applied consistently on the label and in the safety data sheet in order to avoid confusion and convey health and safety information consistently to workers.

Cal/OSHA objected to proposed C.2.4.7 and stated that “[s]tandard language is essential for workers to become accustomed to particular signal words. The proposed change could open the door for legal disputes with OSHA over synonyms and the meaning of ‘other equivalent terms,’ ‘diluted’ and ‘compromised’” (Document ID 0322, Att. 2, pp. 8-9).

OSHA has considered Cal/OSHA's concerns and has concluded that minor variations should be allowed as they can, in some cases, improve communication of safety information to workers. OSHA notes that the provision to allow minor variations in precautionary statements only allows label preparers to use variations that at least equally convey the required safety information to workers. For example, this provision would allow for spelling variations, synonyms, or other equivalent terms appropriate to the region where the product is supplied and used, which may improve readability and comprehensibility for workers in some situations. OSHA also does not agree that these terms would be difficult to enforce or would result in significant litigation issues. For the reasons discussed above, OSHA is finalizing paragraph C.2.4.7 as proposed.

OSHA also proposed to add a new paragraph, C.2.4.10, to address cases where substances or mixtures that are classified for multiple hazards may trigger multiple precautionary statements for medical responses. Precautionary statements involve both an "if" statement, either based on route of exposure or the symptoms being experienced, and a medical response, such as “call a poison center/doctor” or “get medical advice/attention.” In a situation where a substance or mixture is classified for multiple

hazards and therefore triggers multiple precautionary statements, this could result in redundancy of either the “if” statement component or the medical response component. To address this concern, consistent with Rev. 7 (Document ID 0060, pp. 302-303), OSHA proposed a system of prioritization and combination for precautionary statements. Under proposed C.2.4.10(a), when the hazards have similar routes of exposure or health outcomes, labels would usually only need to include one precautionary statement reflecting the medical response at the highest level with the greatest urgency, combined with at least one route of exposure or symptom “if” statement. For example, in a situation where a substance was classified as two different hazards (such as skin corrosion Category 1C and acute toxicity Category 3 for dermal) which required different medical responses to the same route of exposure, the statement, “Immediately call a poison center/doctor/. . .” would be prioritized over the less urgent “call a poison center/doctor” and would be the only medical response required on the label for that route of exposure. Proposed paragraph C.2.4.10(b) would allow for (but not require) combination of medical response statements where multiple routes would trigger similar medical 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. Thus, if a chemical is classified as acute toxicity Category 2 inhalation and acute toxicity Category 2 dermal then the statement can read “if inhaled or on skin immediately call poison center/doctor.” Proposed paragraphs (a) and (b) can also be used in combination. However, 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. The agency requested comments on this system of prioritization in proposed C.2.4.10 and on whether the proposed prioritization provisions would improve clarity on labels.

Several commenters supported the addition of proposed paragraph C.2.4.10.

NIOSH stated that the proposed changes to paragraph C.2.4.10 would clarify hazards, citing a pre-GHS study of the comprehensibility of material safety data sheets (MSDSs) which showed that “wordiness contributed to difficulty in understanding them [Kolp et al. 1993]” (Document ID 0281, Att. 2, p. 5). Dow similarly commented that by reducing the amount of text on labels, the prioritization specified in C.2.4.10 would make the labels less confusing and easier to understand. Dow further observed that some manufacturers are already doing this, and that the proposed change would align with requirements of major trading partners (Document ID 0359, p. 5). Ameren also agreed that precautionary statements for medical responses should be prioritized (Document ID 0309, p. 17).

OSHA also received several critical comments on proposed paragraph C.2.4.10. Cal/OSHA and Worksafe raised concerns that the proposed change would allow label preparers to present medical response precautionary statement for only one of several hazards to users (Document ID 0322, p. 3; 0354, p. 4), and that prioritization can lead to misinterpretation (Document ID 0344, p. 3) or would leave workers, emergency responders and downstream users without the information they need to formulate an appropriate medical response to exposure (Document ID 0322, p. 3; 0405, p. 20). The American Federation of State, County, and Municipal Employees (AFSCME) noted similar concerns and recognized the value specifically in including medical response precautionary statements to address both immediate (acute) and long-term (chronic) medical concerns when needed, since the appropriate medical care may differ for a medical emergency versus potential chronic diseases such as may occur from prolonged or repeated exposures (Document ID 0344, p. 3).

OSHA disagrees with these commenters that the proposed paragraph C.2.4.10, if the general principles are followed as OSHA intended, would result in information being

omitted from the label. However, OSHA acknowledges that the use of the term “usually” is ambiguous and might create confusion. OSHA also agrees that only one precautionary statement will not suffice in every situation. As OSHA discussed in the NPRM, the agency 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. Therefore, to clarify the requirements for combination and prioritization of medical response statements, OSHA is revising C.2.4.10(a) to read “*If the same medical response statement is triggered multiple times, 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.*” OSHA believes this more specific version better expresses the agency’s expectations for when and how label preparers may combine and prioritize medical response statements, to simplify the presentation of medical response information while retaining the information most important for end users to view on the label. Additionally, OSHA notes that nothing in paragraph C.2.4.10 changes the requirements of C.2.2 that all applicable hazard statements must appear on the label, so producers are still required to include all hazards associated with their products under the HCS.

OSHA received several requests for clarification regarding proposed paragraph C.2.4.10. Toby Threet asked OSHA to clarify the meaning of proposed paragraph C.2.4.10(c) (Document ID 0279, pp. 22-23). OSHA intended paragraph C.2.4.10 (c) to create a limited exception to C.2.4.10(a) (which allows for label preparers to present only the highest priority medical response statement) and C.2.4.10(b) (which allows combination of medical response statements for multiple routes of exposure). Paragraph

C.2.4.10(c) requires that, in the specific case where the medical response precautionary statements “Get medical advice/attention if you feel unwell” and “Get immediate medical advice/attention” are both applicable to a chemical or mixture, due to multiple hazards triggering multiple precautionary statements, they must both appear as separate statements on the label. In the NPRM, OSHA explained its intent that both of those statements should appear “without prioritization,” by which the agency meant that both should appear on the label, and that the label preparer does not have discretion to decide that they should be combined into a single statement.

ICT asked OSHA to clarify the extent to which proposed paragraph C.2.4.10 was intended to be mandatory, noting that terms such as “should” and “may” in C.2.4.10(a) and (b) seem to indicate that combining or reducing is optional, while C.2.4.10(c) uses similar language (“should appear”) to indicate something that is required (Document ID 0324, p. 6).

OSHA intended for proposed paragraphs C.2.4.10, (a) and (b) to allow, but not require the label preparer to prioritize and/or combine elements of medical response precautionary statements on the label. In contrast, OSHA intended proposed paragraph C.2.4.10(c) to be a requirement. OSHA agrees with ICT that the use of “should” in C.2.4.10(c) does not clearly convey the agency’s intent and is therefore modifying the proposed language of C.2.4.10(c) to replace “should” with “must”.

ICT further noted that paragraph (f)(2) requires that labels must bear the information specified in Appendix C, and that Appendix D states that precautionary statements in the SDS must be in accordance with paragraph (f). ICT inquired whether it follows that, in a case where medical response statements have been prioritized and/or combined for presentation on the label, the medical response statements may be similarly presented in the SDS (Document ID 0324, pp. 5-6).

ICT is correct that the SDS is not required to include any more or different medical statements than are presented on the label. If a label is only required to have one medical response statement in accordance with paragraph C.2.4.10, then the SDS may also contain only that statement. OSHA further notes that it is permissible, but not required, for SDS preparers to include additional medical response statements beyond those included on the label.

OSHA also received several comments generally requesting clarification regarding the principles in C.2.4.10 (Document ID 0339, p. 3; 0358, p. 3; 0349, p. 2) and two commenters requested that OSHA develop guidance (Document ID 0358, p. 3; 0349, p. 2). OSHA notes that Annex 3 of Rev. 7, Annex 3 (A3.3.2.4) contains useful information on the application of precautionary statements regarding medical response. In A3.3.2.4, Application of precautionary statements concerning medical response, the GHS provides a number of examples of how the principles in C.2.4.10 can be applied when choosing precautionary statements to ensure clarity of the most appropriate safety message (Document ID 0094, pp. 302-303). Because OSHA's language is intended to align with the GHS, the guidance provided in the GHS about how to prioritize and combine precautionary statements also provides information on how to comply with the HCS. Additionally, OSHA will be updating its guidance and anticipates providing additional guidance and examples on this topic.

OSHA requested input on alternative language for paragraph C.2.4.10, based on Rev. 8, in which the medical response precautionary statements would be standardized according to the Hazard Class and Category (86 FR 9576). CGA and GAWDA recommended adoption of the Rev. 8 language on the basis that the standardized statements would make the statement selection process easier when several options are available (Document ID 0310, p. 3). NIOSH supported adoption of the Rev. 8 standardization but recommended that label preparers be given the option to choose a

stronger medical response precautionary statement if supported by available information (Document ID 0281, Att. 2, p. 6; 0423, Tr. 23). In contrast, ACC advised OSHA not to adopt the Rev. 8 provision, which ACC believes would be overly prescriptive, would not provide any additional protection, and would not reduce the cost or difficulty of compliance for manufacturers (Document ID 0347, p. 7). ACC testified that the revisions required under the Rev. 8 provision would be a major financial burden because of the cost of updating product labels and that the changes were semantic in nature, providing the example that “many Appendix C tables include a response statement that directs the user to seek medical care, in addition to the phrase, get medical advice/attention. Revising the label to include the additional phrase is not a meaningful change in the precautionary information being shared with the user” (Document ID 0423, Tr. 105). Michelle Sullivan supported optional use of the Rev. 8 precautionary statements (Document ID 0366, p. 2).

After consideration of the comments received about adopting Rev. 8 revisions to medical precautionary statements, OSHA has decided to finalize C.4.2.10 in alignment with Rev. 7, as proposed, because major U.S. trading partners are also aligning with Rev. 7, and OSHA believes the medical precautionary statements in Rev. 7 and Rev. 8 provide equivalent information to downstream user. Furthermore, as discussed in the HCS compliance directive (Document ID 0007, p. 6), OSHA allows for the use of updated precautionary statements where the messaging directs the user to similar actions. OSHA has determined that the precautionary statements included in Rev. 8 provide similar information and follow the general principles set out in C.2.4.10; therefore, label preparers may use the Rev. 8 precautionary statements in lieu of the Rev. 7 precautionary statements.

In conclusion, OSHA is modifying paragraph C.2.4.10 as explained above to clarify the requirements pertaining to the combination and prioritization of medical response statements and to change the term “should” to “must” in C.4.2.10(c).

OSHA received two comments that recommended the agency add hazard and precautionary phrase codes to Appendix C. DGAC commented that many of their member companies use software that uses these phrase codes to automate hazard classification to populate Section 2 and generate translations, and noted that “We are not suggesting that the codes be required on the labels or SDS, only in Appendix C for reference only” (Document ID 0339, pp. 4-5). Similarly, IHSC recommended that OSHA add the hazard and precautionary statement codes to Appendix C, on the basis that presenting the statement codes in the tables would help users to compare the statements that may be in use under the different versions of the GHS that countries have adopted, and could also assist with translations of SDSs and labels (Document ID 0349, p. 2). This request is out of scope for this rulemaking, as it does not pertain to any of the changes OSHA proposed to the HCS in the NPRM; therefore, the agency is not making the suggested addition.

OSHA also received a comment asking OSHA to change a specific hazard statement. Steven Wodka asked OSHA to change the labeling requirement for chemicals categorized by the HCS as a carcinogen from “Danger May Cause Cancer” to “Danger Causes Cancer” (Document ID 0312, p. 6). OSHA aligned its carcinogen warnings with the GHS in 2012 (77 FR 17742) but did not propose any changes to this language in the 2021 NPRM. Because OSHA did not propose to change this hazard statement, Wodka’s request is out of scope for this rulemaking. Therefore, OSHA is not making the suggested change.

Paragraph C.3.3 of the 2012 HCS required that where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥ 1 percent, and the mixture is not

classified based on testing of the mixture as a whole, a statement that X percent of the mixture consists of ingredient(s) of unknown acute toxicity is required on the label. To clarify the requirements of that paragraph, OSHA proposed in the NPRM to add “(oral/dermal/inhalation)” and “and safety data sheet” to the latter clause so that it reads “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*” (emphasis added). DOD noted that paragraph C.3.3 “should be more explicit about the exact nature of the unknown toxicity...e.g., if dermal toxicity is unknown, the label should be explicit that the product contains materials of unknown dermal toxicity” (Document ID 0299, p. 4). As previously discussed in the Summary and Explanation for Appendix A regarding the similar language added in A.1.3.6.2.3, OSHA intended for the percentage of unknown acute toxicity to be differentiated by route of exposure, given that it is possible to have ingredients with unknown toxicity for more than one relevant route of exposure, and that is reflected in the inclusion of the language “(oral/dermal/inhalation)” in the text of this paragraph. OSHA anticipates updating the HCS guidance and will include discussion on this point to remove any lingering confusion. Accordingly, OSHA is finalizing the revisions to paragraph C.3.3 as proposed.

II. Section C.4.

OSHA is updating the hazard label elements for specific hazard classes and categories. The following discussion on 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 adopting.

(A) Revisions Based on Additions of Hazard Classes and Categories in Appendix B.

OSHA proposed several 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 proposed and is finalizing several changes to the flammable gas hazard class. The changes 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 hazard and precautionary statements for those gases, which OSHA proposed to align with Rev. 7 (Document ID 0060, pp. 307-309), are located in C.4.15. OSHA proposed that 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, OSHA proposed that the hazard statement for the new Category 1B flammable gases would be “Flammable gas.” OSHA also proposed that 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 was also discussed in the Summary and Explanation for Appendix B, OSHA proposed and is finalizing the addition of non-flammable aerosols to the existing “Flammable Aerosols” hazard class and renaming the class “Aerosols.” Consequently, in Appendix C, OSHA proposed to adopt the Rev. 7 hazard and precautionary statements for non-flammable aerosols in C.4.16. OSHA reasoned that these statements would better address the true hazards of aerosols. In cases where aerosols were labeled as gases under pressure, OSHA proposed to require that the label be updated to include the flame pictogram for 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). OSHA also proposed to require the hazard statement “pressurized container, may burst if

heated.” OSHA reasoned that these changes would better differentiate the hazards of non-flammable aerosols from those of gases under pressure.

Finally, OSHA also proposed and is finalizing adoption of the hazard class of desensitized explosives in Appendix B. OSHA consequently proposed to adopt, in Appendix C, the pictogram, signal word, hazard statements, and precautionary statements for desensitized explosives from Rev. 7. OSHA proposed that the labeling information for desensitized explosives would be added at C.4.30.

For flammable gases, aerosols, and desensitized explosives, OSHA proposed to adopt the Rev. 7 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). As OSHA discussed in the NPRM, the agency believes that the information called for by Rev. 7 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 proposed would align the HCS with the GHS, OSHA reasoned that adopting them would ease compliance burdens for U.S. stakeholders that must also comply with international requirements for hazard communication.

OSHA received several comments pertaining to these topics that concern both Appendices B and C. To the extent that the agency received comments on Appendix B that would involve ramifications to Appendix C, those comments have been addressed in the Summary and Explanation for Appendix B. This includes comments requesting that OSHA allow the optional use of the pressurized cylinder icon for non-flammable and flammable aerosols. OSHA disagrees with these comments, as discussed above. Also as discussed in the Summary and Explanation for Appendix B, OSHA received a comment

from Toby Threet about changing the use of the term “aerosol” to “spray cans,” which also included a request to change the hazard statements in C.4.16 to use the word “contents” instead of “aerosol” (Document ID 0279, p. 12). For the same reasons described in the Summary and Explanation for Appendix B, OSHA considers this comment out of scope and declines to accept this proposal.

For the reasons discussed above the agency is finalizing these revisions as proposed.

(B) Hazard Statements, Hazard Categories, and Notes.

OSHA proposed to revise several hazard statements to align with Rev. 7. The hazard statements in the 2012 HCS were adopted from Rev. 3. Since then, the UNSCEGHS continued to discuss the utility and readability of the label elements, including hazard statements, to improve the information presented by clarifying language and eliminating inconsistencies, and to save label space by consolidating or combining language. Except where otherwise discussed below, OSHA proposed to adopt the updated language presented in Annex 3 of Rev. 7 (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).

III. C.4.1 (Acute Toxicity - Oral).

OSHA proposed to consolidate hazard category information for C.4.1 acute toxicity – oral, by deleting the table for Category 3 and combining Categories 1, 2, and 3 in one table, since all three categories have the same precautionary statements. The change does not affect the substantive communication information for categories 1, 2, or 3; it would simply make C.4.1 more concise. OSHA received no comments on this proposed revision and is finalizing it as proposed.

IV. C.4.31 (Label Elements for OSHA Defined Hazards).

OSHA is making several changes to label elements for OSHA defined hazards (C.4.30 in the 2012 HCS and now in 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.

In the NPRM, OSHA proposed to delete the entry for “Pyrophoric Gas.” In Rev. 7, pyrophoric gases were made a category under the hazard class of flammable gases, and OSHA proposed to include them there in the HCS as well. OSHA received no comments on removing pyrophoric gas from proposed C.4.31. Therefore, the agency is finalizing it as proposed.

OSHA also proposed 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” in Annex 4 of Rev. 7 (A4.3.2.3) (Document ID 0085, Att. 8, p. 408). The GHS had previously recognized combustible dust. In Rev. 5, the UN updated A4.3.2.3 to include the 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 (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 (Document ID 0157). In the 2021 NPRM, OSHA therefore proposed to allow either the previously required statement, “May form combustible dust concentrations in air,” or a statement based on Rev. 7 suggested language, “May form explosible dust-air mixture” (Document ID 0060, p. 386). OSHA proposed 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 was proposed to indicate that this language should be added when the material can only create a combustible dust hazard due to the creation of small particles during the processing or handling of the chemical. OSHA did not propose any changes to the signal word of “warning” or any pictogram requirements.

Michele Sullivan asked OSHA to provide guidance on the meaning of square brackets around text in the combustible dust hazard statements, to explain in what circumstances the enclosed text should be used (Document ID 0366, p. 8).

Under 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 (see, e.g., C.4.3, C.4.4, C.4.19, C.4.20, C.4.21, and C.4.28). In the case of combustible dust, OSHA did not propose to provide an explanation for the brackets. OSHA agrees that additional explanation is warranted, and has revised the hazard statement for combustible dust to include the following explanation for the brackets for combustible dust: “Text in square brackets may be used when the material can only create a combustible dust hazard due to the creation of small particles during the processing or handling of the chemical.”

API supported the proposed revision, noting that it is consistent with prior OSHA guidance (Document ID 0316, pp. 24-25). Dow expressed support for the codification of OSHA’s prior statements that label preparers can provide additional information on the Hazard Statement to indicate that the hazard occurs during downstream processing but voiced concern regarding the proposed change in C.4.31 which would allow for use of either the term “combustible dust” or “explosible dust” as part of the hazard phrase, on the basis that allowing for the use of either name without clear definitions for each could lead to confusion. Dow asked OSHA to provide definitions for the terms *combustible*

dust and *explosible dust* to differentiate between them or, alternatively, withdraw its proposal to allow for use of the term *explosible dust* and require use of the term *combustible dust* (Document ID 0359, pp. 5-6).

OSHA acknowledges that neither the GHS nor the HCS include a definition of “Explosible” or “Explosible Dust”, but notes that the term “explosible” is widely used in industry, and OSHA uses the term “explosible” in its publication on the Hazard Communication Guidance for Combustible Dusts (Document ID 0255). OSHA therefore does not find it necessary to provide a new definition in the HCS. For the purposes of the HCS, OSHA believes there is no significant difference between “explosible dust-air mixture” and “combustible dust concentrations in air” and intends that these terms can be used interchangeably by label preparers. Further discussion on these terms can be found in OSHA Publication 3644-04, 2013, Firefighting Precautions at Facilities with Combustible Dust (available at https://www.osha.gov/sites/default/files/publications/OSHA_3644.pdf).

AF&PA and AWC also supported the changes to paragraph C.4.31, noting that “The proposed hazard statements...are similar to existing OSHA guidance and represent a significant improvement over the current regulatory text” (Document ID 0287, p. 5). They also recommended clarifying edits to the footnote in C.4.31 regarding combustible dust: adding “1)” at the beginning of the footnote; reformatting the footnote to be three separate sentences instead of one; and adding the phrase “that follows the approach described” in the second numbered segment of the sentence to clarify that the sentence is not limited to wood, metal, and plastic items and whole grain. The text would then read “... the chemical manufacturer or importer shipping chemicals that are in a form that is not yet a dust must provide a label to customers that follows the approach described under paragraph (f)(4) of this section...” OSHA agrees that these edits clarify the text and

has finalized the labeling provisions for combustible dust as AF&PA and AWC suggested.

OSHA is making further revisions to Appendix C in response to comments which pointed out an oversight in the agency's proposed revisions to the appendix. WHSP and an additional anonymous commenter noted that the "Corrosive to the respiratory tract" hazard statement that OSHA introduced in its proposal to add paragraph A.1.2.4 to Appendix A did not appear in Appendix C of the proposed standard. The commenters asked "what signal word, pictogram, and precautionary statements should appear on the SDS and label when the 'Corrosive to the respiratory tract' hazard statement is used?" (Document ID 0265; 0341, p. 39). As stated above in the Summary and Explanation for Appendix A, OSHA is adding a note to each of the relevant tables in Appendix C to clarify the labelling requirements related to new paragraph A.1.2.4. In accordance with the provisions of paragraph A.1.2.4 included in the final rule, OSHA is adding notes to Tables C.4.3, C.4.4, C.4.5 and C.4.11.

First, OSHA added a note below Table C.4.3, Acute Toxicity- Inhalation, Categories 1 and 2 to indicate the required label elements for corrosive to the respiratory tract. The note requires that if the substance/mixture is determined to be corrosive to the respiratory tract leading to lethality, the corrosivity hazard must also be communicated with the corrosion pictogram and hazard statement "corrosive to the respiratory tract." Second, OSHA added a note to Table C.4.4, Skin Corrosion/Irritation, Categories 1A to 1C. The note indicates that if the classifier determines, based on skin data, that the chemical may be corrosive to the respiratory tract, then the corrosivity hazard must be communicated with the hazard statement "corrosive to the respiratory tract" and the corrosion pictogram. (As instructed in Appendix 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.) Third, OSHA added a note below Table C.4.5, Eye

damage/Irritation, Category 1, indicating that if a classifier determines that a chemical may be corrosive to the respiratory tract based on eye data, then the corrosivity hazard must be communicated with the hazard statement “corrosive to the respiratory tract” and the corrosion pictogram. Fourth, OSHA added a note below Table C.4.11, Specific Target Organ Toxicity (Single Exposure), Category 1. The note states that if the chemical is determined to be corrosive to the respiratory tract, corrosive to the respiratory tract must be communicated with the hazard statement “corrosive to the respiratory tract, if inhaled,” and the corrosivity pictogram in lieu of the current STOT hazard statement and health hazard pictogram. The hazard statement for corrosive to the respiratory tract under STOT SE, unlike the other corrosive to the respiratory tract statements, includes “if inhaled” because A.8.2.1.2 requires the relevant route(s) of exposure by which the classified substance produces damage to be identified.

(A) Revisions to Precautionary Statements.

As mentioned in Rev. 7, A3.3.1.5 (Document ID 0060, p. 301), the original GHS (Document ID 0215) precautionary statements were developed from existing classification systems, including the IPCS International Chemical Safety Card (ICSC) Compilers Guide, the American National Standards, the EU classification and labelling directives, the Emergency Response Guidebook, and EPA’s Pesticide Label Review Manual. Since OSHA’s 2012 updates to the HCS, the UNSCEGHS 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 revisions to precautionary statements in Appendix C.4. As OSHA explained in the NPRM, the intent or reasons provided below for the changes it proposed in the NPRM (and is now finalizing) reflect OSHA’s 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).

(B) Changes in Prevention Column.

1. Wear protective equipment (e.g., gloves/protective clothing).

A precautionary statement for acute toxicity – dermal (all categories) (C.4.2), skin corrosion/irritation (Categories 1A to 1C and Category 2 (as outlined in Appendix C tables in the NPRM)) (C.4.4), eye damage/irritation (Categories 1 and 2A) (C.4.5), and sensitization – skin (C.4.7) specifies personal protective equipment, such as “wear protective gloves” or “wear eye protection/face protection.” OSHA proposed to revise the instruction accompanying “Wear protective gloves/protective clothing,” which previously instructed the chemical manufacturer, importer, or distributor “to specify type of equipment.” The proposed instruction stated that the chemical manufacturer, importer, or distributor “may further specify type of equipment where appropriate” to align with Rev. 7 (Document ID 0060, pp. 347-348, 350-351, 354).

Cal/OSHA, AFSCME and Worksafe objected that, under the proposed version, producers would not be required to specify the types of PPE that are required to handle specific types of chemicals (Document ID 0322, p. 3; 0344, p. 3; 0354, p. 5; 0405, p. 18; 0424, Tr. 196-197). According to Cal/OSHA, the proposed revision “would leave workers who handle chemicals during shipment and at the point-of-use with less information about the type of gloves, protective garments, eyewear and other PPE needed to protect themselves from exposure, and it would complicate an emergency response to a loss of containment during transportation or use” (Document ID 0322, p. 3).

OSHA did not intend for the proposed revision to suggest that label preparers are no longer required to identify the specific types of PPE needed to protect employees. Rather, the proposed revision was to align with Rev. 7, A4.3.8.3.3. As explained there, “[s]pecial requirements may exist for gloves or other protective clothing to prevent skin,

eye or lung exposure. Where relevant, this type of PPE should be clearly stated. For example, ‘PVC gloves’ or ‘nitrile rubber gloves’, and thickness and breakthrough time of the glove material” (Document ID 0060, p. 385). While this level of specificity is appropriate for some chemicals and mixtures, there are also chemicals and mixtures for which the more general prevention statement to wear protective gloves is adequate. OSHA’s intent in aligning with the GHS language is to continue to require the label preparer to specify the appropriate PPE and maintain the longstanding requirement of the HCS that label preparers *must* specify the type of protective gloves and/or equipment when a specific type (such as PVC or nitrile) must be used to protect workers. The label preparer may use a more general statement only when a specific type of PPE is not needed to protect workers.

OSHA therefore agrees with Cal/OSHA that the use of “may” in the proposed revision could be misinterpreted to mean that label preparers are not required to specify the type of gloves and clothing which will be protective whenever a specific type is needed for a given chemical or mixture. Accordingly, OSHA is amending the instruction accompanying “Wear protective gloves/protective clothing” in Appendix C to read “Chemical manufacturer, importer, or distributor to specify type of equipment where appropriate”. OSHA added this statement to C.4.2, C.4.4, C.4.5 and C.4.7.

OSHA also proposed to adopt a precautionary statement revision and instruction adding the term “/hearing protection. . .” for several hazard classes, in alignment with similar changes made in Rev. 7. 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 (Document ID 0219). Accordingly, the UNSCEGHS revised the precautionary statement to read, “Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. . .” (Document ID 0147). Consistent with

Rev. 7 (Document ID 0060, pp. 284-285), OSHA proposed to adopt this revised precautionary statement and instruction for germ cell mutagenicity (C.4.8), all categories; carcinogenicity (C.4.9), all categories; reproductive toxicity (C.4.10), all categories; explosives (C.4.14), unstable explosives and Divisions 1.1-1.5; flammable gases (C.4.15), Category 1A, pyrophoric; flammable liquids (C.4.19), all categories; flammable solids (C.4.20), all categories; self-reactive substances and mixtures (C.4.21), all categories; pyrophoric liquids (C.4.22), Category 1; pyrophoric solids (C.4.23), Category 1; self-heating substances and mixtures (C.4.24), all categories; substances and mixtures which, in contact with water, emit flammable gases (C.4.25), all categories; oxidizing liquids (C.4.26), all categories; oxidizing solids (C.4.27), all categories; organic peroxides (C.4.28), all categories; and desensitized explosives (proposed C.4.30), all categories.

NIOSH commented that the addition of hearing protection to the list of PPE shown in the ‘prevention’ columns for the hazard classes of germ cell mutagenicity (C.4.8), carcinogenicity (C.4.9), and reproductive toxicity (C.4.10) “seems inappropriate because hearing protection will not protect against exposure to these hazardous substances” (Document ID 0281, p. 5).

OSHA notes that the use of the backslash “/” as outlined in C.2.4.2 indicates that the label and SDS preparer can choose the appropriate phrases. OSHA agrees that hearing protection is not an appropriate recommendation for the hazard classes of germ cell mutagenicity (C.4.8), carcinogenicity (C.4.9), and reproductive toxicity (C.4.10), and would not expect that this would be included by label and SDS preparers for these hazard classes. Since OSHA does not believe hearing protection is appropriate for these hazards and in order to minimize the misuse of this statement, OSHA is not adding the term “hearing protection” for those hazard classes.

For C.4.15, Flammable Gases, NIOSH recommended adding PPE to include protective gloves/protective clothing/eye protection/face protection” for Hazard Categories 1A, Chemically Unstable Gas A, and 1B, Chemically Unstable Gas B (Document ID 0281, Att. 2, p. 6). While OSHA updated the presentation of the hazard category for flammable gas it did not propose to make substantial changes to the actual statements required and therefore views these changes as out of scope. The only exceptions to this are the changes made to the prevention column for 1A pyrophoric gases, where PPE was added to address the specific hazard of pyrophoricity and that language mirrors the precautionary statements of pyrophoric solids and pyrophoric liquids, and it is thus not one of the categories NIOSH recommends making changes to. The agency also notes that PPE is not included in Rev. 7 for the hazard categories NIOSH indicated (Document ID 0060, pp. 307-309). However, label preparers can add additional statements they deem appropriate.

NIOSH additionally recommended adding “respiratory protection” to the list of PPE shown in the prevention column for C.4.8 Germ Cell Mutagenicity, C.4.9 Carcinogenicity, and C.4.10 Reproductive Toxicity (Document ID 0281, Att. 2, p. 5). AFSCME similarly commented that since inhalation is a main route of entry when working with chemicals, respiratory protection language should be included in the PPE specifications in the tables that do currently list specific types of PPE (Document ID 0344, pp. 3-4). NIOSH also suggested PPE-related changes for several hazard classes in which OSHA either did not propose any revision to the prevention column or did not propose any PPE-related revisions. NIOSH recommended adding PPE to include respiratory protection/protective clothing/protective gloves to the prevention column for C.4.11 (Specific Target Organ Toxicity, Single Exposure) and C.4.12 (Specific Target Organ Toxicity, Repeated Exposure). For C.4.16, Aerosols, and C.4.17, Oxidizing Gases, NIOSH recommended adding PPE to include protective gloves/protective clothing/eye

protection/face protection to the prevention column. For C.4.18, Gases Under Pressure (compressed gas, liquified and dissolved gas), NIOSH recommended adding PPE to include eye protection/face protection (Document ID 0281, p. 6).

Regarding NIOSH and AFSCME's requests to add the term "respiratory protection" as an option in the PPE prevention column for Germ Cell Mutagenicity, Carcinogenicity, and Reproductive Toxicity, and in the prevention column for various other hazard classes, such a revision would be out of scope for this rulemaking since OSHA did not raise the possibility of adding "respiratory protection" to any of these PPE precautionary statements in the NPRM. However, OSHA notes that it is finalizing the ellipses that it proposed to include at the end of the lists of PPE in the prevention column for these hazards, which allows addition of other types of PPE (including respiratory protection) and which should be added if appropriate. With regard to the other types of PPE that NIOSH recommended adding, these changes too would be outside the scope of this rulemaking because they are unrelated to what OSHA proposed in the NPRM.

Cal/OSHA commented that OSHA should strengthen the precautionary statements to indicate that the PPE is required and suggested the agency change the language to "Chemical manufacturer, importer, or distributor to specify the appropriate personal protective equipment as required" (Document ID 0322, Att. 2, p. 11-13). OSHA disagrees with Cal/OSHA's suggested change. The precautionary statement indicates that PPE should be worn with the declarative statement of "Wear protective gloves/. . ." which makes clear what PPE is needed in order to safely use the chemical. Cal/OSHA's suggested revision only changes the language around the duty of the label preparer to specify the details of the PPE, and in this case "as required" does not add strength to this requirement because the language already makes clear that the label preparer must specify the appropriate PPE. For these reasons, OSHA declines to alter the precautionary statement as Cal/OSHA suggests.

For C.4.13, Aspiration Hazard, NIOSH recommended adding a statement that “Mouth pipetting is to be prohibited. When pipetting is required, use a pipette bulb or a mechanical device” (Document ID 0281, p. 6). While OSHA agrees this is sound laboratory practice, it was not discussed in the NPRM and would therefore be out of scope for this rulemaking. OSHA also notes that the suggested statement is not included in the GHS, and that 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories, Appendix A, Paragraph E, provides a list of general procedures from the National Research Council for working with chemicals, including “Pipetting should never be done by mouth.”

2. Avoid Contact During Pregnancy/While Nursing.

In C.4.10, for reproductive toxicity (effects on or via lactation), OSHA proposed to revise a precautionary statement that said to avoid contact “during pregnancy/while nursing” so it would read “during pregnancy and while nursing”. OSHA proposed this revision to clarify that the chemical label preparer is not to choose between “during pregnancy” and “while nursing” but is to include both scenarios on the label. OSHA also noted that the proposed change would align with Rev. 7 (Document ID 0060, p. 358). OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

3. Do Not Handle Until all Safety Precautions Have Been Read and Understood.

For unstable explosives in C.4.14, OSHA proposed to delete a precautionary statement included in the 2012 HCS about not handling until all safety precautions have been read and understood. OSHA reasoned that a statement to obtain special instructions before use is already included and that statement is shorter and more relevant to safety. OSHA also noted that the proposed change would align with Rev. 7 (Document ID 0060, p. 304). OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

4. Do Not Subject to Grinding/Shock/Friction.

OSHA also proposed adding the precautionary statement “Do not subject to grinding/shock/friction/. . .” to the table for unstable explosives in C.4.14. As OSHA explained in the NPRM, that statement was already included for the other explosives categories in the HCS and is also relevant for unstable explosives. For each of the explosives categories that contain that statement, OSHA proposed to add an explanatory conditional note clarifying that the statement applies only if the explosive is mechanically sensitive. OSHA noted that these proposed changes would align with Rev. 7 (Document ID 0060, p. 304). OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

5. Keep Away From Heat/Sparks/Open Flames/Hot Surfaces.

In the NPRM, OSHA noted that several of the hazard classes that include flammable chemicals require precautionary statements and instructions about keeping away from ignition sources (heat/sparks/open flames/hot surfaces). Those statements generally require the label preparer to select one or more of the ignition sources listed, as applicable. OSHA proposed to include more ignition sources in the statement and to require that they all be listed on the label. The revised statement would read, “Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources.” OSHA stated its belief that this change, which is consistent with Rev. 7 (Document ID 0060, p. 280), would improve hazard communication by making users aware of additional ignition sources that should be avoided. The change was proposed for precautionary statements for explosives (divisions 1.1-1.5 in C.4.14), flammable gases (C.4.15), aerosols (C.4.16), flammable liquids (C.4.19), flammable solids (C.4.20), self-reactive substances and mixtures (C.4.21), pyrophoric liquids (C.4.22), pyrophoric solids (C.4.23), oxidizing liquids (C.4.26), oxidizing solids (C.4.27), organic peroxides (C.4.28), and desensitized explosives (C.4.30).

NPGA objected to the proposed change because it would require all ignition sources to be listed. NPGA commented that “the chemical manufacturer, importer or distributor is best equipped to determine which ignition sources should be listed. Further to this, it is not clear how this change improves safety to the level that it justifies the cost of redesigning, printing and relabeling all containers” (Document ID 0364, p. 5).

OSHA disagrees with NPGA that the chemical manufacturer, importer, or distributor would be best equipped to determine which ignition sources are relevant, since there may be ignition sources at worksites where the chemical is used that the manufacturer, importer, or distributor is unaware of. OSHA believes the value of this clarification is evident because expanding the list of potential ignition sources increases worker awareness of and protection from the variety of ignition sources that may be present at their worksite. Furthermore, due to the significant changes included in this final rule to several aspects of C.4.15, label preparers will already need to redesign these labels and print new ones. Therefore, this change alone does not specifically incur the costs that NPGA cites as either those costs would exist without the addition of this provision or are not costs due to other flexibilities provided. In addition, contrary to NPGA’s assertion, all containers would not need to be relabeled. OSHA is finalizing a new sentence in paragraph (f)(11) that allows manufacturers, importers, and distributors to not relabel containers that have already been released for shipment. For these reasons, OSHA disagrees with NPGA’s arguments and is finalizing these revisions as proposed.

6. Keep Wetted With.

In the 2012 HCS a conditional instruction used for Divisions 1.1-1.3 and 1.5 explosives in C.4.14 stated that the chemical manufacturer, importer, or distributor is to include the precautionary statement “Keep wetted with. . .” under conditions where drying out would increase the explosion hazard, except as needed for manufacturing or operating processes. Rev. 7 changed 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” (Document ID 0060, p. 305). OSHA proposed to make the same change in order to clarify when the “Keep wetted with. . .” statement is appropriate. OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

OSHA further notes that the “Keep wetted with. . .” precautionary statement also appears in C.4.30, desensitized explosives. Consistent with Rev. 7 (Document ID 0060, p. 334), OSHA did not propose 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.

7. Keep Only in Original Packaging.

OSHA proposed to revise the statement “Keep only in original container” to “Keep only in original packaging” for self-reactive substances and mixtures (C.4.21), organic peroxides (C.4.28), and corrosive to metals (C.4.29). OSHA also proposed that the revised statement would be added to explosives in Divisions 1.1-1.5 (C.4.14). OSHA reasoned that the proposed change in term is appropriate because the term “packaging” is more inclusive than “container” and would include the transport packaging as well as the immediate container. OSHA also noted that the proposed changes are consistent with Rev. 7 (Document ID 0060, p. 281). OSHA received no comments on these proposed revisions. Therefore, the agency is finalizing them as proposed.

8. Ground and 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 proposed changing “Ground/bond” to “Ground and bond” to clarify that both of those precautions are to be included on the label. 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. OSHA proposed making this change for explosives (Divisions 1.1 to 1.5 in C.4.14), flammable liquids (Categories 1 to 3 in C.4.19), and flammable solids (C.4.20). In addition, OSHA proposed to revise the 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 (C.4.19) and to explosives and flammable solids only if they are electrostatically sensitive (C.4.14 and C.4.20). OSHA also proposed 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 (C.4.21) and organic peroxides (C.4.28) because the precaution is also appropriate for those hazard classes. OSHA noted that the proposed changes would align with Rev. 7 (Document ID 0060, p. 282). OSHA received no comments on these proposed revisions. Therefore, the agency is finalizing them as proposed.

9. Keep Away From Clothing and Other Combustible Materials.

OSHA proposed to standardize precautionary statements regarding combustible materials for oxidizing chemicals. In the 2012 HCS, the tables for oxidizing gases (C.4.17), oxidizing liquids (C.4.26, hazard categories 2 and 3), and oxidizing solids (C.4.27, hazard categories 2 and 3) required the precautionary statement “Keep/Store away from clothing/. . . /combustible materials,” along with instructions for the chemical manufacturer, importer, or distributor to specify incompatible materials. The table for Category 1 in C.4.26 required the precautionary statement “Keep/Store away from clothing and other combustible materials.” OSHA proposed to change these statements to read: “Keep away from clothing and other combustible materials,” and to delete the instruction regarding incompatible materials, to make the statement consistent with the

statement currently applicable to Category 1 in oxidizing solids (C.4.27). OSHA reasoned that the proposed change is appropriate because the general term “combustible materials” encompasses any other materials that are incompatible with oxidizers. In addition, OSHA reasoned that 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. OSHA also proposed to remove the redundant statement “Take any precaution to avoid mixing with combustibles/. . .” under oxidizing liquids (C.4.26) and oxidizing solids (C.4.27), since this information is duplicative of the “keep away from” statement. OSHA noted that the proposed changes would be consistent with Rev. 7 (Document ID 0060, p. 280).

OSHA proposed to remove the “Keep/store away from clothing/. . . /combustible materials” precautionary statement, along with its instruction, for self-reactive substances and mixtures (C.4.21) and organic peroxides (C.4.28). As OSHA explained in the NPRM, 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. OSHA noted these proposed changes would also align with Rev. 7 (Document ID 0060, pp. 318-320, 330-332).

OSHA received no comments on these proposed revisions. Therefore, the agency is finalizing them as proposed.

10. Keep Valves and Fittings Free From Oil and Grease.

For oxidizing gases (C.4.17), a precautionary statement in the 2012 HCS allowed the chemical manufacturer, importer, or distributor to specify that either “reduction valves” or “valves and fittings” be kept free from oil and grease. OSHA proposed to

revise the statement to “Keep valves and fittings free from oil and grease.” OSHA reasoned that the change would be appropriate because all valves and fittings must be kept free of oil and grease, not just the reduction valves attached to pressure receptacles, and also noted it would be consistent with Rev. 7 (Document ID 0060, p. 312). OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

11. Wear Cold Insulating Gloves/Face Shield/Eye Protection.

OSHA proposed to revise the precautionary statement for refrigerated liquefied gases (C.4.18), which in the 2012 HCS required the use of either cold insulated gloves, a face shield, or eye protection. The revised precautionary statement reads “Wear cold insulating gloves and either face shield or eye protection.” OSHA proposed the change to 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, and noted that it would align with Rev. 7 (Document ID 0060, p. 314). OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

12. Keep Container Tightly Closed.

The precautionary statement “Keep container tightly closed” is used for flammable liquids (categories 1 to 3 in C.4.19). Rev. 7 contains a conditional instruction for flammable liquids indicating that the statement is to be used if the liquid is volatile and may generate an explosive atmosphere (Document ID 0060, p. 321). OSHA proposed to add this conditional instruction to the precautionary statement for flammable liquids (categories 1 to 3) because it clarifies the types of flammable liquids for which the statement applies.

OSHA also proposed to add the precautionary statement “Keep container tightly closed” to pyrophoric liquids (C.4.22), pyrophoric solids (C.4.23), and desensitized explosives (new C.4.30) (as part of adopting the new hazard class of desensitized

explosives). OSHA reasoned that 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 preliminarily determined that a conditional note is not necessary. The agency noted that these proposed changes would also align with Rev. 7 (Document ID 0060, p. 281).

OSHA received no comments on these proposed revisions. Therefore, the agency is finalizing them as proposed.

13. Take Precautionary Measures Against Static Discharge.

For flammable liquids (C.4.19, Hazard Categories 1 to 3), OSHA proposed to revise the precautionary statement “Take precautionary measures against static discharge” to “Take action to prevent static discharge.” As explained in the NPRM, the proposed revision would simply shorten the statement and clarify what action needs to be taken. OSHA also proposed to add a note that this precautionary statement is to be used if the liquid is volatile and may generate an explosive atmosphere. OSHA noted that these proposed changes are consistent with Rev. 7 (Document ID 0060, p. 315). OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

14. Flammable Liquids/Solids Precautionary Statements and Conditional Instructions.

OSHA proposed additional conditional instructions for flammable liquids (C.4.19) and flammable solids (C.4.20). For some categories of flammable liquids (Categories 1 to 3) and flammable solids (categories 1 and 2), OSHA proposed to modify one of the precautionary statements to add square brackets in the phrase “Use explosion-proof [electrical/ventilating/lighting/. . .] equipment.” As OSHA explained in the NPRM, the agency believes that SDS and label creators are not properly and specifically identifying the prevention measures for the particular chemical, but rather are listing the entire line without the required details, and the brackets are intended to help clarify this

issue. For both liquids and solids, OSHA proposed adding a conditional instruction to indicate that the text in square brackets may be used to specify specific electrical, ventilating, lighting, or other equipment if necessary and as appropriate. For liquids, OSHA also proposed a new conditional instruction to clarify that the statement is required if the chemical is volatile and may generate an explosive atmosphere. OSHA noted that these proposed changes would align with Rev. 7 (Document ID 0060, p. 282).

OSHA also proposed to add a conditional instruction to the precautionary statement to use non-sparking tools for flammable liquids (C.4.19, categories 1 to 3). 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 reasoned that the conditions need to be specified. OSHA noted that this proposed change is also consistent with Rev. 7 (Document ID 0060, p. 315).

OSHA received no comments on these changes to the precautionary statements and additional conditional instructions it proposed for flammable liquids (C.4.19) and flammable solids (C.4.20). Therefore, the agency is finalizing them as proposed.

15. Keep Cool.

For self-reactive substances and mixtures (C.4.21) and organic peroxides (C.4.28), OSHA proposed to move the precautionary statement “Keep cool” from the storage column to the prevention column. OSHA reasoned that the precautionary statement is not needed in the storage column because that column includes a precautionary statement about storage temperatures not to be exceeded under storage conditions, and as discussed below, OSHA also proposed to add conditional instructions to that column to inform users of when a storage temperature would need to be listed. To ensure that the chemicals are kept at appropriate temperatures at all times (not just during

storage), OSHA proposed to place “Keep cool” in the prevention column; but OSHA also proposed to include a conditional instruction indicating that the precautionary statement may be omitted if storage temperatures are included on the label. The agency noted that the proposed revision would not materially change the information that is presented on the label and is consistent with Rev. 7 (Document ID 0060, pp. 318-320, 330-332).

For self-heating substances and mixtures (C.4.24), a combined precautionary statement included in the 2012 HCS instructed the user to keep cool and protect from sunlight. OSHA proposed 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 proposed 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 reasoned that these proposed changes would provide the label preparer better instructions and would provide the appropriate level of information on the label without repetition. OSHA noted that the proposed changes would also align with Rev. 7 (Document ID 0060, p. 323). OSHA received no comments on these proposed revisions. Therefore, the agency is finalizing them as proposed.

16. Do Not Allow Contact With.

OSHA proposed 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 proposed Category 1A, pyrophoric gases (C.4.15), pyrophoric liquids (C.4.22), and pyrophoric solids (C.4.23)) or water (for substances and mixtures which, in contact with water, emit flammable gases (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, OSHA reasoned that 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. OSHA noted that these proposed changes would align with Rev. 7 (Document ID 0060, p. 280). OSHA received no comments on these proposed revisions. Therefore, the agency is finalizing them as proposed.

17. Handle and Store Contents Under Inert Gas.

For substances and mixtures which, in contact with water, emit flammable gases (C.4.25, all categories), OSHA proposed changing the precautionary statement “Handle under inert gas. Protect from moisture” to “Handle and store contents under inert gas/. . . Protect from moisture” to clarify that these substances should always be under inert atmospheres. In addition, OSHA proposed to add conditional instructions to indicate that if the substance or mixture reacts readily with moisture in air, then the chemical manufacturer, importer or distributor must also specify the appropriate liquid or gas if inert gas is not appropriate. As explained in the NPRM, OSHA anticipated 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) (86 FR 9717). The agency noted that this proposed change is also consistent with Rev. 7 (Document ID 0060, pp. 324-325).

OSHA also proposed to add the statement “Handle and store contents under inert gas/. . .” to pyrophoric liquids (C.4.22) and pyrophoric solids (C.4.23) and 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. As explained in the NPRM, pyrophoric chemicals, by definition, are likely to ignite when in contact with air. Both C.4.22 and C.4.23 of the 2012 HCS contained 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 proposed to include in the prevention column, OSHA proposed to delete this language from the storage column. OSHA reasoned that the language it proposed for the prevention column would emphasize that pyrophoric chemicals must be handled, as well as stored, under inert atmospheres. OSHA noted that the statements it proposed to add to the prevention column for C.4.22 (pyrophoric liquids) and C.4.23 (pyrophoric solids) regarding handling and storing contents under inert gas were included in Table A3.2.2 of Rev. 7 but were inadvertently left off of tables in Annex 3, Section 3 for both pyrophoric liquids and pyrophoric solids (Document ID 0060, p. 281). OSHA received no comments on these proposed revisions. Therefore, the agency is finalizing them as proposed.

18. Wear Fire Resistant or Flame Retardant Clothing.

Category 1 oxidizing liquids (C.4.26) and Category 1 oxidizing solids (C.4.27) of the 2012 HCS had the precautionary statement “Wear fire/flame resistant/retardant clothing.” That statement was intended 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 proposed to replace the 2012 HCS statement with “Wear fire resistant or flame retardant clothing” in order clarify OSHA’s intent. The agency also noted that the proposed change is consistent with Rev. 7 (Document ID 0060, p. 285). OSHA received no comments on these proposed revisions. Therefore, the agency is finalizing them as proposed.

19. Changes in Response Column.

Several of the revisions OSHA proposed for the response column are simply editorial changes intended to improve clarity, correct simple omissions of a word or phrase, or more efficiently and concisely combine different precautionary statements. For example, OSHA proposed 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 Rev. 7 (Document ID 0060, pp. 293-294), and the additional phrase would add clarity. In a number of cases, OSHA proposed 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 proposed to 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 changes that are simply editorial in nature (although, as discussed above, OSHA will make available a redline version of Appendix C on OSHA's website (<https://www.osha.gov/dsg/hazcom>)). The discussion below highlights substantive changes to the response column in Appendix C.

20. Rinse Skin With Water [or Shower].

The HCS 2012 precautionary statements for Categories 1A to 1C of skin corrosion/irritation (C.4.4) and Categories 1 to 3 of flammable liquids (C.4.19) indicated 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 proposed 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. OSHA reasoned 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. OSHA also noted that the proposed change would align with Rev. 7 (Document ID 0060, p. 289). OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

21. Get Medical Advice/Attention.

In the 2012 HCS, a number of health hazards (i.e., skin corrosion/irritation (Category 2 in C.4.4), eye damage/irritation (Categories 2A and 2B in C.4.5), sensitization—skin (C.4.7), germ cell mutagenicity (C.4.8), carcinogenicity (C.4.9), reproductive toxicity (C.4.10), specific target organ toxicity—repeated exposure (C.4.12), and refrigerated liquefied gases (C.4.18)) had combined precautionary statements that included the statement “get medical advice/attention.” OSHA proposed to add an instruction indicating that the chemical manufacturer, importer, or distributor is to select medical advice or attention as appropriate in order 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 Rev. 7 (Document ID 0060, p. 287).

ACC disagreed with the mandatory addition of the requirement to choose between medical advice or medical attention, stating that it would provide no added benefit to those handling the chemical and that it would be costly for companies required to modify the statement (Document ID 0347, pp. 19-20).

OSHA disagrees with ACC’s assertion that a requirement to select medical advice or attention would not benefit those handling the chemical. Getting medical *attention* in response to a toxic exposure indicates that in-person evaluation is required, while getting medical *advice* indicates that consultation may take place by remote means. There may be situations in which it is always more appropriate for an exposed worker to seek in-person evaluation and therefore clarifying between attention and advice is substantively different and conveys important information to workers. OSHA also finds this is not an overly burdensome requirement, given the importance of specifying whether medical attention or medical advice is required following exposure. OSHA also notes that Rev. 8 has replaced all medical precautionary statements that included “advice/attention” with statements that provide more detailed instructions. As was discussed above, OSHA is aligning with Rev. 7 in this and most other updates to the HCS, but will allow the use of

precautionary statements included in Rev. 8. OSHA is therefore finalizing this revision as proposed.

22. If Inhaled: Remove Person to Fresh Air and Keep Comfortable for Breathing.

A precautionary statement used for sensitization—respiratory (C.4.6) in the 2012 HCS stated “If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.” OSHA proposed to remove the phrase “if breathing is difficult,” reasoning that including two conditions, “if inhaled” and “if breathing is difficult,” is confusing and unnecessary. OSHA also noted that removing the phrase would make the precautionary statement consistent with the statement as it appears in other hazard classes in Appendix C.4, such as acute toxicity—inhale (C.4.3) and would be consistent with Rev. 7 (Document ID 0060, p. 353). OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

23. Take Off Contaminated Clothing and Wash it Before Reuse.

A precautionary statement for skin sensitization (C.4.7) in the 2012 HCS said to wash contaminated clothing before reuse. OSHA proposed to add the phrase “Take off contaminated clothing and” to this precautionary statement. As explained in the NPRM, the phrase was inadvertently omitted for skin sensitization in Rev. 3 (Document ID 0085, Att. 7), and therefore in the updates to the HCS in 2012 as well, but it has since been added to Rev. 7 (Document ID 0060, p. 293). OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

24. If Exposed or Concerned.

For specific target organ toxicity (single exposure) (C.4.11), OSHA proposed to revise a precautionary statement indicating “If exposed” to “If exposed or concerned.” OSHA reasoned that the revision, which would be consistent with language already used for the germ cell mutagenicity (C.4.8), carcinogenicity (C.4.9), and reproductive toxicity (C.4.10) hazard classes, would maintain consistency throughout C.4 and with Rev. 7

(Document ID 0060, p. 360). OSHA received no comments on this proposed revision.

Therefore, the agency is finalizing it as proposed.

V. Division 1.4 Explosives (C.4.14) Precautionary Statements,

For Division 1.4 explosives, the HCS provides fire-fighting precautionary statements and instructions on when to apply them (C.4.14). OSHA proposed two changes to these statements. First, OSHA proposed to change the instructional note from “except if explosives are 1.4S ammunition and components thereof” to “except for explosives of division 1.4 (compatibility group S) in transport packaging” to provide clarity about when the note applies; there is no intended change in meaning. Second, OSHA proposed 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 reasoned that the proposed new statement would be more appropriate and protective because it specifies the explosion risk due to fire associated with Division 1.4 (Compatibility Group S) explosives. OSHA also noted that these proposed changes would align with Rev. 7 (Document ID 0060, p. 306). OSHA received no comments on these revisions, and is therefore finalizing them as proposed.

Toby Threet commented that OSHA should revise another precautionary statement which appears in C.4.14 as well as other categories: “Do NOT fight fire when fire reaches explosives.” According to Threet, this statement “implies that it is OK to fight the fire until almost the very moment when the fire reaches the explosives... Fire... can ignite things, even if the fire (i.e., the flame) has not ‘reached’ them yet.” Threet suggested “Stop fighting fire before it nears explosives” and “Leave the area before fire nears explosives” as alternatives to the existing language (Document ID 0279, p. 23-24).

OSHA notes that the existing precautionary statement was adopted from the GHS in 2012 and OSHA did not propose to modify it in the NPRM. Threet’s suggestion to change it is therefore outside the scope of this rulemaking. Furthermore, updates to the

GHS have not changed this precautionary statement (Document ID 0060, p. 306) and OSHA is not aware of any confusion regarding the meaning of this statement or any incidents where misinterpretation of this statement has caused harm to workers. OSHA therefore has not accepted Threet's recommendation.

(A) Eliminate All Ignition Sources, if Safe To Do So.

For flammable gases (C.4.15), a precautionary statement in the 2012 HCS instructed the user to "Eliminate all ignition sources if safe to do so." OSHA proposed to revise the statement to "In case of leakage, eliminate all ignition sources" by adding the phrase "in case of leakage" to stress the dangers of flammable gas leaks, even where the leaking gas is not yet burning, because the leak could create an explosive atmosphere; and by deleting the term "if safe to do so" because it could discourage quick action. OSHA reasoned that eliminating gas leaks or ignition sources would not be expected where a fire would hinder that action. OSHA also proposed to add this statement to all of the new flammable gas categories it proposed in the NPRM. OSHA noted that these proposed changes would be consistent with Rev. 7 (Document ID 0060, pp. 307-309).

Toby Threet commented regarding the precautionary statement "In case of leakage, eliminate all ignition sources" that eliminating ignition sources may require a person to enter a hazardous area and suggested that the statement should be "In case of leakage, eliminate all ignition sources if safe to do so" (Document ID 0279, p. 24).

As discussed above, OSHA proposed to delete the phrase "if safe to do so" because it could discourage quick action. OSHA believes that removing the phrase "if safe to do so" will not cause workers to enter a hazardous area in order to eliminate ignition sources. OSHA believes that workers will have training on the safe use and handling of chemicals under OSHA regulations such as the HCS, as well as the requirement under the PSM standard to implement an emergency action plan, which must include procedures for handling small releases (29 CFR 1910.119(n)). Additionally,

OSHA's regulations for hazardous waste operations and emergency response ensure that workers will be made aware of dangers related to gas leaks and the work practices that will minimize risks from these hazards (see 29 C.F.R. 1910.120 and 1926.65). OSHA concludes that these additional regulatory requirements will ensure that employees do not place themselves in harm's way in the event of a gas leak, particularly where there is a source of ignition present. Therefore, OSHA has not included "if safe to do so" in the precautionary statement.

For the reasons discussed above, OSHA is finalizing the changes to the precautionary statement regarding eliminating ignition sources in case of flammable gas leaks as proposed.

(B) Type A and B Self-Reactive Substances and Mixtures (C.4.21).

For Type A self-reactive substances and mixtures (C.4.21), OSHA proposed 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 statements OSHA proposed to delete, OSHA proposed to add the statement "In case of fire: Explosion risk. Evacuate area. DO NOT fight fire when fire reaches explosives." OSHA explained that it proposed these changes because it is dangerous to fight a fire involving this type of material so individuals should always be advised against it, and noted that these changes would align with Rev. 7 (Document ID 0060, p. 318).

For Type B self-reactive substances and mixtures (C.4.21), OSHA proposed to combine existing precautionary statements and to delete duplicate phrases that would occur with the new combination. As noted in the NPRM, OSHA did not intend these changes to alter the meaning of the statements. OSHA proposed 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, in order to preserve the

conditions of use with the new combination of phrases. OSHA noted that these proposed changes would align with Rev. 7 (Document ID 0060, p. 319).

OSHA received no comments on these proposed revisions. Therefore, the agency is finalizing them as proposed.

(C) 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 Rev. 3 (Document ID 0085, Att. 7, pp. 65-67) or in the 2012 HCS for organic peroxides (C.4.28). The UNSCEGHS has since adopted these precautionary statements (Document ID 0060, pp. 330-332). OSHA proposed to adopt the Rev. 7 precautionary statements in the response column for organic peroxides as for self-reactive substances and mixtures (C.4.21). OSHA reasoned that 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 (Document ID 0095). OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

(D) Immerse in Cool Water or Wrap in Wet Bandages.

For pyrophoric liquids (C.4.22), pyrophoric solids (C.4.23), and categories 1 and 2 of substances and mixtures which in contact with water emit flammable gases (C.4.25), a precautionary statement in the 2012 HCS indicated 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 proposed to change the forward slash to an “or” and the “with” to “in” so that the statement would read “Immerse in cool water or wrap in wet bandages” in order to make clear that the chemical manufacturer, importer, or distributor 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 (C.4.25), OSHA proposed 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.” OSHA reasoned that, 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. OSHA also noted that the proposed changes would align with Rev. 7 (Document ID 0060, p. 324). OSHA received no comments on these proposed revisions. Therefore, the agency is finalizing them as proposed.

(E) Changes in Storage Column.

1. Store Separately.

For self-reactive substances and mixtures (C.4.21), self-heating substances and mixtures (C.4.24), and organic peroxides (C.4.28), OSHA proposed to revise the precautionary statement “Store away from other materials” to “Store separately.” OSHA reasoned that the revised statement is preferable because it is shorter and more appropriate. OSHA also proposed 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. OSHA noted that these proposed changes are consistent with Rev. 7 (Document ID 0060, p. 297). OSHA received no comments on these proposed revisions. Therefore, the agency is finalizing them as proposed.

2. Store Contents Under. . .

OSHA proposed to delete a precautionary statement that says “Store contents under . . .” and an instructional note that the chemical manufacturer, importer, or distributor is to specify the appropriate liquid or inert gas which were previously in pyrophoric liquids (C.4.22) and solids (C.4.23). 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 (Document ID 0152, p. 46). OSHA reasoned that placing the

statement in the prevention column would be 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. OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

3. Maintain Air Gap Between Stacks or Pallets.

For self-heating substances and mixtures (C.4.24), OSHA proposed to revise the precautionary statement that currently says “Maintain air gap between stacks/pallets” so it reads instead “Maintain air gap between stacks or pallets” in order to clarify that chemical label preparers are not to choose between “stacks” or “pallets” but are to include both words on the label. OSHA noted that this proposed change would align with Rev. 7 (Document ID 0060, p. 323). OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

4. Store in Corrosion Resistant/ . . . Container With a Resistant Inner Liner.

A precautionary statement for the corrosive to metals (C.4.29) class in the 2012 HCS said to store in a “corrosive resistant/ . . . container with a resistant inner liner.” OSHA proposed to change the word “corrosive” to “corrosion” because it is the technically correct term. In addition, OSHA proposed to insert a new conditional instruction to indicate that the precautionary statement may be omitted if the statement “Keep only in original packaging” is included on the label. OSHA reasoned that this would eliminate the redundancy of including both statements. OSHA noted that these proposed changes would align with Rev. 7 (Document ID 0060, p. 333). OSHA received no comments on this proposed revision. Therefore, the agency is finalizing it as proposed.

(F) Additional Instructional Notes.

For acute toxicity—inhale (C.4.3) (category 1-3) and specific organ toxicity (single exposure, category 3) (C.4.11), OSHA proposed 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 proposed 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 agency intended these edits is to improve clarity and make the instruction more consistent with a newly added instruction for flammable liquids (C.4.19). OSHA noted that this proposed change would be consistent with Rev. 7 (Document ID 0060, p. 281).

For flammable liquids (C.4.19), OSHA proposed 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 proposed 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 stated in the NPRM its preliminary finding that the precautionary statement “Store in a well ventilated place” would provide the appropriate level of protection, and noted that these proposed changes would align with Rev. 7 (Document ID 0060, pp. 315-316).

For explosives (C.4.14), OSHA proposed minor edits to precautionary statements and instructions for storing in accordance with local/regional/national/international regulations to clarify that the chemical manufacturer, importer, or distributor is to specify the contents of the applicable regulations. OSHA noted that these proposed changes would be consistent with Rev. 7 (Document ID 0060, p. 295). APA expressed concern that this would require responsible parties to list regulations regarding the storage of explosives from every country, district, region, and municipality in the world, and that “Shipping internationally would not only become a nightmare for the manufacturer / creator of the SDS but impossible.” They also asked that OSHA consider allowing manufacturers to just list the storage information for the country of origin of the

manufacturer instead, along with a statement that customers should consult their local regulations (Document ID 0337, pp. 3-4).

OSHA does not believe the proposed requirements are as burdensome as the APA suggests. First, although APA framed this as an issue regarding the SDS, the disposal requirements they point to in Appendix C are only required on labels. OSHA is not suggesting that label preparers need to address any regulations outside of the United States and thus the breadth of what is required is much narrower than what APA suggested. The agency has provided guidance indicating that when chemicals are prepared for direct shipment to a destination outside of the U.S. and are placed inside of a DOT or other similarly-approved shipping container, the manufacturer can label the sealed containers for the destination country (HCS labeling of imports and exports, 2015, available at <https://www.osha.gov/laws-regs/standardinterpretations/2015-09-10>). Additionally, OSHA is not suggesting that the label preparer needs to include every state, local, or federal regulation. Rather, they must include the content of the storage requirements, and since explosives are heavily regulated, for instance under OSHA 29 CFR 1910.109 as well as ATF 27 CFR 555 subpart K, OSHA does not anticipate that storage requirements will vary widely across states and localities in the United States, so label preparers may only need to include federal requirements or a few additional state or local requirements in addition to the federal requirements. OSHA also believes that producers of highly hazardous materials, such as explosives, already have programs in place to instruct their customers on how to safely ship, use, store and dispose of explosives in the United States, and therefore can readily identify state and local storage regulations that may differ from federal regulations. For these reasons, OSHA declines to accept APA's alternative suggestion for this language.

The 2012 HCS Appendix C sections on aerosols (C.4.16), self-reactive substances (C.4.21), self-heating substances and mixtures (C.4.24), and organic peroxides (C.4.28)

included precautionary statements addressing storage temperatures not to be exceeded, with temperatures listed in degrees Celsius/Fahrenheit. The GHS added an instruction that the chemical manufacturer should use the applicable temperature scale for the region they are supplying (Document ID 0060, p. 297). In other OSHA standards, the primary temperature scale used is Fahrenheit. Therefore, OSHA proposed to require only the Fahrenheit scale in the precautionary statements, but to allow the chemical manufacturer, importer or distributor to include the temperature in Celsius (as noted by the parentheses “()” around °C) in addition to the required temperature in Fahrenheit.

In addition, for self-reactive substances and mixtures (C.4.21) and organic peroxides (C.4.28), OSHA proposed to add conditional instructions to two precautionary statements. The first conditional instruction was proposed to clarify that the statement to store in a well-ventilated place should not be used for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may occur. The second was proposed to clarify that a storage temperature is only needed if temperature control is required or deemed necessary. OSHA noted that these proposed changes would align with Rev. 7 (Document ID 0060, pp. 295, 297).

OSHA received no comments on these proposed revisions, other than the comment on storage of explosives. Therefore, the agency is finalizing them as proposed.

VI. Changes in Disposal Column.

For most of the health and physical hazards addressed by Appendix C, the HCS includes a precautionary statement to dispose of contents/container in accordance with local/regional/national/international regulations (to be specified). OSHA proposed 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. OSHA noted that this proposed change would align with Rev. 7 (Document ID 0060, pp. 298-299).

ACC disagreed with the proposed instructional note to the disposal precautionary statement. They urged OSHA “to retain flexibility,” noting that some of their members’ use disposal precautionary statements that are more general and asserting that there is “no added benefit to whomever is handling the chemical by specifying if the phrase applies to the contents and/or container” (Document ID 0347, p. 19). OSHA disagrees. Workers need to know whether they need to exercise the same level of caution when disposing of the contents and the container. Without such specificity, workers confront ambiguous messaging that may put them at greater risk if they do not understand what is intended. The agency is therefore finalizing this change as proposed.

OSHA also proposed to revise the precautionary note for disposal of explosives (C.4.14). The 2012 HCS tables for explosives (C.4.14), except for hazard category division 1.6, included a precautionary statement to dispose of contents/container in accordance with local/regional/national/international regulations (to be specified). However, as explained in the NPRM, 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. OSHA found this issue to be of particular concern for explosives such as fireworks, signal flares, and ammunition. Poorly formulated advice on the label may lead to the disposal of such explosive waste in a way that poses a risk to the workers that handle the waste (Document ID 0156). Therefore, OSHA proposed 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” and to add an instructional note 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. OSHA proposed this change 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. OSHA noted that this proposed change is consistent with Rev. 7 (Document ID 0060, p. 299).

APA raised the same concerns with regards to OSHA's proposed revision to the disposal precautionary note for explosives as it did on the storage precautionary statement and also suggested that manufacturers should instead provide information for storage and disposal for the country where the manufacturer is located and then alert customers and recipients of the products on the SDS to consult local regulations for proper storage and disposal (Document ID 0337, pp. 3-4).

OSHA disagrees that this proposal creates a new, unwieldy burden for manufacturers. The intent of this language was to clarify requirements, not create a new one. Label preparers were already required to provide this information in the disposal column, and OSHA is not aware of any concerns raised by other regulated parties regarding this requirement or its feasibility. Therefore, OSHA disagrees with APA's suggested revision, which the agency believes would put undue burden on the downstream users and could be confusing to them, and is finalizing the changes to the disposal column for explosives as proposed.

(A) GHS Revisions That OSHA Is Not Adopting.

Rev. 7 includes a small number of revisions that OSHA did not propose to adopt for this update to Appendix C. In general, OSHA did 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 other specific provisions in Rev. 7 (Document ID 0060) that OSHA did not propose to adopt.

In the HCS, 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 Rev. 7 (Document ID 0060, p. 283) 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), Rev. 7 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 (Document ID 0060, p. 292). OSHA did not propose to adopt these conditional instructions because it believes that the rules in C.2.4 regarding precautionary statement text provide the necessary flexibility. The agency received no comments on its decision not to include these conditional instructions in the HCS.

In Rev. 7, the precautionary statements used in flammable liquids (C.4.19) and flammable solids (C.4.20) 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 (Document ID 0060, p. 282). OSHA did not propose 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 received no comments on its preliminary decision not to include this conditional instruction in the HCS.

Under the HCS, a precautionary statement for gases under pressure (C.4.18) currently says “Protect from sunlight.” 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” (Document ID 0060, p. 313). These special packaging instructions are not applicable to cylinders used in the United States; therefore, OSHA did not propose to add this conditional instruction to C.4.18. OSHA received no comments on its preliminary decision not to include this conditional instruction in the HCS. OSHA has therefore decided not to include these revisions.

F. Appendix D

Appendix D provides specific requirements for what information chemical manufacturers, distributors, importers, and employers must provide on the SDS, including rules regarding specific headings, sub-headings, and information to be contained under each subheading. The information specified as mandatory in Appendix D is the minimum required information on the SDS, however, an SDS may include additional information as long as it does not contradict or undermine the required SDS elements.

In the NPRM, OSHA proposed several changes in Appendix D to align with Rev. 7, clarify existing requirements about which stakeholders have expressed confusion, and ensure consistency with updated scientific principles (86 FR 9576; Document ID 0060, pp. 377-399).

I. Introductory Text.

In the introductory section of Appendix D, OSHA proposed to add a sentence stating that “[w]hile 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.” OSHA proposed this change to clarify the existing text. As the information within each section can be listed in any order, OSHA noted that it did not anticipate any increased burden on SDS preparers from this change.

API commented that the proposed revision could be helpful, especially in light of other changes OSHA proposed regarding the presentation of physical and chemical properties elsewhere on the SDS (Document ID 0316, p. 27). Similarly, Michele Sullivan supported the proposal and commented that the proposed clarification would provide flexibility (Document ID 0366, p. 8). OSHA received no comments objecting to the proposed clarification, and is therefore finalizing the addition of the proposed sentence to the introductory paragraph of Appendix D.

II. Section 1: Identification.

Section 1 of Table D.1 requires SDS preparers to provide identifying information. In the NPRM, OSHA proposed to clarify that the address and telephone number of the chemical manufacturer, importer, or other responsible party which the HCS requires must be United States domestic.

API and NAIMA supported the proposed revision (Document ID 0316, p. 27; 0338, p. 9; 0366, p. 8). Michele Sullivan also supported it, and stated that it would be helpful to clarify that the address and phone number provided in the SDS must be in the United States since there has been confusion about this in the past (Document ID 0366, p. 8).

ACC sought clarification on how this revision would impact foreign suppliers and inquired what the options would be for a foreign supplier who ships products into the United States to comply with this provision. In addition, ACC recommended that OSHA make this requirement non-mandatory “due to length and complexity of the chemicals supply chain” (Document ID 0347, p. 21). NACD commented that the proposed revision

would present challenges for foreign suppliers who are not willing to have U.S. addresses and phone numbers, which would in turn require importers to generate a new SDS with their own U.S. address and phone number and assume the liability for all the information in the SDS. However, NACD also pointed out that having a U.S. address and phone number on the SDS would be consistent with labeling requirements specified in Appendix C and could help demonstrate to foreign suppliers and importers that this is required (Document ID 0329, pp. 7-8).

OSHA disagrees that the proposed language would impose new burdens on either foreign suppliers or domestic importers. As OSHA discussed in the NPRM, a U.S. telephone number and U.S. address were already required on the SDS based on the previously existing requirements of Appendix D, which requires that the name, address, and telephone number of the responsible party, such as the chemical manufacturer or importer, be listed on the SDS (86 FR 9722). OSHA explained in a 2016 LOI that when chemicals are imported into the United States, the importer (defined by the HCS as being the first business with employees in the United States to receive hazardous chemicals produced in other countries for distribution in the United States) is the responsible party for purposes of compliance with the HCS and is required to use a U.S. address and U.S. phone number on the SDS (Document ID 0090).

Therefore, in response to ACC's question and NACD's concern regarding foreign suppliers, OSHA notes that foreign companies that ship products to importers in the United States are not required to maintain U.S. contact information or to include their address and telephone number on the SDS. Furthermore, NACD's comment that importers must include their own U.S. address and phone number on the SDS and must assume responsibility for information in the SDS is correct, but is not a new burden associated with OSHA's proposed change.

OSHA believes it is important to codify the requirement for a U.S. telephone number and U.S. address in Section 1 of Table D.1 in the text of the HCS to minimize any further confusion. This change would clarify the existing requirement, which—as comments received by the agency demonstrate—continues to be a point of confusion in cases where hazardous chemicals are imported to the United States. ACC’s request to make the inclusion of a U.S. phone number and address non-mandatory would conflict with the pre-existing requirement as explained in the 2016 interpretation discussed above, adding to rather than mitigating stakeholder confusion. OSHA is therefore finalizing the proposed revision to clarify that the address and telephone number of the chemical manufacturer, importer, or other responsible party which the HCS requires in Section 1 of the SDS must be United States domestic.

III. Section 2: Hazard(s) identification.

In Section 2, Hazard(s) identification, OSHA proposed to clarify where and how chemical hazard information should be presented. First, OSHA proposed to clarify that Section 2 (a) must include any hazards associated with a change in the chemical’s physical form under normal conditions of use. OSHA also proposed a new Section 2 (c) to clarify that hazards identified under normal conditions of use that result from a chemical reaction (changing the chemical structure of the original substance or mixture) needed to be included. To accommodate the new proposed Section 2 (c), OSHA proposed to move existing Section 2 (c) and (d) to Section 2 (d) and (e).

As OSHA noted in the NPRM, the proposed revisions to Section 2 would require 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, to be presented in Section 2 (a), and new hazards created by a chemical reaction under normal conditions of use to be presented in Section 2 (c). OSHA believed this would sufficiently differentiate

the different types of hazards presented under normal conditions of use. OSHA sought stakeholder comments on this issue.

After reviewing stakeholders' comments pertaining to proposed changes in paragraph (d)(1), OSHA made significant changes to proposed paragraph (d) and made related changes to proposed Appendix D requirements for Table D.1 Section 2 of the SDS. As previously described in the Summary and Explanation for paragraph (d)(1), OSHA removed the terms "under normal conditions of use and foreseeable emergencies" from paragraph (d)(1). In the final rule, paragraph (d)(1) has two subparagraphs, indicating that hazard classification must include hazards associated with the chemical's intrinsic properties including: (i) a change in the chemical's physical form and; (ii) chemical reaction products associated with known or reasonably anticipated uses or applications.

To align with these changes to paragraph (d)(1), in Section 2 (a), OSHA replaced its original proposed language with "in accordance with paragraph (d)(1)(i) of § 1910.1200." OSHA also removed the proposed language from Section 2 (c) and replaced it with "Hazards classified under paragraph (d)(1)(ii) of § 1910.1200." The new language in these two paragraphs clarifies OSHA's intentions and fully aligns Appendix D with paragraph (d)(1) so that there is no conflict between those two sections that would create confusion. Further discussion of the scope of these requirements and comments regarding these changes that were not specific to the language in Section 2 can be found in the Summary and Explanation for paragraph (d).

OSHA received several comments specific to the proposed changes to Section 2 of Table D.1. NIOSH and Ameren supported the proposed changes (Document ID 0281, Att. 2, p. 6; 0309, p. 13). ACC commented that the proposed change to paragraph (d)(1) used the words "hazard classification shall include...", but the original proposed Section 2 (c) in Table D.1 only said "Hazards identified under normal conditions of use....",

without referring to classification. ACC found the proposed language unclear as to whether manufacturers and importers need to classify for reaction hazards, or just mention them in Section 2 of the SDS (Document ID 0347, p. 21). As noted above, OSHA is changing Section 2 (c) to begin with “Hazards *classified* under paragraph (d)(1)(ii)...” (emphasis added) to clarify this issue and better align Section 2 with paragraph (d)(1).

An anonymous commenter asked whether hazardous substances formed by chemical reactions under normal conditions of use must be disclosed in Section 3 and/or Section 8 of the SDS (Document ID 0267). For situations where hazardous substances form during use but the substance is not present in its hazardous state in the mixture as shipped, manufacturers are not required to provide this information in Sections 3 or 8 because the resulting hazardous substance is not an ingredient or constituent. However, as discussed in a 2016 LOI, OSHA expects manufacturers to include information on substances formed by chemical reactions in Sections 2 and 10 (available at <https://www.osha.gov/laws-regs/standardinterpretations/2016-05-20>). OSHA notes that this requires the inclusion of occupational exposure limits, including PELs and TLVs, under Section 10 (d): Conditions to Avoid.

The High Temperature Industrial Wool Coalition (HTIW) urged OSHA to allow hazards from a downstream chemical reaction to be addressed in Section 16 of the SDS, rather than Section 2, in cases “where the nature of the hazard is unclear, and the potential [hazard] is extremely limited” (Document ID 0330, p. 3). By way of example, HTIW explained that glassy refractory ceramic fibers (RCF) do not contain crystalline silica, but that depending on the duration and temperature of exposure, fiber chemistry, and/or the presence of fluxing agents or furnace contaminants, devitrifying RCF may form crystalline silica dust in amounts which HTIW said were usually undetectable in the furnace conditions. HTIW stated that they believe the evidence is not sufficient to list

RCF as a hazard in Section 2 of the SDS. They noted that “the possibility of hazard is discussed in Section 16, which addresses other potential issues” and opined that in this case, inclusion of after-service RCF in Section 2 of the SDS would “overemphasize the potential hazard, potentially fostering misunderstanding of the issue and leading to unnecessary or inappropriate workplace ‘corrective’ actions” (Document ID 0330, pp. 3-5).

OSHA disagrees with HTIW’s suggestion and with its conclusion that the hazard presented by RCF should be excluded from Section 2 because, as HTIW explained in its example, RCF may form crystalline silica dust in the process. Section 2 requirements are set to address these very types of situations. Manufacturers must provide additional information on toxicity, if known, in Section 11, and may provide additional information in Section 16. However, any hazard information must be included in Section 2. Classification is based on the intrinsic properties of the chemical, not the anticipated level of exposure in the workplace, except in cases where the chemical is bound in such a way as to be incapable of resulting in exposure (see OSHA, Feb. 10, 2015, Letter of Interpretation, available at <https://www.osha.gov/laws-regs/standardinterpretations/2015-02-10-0>). OSHA, therefore, does not agree that hazards from downstream chemical reactions may be addressed solely in Section 16 under the circumstances described by HTIW.

Finally, OSHA received a question pertaining to Section 2 (e), which addresses requirements for stating the percentage of ingredients of unknown toxicity in a mixture. The anonymous commenter noted that Appendix A paragraph A.1.3.6.2.3, Appendix C paragraph C.3.3, and Appendix D of the proposed standard require a statement of the concentration of ingredients of unknown acute toxicity to appear in Section 2 of the SDS and on the label. They asked, in the case of a mixture for which the exact concentration(s) of hazardous component(s) are withheld as trade secrets and are reported as prescribed

concentration range(s) in Section 3 of the SDS, in accordance with proposed paragraph (i)(1)(iv), whether it would be permissible to report the percentage of ingredient(s) of unknown acute toxicity as a range corresponding to one of the prescribed ranges in Section 2 of the SDS, or whether the exact percentage of those ingredients must be reported (Document ID 0266).

Manufacturers are required to state the exact percentage of a mixture that is composed of ingredients of unknown acute toxicity if the concentration of at least one such ingredient is $\geq$ one percent and the mixture is not classified based on testing of the mixture as a whole. In this case, manufacturers are not required to report the individual concentrations of ingredients with unknown toxicity in Section 2, but rather the total percentage of unknown toxicity, which may include multiple chemicals. They may not use the prescribed ranges included in paragraph (i) for the purpose of reporting the concentration of unknown acute toxicity. To the extent that this presents concerns for CBI due to a single chemical having unknown toxicity, OSHA notes that SDS preparers still have the option to withhold the name of that chemical.

Based on the comments received, OSHA is finalizing different language from its proposal in Section 2, as described above, to more accurately convey its intent and align the text of Section 2 with the revised regulatory text of paragraph (d)(1).

IV. Section 3: Composition/Information on Ingredients.

Section 3 of the SDS contains information on the composition of the chemical and its ingredients, with specific requirements for substances and mixtures, as well as for chemicals where a trade secret is claimed. In the NPRM, OSHA proposed several changes to this section. Under the subheading *For Substances* OSHA proposed to add “(constituents)” to paragraph (d) to clarify the term “additives.” The intention of this proposal was to clarify 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 received

no comments objecting to the addition of “(constituents)” in Section 3 and is therefore finalizing it as proposed.

OSHA also proposed to revise the information required for mixtures. Section 3 requires, among other things, the chemical name of each ingredient in a mixture that is classified as a health hazard. OSHA proposed requiring the inclusion of the CAS number or other unique identifier for these ingredients. As noted in the NPRM, CAS numbers are unique numerical identifiers assigned by the American Chemical Society (ACS), internationally recognized as being reliable and readily validated; unique to only one compound, substance or chemical; and a common link between various nomenclatures that may be used as descriptors for a substance or compound (86 FR 9722). OSHA believes that the proposed requirement would provide the downstream user with important information, since it provides a unique descriptor of the chemical, whereas the chemical identity may be ambiguous.

PLASTICS and API supported the proposed requirement to include the CAS number or other unique identifier for ingredients in mixtures (Document ID 0314, p. 21; 0316, p. 28). ICT commented that CAS numbers are not assigned to all chemicals and accession numbers exist only for substances on the confidential TSCA inventory and therefore identifying numbers may not be available for all chemicals which SDS preparers are required to disclose in Section 3. ICT suggested that OSHA should allow manufacturers to use “not available” for those chemicals without identifying numbers (Document ID 0324, p. 6).

OSHA recognizes that a CAS number may not be available for all chemicals. OSHA notes, however, that the proposal required manufacturers to provide CAS *or other* unique identifier numbers for hazardous ingredients. While OSHA intends that CAS numbers be provided when available, in cases where a CAS number is not available or is protected as CBI, another unique identifier must be provided. For example, an

identification number used internally by the manufacturer (e.g., product number) can be used to identify the ingredient upon request in emergency and non-emergency situations. Accordingly, OSHA disagrees with ICT's concern that SDS preparers will be unable to provide an appropriate unique identifier.

However, ICT's comment does raise the concern that in choosing an identifier, an SDS preparer might select one for which the source is not readily apparent. Certain product numbers or other identifiers used internally by the manufacturer may be of little use when placed on the SDS without context. Though OSHA proposed to permit the use of "other unique identifiers" for mixtures in Section 3 of the SDS, the agency wishes to clarify that it would only consider such a number to be an adequate identifier if it can actually be used by downstream recipients of the SDS to identify the chemical. Accordingly, OSHA has added a requirement in the final rule that, where a preparer of an SDS uses a unique identifier other than a CAS number, they must include the source of that unique identifier. This will ensure that any unique identifier functions as such for recipients of the SDS. OSHA is finalizing this language with the changes described above.

OSHA also proposed a set of changes in Section 3 to reflect the proposed revision to paragraph (i), Trade secrets, which would allow companies to withhold concentration ranges as a trade secret. Under the proposed language in Section 3, when a company withholds the concentration or concentration range as a trade secret, it must provide a chemical concentration range in accordance with the prescribed concentration ranges in paragraph (i)(1)(iv).

OSHA received a variety of comments about the proposed revisions to paragraph (i), which the agency addressed in the Summary and Explanation for paragraph (i). Ameren supported the proposed changes to Section 3 of the SDS, stating that the changes could allow downstream manufacturers to more accurately classify their products where

the mixture in question is one of their ingredients (Document ID 0309, p. 13). Toby Threet commented that the language in this section on trade secrets needed clarification. First, Threet noted that the word “or” in the phrase “...the specific chemical identity, exact percentage (concentration), or concentration range of composition has been withheld as a trade secret is required...” could imply that a trade secret may be claimed for only one of these three categories. Threet suggested that it is possible that both the specific chemical identity and either the exact concentration or the concentration range may need to be withheld and therefore an “and/or” should be inserted in an appropriate location in the sentence (Document ID 0279, p. 24).

Toby Threet also commented that in the proposed language, the word “composition” normally refers to or includes chemical identities but in the proposed text, the word is used twice to refer to the concentration. Threet suggested that this could cause confusion and SDS preparers may believe that when the concentration of chemical is withheld, the chemical identity must be disclosed. Further, Threet suggested that the proposed language implied that an SDS could merely acknowledge that something was withheld as a trade secret but not specify which category of information was withheld, and recommended that OSHA add “as appropriate” to clarify (Document ID 0279, pp. 24-25).

ICBA commented that the proposed language, which states the chemical composition must be provided in accordance with the prescribed concentration ranges, did not align with the language in paragraph (i)(1)(iv), which requires that the concentration must be provided in accordance with the prescribed ranges. ICBA expressed concern that requiring the chemical composition as part of the concentration ranges could reveal industry trade secrets, and requested that OSHA change the language in Appendix D to reflect the same requirement as paragraph (i)(1)(iv) (Document ID 0291, pp. 4-5). Michele Sullivan asked OSHA to clarify that both the specific chemical

identity and the percentage concentration or concentration range can be claimed as trade secrets at the same time (Document ID 0366, p. 9).

After reviewing comments from stakeholders, OSHA is modifying the proposed text under *For All Chemicals Where a Trade Secret is Claimed* in Section 3 of Table D.1. OSHA is adding “and/or” to the first sentence and modifying the language about concentrations to read “When a trade secret is claimed in accordance with paragraph (i) of § 1900.1200, a statement that the specific chemical identity, and/or concentration (exact or range) of the composition has been withheld as a trade secret is required.” This should clarify that manufacturers can claim the chemical identity and the concentration (exact or range) as trade secrets at the same time or can claim any subset of these as a trade secret. OSHA also agrees with the comments regarding the use of the term “composition” in the second sentence and has accordingly reworded to clarify that when the concentration or concentration range is withheld as a trade secret, the HCS requires SDS preparers to use the prescribed concentration ranges in § 1910.1200(f)(1)(iv)-(vi) in Section 3. OSHA is not, however, adding “as appropriate” to the first sentence because the proposed language already makes clear that the SDS must include a statement about which information is withheld as a trade secret. OSHA is finalizing this version of the language regarding trade secrets in Section 3.

In addition, as described in the NPRM, the HCS requires Section 3 of the SDS to include the chemical name and concentration (exact percentage or ranges) of all ingredients which are classified as “health hazards” in accordance with paragraph (d). OSHA did not propose changes to this requirement but requested comments on whether the requirement should be expanded to also include chemicals classified as physical hazards and HNOCs. In particular, OSHA asked whether expanding the requirements for Section 3 in this way would ensure that both users and manufacturers fully understand any potential hazard when handling the chemical and whether such a change would result

in the provision of additional information that would allow downstream manufacturers to more accurately classify their products where a mixture with an ingredient that presents a physical hazard or HNOC is one of their ingredients (86 FR 9689).

NIOSH supported expanding Section 3's requirements to all classified chemicals for its potential to improve worker safety (Document ID 0281, Att. 2, p. 6; 0423, Tr. 24). Similarly, John Baker supported the change, noting it would be beneficial particularly because of the potential for some nanoscale materials to form combustible dusts (Document ID 0302). NABTU also stated that OSHA should expand the requirements and that doing so would provide construction workers and their employers with more complete information on all exposure hazards. NABTU commented that "specifying physical hazards will also require more careful examination of potentially deleterious effects to workers beyond health effects" and noted that construction workers would benefit from additional information about a variety of hazards, such as aerosols, flammable gases and liquids, and HNOCs. NABTU also expressed the belief that the HNOC classification would be used infrequently (Document ID 0334, pp. 2-3; 0425, Tr. 23).

Several commenters opposed expanding the requirements of Section 3 to include ingredients classified as presenting physical hazards or HNOCs (see, e.g., Document ID 0293; 0316, pp. 28-29; 0327, p. 7; 0345, p. 6; 0346, pp. 2-3; 0347, pp. 22-23; 0359, p. 6; 0361, p. 3; 0366, p. 9). Several commenters stated that because the physical hazards of a mixture as a whole cannot be determined based on the physical properties of its ingredients, this requirement would only add complexity to the SDS without increasing worker protection, and could make it harder for workers to find relevant information (Document ID 0293; 0327, p. 7; 0329, p. 9; 0345, p. 6; 0346, pp. 2-3; 0347, pp. 22-23; 0359, p. 6; 0366, p. 9).

Givaudan, Dow, ACC, and Michele Sullivan recommended against expanding Section 3's requirements because it would be inconsistent with the GHS and requirements of other U.S. trade partners (Document ID 0293; 0347, p. 22; 0359, p. 6; 0366, p. 9). Dow noted that doing so could put the United States at a competitive disadvantage since some of these components may be considered intellectual property (Document ID 0359, p. 6). The Flavor and Extract Manufacturers Association, HCPA, NACD, and ADM also stated that expanding the Section 3 requirements would not provide any additional helpful information regarding safe handling of chemicals because other sections of the SDS provide that information (Document ID 0327, p. 7; 0329, p. 9; 0346, pp. 2-3; 0347, pp. 22-23; 0361, p. 3). NAIMA opposed expanding Section 3 requirements, noting that doing so would impose significant burdens (Document ID 0338, p. 10). OSHA appreciates stakeholders' response to its request for comments. OSHA will consider these comments in determining whether Section 3's requirements should be expanded in a future update.

OSHA received one comment from an anonymous commenter about inaccurate information presented in Section 3 of SDSs. The commenter provided examples of inaccurate information such as SDSs listing chemical composition as "100% fertilizer" or "mixture," and not providing accurate nutrient percentages (Document ID 0308). Although this comment is beyond the scope of this rulemaking because it does not relate to OSHA's proposed updates to the HCS, OSHA notes that many of the changes in this final rule are intended to clarify the requirements of the HCS for SDS preparers, in order to improve the accuracy of SDSs.

OSHA received a request from PRINTING regarding the existing requirement to list impurities and stabilizing additives. PRINTING requested guidance stating that downstream manufacturers may continue to rely on information provided by their upstream suppliers. (Document ID 0357, p. 3; 0423, Tr. 184-185). OSHA agrees that its

modifications to paragraph (d) and Appendix D, Table D.1 Section 3 have not altered the ability of downstream manufacturers to rely on information from upstream suppliers.

V. Section 8: Exposure controls/personal protection.

Section 8 of the SDS includes information on exposure controls and personal protection. Section 8 (a) requires the SDS to include the OSHA PEL, the ACGIH TLV, and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the SDS, when available. OSHA proposed to revise Section 8 (a) to clarify that this requirement applies to all ingredients or constituents listed in Section 3 regardless of the concentration at which they are present in a mixture. As OSHA noted in the NPRM, however, if the ingredient or constituent does not have an OSHA PEL, ACGIH TLV, or any other exposure limit or range used or recommended by the SDS preparer, then the ingredient or constituent would not need to be listed in Section 8.

Several commenters supported this proposed revision to Section 8 (a) (Document ID 0313, p. 8; 0316, p. 29; 0338, pp. 8-9). Specifically, NAIMA strongly supported the proposed revision and pointed out that sharing information about PELs and TLVs with users communicates a clear message about appropriate protections and supports intelligent and informed choice on the use of respiratory protection (Document ID 0338, pp. 8-9).

The American Pyrotechnics Association (APA) described the proposal as “adding known permissible exposure limits (PELs) and Threshold Limit Values (TLVs) for every ingredient or constituent listed in Section 3 of the SDS...” and argued that PELs and TLVs are irrelevant for finished pyrotechnic products because (1) these products are designed to combust and are consumed by the reaction before any personal exposure can occur and (2) if the products broke open in the workplace workers would not be exposed to the chemicals themselves. APA added that they “believe this is also applicable to

numerous mixtures and compositions wherein the hazardous substances do not segregate nor return to their separate ingredients after being bound together chemically and/or physically” and that including numerous PELs and TLVs would lengthen the SDS. They requested that OSHA revisit this proposal (Document ID 0337, p. 4).

APA’s comment that OSHA has “proposed adding” known PELs and TLVs for every ingredient or constituent misconstrues the nature of OSHA’s proposal. Following the publication of the 2012 HCS, the agency received requests to clarify how an ingredient’s concentration and role in hazard classification relate to Section 8 requirements and requirements to list the ingredients in Section 3 and, as discussed in the NPRM (86 FR 9722), OSHA has issued LOIs clarifying that the required exposure limits must be provided for any ingredient or constituent identified in Section 3 of the SDS (see, e.g., Document ID 0088). OSHA’s proposal in this rulemaking thus does not change any existing requirements; it simply clarifies which ingredients Section 8 (a) applies to.

In addition, OSHA is not persuaded by APA’s argument that the consumption of chemicals contained in pyrotechnic products during their use precludes occupational exposure to those chemicals. APA provided no evidence demonstrating that the consumption of chemical components during use of pyrotechnics results in no exposures to individuals in the vicinity. Furthermore, APA’s comment specifically references circumstances where workers can experience exposure to hazardous chemical components of pyrotechnic products: such products can rupture in the workplace and workers must clean up the spilled materials resulting from such accidents. For the reasons discussed above, OSHA declines APA’s request to reconsider the application of Section 8 (a)’s requirements to individual ingredients of chemical mixtures.

Therefore, after reviewing the comments received on the inclusion of the proposed language in Section 8 (a) to clarify that this requirement applies to all

ingredients or constituents listed in Section 3 regardless of the concentration, OSHA is finalizing the requirement as proposed.

OSHA also proposed to add a new requirement for SDS preparers to include a range of exposure limits in Section 8 whenever a range is used or recommended by the chemical manufacturer, importer, or employer preparing the SDS. As explained in the NPRM, OSHA proposed this requirement due to the availability of new tools, such as occupational exposure banding or hazard banding methods, that provide a concentration range (band) based on toxicity and hazard information associated with a known chemical with similar properties. This range can help inform appropriate risk management decisions where a specific occupational exposure limit (OEL) or PEL is not available or is out of date (86 FR 9722).

NIOSH, NABTU, and John Baker supported the proposed revision (Document ID 0281, Att. 2, p. 6; 0302; 0334, p. 3; 0425, Tr. 23-24). NABTU stated that, since quantitative and health-based occupational exposure limits are only available for a small number of chemicals, the inclusion of a range of exposure limits such as occupational exposure banding improves hazard communication and safeguards workers. NABTU added that exposure banding would move OSHA closer to the precautionary principle embodied in the EU's REACH regulations that is intended to protect workers when uncertainty exists about chemical hazards (Document ID 0334, p. 3; 0425, Tr. 23-24).

John Baker recommended that the SDS should include a hyperlink or other instructions on where the user can find supporting documentation regarding how the range was established. Baker gave the example of ranges established for nanomaterials, stating that these may be highly dependent on parameters selected for the banding analysis (Document ID 0302). OSHA agrees that supporting documentation can provide valuable information about exposure ranges. However, based on the format of and preparation process for SDSs the agency does not believe it is practical to require

inclusion of this information. Maintaining accurate and up-to-date hyperlinks and/or instructions on where to locate appropriate contextual information can be burdensome for SDS preparers, and employees who only have access to paper copies of SDSs would not be able to use hyperlinks or similar instructions to find supporting documentation. OSHA also notes that SDS preparers may provide information on supporting documentation to users in Section 16 of the SDS. OSHA is therefore not mandating inclusion of a hyperlink or instructions for locating supporting information on how the range was established.

OSHA received no comments objecting to the proposed requirement for SDS preparers to include a range of exposure limits whenever a range is used or recommended by the chemical manufacturer, importer, or employer preparing the SDS, and is finalizing the requirement as proposed.

Several commenters did not oppose the proposed revisions but suggested additional changes to the section. NIOSH recommended adding the NIOSH Recommended Exposure Limit (REL) to the list of relevant exposure limits, noting NIOSH is the only organization that offers OELs in some cases, such as engineered nanomaterials (Document ID 0281, Att. 2, p. 6; 0423, Tr. 24). NABTU similarly stated that, because few occupational exposure limits for engineered nanomaterials have been established, NIOSH RELs should be required on SDSs to convey the most accurate and appropriate hazard information for engineered nanomaterials (Document ID 0464, p. 7). Cal/HESIS also recommended adding the NIOSH REL to the list of occupational exposure limits, as well as California's Risk Management Limit for Carcinogens (RML-CA). Cal/HESIS further recommended requiring state- or territory-specific PELs (such as Cal/OSHA PELs) to be listed for substances that lack federal occupational exposure limits and are sold in a particular state with an OSHA-approved State Plan. Cal/HESIS reasoned that SDSs should advise employers and workers that an exposure limit has been established by a specific state or other non-regulatory organization for a substance, even

if a PEL is not established by federal OSHA. Cal/HESIS provided supporting information from its review of SDSs for products sold in California that contained 1-bromopropane, a carcinogen that lacks a federal OSHA PEL, and the agency found that 80 percent of SDSs did not include the Cal/OSHA PEL for 1-bromopropane. Therefore, Cal/HESIS concluded, California users of these SDSs could erroneously conclude California does not regulate 1-bromopropane (Document ID 0313, p. 8).

ICT suggested that OSHA should add a provision from Section G.5.d of OSHA's compliance directive (Document ID 0007), which allows chemical manufacturers and importers to state "The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits" in Section 8 of the SDS (Document ID 0066, p. 66). ICT requested that OSHA modify Section 8 to codify this language, noting that Section 3 of the SDS often contains substances that do not have established OELs (Document ID 0324, pp. 6-7).

OSHA agrees with those commenters who stated that the NIOSH REL and state-specific limits can provide important information to chemical users; however, the suggested changes are out of scope for this rulemaking. While OSHA did propose to add "or range" to Section 8, indicating a broader scope of what needs to be listed, it did not propose to add RELs or otherwise modify the information required regarding OELs. Adding these limits as requirements would be a substantive change to the content of an SDS. Because OSHA did not indicate in the proposal that it was considering such a change, the agency believes stakeholders lacked sufficient notice for OSHA to adopt the commenters' suggestions in this final rule. The agency notes, however, that Section 8 (a) may include any exposure limit or range used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available.

With regard to ICT's request to add language from OSHA's directive, OSHA notes that ICT did not provide any justification for why adding this language to the HCS text of Appendix D would be useful and OSHA has not received any other comments suggesting that there is ambiguity about the fact that employers are allowed to add that statement. To the extent that ICT is requesting that OSHA mandate the inclusion of that statement about no other known exposure limits on SDSs, OSHA did not propose such a change and the agency considers such a suggestion outside the scope of this rulemaking.

ACC submitted a comment requesting that OSHA remove the requirement to list OELs developed by voluntary standards organizations such as ACGIH TLVs. ACC suggested that OSHA should only require the listing of OELs that have been developed through a federal rulemaking process because those limits have been determined to be feasible. ACC argued that the requirement to include OELs developed by voluntary standards organizations creates the erroneous impression that they carry the same regulatory weight as OSHA PELs (Document ID 0347, p. 24).

Inclusion of the TLVs and other OELs on the SDS has been a requirement since 1983 (48 FR 53280, 53343). During the rulemaking process for the 2012 HCS, OSHA received comments similar to ACC's; the agency explained and reaffirmed its longstanding position that TLVs and other OELs provide useful information and should continue to be included (77 FR 17573, 17731-34). OSHA continues to affirm this position. Regardless, this comment is out of scope because the agency did not propose a change to this requirement.

OSHA also received one comment regarding Section 8 (c), which the agency did not propose to change in the NPRM. Monica Hale commented that OSHA should add a requirement for manufacturers to list the specific types of required PPE in Section 8 based on the "actual hazard" and should not be permitted to include generic statements such as "use appropriate glove" or "use appropriate NIOSH Approved Respirator"

(Document ID 0286). Because OSHA did not propose to change Section 8(c), this comment is out of scope for this rulemaking and the agency has not added the suggested language. Several other commenters raised similar concerns with regard to the language about PPE required on labels in Appendix C, and this issue is discussed in more depth in the Summary and Explanation of Appendix C.

In conclusion, for the reasons discussed above, OSHA is finalizing all changes as proposed in Section 8 of the SDS.

VI. Section 9: Physical and chemical properties.

OSHA proposed several updates to Section 9, Physical and chemical properties. OSHA proposed to revise the text of Section 9 to align with Rev. 7 by listing the required physical and chemical properties of the chemical in the same order that appears in Annex 4 of the GHS (Document ID 0060, p. 38). OSHA reasoned that this change would simplify the preparation of SDSs for chemical manufacturers who prepare them for global distribution. Similarly, OSHA also proposed aligning Section 9 with Rev. 7 by 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” 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 for solids. OSHA stated in the NPRM that particle characteristics only apply to solids and should include the particle size (median and range) and, if available and appropriate, further properties such as size distribution (range), shape, aspect ratio, and specific surface area (86 FR 9723).

OSHA received several comments on these proposed changes. API requested clarification on whether the physical and chemical properties must be ordered on the SDS in the same sequence that OSHA proposed to list them in the text of Appendix D (Document ID 0316, pp. 29-30). NACD expressed concern that individuals who read

SDSs and labels would need to adjust to a re-ordered list of physical and chemical properties and that making this change would not enhance safety (Document ID 0329, p. 9).

As OSHA explained in the NPRM, the proposal to list the required physical and chemical properties of the chemical in the same order that appears in the GHS applies to the order in which they appear in the text of the HCS, not to the order in which they appear on the SDS. SDS preparers are not required to list the physical and chemical properties in any particular order (86 FR 9722-9723). This also means that the order of the physical and chemical properties on the SDSs would not need to change and therefore individuals who use SDSs would not need to adjust or relearn anything about where the information is located.

NIOSH recommended that information on odor threshold be retained on the SDS because detection of odor can be usefully combined with other information on toxic potency, for example, in cases where an odor threshold concentration can be compared to health-based ambient criteria (Document ID 0281, Att. 2, p. 7). Cal/OSHA commented that since odor threshold can be an important way to “roughly” assess the risk level, it should be provided for all chemicals. Cal/OSHA recommended retaining the odor threshold along with a statement regarding olfactory fatigue (Document ID 0322, Att. 2, p. 13). NIOSH and Cal/HESIS commented that, since the evaporation rate can be important for assessing the risk from material spills, it should be retained on the SDS (Document ID 0281, Att. 2, p. 7; 0423, Tr. 24-25; 0313, p. 9).

OSHA did not intend to eliminate the requirement to state the odor threshold on the SDS. The agency proposed to remove “Odor threshold” as a separate property from Section 9 in order to align with Rev. 7, which does not require an “Odor threshold” property in Section 9. However, Annex 4 of Rev. 7 states that a substance’s odor property should indicate the odor threshold, if available (Document ID 0060, p. 387). OSHA’s

intent was to align with Rev. 7 by eliminating “odor threshold” from the list of properties but maintaining the requirement to report it by requiring it under the existing odor property already in Section 9. To prevent any future confusion, OSHA is adding a parenthetical stating “includes odor threshold” in Section 9 (c) Odor, thus indicating that SDSs preparers need to specify odor threshold for the substance, if available. OSHA is declining the recommendation to require a statement regarding olfactory fatigue since this recommendation does not align with Rev. 7 and Section 9 information requirements are limited to physical and chemical properties. However, OSHA notes that manufacturers may elect to include a statement regarding olfactory fatigue.

With regard to evaporation rate, OSHA did propose to remove it from the list of properties in Section 9 to align with Rev. 7. The UNSCEGHS agreed to remove “evaporation rate” during revision of the GHS Annex 4 on the basis that it “is effectively covered by the vapour pressure, and all aspects that are important with regard to occupational safety and the risk of exposure can be dealt with based on the vapour pressure and the saturated vapour concentration” (Document ID 0129, p. 3). However, OSHA agrees with the point made by NIOSH and Cal/HESIS that “Evaporation rate” is important to include in Section 9, as ready access to this information may be needed to evaluate the health and fire hazard qualities of chemicals and other substances in emergency situations. OSHA is therefore adding a parenthesis stating “includes evaporation rate” in Section 9 (o), *Vapor pressure*.

NIOSH, Cal/HESIS, NABTU and John Baker supported the addition of “particle characteristics” as a new physical property in Section 9 (Document ID 0281, p. 7; 0313, pp. 8-9; 0302; 0423, Tr. 24; 0425, Tr. 24; 0464, p. 7). Cal/HESIS recommended that the proposed text should be revised to specifically include particle size distribution as a required type of particle characteristic, noting that particle size is an important determinant of particle behavior in air and how the inhaled particles are deposited in the

respiratory system (Document ID 0313, pp. 8-9). NIOSH stated that “particle characteristics are critical determinants of the toxicity of inhaled particles” and provided suggested particle characteristics with standardized methods (Document ID 0456, Att. 2, p. 3). NIOSH suggested that surface reactivity and density are also important determinants of the toxicity of particles, and suggested standardized test methods for those measurements (Document ID 0456, Att. 2, p. 3). In addition, NIOSH stated that over the last 20 years particle characteristics have become critical in terms of their hazard potential and the kinds of control approaches that are needed, particularly with the advancement of commercial nanotechnology (Document ID 0423, Tr. 40-41). NABTU concurred with NIOSH’s assertion and pointed out that manufacturers are utilizing nanoparticles (or engineered nanomaterials) increasingly in numerous industry sectors, but not necessarily including information about nanoparticles in SDSs, and there is a clear need to improve hazard communication concerning particle size and other particle characteristics in order to understand the associated hazards to construction workers (Document ID 0425, Tr. 24; 0464, p. 7).

OSHA agrees that particle size distribution can be an important indicator of the potential for a solid particle to pose a hazard; as discussed in the NPRM, particles that are less than 100 microns increase the likelihood of exposure, especially through the route of inhalation (86 FR 9723; Document ID 0060, p. 117; 0129). OSHA also agrees with NIOSH regarding surface reactivity and density; if information on these characteristics is available, it should be included in the SDS. OSHA is not, however, including a list of particle characteristics that must be included because not all of this information is available for all chemicals covered by this provision. Additionally, because the HCS does not require testing, OSHA is not requiring testing for particle characteristics as NIOSH suggested, but notes that manufacturers must include these measurements, if available.

John Baker argued that the proposed requirement to provide particle characteristics to Section 9 of the SDS should not be restricted to solids because liquids containing nanoparticles could pose a hazard particularly if there is a change in physical form (Document ID 0302).

OSHA recognizes that solid nanoparticles in liquid can pose a hazard, especially when the liquid is aerosolized and the nanoparticles become airborne. In the NPRM, when OSHA stated that “particle characteristics apply to solids only...,” it intended to include nanoparticles in its meaning of solid (86 FR 9723). Nanoparticles in a liquid are themselves in a solid form, and therefore SDS preparers are required to list characteristics of those nanoparticles in Section 9.

Some commenters expressed confusion over the addition of “particle characteristics.” ICBA and PLASTICS asked for clarification about what data OSHA is seeking to capture by adding this term to Section 9 (Document ID 0291, p. 5; 0314, p. 21). As noted above, OSHA included in the NPRM a list of particle characteristics it intended for SDS preparers to provide, when available, and agrees with NIOSH that surface reactivity and density are also relevant particle characteristics that should be included.

NAIMA opposed the addition of “particle characteristics” as a new physical property in Section 9, including the proposed requirements to include median and range of particle size, size distribution, aspect ratio, and specific surface area. According to NAIMA, these particle characteristics are highly sensitive to certain production characteristics, and it would be hard to address attrition that might occur during application (Document ID 0338, p. 8).

In response to NAIMA’s comment, OSHA notes that the requirement pertaining to particle characteristics is limited to cases where a substance’s particle characteristics are available and appropriate. If particle characteristics are not known, OSHA does not

expect importers or manufacturers to perform testing to determine particle characteristics, consistent with the fact that the HCS does not require testing. However, the agency notes that many manufacturers already have this information available since this is an important commercial attribute provided to customers. Additionally, OSHA would not expect the SDS preparer to include the particle characteristics following attrition that could occur during downstream processing since, as NAIMA pointed out, this would be difficult to predict for all situations.

For the reasons discussed above, OSHA is finalizing the proposed revisions with clarifying additions in Section 9 (c) and (o).

VII. Footnote in Sections 7 and 9.

OSHA requested comments on whether it should add a footnote to Section 9 that is similar to the footnote the agency proposed to add to Appendix B.6.3. This footnote would explain that to determine the appropriate storage container size and type, the boiling point for a flammable liquid must be determined by paragraph (a)(5) of OSHA's Flammable Liquids standard (29 CFR 1910.106(a)(5)), which allows for an alternate method to determine the boiling point under certain circumstances. If a manufacturer uses the alternative method to determine the boiling point for storage purposes, they must note that on the SDS in Sections 7 and 9 if the classification for storage differs from the classification listed in Section 2 of the SDS.

ACC objected to the proposed note, including the requirements pertaining to Sections 7 and 9 of the SDS, because they believe that it would not provide any additional worker protection. ACC further asked OSHA to clarify why this provision was proposed, noting that it is not in the GHS Rev. 7 or 8 (Document ID 0347, p. 23). OSHA addressed ACC's comments, along with other comments specifically on the footnote in B.6.3, in the Summary and Explanation for Appendix B and finalized the footnote, with modifications for clarity.

OSHA received one comment specifically on the addition of the footnote to Appendix D, from Ameren, which agreed that it would be appropriate to add a footnote like the one proposed for B.6.3 to Appendix D for Section 9 (Document ID 0309, p. 17). OSHA agrees that a similar footnote should be included in Appendix D since Appendix D, Table D.1 lists what must be included in the SDS, and the footnote requires that in some cases this additional information is added to the SDS. However, OSHA has concluded that the footnote should be referenced in both Section 7 and Section 9, since it refers to information in both SDS sections. Adding the footnote, as modified, will ensure that if the storage recommendations appear to be in conflict with classification for flammable liquids in section 2 of the SDS, the preparer will appropriately mark the SDS in both Section 7 and Section 9 so the downstream user knows that the recommendations for storage of flammable liquids are correct. While OSHA believes this will be a rare occurrence, the addition of the use of the alternative method for boiling point ensures that the accuracy of the SDS is not in doubt. Therefore, OSHA is adding the footnote, as modified for B.6.3, in Appendix D.

VIII. Section 10: Stability and reactivity.

Section 10 of the SDS, Stability and reactivity, includes the requirement in Section 10 (c) that preparers include information about the possibility of hazardous reactions. In the NPRM, OSHA proposed to clarify that this includes hazardous reactions associated with foreseeable emergencies.

OSHA received several comments expressing concerns about the proposed requirement. These arguments largely mirror the arguments raised regarding paragraph (d). For instance, commenters raised concerns about the feasibility of preparing comprehensive hazard classifications for every possible use of a product (Document ID 0277, p. 3); the vagueness and breadth of the language proposed (Document ID 0347, pp. 25-26); the difficulty of obtaining continuous information from downstream users

(Document ID 0348, p. 2); and the likelihood of over-warnings to avoid risk of regulatory citations and confusion about what hazards are associated with a chemical substance (Document ID 0356, pp. 9-10). These arguments and others are discussed further in the Summary and Explanation for paragraph (d).

Several commenters also suggested changes to the proposed text. Tom Murphy suggested that Section 10 (c) should be limited to universal conditions applicable to anyone in possession of the chemical product (Document ID 0277, p. 3). ACC suggested adding the phrase “for directed uses” (Document ID 0347, pp. 25-26). The Vinyl Institute suggested removing the proposed text from Section 10 of Table D.1 for the same reason they opposed the proposed revisions to paragraph (d) (Document ID 0369, Att. 2, p. 8) (see the Summary and Explanation of paragraph (d)).

The proposed change in Section 10 (c) was consistent with the language OSHA proposed for paragraph (d)(1). OSHA proposed to add “including those associated with foreseeable emergencies” in Section 10 (c) to clarify that possible hazardous reactions also include hazardous reactions which may occur during foreseeable emergencies and to be consistent with the proposed revision to paragraph (d)(1). While the version of paragraph (d)(1) that OSHA is finalizing no longer aligns with the proposed change in 10 (c), OSHA still believes this clarification is warranted to ensure that downstream users are aware of potential hazardous reactions associated with foreseeable emergencies. OSHA is not convinced that this would be a heavy burden since it is not tied to the classification process but a general warning of when a hazardous situation can occur. Therefore, adding the phrase “for directed use” as ACC suggests would not capture the intent of this requirement. This revision is also consistent with the GHS which indicates that the SDS preparer should describe the conditions in which the hazardous reaction could occur (Document ID 0060, p. 400).

IX. Section 11: Toxicological information.

OSHA proposed to revise Section 11, Toxicological information, to align with Rev. 7 (Document ID 0060, p. 395) by adding a new Section 11 (e), Interactive Effects. Because of that proposed change, OSHA also proposed moving the former Section 11 (e) to Section 11 (f). Additionally, OSHA proposed to add a new Section 11 (g) providing that when specific chemical data or information is not available, SDS preparers must indicate if alternative information was used and what method was 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).

With regard to proposed Section 11 (e), several commenters requested a definition of “interactive effects” and sought clarification of specific requirements of the proposal. Tom Murphy commented that the proposal did not contain a definition of interactive effects and that a lack of clarity creates a “potential for systemic failure.” Murphy suggested that this issue could be resolved by defining the term interactive effects or striking the requirement (Document ID 0277, p. 2). Similarly, ACC requested clarification of “interactive effects” as they felt it was not clear from the NPRM or GHS what this proposed provision entails (Document ID 0347, p. 26).

Michele Sullivan asked why OSHA proposed to add interactive effects to the SDS, suggesting that the requirement was inadequately explained in both the GHS and NPRM and noting it is not included in UN GHS Table 1.5.2 Minimum information for an SDS. Sullivan suggested that including this information was not “necessary or related to worker safety” and that OSHA should align as closely as possible with the GHS Table 1.5.2 from the UN GHS Purple Book to promote global harmonization (Document ID 0366, p. 9).

While “interactive effects” are not listed in Table 1.5.2, the term is mentioned in Appendix 4 Guidance on the preparation of the safety data sheet (SDS) paragraph

4.3.11.11 (Document ID 0060, p. 401). “Interactive effects” such as synergistic or antagonistic effects occur when some or all individual components (ingredients) of a mixture influence the toxicity of individual ingredients and the combined effects deviate from additive predictions (see related considerations in Appendix A.0.4 - Considerations for the classification of mixtures). When an SDS preparer has information that the combination of chemicals in a mixture have a different level and/or type of toxicity than would be predicted by adding the toxicity of its components, the preparer should state that on the SDS and describe the nature of the interactive effects. OSHA recognizes that testing and studies are often required to produce information on interactive effects. Since neither the GHS nor OSHA require testing, this information need only be disclosed if the toxicological data is available without testing. OSHA disagrees with Michele Sullivan’s comment that this requirement would not benefit worker safety; OSHA proposed adding this provision because it understood this to be a gap in the information provided in the SDS that could be important for understanding the hazards present in a workplace.

With regard to proposed Section 11 (g), ACC supported the inclusion of QSAR (quantitative SAR) and read across, which it characterized as “powerful and valuable tools for evaluating toxicological information.” However, ACC requested clarity regarding what OSHA intended with the phrase “if alternative information is used” in proposed Section 11(g). (Document ID 0347, p. 26).

In the NPRM, OSHA noted several tools that would qualify as “using alternative information” under proposed Section 11 (g), including SAR, QSAR, and read across, which are used in the absence of specific data on a particular chemical to predict activities, properties, and endpoint information of untested chemicals based on their structural similarity to tested chemicals (86 FR 9723). When SDS preparers lack known chemical specific data, OSHA intends for this provision to require preparers to note that they have used other methods such as SAR, QSAR, and read across to provide

toxicological information in Section 11, and then to describe the method they used for translating the non-specific data into toxicological information relevant to the untested chemical in question. Making such information accessible in the SDS to health and safety professionals could be useful to determine what kind of controls and PPE may be needed to protect workers who handle these chemicals.

NACD commented that the proposed Section 11 (g) “essentially asks [SDS] preparers to provide information about their data sources.” NACD recommended that OSHA clarify when this is required and what specific information the agency is seeking. They also suggested that OSHA should update its chemical registries and chemical substance guidebook online (Document ID 0329, p. 9). OSHA notes that, while it is not clear which specific materials NACD is asking OSHA to update, the agency will be updating its HCS guidance to provide additional information and support for compliance with the final rule and anticipates including these topics.

Proposed Section 11 (g) requires that SDS preparers note if the toxicity information for a chemical on the SDS is derived from studies which used data that is not specific to the chemical in question and which method was used to make that determination (for instance, QSAR or read-across methods). As NIOSH stated at the hearing, “structure-activity relationships, analogs of chemicals, and chemical families are all useful characteristics for understanding the toxicity of a chemical, particularly when there is little toxicity information about the particular chemical of interest” (Document ID 0423, Tr. 42-43). NIOSH noted that it would be particularly useful to include such information on the SDS “for those chemicals for which the chemical families or the SAR have been well studied and well supported in the scientific literature” (Document ID 0423, Tr. 42-43). NIOSH also cautioned that “when the analogs, the SAR, and the chemical families are not well-defined or there is conflicting information about the critical characteristics of the analog chemicals for comparison” it can be difficult to

interpret that information. Further, because no standard set of information on which to characterize SAR, analog, or chemical families currently exists, it may be difficult to provide guidelines to employers on what information to include (Document ID 0423, Tr. 42-43). OSHA agrees with this analysis of the state of the science regarding these methodologies. Ultimately, the SDS preparer must include the information in the toxicological information section unless they determine that it is of such a quality as would not materially aid hazard communication.

Michele Sullivan also noted that Section 11 (g) does not appear in GHS Table 1.5.2 and therefore is not harmonized with the GHS, so SDS preparers should be allowed to use alternative methods (i.e., SAR, QSAR, read-across) to derive toxicity information but they should not be required to specify that alternative methods were used on the SDS because it would not be helpful or necessary for workers' safety (Document ID 0366, p. 9).

While OSHA supports the use of alternative methods to derive toxicity information, the agency notes that most of these methods would not be used as stand-alone (without the addition of in vivo or in vitro data) to classify hazardous substances. The requirement to provide information on the use of alternative methods in the classification allows the reader to evaluate the basis for the classification. Further, OSHA disagrees with the assertion that the proposed requirement does not align with GHS simply because the requirement is not listed on Table 1.5.2. Table 1.5.2 in the GHS is meant to list minimum information for an SDS (Document ID 0060, pp. 38-39). The GHS provides more detail about SDS requirements in the paragraph A4.3.11.12 of Annex 4 which specifies that when genetic data are used, or where data are not available, that information should be noted in the SDS (Document ID 0060, p. 396).

For the reasons discussed above, OSHA is finalizing all of the changes to Section 11 of the SDS as proposed, including new Section 11 (e), the shifting of the prior Section 11 (e) to Section 11 (f), and the new Section 11 (g).

X. Section 14: Transport information (Nonmandatory).

OSHA proposed to change non-mandatory Section 14 (f), *Transport information*, to read “Transport in bulk according to IMO instruments” instead of “Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)” to be consistent with the text in Rev. 7, which better aligns with the IMO (Document ID 0060, p. 39; 0141).

OSHA received no comments objecting to the revision in Section 14. Therefore, OSHA is finalizing Section 14 as proposed.

G. Out of Scope Comments.

As explained in the introduction to the Summary and Explanation, OSHA addresses all relevant comments submitted as part of a rulemaking. The agency received some comments that were submitted as part of the rulemaking process but are outside the scope of the rulemaking. This section addresses any such comments that are not addressed in other sections of the Summary and Explanation.

DOD commented that OSHA should expand the types of hazards reported on SDSs and labels by aligning with the EU REACH regulation (Document ID 0299, p. 5). OSHA did not propose the adoption of any provision within REACH and cannot expand the types of hazards covered by the HCS without notice and comment on the issue, so the agency declines to adopt DOD’s proposed changes.

OSHA received an anonymous comment regarding the classification of plastic articles which requested that “the correct approach for the classification of polymer compounds and concentrates... be specified in the proposed rule” (Document ID 0269). Since articles are exempt from the HCS and OSHA did not propose any changes to the

standard that are relevant to the commenter's concerns, this comment is out of scope for this rulemaking and the agency declines to take the action requested in this comment.

An anonymous commenter suggested that OSHA should revise the training requirements for SDSs to reduce the amount of training but make it more useful for workers (Document ID 0300). OSHA did not propose any changes to the training provisions of the HCS, therefore the suggestion is out of scope for this rulemaking and the agency declines to adopt the commenter's proposed changes.

OSHA received another anonymous comment asking OSHA to extend the HCS to workers who are not currently covered by the standard, including State employees not covered by OSHA's regulations (Document ID 0306). The comment suggested a number of options for extending the population of workers covered by the HCS that are not within OSHA's power to implement. The agency appreciates the dilemma faced by the commenter and those not protected by the HCS, but States are specifically exempted from being an employer under the OSH Act (29 USC 652(5)). OSHA therefore cannot take any action in response to this comment.

Loren Lowry, a private citizen, commented that SDS preparers and hazard classifiers do not apply the HCS or GHS the same way when developing hazard classifications for the same chemicals (Document ID 0333). OSHA recognizes this issue and has developed guidance to help stakeholders correctly apply the HCS hazard classification criteria to their chemical or substance. In addition, Lowry noted that countries are able to adopt parts or all of the GHS which leads to disharmonization (Document ID 0333, p. 1). While OSHA recognizes the issue as well, it is not within the agency's power to address uneven or incomplete adoption of the GHS amongst foreign nations.

WHSP submitted comments related to nanotechnology and international developments (Document ID 0341). While the agency appreciates the submission, these comments are outside the scope of this rulemaking.

Cal/OSHA commented that the decision-making procedures for classifying and labelling chemicals are absent from this proposal (Document ID 0322, Att. 1, p. 2). OSHA notes that this issue was discussed during the 2012 HCS update (77 FR 17719, 17795, 17799) and OSHA did not propose any changes related to this issue in this rulemaking. Therefore, Cal/OSHA's comments on this matter are outside the scope of this rulemaking and OSHA declines to make any changes to the rule in response.

XV. Issues and Options Considered

In the NPRM, OSHA solicited public feedback on specific issues associated with the proposed revisions to the HCS in the Issues and Options section, including timeframes for updates, issues related to proposed regulatory text and appendices (e.g., questions on (f)(12) small container labeling requirements), economic analyses, and potential guidance documents. The Issues and Options section also presented optional potential changes to the regulatory text and appendices associated with Rev. 8 of the GHS (e.g., inclusion of non-animal test methods in Appendix A.3.1 - skin irritation and corrosion). For discussion of issues and options related to economic analyses, regulatory text, and appendices, please refer to those specific discussions in Section VI, Final Economic Analysis and Regulatory Flexibility Analysis, or Section XIV, Summary and Explanation of the Final Rule, for that specific provision. The remainder of this discussion addresses comments submitted on the timeframe for updates to the HCS and on electronic labeling.

A. Timeframe for Updates to the HCS.

Since aligning the HCS with 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, Rev. 9 was published in July 2021 (available at <https://unece.org/transport/standards/transport/dangerous-goods/ghs-rev9-2021>).

Regulatory authorities around the world have implemented the GHS at stages ranging from Rev. 1 through Rev. 7. Few regulatory authorities have put programs in place to update their regulations on a routine schedule. The EU has made the most regular updates, and in March 2019, the European Commission (EC) published the adaptation of technical progress (ATP) to EC regulation 1272/2008 (the CLP regulation) to align with both the sixth and seventh revised editions of the GHS (Document ID 0176). These changes to the CLP regulation became effective October 2020. Other regulatory authorities, such as those in Canada, Australia, and New Zealand, have updated their regulations to align with the GHS and have either finalized or are in the process of aligning with Rev. 7; however, none of these countries have a mandate on how often they should do so (Document ID 0172; 0168; 0187). Similarly, to date, OSHA has not adopted a specific timeframe for regularly updating the HCS to implement GHS updates.

OSHA requested 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. The agency received several comments on the question but received no consensus on a *specific* timeframe for updating the HCS.

Hugo Hidalgo commented that “the revision and updates to the HCS must be close together with the GHS latest versions to ensure alignment with the rest of the world, requiring a strong relationship with US major trading partners” (Document ID 0297, p. 4).

CGA and GAWDA commented that OSHA should review the HCS every two revisions of the GHS to determine if the changes are substantive enough to reach “a threshold that would necessitate” implementing a change, which they noted “would help

to ensure that the time, cost, and effort required to meet new requirements would result in enhanced employee safety” (Document ID 0310, p. 3). Similarly, SAAMI suggested that OSHA realign with the GHS every four years or two revisions (Document ID 0370, pp. 2-3). Hach recommended updates to the HCS every 8 years, or every fourth revision, while Michele Sullivan indicated that every 5 or 6 years may be more appropriate (Document ID 0323, p. 11; 0366, p. 10). Others indicated it would be more appropriate to coordinate updates either with trading partners or the DOT (Document ID 0279, p. 3; 0347, p. 27; 0364, pp. 2-3).

The Flavor Extract Manufacturers Association, Hawkins, and FCA suggested that OSHA should maintain a regular schedule for updates to provide more regulatory certainty to companies, but did not provide a suggested schedule (Document ID 0346, p. 3; 0423, Tr. 193; 0349, p. 6). IHSC noted “it is important to periodically revise the standard to stay aligned with the international standards to take advantage of the hard work done by our representatives to the UN subcommittee and the various working agencies” (Document ID 0349, p. 1).

Cal/HESIS recommended that OSHA update the HCS “only when there are significant changes to the GHS that would justify opening rulemaking” and that OSHA should have flexibility in determining the need as a fixed schedule “may not be in the interest of all involved given the resources and effort required” (Document ID 0313, p. 3). Some other stakeholders’ comments similarly suggested that OSHA should update the HCS when significant or substantial changes to the GHS have occurred, or when these changes will lead to improved worker protections (Document ID 0309, p. 11; 0327, p. 3; 0329, p. 2; 0344, p. 3; 0368, p. 11).

NIOSH also recommended that OSHA update the HCS only when significant changes to the GHS warrant rulemaking, noting that “[a]dhering to a regular schedule to update the OSHA HCS might not be prudent given the resources and effort required—

especially if there were minor adjustments to the GHS that would not require major revisions to the HCS” (Document ID 0456, Att. 2, p. 2). Dow also supported updating the HCS when there are substantial updates in order to maintain harmonization with trading partners, but noted that “an update should be justified by advancement in science or technology resulting in clear benefits to worker safety” (Document ID 0359, p. 1). NAIMA supported less frequent HCS updates to incorporate significant changes to the GHS because there are significant compliance costs associated with HCS updates (Document ID 0461, pp. 8-9).

After careful consideration, the agency agrees with commenters who argued it is more prudent to only update the HCS when significant changes have occurred to the GHS that require realignment to improve worker safety.

B. Electronic Labeling.

In the NPRM, OSHA requested comments on using electronic technology, such as quick response (QR) codes and radio-frequency identification (RFID) for labeling chemical packaging. OSHA was interested in gathering information from stakeholders on what technological, economic, and security challenges employers would face if electronic labeling was permitted in a future HCS revision. The agency also requested comments on the types of electronic chemical labeling already in existence or under development, information on the types of electronic coding systems utilized and the costs incurred, and benefits achieved from the programs if implemented. In addition, OSHA asked what backup measures are in place to ensure immediate access to the hazard information. OSHA was interested in gathering information about workers' experiences with electronic labels, and foreseeable challenges that OSHA should consider (e.g., worker accessibility to electronic label information) (86 FR 9690).

Many commenters supported exploring the use of electronic labels in the future (Document ID 0309, p. 13; 0327, p. 6; 0347, pp. 20-21; 0297, p. 3). Commenters stated

that using technology (e.g., QR codes and RFID) for labels and SDSs will provide a quick (Document ID 0261), easy (Document ID 0368, p. 8), universal (Document ID 0271), and efficient (Document ID 0281, Att. 2, p. 7) way to access hazard information about the chemicals at workplaces. Givaudan indicated strong support and urged OSHA to implement the use of electronic labels (Document ID 0293, p. 1). Hugo Hidalgo indicated that given the worldwide use of this technology, hard copies should not be the only way to comply with the HCS (Document ID 0297, p. 4).

Some commenters suggested that OSHA should make electronic labeling optional, but raised concerns about the possibility of broad implementation (Document ID 0316, p. 7; 0329, p. 9). Specifically, API indicated that this provision should be optional and further stakeholder engagement would be beneficial as there may be concerns related to wide use of electronic labels, including limited use of mobile phones in many workplaces, additional costs for implementation, and no demonstrated need for (and perhaps limited benefit of) electronic labels (Document ID 0316, pp. 7-8). They indicated that using digital hazard information during the transport phase could be useful, but implementing such provisions could require extensive revisions to the GHS (Document ID 0316, p. 8). Relatedly, IMA-NA commented that this would be costly and not work as a blanket approach across industries (Document ID 0363, pp. 8-9).

Additionally, NIOSH supported OSHA's consideration of utilizing newer technology options, such as QR codes, RFID, or website addresses, to link to pertinent labeling information and SDSs. However, they also commented that electronic labeling should not be a substitute for maintaining label information and SDSs in the workplace in a physical form because in emergencies there must be a backup means of accessing the label and SDS in case the container becomes compromised or inaccessible (Document ID 0281, Att. 2, p. 7).

Similarly, NABTU commented that electronic technology for labeling could improve the ability of manufacturers and importers to provide chemical hazard information, including access to emergency medical and first aid information, which they noted remains a challenge on construction sites. However, they stated that it should not be substituted for the hazard information and pictograms already required on labels. They provided examples of QR codes that are already being used in the construction industry to train workers on using hazardous equipment, working at heights, and accessing SDSs for masonry and concrete products. NABTU pointed out that the HCS already permits employers to provide electronic access to SDSs, therefore “amending the HCS to permit use of QR codes on labels for SDSs would not materially alter the standard’s requirement for SDSs but would encourage use of the technology” (Document ID 0334, p. 5).

HCPA supported OSHA’s exploration of the HCS permitting electronic labeling in some situations. They stated that the product identifier, pictograms, and hazard statements should remain on labels affixed to the product, but employers should be able to convey other aspects digitally. In their view, this would allow employees to access the most important information in the event of an emergency, but they could still have ready access to the rest of the information. They specifically noted that it would facilitate employee access to SDSs in the case of an electrical failure. Additionally, HCPA stated that manufacturers and importers should still have labels online with complete information that can be downloaded, printed, and applied to containers when the employer cannot access information digitally (Document ID 0327, p. 6). Similarly, ADM supported the use of electronic labeling to provide enhanced safety information and reduce label sizes, but suggested that essential information should still be required on printed labels, including signal words and hazard statements, in the event of a power failure or for businesses not fully equipped with the latest technologies (Document ID 0361, p. 3).

NACD stated that use of electronic labels and SDSs could benefit small packages and emergency responders, but requiring the use of electronic devices might present challenges because, among other things, some employers do not allow workers to use cell phones, there would need to be a standard format across operating systems, and network accessibility is not universal (Document ID 0329, p. 9).

ACC supported the use of electronic labeling for chemical packaging and particularly supported the distribution of SDSs via electronic means. However, ACC noted a number of issues would need to be clarified in order to determine whether it would be realistic to incorporate electronic labeling in the HCS, including what would be considered an electronic label, whether it would only add to the label or replace elements of the label, and whether it would apply to the label or the SDS. ACC also raised concerns about using electronic devices in restricted areas due to potential fire hazards. Additionally, ACC requested clarification on how these changes would be coordinated with maintaining the pertinent data online for products. ACC suggested that OSHA provide clarification on the timing of OSHA's adoption of electronic labeling and create a working group rather than attempting to address the issue in this rulemaking (Document ID 0347, pp. 20-21).

Similarly, Dow raised concerns regarding the potential fire and explosion hazards that would occur if unrated electronic devices such as cell phones were used in "electrically classified areas" to read electronic labels. Dow also stated that codes would have to link to a website to access the label information, which can be challenging for companies to maintain and update for extended periods at the same web address. Further, workers might be unable to access important safety information on the label if a company fails to maintain its website due to the company restructuring or shutting down. For these reasons, Dow suggested that electronic labeling should only be voluntary (Document ID 0359, pp. 6-7).

OSHA appreciates commenters providing information on electronic labeling.

OSHA is not proposing any new changes in this rulemaking on this issue, but the agency will consider these comments and concerns in future discussions at the UN and in future HCS revisions.

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.

Authority and Signature

This document was prepared under the direction of Douglas L. Parker, 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 58393-94); and 29 CFR part 1911.

Signed at Washington, DC.

Douglas L. Parker,
Assistant Secretary of Labor for Occupational Safety and Health.

For the reasons set forth in the preamble, Chapter XVII of Title 29, part 1910 of the Code of Federal Regulations is 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 as follows:

a. Revise paragraph (a), the introductory text of paragraph (e), and the introductory text of paragraph (h);

b. Redesignate paragraphs (h)(27) and (28) as (h)(28) and (29) and add new paragraph (h)(27);

c. Redesignate paragraphs n through (bb) as shown in the following redesignation table:

Old Paragraph	New Paragraph
n	p
o	s
p through x	t through bb
y	o
z	cc
aa	r
bb	dd

d. Add new paragraphs (n) and (q); and

e. Revise newly redesignated paragraphs (v) and (dd).

The revisions and additions read as follows:

§ 1910.6 Incorporation by Reference.

(a)(1) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Occupational Safety and Health Administration (OSHA) must publish a document in the Federal Register and the material must be available to the public.

(i) The standards of agencies of the U.S. Government, and organizations which are not agencies of the U.S. Government which are incorporated by reference in this part, have the same force and effect as other standards in this part. Only the mandatory provisions (i.e., provisions containing the word “shall” or other mandatory language) of standards incorporated by reference are adopted as standards under the Occupational Safety and Health Act.

(ii) Any changes in the standards incorporated by reference in this part and an official historic file of such changes are available for inspection in the Docket Office at the national office of OSHA, U.S. Department of Labor, Washington, DC 20210; telephone: 202–693–2350 (TTY number: 877–889–5627).

(2) All approved incorporation by reference (IBR) material is available for inspection at OSHA and at the National Archives and Records Administration (NARA).

(i) Contact OSHA 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).

(ii) For information on the availability of these standards at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

(3) The IBR material may be obtained from the sources in the following paragraphs of this section or from one or more private resellers listed in this paragraph (a)(3). For material that is no longer commercially available, contact OSHA (see paragraph (a)(2)(i) of this section).

(i) Accuris Standards Store, 321 Inverness Drive, South Englewood, CO, 80112; phone: (800) 332-6077; website: <https://store.accuristech.com>.

(ii) American National Standards Institute (see paragraph (e) for contact information).

(iii) GlobalSpec, 257 Fuller Road, Suite NFE 1100, Albany, NY 12203-3621; phone: (800) 261-2052; website: <https://standards.globalspec.com>.

(iv) Nimonik Document Center, 401 Roland Way, Suite 224, Oakland, CA, 94624; phone (650)591-7600; email: info@document-center.com; website: www.document-center.com.

(v) Techstreet, phone: (855) 999-9870; email: store@techstreet.com; website: www.techstreet.com.

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(e) American National Standards Institute (ANSI), 25 West 43rd Street, Fourth Floor, New York, NY 10036–7417; phone: (212) 642–4980; email: info@ansi.org; website: www.ansi.org.

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(h) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959; phone: (610) 832–9585; email: sevice@astm.org; website: www.astm.org. (27) ASTM D4359-90, Standard Test Method for Determining Whether a Material is a Liquid or a Solid, approved July 1, 2019; IBR approved for § 1910.1200.

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(27) ASTM D 4359-90, Standard Test Method for Determining Whether a Material is a Liquid or a Solid, Approved 2019, IBR approved for § 1910.1200.

(n) German Institute for Standardization (DIN) (Beuth Verlag GmbH) Am DIN-Platz Burggrafenstraße 6 10787 Berlin, Germany; phone: +49 30 58885 70070; website: <https://din.de/en/about-standards/buy-standard>.

(1) DIN 51794:2003-05 - Determining the ignition temperature of petroleum products, May 2003, IBR approved for appendix B to § 1910.1200.

(2) [Reserved]

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(q) International Electrotechnical Commission (IEC), IEC Secretariat, 3 rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland; phone: +41 22 919 02 11; email: sales@iec.ch; website: <https://www.iec.ch>.

(1) IEC 60079-20-1, Explosive atmospheres – Part 20-1: Material characteristics for gas and vapor classification – Test methods and data, Edition 1.0, 2010-01; IBR approved for appendix B to § 1910.1200.

(2) [Reserved]

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(v) International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8 CP 401 - 1214 Vernier, Geneva, Switzerland; phone: +41 22 749 01 11; email: central@iso.org; website: www.iso.org/store.html.

(1) ISO 817:2014(E), Refrigerants – Designation and safety classification, Third edition, 2014-04-15; IBR approved for appendix B to § 1910.1200.

(2) ISO 10156:1996 (E), Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Second Edition, Feb. 15, 1996; IBR approved for appendix B to § 1910.1200.

(3) ISO 10156:2017(E), Gas Cylinders - Gases and gas mixtures - Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets, Fourth edition, 2017-07; IBR approved for appendix B to § 1910.1200.

(4) 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, Aug. 1, 2005; IBR approved for appendix B to subpart Z.

(5) ISO 13943:2000 (E/F); Fire Safety—Vocabulary, First Edition, April, 15, 2000, IBR approved for appendix B to § 1910.1200.

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(dd) United Nations (UN), United Nations Publications, P.O. Box 960 Herndon, VA 20172; phone: (703) 661-1571;; e-mail: order@un.org; website: <https://shop.un.org/>.

(1) ADR 2019, European Agreement Concerning the International Carriage of Dangerous Goods by Road; Annex A: General provisions and provisions concerning dangerous substances and articles; (Volumes I and II) including December 2018 corrigendum to Volume II, applicable January 1, 2019; IBR approved for § 1910.1200.

(2) ST/SG/AC.10/Rev.4 (“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.

(3) ST/SG/AC.10/11/Rev.6 (“UN ST/SG/AC.10/11/Rev.6”), Recommendations on the Transport of Dangerous Goods: Manual of Tests and Criteria, sixth revised edition, copyright 2015; IBR approved for appendix B to § 1910.1200.

3. Amend § 1910.1200 as follows:

- a. Revise paragraphs (a)(1) and (b)(6)(x);
- b. Revise and republish paragraph (c);
- c. Revise paragraphs (d)(1), (e)(4), (f)(1), (5), and (11);

d. Add paragraph (f)(12); and

e. Revise paragraphs (g)(1) and (2), (7) and (10), (i)(1) through (3), (j), and appendices A through D.

The revisions and additions read as follows:

§ 1910.1200 Hazard Communication Standard.

(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), primarily 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) *Article* means a manufactured item other than a fluid or particle:

(i) Which is formed to a specific shape or design during manufacture;

(ii) Which has end use function(s) dependent in whole or in part upon its shape or design during end use; and

(iii) Which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Bulk shipment means any hazardous chemical transported where the mode of transportation comprises the immediate container (i.e. contained in tanker truck, rail car, or intermodal container).

Chemical means any substance, or mixture of substances.

Chemical manufacturer means an employer with a workplace where chemical(s) are produced for use or distribution.

Chemical name means the scientific designation of a chemical in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) rules of nomenclature, or a name that will clearly identify the chemical for the purpose of conducting a hazard classification.

Classification means to identify the relevant data regarding the hazards of a chemical; review those data to ascertain the hazards associated with the chemical; and decide whether the chemical will be classified as hazardous according to the definition of hazardous chemical in this section. In addition, classification for health and physical hazards includes the determination of the degree of hazard, where appropriate, by comparing the data with the criteria for health and physical hazards.

Combustible dust means finely divided solid particulates of a substance or mixture that pose a flash-fire hazard or explosion hazard when dispersed in air or other oxidizing media.

Commercial account means an arrangement whereby a retail distributor sells hazardous chemicals to an employer, generally in large quantities over time and/or at costs that are below the regular retail price.

Common name means any designation or identification such as code name, code number, trade name, brand name or generic name used to identify a chemical other than by its chemical name.

Container means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

Designated representative means any individual or organization to whom an employee gives written authorization to exercise such employee's rights under this section. A recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.

Director means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Distributor means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to employers.

Employee means a worker who may be exposed to hazardous chemicals under normal operating conditions or in foreseeable emergencies. Workers such as office workers or bank tellers who encounter hazardous chemicals only in non-routine, isolated instances are not covered.

Employer means a person engaged in a business where chemicals are either used, distributed, or are produced for use or distribution, including a contractor or subcontractor.

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.)

Foreseeable emergency means any potential occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which could result in an uncontrolled release of a hazardous chemical into the workplace.

Gas means 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).

Hazard category means the division of criteria within each hazard class, e.g., oral acute toxicity and flammable liquids include four hazard categories. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally.

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.

Hazard class means the nature of the physical or health hazards, e.g., flammable solid, carcinogen, oral acute toxicity.

Hazard not otherwise classified (HNOC) means an adverse physical or health effect identified through evaluation of scientific evidence during the classification process that does not meet the specified criteria for the physical and health hazard classes addressed in this section. This does not extend coverage to adverse physical and health effects for which there is a hazard class addressed in this section, but the effect either

falls below the cut-off value/concentration limit of the hazard class or is under a GHS hazard category that has not been adopted by OSHA (e.g., acute toxicity Category 5).

Hazard statement means a statement assigned to a hazard class and category that describes the nature of the hazard(s) of a chemical, including, where appropriate, the degree of hazard.

Health hazard means a chemical which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A to §1910.1200 -- Health Hazard Criteria.

Immediate outer package means the first package enclosing the container of hazardous chemical.

Immediate use means that the hazardous chemical will be under the control of and used only by the person who transfers it from a labeled container and only within the work shift in which it is transferred.

Importer means the first business with employees within the Customs Territory of the United States which receives hazardous chemicals produced in other countries for the purpose of supplying them to distributors or employers within the United States.

Label means an appropriate group of written, printed or graphic information elements concerning a hazardous chemical that is affixed to, printed on, or attached to the immediate container of a hazardous chemical, or to the outside packaging.

Label elements means the specified pictogram, hazard statement, signal word and precautionary statement for each hazard class and category.

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). Either ASTM D4359-90 (R2019) (incorporated by reference, see § 1910.6); or the test for determining fluidity (penetrometer test) prescribed in section 2.3.4 of ADR 2019 (incorporated by reference, see § 1910.6) can establish whether a viscous substance or mixture is a liquid if a specific melting point cannot be determined.

Mixture means a combination or a solution composed of two or more substances in which they do not react.

Physical hazard means a chemical that is classified as posing one of the following hazardous effects: explosive; flammable (gases, liquids, or solids); aerosols; oxidizer (gases, liquids, or solids); 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.

Pictogram means a composition that may include a symbol plus other graphic elements, such as a border, background pattern, or color, that is intended to convey specific information about the hazards of a chemical. Eight pictograms are designated under this standard for application to a hazard category.

Precautionary statement means a phrase that describes recommended measures that should be taken to minimize or prevent adverse effects resulting from exposure to a hazardous chemical, or improper storage or handling.

Produce means to manufacture, process, formulate, blend, extract, generate, emit, or repackage.

Product identifier means the name or number used for a hazardous chemical on a label or in the SDS. It provides a unique means by which the user can identify the chemical. The product identifier used shall permit cross-references to be made among the list of hazardous chemicals required in the written hazard communication program, the label and the SDS.

Released for shipment means a chemical that has been packaged and labeled in the manner in which it will be distributed or sold.

Responsible party means someone who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

Safety data sheet (SDS) means written or printed material concerning a hazardous chemical that is prepared in accordance with paragraph (g) of this section.

Signal word means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label. The signal words used in this section are “danger” and “warning.” “Danger” is used for the more severe hazards, while “warning” is used for the less severe.

Simple asphyxiant means a substance or mixture that displaces oxygen in the ambient atmosphere, and can thus cause oxygen deprivation in those who are exposed, leading to unconsciousness and death.

Solid means a substance or mixture which does not meet the definitions of liquid or gas.

Specific chemical identity means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.

Substance means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Trade secret means any confidential formula, pattern, process, device, information or compilation of information that is used in an employer's business, and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it. Appendix E to §1910.1200—Definition of Trade Secret, sets out the criteria to be used in evaluating trade secrets.

Use means to package, handle, react, emit, extract, generate as a byproduct, or transfer.

Work area means a room or defined space in a workplace where hazardous chemicals are produced or used, and where employees are present.

Workplace means an establishment, job site, or project, at one geographical location containing one or more work areas.

(d)(1)(i) 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. The hazard classification shall include any hazards associated with the chemical's intrinsic properties including:

(A) a change in the chemical's physical form and;

(B) chemical reaction products associated with known or reasonably anticipated uses or applications.

(ii) 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 identified and classified under (d)(1)(ii) 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, U.S. address, and U. S. telephone number of the chemical manufacturer, importer, or other responsible party.

* * * * *

(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. 5101 et seq.) and regulations issued under that Act by the Department of Transportation (49 CFR subtitle B).

(ii) The label for bulk shipments of hazardous chemicals must be on the immediate container, transmitted with the shipping papers or the bills of lading, or, with the agreement of the receiving entity, transmitted by 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 a shipped container, the pictogram specified in appendix C.4 to this section for the same hazard is not required on the label.

* * * * *

(11) *Label Updates.* (i) 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. For chemicals that have been released for shipment and are awaiting future distribution, chemical manufacturers, importers, distributors, or employers have the option not to relabel those containers; however, if they do not relabel the containers, they must either provide the updated label for each individual container with each shipment or, with the agreement of the receiving entity, transmit the labels by electronic or other technological means.

(ii) 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 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) *Safety data sheets.* (1) Chemical manufacturers and importers shall obtain or develop a safety data sheet for each hazardous chemical they produce or import.

Employers shall have a safety data sheet in the workplace for each hazardous chemical which they use.

(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):

- (i) Section 1, Identification;
- (ii) Section 2, Hazard(s) identification;
- (iii) Section 3, Composition/information on ingredients;
- (iv) Section 4, First-aid measures;
- (v) Section 5, Fire-fighting measures;
- (vi) Section 6, Accidental release measures;
- (vii) Section 7, Handling and storage;
- (viii) Section 8, Exposure controls/personal protection;
- (ix) Section 9, Physical and chemical properties;
- (x) Section 10, Stability and reactivity;
- (xi) Section 11, Toxicological information.
- (xii) Section 12, Ecological information;
- (xiii) Section 13, Disposal considerations;
- (xiv) Section 14, Transport information;
- (xv) Section 15, Regulatory information; and
- (xvi) Section 16, Other information, including date of preparation or last revision.

Note 1 to paragraph (g)(2): To be consistent with the GHS, an SDS must also include the headings in paragraphs (g)(2)(xii) through (g)(2)(xv) of this section in order.

Note 2 to paragraph (g)(2): OSHA will not be enforcing information requirements in sections 12 through 15, as these areas are not under its jurisdiction.

* * * * *

(7)(i) Distributors shall ensure that safety data sheets, and updated information, are provided to other distributors and employers with their initial shipment and with the first shipment after a safety data sheet is updated;

(ii) The distributor shall either provide safety data sheets with the shipped containers, or send them to the other distributor or employer prior to or at the time of the shipment;

(iii) Retail distributors selling hazardous chemicals to employers having a commercial account shall provide a safety data sheet to such employers upon request, and shall post a sign or otherwise inform them that a safety data sheet is available;

(iv) Wholesale distributors selling hazardous chemicals to employers over-the-counter may also provide safety data sheets upon the request of the employer at the time of the over-the-counter purchase, and shall post a sign or otherwise inform such employers that a safety data sheet is available;

(v) If an employer without a commercial account purchases a hazardous chemical from a retail distributor not required to have safety data sheets on file (*i.e.*, the retail distributor does not have commercial accounts and does not use the materials), the retail distributor shall provide the employer, upon request, with the name, address, and telephone number of the chemical manufacturer, importer, or distributor from which a safety data sheet can be obtained;

(vi) Wholesale distributors shall also provide safety data sheets to employers or other distributors upon request; and,

(vii) Chemical manufacturers, importers, and distributors need not provide safety data sheets to retail distributors that have informed them that the retail distributor does not sell the product to commercial accounts or open the sealed container to use it in their own workplaces.

* * * * *

(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) *Trade secrets.* (1) The chemical manufacturer, importer, or employer may withhold the specific chemical identity, including the chemical name, other specific identification of a hazardous chemical, and/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 below 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 ranges of paragraphs (i)(1)(iv)(A) to (G) of this section, a single range created by the combination of two applicable consecutive ranges between paragraphs (i)(1)(iv)(A) and (G) of this section 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) Manufacturers may provide a range narrower than those prescribed in (i)(1)(v).

(vii) 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) of this section.

(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:

(i) The request is in writing;

(ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:

(A) To assess the hazards of the chemicals to which employees will be exposed;

(B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

(C) To conduct pre-assignment or periodic medical surveillance of exposed employees;

(D) To provide medical treatment to exposed employees;

(E) To select or assess appropriate personal protective equipment for exposed employees;

(F) To design or assess engineering controls or other protective measures for exposed employees; and,

(G) To conduct studies to determine the health effects of exposure.

(iii) The request explains in detail why the disclosure of the specific chemical identity or percentage composition is essential and that, in lieu thereof, the disclosure of the following information to the health professional, employee, or designated representative, would not satisfy the purposes described in paragraph (i)(3)(ii) of this section:

(A) The properties and effects of the chemical;

(B) Measures for controlling workers' exposure to the chemical;

(C) Methods of monitoring and analyzing worker exposure to the chemical; and,

(D) Methods of diagnosing and treating harmful exposures to the chemical;

(iv) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and,

(v) The health professional, and the employer or contractor of the services of the health professional (*i.e.* downstream employer, labor organization, or individual employee), employee, or designated representative, agree in a written confidentiality agreement that the health professional, employee, or designated representative, will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (i)(6) of this section, except as authorized by the terms of the agreement or by the chemical manufacturer, importer, or employer.

* * * * *

(j) *Dates*—(1) *Effective date*. This section shall become effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

(2) *Substances*. (i) Manufacturers, importers, and distributors, evaluating substances shall be in compliance with all modified provisions of this section no later than January 19, 2026.

- (ii) For substances, all employers shall, as necessary, update any alternative workplace labeling used under paragraph (f)(6) of this section, update the hazard communication program required by paragraph (h)(1) of this section , and provide any additional employee training in accordance with paragraph (h)(3) of this section for newly identified physical hazard, or health hazards or other hazards covered under this section no later than July 20, 2026.

(3) *Mixtures.* (i) Chemical manufacturers, importers, and distributors evaluating mixtures shall be in compliance with all modified provisions of this section no later than July 19, 2027.

(ii) For mixtures, all employers shall, as necessary, update any alternative workplace labeling used under paragraph (f)(6) of this section, update the hazard communication program required by paragraph (h)(1) of this section, and provide any additional employee training in accordance with paragraph (h)(3) of this section for newly identified physical hazards, health hazards, or other hazards covered under this section no later than January 19, 2028.

(4) *Compliance.* Between [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] and the dates specified in paragraphs (j)(2) and (3) of this section, as applicable, chemical manufacturers, importers, distributors, and employers may comply with either this section or § 1910.1200 revised as of July 1, 2023, or both during the transition period.

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 A.5, A.6, and A.7 of this section 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 LD₅₀/LC₅₀ 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 estimate (ATE) values and criteria for acute toxicity hazard categories

Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) <i>see:</i> Note (a) Note (b)	ATE ≤ 5	>5 ATE ≤ 50	>50 ATE ≤ 300	>300 ATE ≤ 2000
Dermal (mg/kg bodyweight) <i>see:</i> Note (a) Note (b)	ATE ≤ 5	>50 ATE ≤ 200	>200 ATE ≤ 1000	>1000 ATE ≤ 2000
Inhalation - Gases (ppmV) <i>see:</i> Note (a) Note (b) Note (c)	ATE ≤ 100	>100 ATE ≤ 500	>500 ATE ≤ 2500	>2500 ATE ≤ 20000
Inhalation - Vapors (mg/l) <i>see:</i> 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) <i>see:</i> 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 LD₅₀/LC₅₀ where available
- (b) The acute toxicity estimate (ATE) for the classification of a substance or ingredient in a mixture is derived using:
 - (i) the LD₅₀/LC₅₀ 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 LD₅₀ 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.

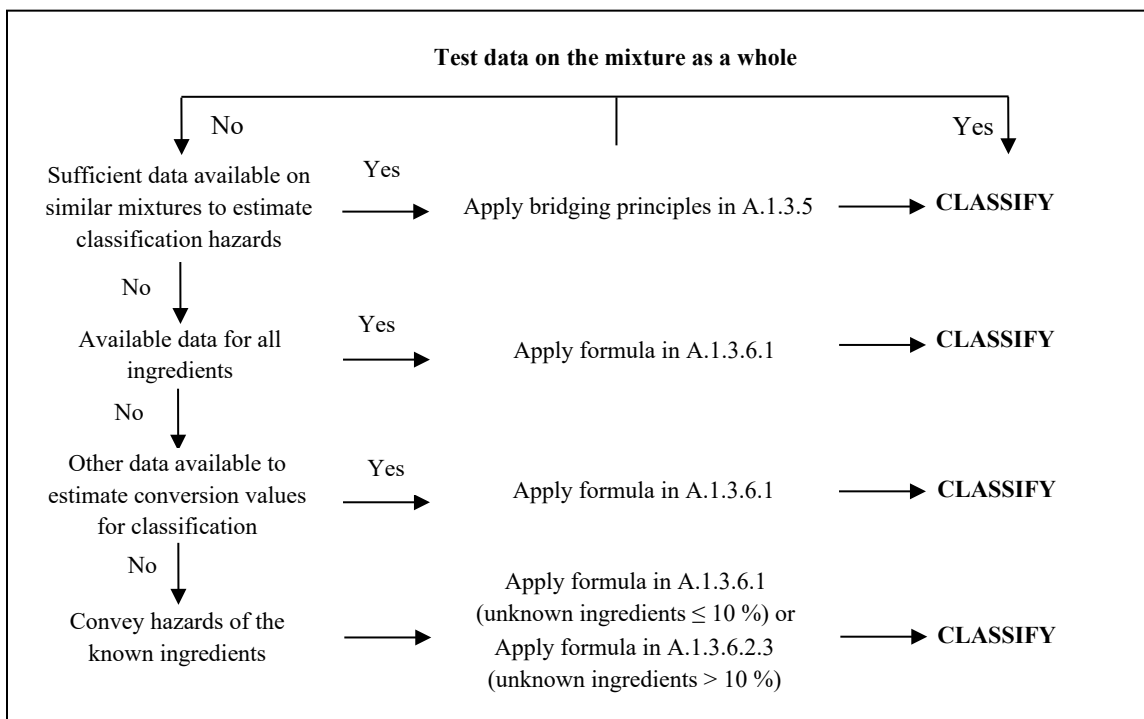
A.1.2.4.1 If the classifier determines the chemical is corrosive to the respiratory tract and data are available that indicate that the effect leads to lethality, then in addition to the appropriate acute toxicity pictogram and hazard statement, the chemical must be labelled with the hazard statement “corrosive to the respiratory tract” and the corrosive pictogram.

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). If data is insufficient for classification under STOT, but the classifier determines, based on skin or eye data, that the chemical may be corrosive to the respiratory tract, then the hazard must be addressed using data for classification in the skin corrosion/irritation hazard class (see A.2) or Serious Eye Damage/Eye irritation hazard class (see A.3).

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 $\geq 1\%$ (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

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 hazard categories, or have an oral or dermal LD₅₀ greater than 2000 but less than or equal to 5000 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:

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

where:

C_i = concentration of ingredient i ;

n ingredients and i is running from 1 to n ;

ATE_i = 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 $\geq 1\%$, 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 $\times$ 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 $\leq 10\%$ 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 $\leq 10\%$, the formula presented in A.1.3.6.1 is corrected to adjust for the percentage of the unknown ingredient(s) as follows:

$$\frac{100 - \left(\sum C_{\text{unknown}} \text{ if } > 10\% \right)}{\text{ATE}_{\text{mix}}} = \sum \frac{C_i}{\text{ATE}_i}$$

Table A.1.2: Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for use in the formulas for the classification of mixtures

Exposure routes	Classification category or experimentally obtained acute toxicity range estimate	Converted Acute Toxicity point estimate
Oral (mg/kg bodyweight)	0 < Category 1 $\leq$ 5	0.5
	5 < Category 2 $\leq$ 50	5
	50 < Category 3 $\leq$ 300	100
	300 < Category 4 $\leq$ 2000	500
Dermal (mg/kg bodyweight)	0 < Category 1 $\leq$ 50	5
	50 < Category 2 $\leq$ 200	50
	200 < Category 3 $\leq$ 1000	300
	1000 < Category 4 $\leq$ 2000	1100
Gases (ppmV)	0 < Category 1 $\leq$ 100	10
	100 < Category 2 $\leq$ 500	100
	500 < Category 3 $\leq$ 2500	700
	2500 < Category 4 $\leq$ 20000	4500

Vapors (mg/l)	0	< Category 1 ≤ 0.5	0.05
	0.5	< Category 2 ≤ 2.0	0.5
	2.0	< Category 3 ≤ 10.0	3
	10.0	< Category 4 ≤ 20.0	11
Dust/mist (mg/l)	0	< Category 1 ≤ 0.05	0.005
	0.05	< Category 2 ≤ 0.5	0.05
	0.5	< Category 3 ≤ 1.0	0.5
	1.0	< Category 4 ≤ 5.0	1.5

Note: Gas concentrations are expressed in parts per million per volume (ppmV).

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 initial exposure to a substance or mixture.

Skin irritation refers to the production of reversible damage to the skin occurring after initial exposure to a substance or mixture.

A.2.1.2 To classify, all available and relevant information on skin corrosion/irritation is collected and its quality in terms of adequacy and reliability is assessed. Wherever possible classification should be based on data generated using internationally validated and accepted methods, such as OECD Test Guidelines (TG) or equivalent methods. Sections A.2.2.1 to A.2.2.6 provide classification criteria for the different types of information that may be available.

A.2.1.3 A *tiered approach* (see A.2.2.7) organizes the available information into levels/tiers and provides for decision-making in a structured and sequential manner. Classification results directly when the information consistently satisfies the criteria. However, where the available information gives inconsistent and/or conflicting results within a tier, classification of a substance or a mixture is made on the basis of the weight of evidence within that tier. In some cases when information from different tiers gives inconsistent and/or conflicting results (see A.2.2.7.3) or where data individually are insufficient to conclude on the classification, an overall weight of evidence approach is used (see A.0.3).

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), which can be used by those authorities requiring more than one designation for corrosivity.

Corrosive substances should be classified in Category 1 where sub-categorization is not required by a competent authority or where data are not sufficient for sub-categorization.

When data are sufficient, substances may be classified in one of the three sub-categories 1A, 1B, or 1C.

(b) Category 2 (skin irritation)

A.2.2.1 Classification based on standard human data

Existing reliable and good quality human data on skin corrosion/irritation should be given high weight for classification. Existing human data could be derived from single or repeated exposure(s), for example in occupational, consumer, transport or emergency response scenarios and epidemiological and clinical studies in well-documented case reports and observations (see A.0.2.6 and A.0.3). 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.

A.2.2.2 Classification based on standard animal test data

OECD TG 404 is the currently available internationally validated and accepted animal test for classification as skin corrosive or irritant (See Table A.2.1 and A.2.2) and is the standard animal test. The current version of OECD TG 404 uses a maximum of 3 animals. Results from animal studies conducted under previous versions of OECD TG 404 that used more than 3 animals are also considered standard animal tests.

A.2.2.2.1 Skin corrosion

A.2.2.2.1.1 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 initial exposure up to a 4-hour duration.

A.2.2.2.1.2 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.2.2.1

A.2.2.2.2 Skin Irritation

A.2.2.2.2.1 A substance is irritant to skin when it produces reversible damage to the skin following its application for up to 4 hours.

A.2.2.2.2.2 A single irritant category (Category 2) is presented in the Table A.2.2. A substance is irritant to skin, when after the first application, it produces reversible damage to the skin following its application for up to 4 hours. 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.2.2.2.2.3 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.2.2.2.2.4. 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 should be designated as an irritant if at least 1 of 3 tested animals shows a very elevated mean score according to test method used throughout the study, including lesions persisting at the end of an observation period of normally 14 days. Other responses should also fulfil 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

	Criteria
Irritant (Category 2)	(1) Mean score of $\geq 2.3 \leq 4.0$ 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.2.2.3 Classification based on *in vitro/ex vivo* data

A.2.2.3.1 The currently available individual *in vitro/ex vivo* test methods address either skin irritation or skin corrosion, but do not address both endpoints in one single test. Therefore, classification based solely on *in vitro/ex vivo* test results may require data from more than one method.

A.2.2.3.2 Wherever possible classification should be based on data generated using internationally validated and accepted *in vitro/ex vivo* test methods, and the classification criteria provided in these test methods needs to be applied. *In vitro/ex vivo* data can only be used for classification when the tested substance is within the applicability domain of the test methods used. Additional limitations described in the published literature should also be taken into consideration.

A.2.2.3.3 Skin corrosion

A.2.2.3.3.1 Where tests have been undertaken in accordance with OECD Test Guidelines (TGs) 430, 431, or 435, a substance is classified for skin corrosion in category 1 (and, where possible and required into sub-categories 1A, 1B, or 1C) based on the criteria in Table A.2.6.

A.2.2.3.3.2 Some *in vitro/ex vivo* methods do not allow differentiation between sub-categories 1B and 1C. Where existing *in vitro/ex vivo* data cannot distinguish between the sub-categories, additional information has to be taken into account to differentiate between these two sub-categories. Where no or insufficient additional information is available, category 1 is applied.

A.2.2.3.3.3 A substance identified as not corrosive should be considered for classification as skin irritant.

A.2.2.3.4 Skin irritation

A.2.2.3.4.1 Where a conclusion of corrosivity can be excluded and where tests have been undertaken in accordance with OECD Test Guideline 439, a substance is classified for skin irritation in category 2 based on the criteria in Table A.2.7.

A.2.2.3.4.2 A negative result in an internationally accepted and validated *in vitro/ex vivo* test for skin irritation, e.g., OECD TG 439, can be used to conclude as not classified for skin irritation.

A.2.2.4 Classification based on other, existing skin data in animals

Other existing skin data in animals may be used for classification, but there may be limitations regarding the conclusions that can be drawn if a substance is highly toxic via the dermal route, an *in vivo* skin corrosion/irritation study may not have been conducted 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 of skin corrosion/irritation in acute toxicity studies are made, these data may be used for

classification, provided that the dilutions used and species tested are relevant. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes. This is generally indicated in the standardized test methods.

A.2.2.5 *Classification based on chemical properties*

Skin effects may be indicated by pH extremes such as ≤ 2 and ≥ 11.5 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 may not be corrosive despite the low or high pH, this needs to be confirmed by other data, preferably from an appropriate validated *in vitro/ ex vivo* test. Buffering capacity and pH can be determined by test methods including OECD TG 122.

A.2.2.6 *Classification based on non-test methods*

A.2.2.6.1 Classification, including non-classification, can be based on non-test methods, with due consideration of reliability and applicability, on a case-by-case basis. Such methods include computer models predicting qualitative structure-activity relationships (structural alerts, SAR); quantitative structure-activity relationships (QSARs); computer expert systems; and read-across using analogue and category approaches.

A.2.2.6.2 Read-across using analogue or category approaches requires sufficiently reliable test data on similar substance(s) and justification of the similarity of the tested substance(s) with the substance(s) to be classified. Where adequate justification of the read-across approach is provided, it has in general higher weight than (Q)SARs.

A.2.2.6.3 Classification based on (Q)SARs requires sufficient data and validation of the model. The validity of the computer models and the prediction should be assessed using internationally recognized principles for the validation of (Q)SARs. With respect to reliability, lack of alerts in a SAR or expert system is not sufficient evidence for no classification.

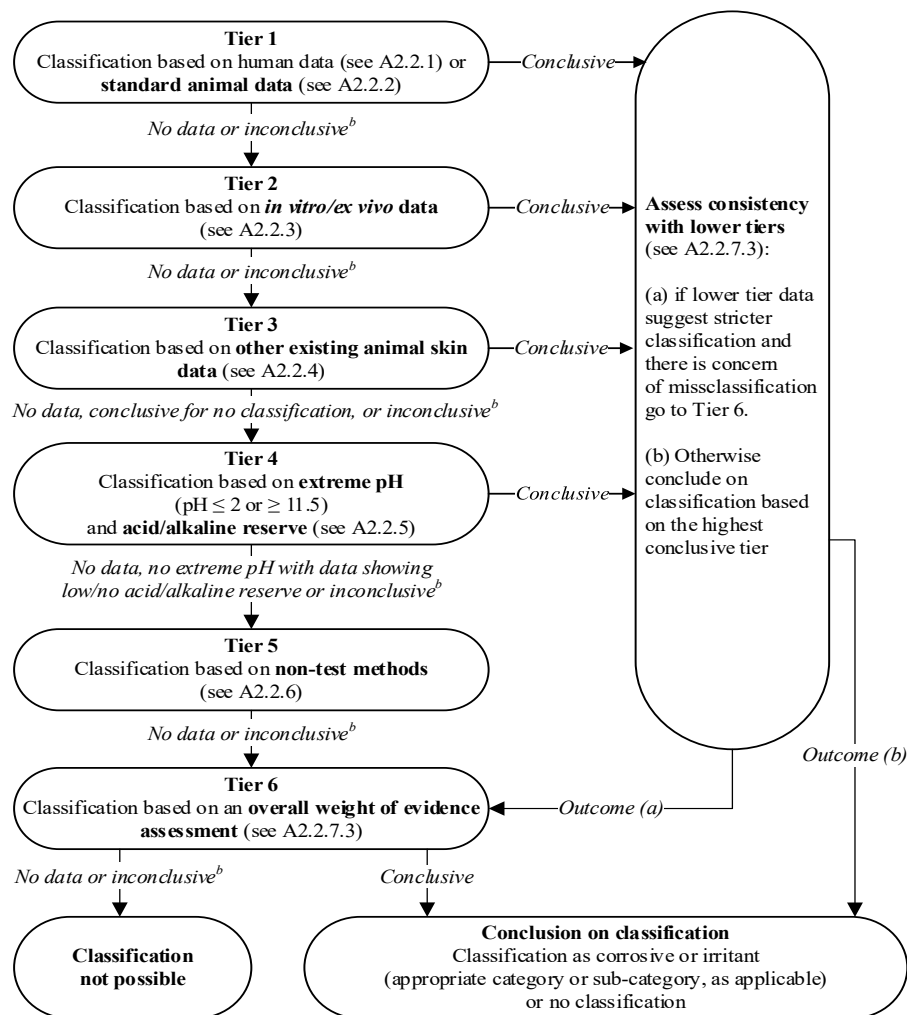
A.2.2.7 *Classification in a tiered approach*

A.2.2.7.1 A tiered approach to the evaluation of initial information should be considered, where applicable (Figure A.2.1), recognizing that not all elements may be relevant. However, all available and relevant information of sufficient quality needs to be examined for consistency with respect to the resulting classification.

A.2.2.7.2 In the tiered approach (Figure A.2.1), existing human and animal data form the highest tier, followed by *in vitro/ex vivo* data, other existing skin data in animals, and then other sources of information. Where information from data within the same tier is inconsistent and/or conflicting, the conclusion from that tier is determined by a weight of evidence approach.

A.2.2.7.3 Where information from several tiers is inconsistent and/or conflicting with respect to the resulting classification, information of sufficient quality from a higher tier is generally given a higher weight than information from a lower tier. However, when information from a lower tier would result in a stricter classification than information from a higher tier and there is concern for misclassification, then classification is determined by an overall weight of evidence approach. The same would apply in the case where there is human data indicating irritation but positive results from an *in vitro/ex vivo* test for corrosion.

Figure A.2.1: Application of the tiered approach for skin corrosion and irritation



(a) Before applying the approach, the explanatory text in A.2.2.7 should be consulted. Only adequate and reliable data of sufficient quality should be included in applying the tiered approach.

(b) Information may be inconclusive for various reasons, *e.g.*:

- The available data may be of insufficient quality, or otherwise insufficient/inadequate for the purpose of classification, *e.g.*, due to quality issues related to experimental design and/or reporting.
- The available data may be insufficient to conclude on the classification, *e.g.*, they might be adequate to demonstrate irritancy, but inadequate to demonstrate absence of corrosivity.
- The method used to generate the available data may not be suitable for concluding on no classification (see A.2.2. for details). Specifically, *in vitro/ex vivo* and non-test methods need to be validated explicitly for this purpose.

A.2.3 Classification criteria for mixtures

A.2.3.1 Classification of mixtures when data are available for the complete mixture

A.2.3.1.1 In general, 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) and A.2.3.1.2 and A.2.3.1.3. If classification is not possible using the tiered approach, then the approach described in A.2.3.2, or, if that is not applicable A.2.2.3.3 should be followed.

A.2.3.1.2 *In vitro/ex vivo* data generated from validated test methods may not have been validated using mixtures; although these methods are considered broadly applicable to mixtures, they can only be used for classification of mixtures when all ingredients of the mixture fall within the applicability domain of the test methods used. Specific limitations regarding applicability domains are described in the respective test methods, and should be taken into consideration as well as any further information on the limitations from the published literature. Where there is reason to assume or evidence indicating that the applicability domain of a particular test method is limited, data interpretation should be exercised with caution, or the results should be considered not applicable.

A.2.3.1.3 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, this needs to be confirmed by other data, preferably from an appropriate validated *in vitro/ex vivo* test.

A.2.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.2.3.2.1 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.2.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.2.3.3.1 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 $\geq 1\%$ (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.2.3.3.2 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.2.3.3.3 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.2.3.3.4 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.2.3.3.1 and A.2.3.3.2 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 $\geq 1\%$ of a corrosive ingredient and as skin irritation Category 2 when it contains $\geq 3\%$ 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.2.3.3.5 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.2.3.3.6 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 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 mixture must 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 a Category 1 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 $\text{pH} \leq 2$	$\geq 1\%$	Category 1
Base with $\text{pH} \geq 11.5$	$\geq 1\%$	Category 1
Other corrosive (Category 1) ingredient	$\geq 1\%$	Category 1
Other irritant (Category 2) ingredient, including acids and bases	$\geq 3\%$	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 TableA.3.1).
- (b) Category 2 (eye irritation/reversible effects on the eye):
substances that have the potential to induce reversible eye irritation (see TableA.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.3.2.1.2 Eye irritation (Category 2)/Reversible effects on the eye

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.3.2.1.3 For those substances where there is pronounced variability among animal responses this information must 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 oedema (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.3.2.2 Classification in a tiered approach

A.3.2.2.1 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.3.2.2.2 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.3.2.2.3 *In vitro* alternatives that have been validated and accepted should be used to make classification decisions.

A.3.2.2.4 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 to be confirmed by other data, preferably by data from an appropriate validated *in vitro* test.

A.3.2.2.5 In some cases sufficient information may be available from structurally related substances to make classification decisions.

A.3.2.2.6 The tiered approach provides guidance on 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.

A.3.2.2.7 The tiered approach explains how to organize existing information and to make a weight-of-evidence decision about hazard assessment and hazard classification. 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.

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
	↓ Negative data/Insufficient data/No data	↘ Eye irritant →	Category 2^b
1b:	Existing human or animal data, skin corrosion ↓ Negative data/Insufficient data/No data	→ Skin corrosion	Category 1
1c:	Existing human or animal serious eye damage/eye irritation data ^a ↓ No/Insufficient data	→ Existing data showing that substance does not cause serious eye damage or eye irritation	Not classified
2:	Other, existing skin/eye data in animals ^c	→ Yes, other existing data showing that substance may cause serious eye damage	Category 1 ^b
	↓ No/Insufficient data	↘ Yes, other existing data showing that substance may cause-eye irritation →	Category 2^b

Step	Parameter	Finding	Conclusion
3:	Existing <i>ex vivo/in vitro</i> eye data ^d No/Insufficient data/Negative response ↓	Positive: serious eye damage ↘ Positive: eye irritant	Category 1 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.

A.3.3 Classification criteria for mixtures

A.3.3.1 Classification of mixtures when data are available for the complete mixture

A.3.3.1.1 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.3.3.1.2 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.3.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.3.3.2.1 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.3.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.3.3.3.1 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 $\geq 1\%$ (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.3.3.3.2 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.3.3.3.3 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.3.3.3.4 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.3.3.3.1 and A.3.3.3.2 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.3.3.1.2) 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 $\geq 1\%$ of a skin corrosive or serious eye damaging ingredient and as Eye Irritation (Category 2) when it contains $\geq 3\%$ 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.3.3.3.5 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.3.2, Figure A.3.1 and explained in detail in this chapter.

A.3.3.3.6 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 $\leq 1\%$ (corrosive to the skin or seriously damaging to the eye) or $\leq 3\%$ (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	$\geq 3\%$	$\geq 1\%$ but $< 3\%$
Eye irritation (Category 2)		$\geq 10\%$ ^b
10 x (Skin corrosion (Category 1) + Serious eye damage (Category 1)) ^a + Eye irritation (Category 2)		$\geq 10\%$

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 doesnot apply, that would trigger classification of the mixture as hazardous to the eye

Ingredient	Concentration	Mixture classified as:
Acid with pH < 2	$\geq 1\%$	Serious eye damage (Category 1)
Base with pH ≥ 11.5	$\geq 1\%$	Serious eye damage (Category 1)
Other skin corrosive or serious eye damage (Category 1) ingredients	$\geq 1\%$	Serious eye damage (Category 1)
Other eye irritant (Category 2) ingredients	$\geq 3\%$	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.

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.4.2.1.3 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.

¹ As of [INSERT DATE of PUBLICATION IN THE FEDERAL REGISTER], 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.4.2.1.2.4 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.4.2.1.2.3 Data from appropriate animal studies² which may be indicative of the potential of a substance to cause sensitization by inhalation in humans³ 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.

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.

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 $\leq 500 \mu\text{g}/\text{cm}^2$ (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 $> 500 \mu\text{g}/\text{cm}^2$ (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.⁹

A.4.2.2.3.2 Animal test results for sub-category 1A can include data with values indicated in the following Table A.4.3:

Table A.4.3: Animal test results for sub-category 1A

Assay	Criteria
Local lymph node assay	EC3 value $\square$ 2%
Guinea pig maximization test	$\geq 30\%$ responding at $\square$ 0.1% intradermal induction dose or $\geq 60\%$ responding at $> 0.1\%$ to $\square$ 1% intradermal induction dose
Buehler assay	$\geq 15\%$ responding at $\square$ 0.2% topical induction dose or $\geq 60\%$ responding at $> 0.2\%$ to $\square$ 20% topical induction dose

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.

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 Table A.4.4 below:

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			$\geq 0.1\%$
Skin Sensitizer Sub-category 1B			$\geq 1.0\%$

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 structure 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 maybe 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

<u>CATEGORY 1:</u>	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/genotoxic 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.
<u>CATEGORY 2:</u>	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. <i>NOTE: Substances which are positive in in vitro mammalian mutagenicity assays, and which also show structure activity relationship to known germ cell mutagens, should be considered for classification as Category 2 mutagens.</i>

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 mixtures⁵

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 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.

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 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.

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 substances⁶

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

<u>CATEGORY 1:</u>	Known or presumed human carcinogens The placing of a substance in Category 1 is done on the basis of epidemiological and/or animal data. An individual substance may be further distinguished: Category 1A: Known to have carcinogenic potential for humans; the placing of a substance is largely based on human evidence. Category 1B: Presumed to have carcinogenic potential for humans; the placing of a substance is largely based on animal evidence. Based on strength of evidence together with additional considerations, 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). Alternatively, evidence may be derived from animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen). In addition, on a case by case basis, scientific judgement 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. Classification: Category 1 (A and B) Carcinogen
<u>CATEGORY 2:</u>	Suspected human carcinogens The placing 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 1. Based on strength of evidence together with additional considerations, such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies. Classification: Category 2 Carcinogen

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).

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 mixtures⁷

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 a 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.

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 carcinogenicity⁸

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 29 CFR part 1910, subpart Z, chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen.

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.

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 LARC and NTP to GHS.

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 behavior, 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

<u>CATEGORY 1:</u>	Known or presumed human reproductive toxicant This category includes substances which are known to have produced an adverse effect on sexual function and fertility or on development in humans or for which 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. For regulatory purposes, a substance can be further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).
<u>CATEGORY 1A:</u>	Known human reproductive toxicant The placing of the substance in this category is largely based on evidence from humans.
<u>CATEGORY 1B:</u>	Presumed human reproductive toxicant The placing of the substance in this category is largely based on evidence from experimental animals. Data from animal studies should provide clear 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.
<u>CATEGORY 2:</u>	Suspected human reproductive toxicant This category includes substances for which 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 could be the more appropriate classification.

Figure A.7.1(b): Hazard category for effects on or via lactation

<u>EFFECTS ON OR VIA LACTATION</u> Effects on or via lactation are allocated to a separate single category. It is appreciated that for many substances there is no information on the potential to cause adverse effects on the offspring via lactation. However, substances which are absorbed by women and have been shown to interfere with lactation, or which may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child, should 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 would 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.

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 $\times$ 100)

(c) Fertility index (Number of animals with implants/Number of matings $\times$ 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 mixtures⁹

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.

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.

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.7.3.1.1 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

<u>CATEGORY 1:</u>	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 Placing a substance in Category 1 is done 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 3.8.2.1.9) to be used as part of weight-of-evidence evaluation.
<u>CATEGORY 2:</u>	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 Placing a substance in Category 2 is done 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 3.8.2.1.9) in order to help in classification. In exceptional cases, human evidence can also be used to place a substance in Category 2 (see 3.8.2.1.9).
<u>CATEGORY 3:</u>	Transient target organ effects There are target organ effects for which a substance/mixture may 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/mixtures may be classified specifically for these effects as discussed in 3.8.2.2. NOTE: For these categories the specific target organ/system that has been primarily affected by the classified substance may be identified, or the substance may be identified as a general toxicant. Attempts should be made to determine the primary target organ/system of toxicity and classify for that purpose, e.g. hepatotoxicants, neurotoxicants. One should carefully evaluate the data and, where possible, 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

Route of exposure	Units	Guidance value ranges for:		
		Category 1	Category 2	Category 3
Oral (rat)	mg/kg body weight	$C \leq 300$	$2000 \geq C > 300$	Guidance values do not apply
Dermal (rat or rabbit)	mg/kg body weight	$C \leq 1000$	$2000 \geq C > 1000$	
Inhalation (rat) gas	ppmV/4h	$C \leq 2500$	$20,000 \geq C > 2500$	
Inhalation (rat) vapor	mg/l/4h	$C \leq 10$	$20 \geq C > 10$	
Inhalation (rat) dust/mist/fume	mg/l/4h	$C \leq 1.0$	$5.0 \geq C > 1.0$	

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.*, < 2000 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.*, ≥ 2000 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 reproduced 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	$\geq 1.0 \%$	
Category 2 Target organ toxicant		$\geq 1.0 \%$

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 $\geq 1\%$ (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 detoxification 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	$C \leq 10$
Dermal (rat or rabbit)	mg/kg body weight/day	$C \leq 20$
Inhalation (rat) gas	ppmV/6h/day	$C \leq 50$
Inhalation (rat) vapor	mg/liter/6h/day	$C \leq 0.2$
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	$C \leq 0.02$

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	$10 < C \leq 100$
Dermal (rat or rabbit)	mg/kg body weight/day	$20 < C \leq 200$
Inhalation (rat) gas	ppmV/6h/day	$50 < C \leq 250$
Inhalation (rat) vapor	mg/liter/6h/day	$0.2 < C \leq 1.0$
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	$0.02 < C \leq 0.2$

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	$\geq 1.0 \%$	
Category 2 Target organ toxicant		$\geq 1.0 \%$

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 labeling, 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:

$$\frac{\text{Dynamic viscosity (mPa} \cdot \text{s)}}{\text{Density (g/cm}^3\text{)}} = \text{Kinematic viscosity (mm}^2\text{/s)}$$

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 (<i>See note</i>); or (b) If it is a hydrocarbon and has a kinematic viscosity $\leq 20.5 \text{ mm}^2/\text{s}$, 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 $\geq 1\%$.

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 $\geq 10\%$, and the mixture has a kinematic viscosity of $\leq 20.5 \text{ mm}^2/\text{s}$, 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 $\geq 10\%$, and it has a kinematic viscosity of $\leq 20.5 \text{ mm}^2/\text{s}$, 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 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 of this appendix) or an oxidizing solid (see B.14 of this appendix) is determined by Test Series 8 tests of UN ST/SG/AC.10/.

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 or sensitivity.

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.10/11/Rev.6 (incorporated by reference; see §1910.6) which are exempted from classification as explosives (based on a negative result in Test Series 6 in Part I, Section 16 of UN ST/SG/AC.10/11/Rev.6 (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.

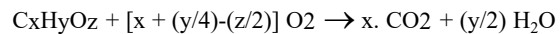
B.1.3.3 If a mixture contains any known explosives, the acceptance procedure is necessary for classification.

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:



using the formula: oxygen balance = $-1600 [2x + (y/2) - z]$ /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 °F) 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 °F) or below.
	Chemically unstable gas	A	Flammable gases which are chemically unstable at 20 °C (68 °F) 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 °F) 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 °F) 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 maybe a delay.

NOTE 4: In the absence of data on its pyrophoricity, a flammable gas mixture shall 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 10156:1996 or ISO 10156:2017 (incorporated by reference; see §1910.6) and, if using fundamental burning velocity for Category 1B, use Annex C: Method of test for burning velocity measurement of flammable gases of ISO 817:2014(E) (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 or DIN 51794:2003 (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.10/11/Rev.6 (incorporated by reference; see §1910.6). If the calculations performed in accordance with ISO 10156:1996 or ISO 10156:2017 (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 AND CHEMICALS UNDER PRESSURE

B.3.1 Aerosols

B.3.1.1 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.3.1.2 Classification criteria

B.3.1.2.1 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 B, *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.

B.3.1.2.2 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 $\geq 85\%$ 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/m ³ ; or (ii) Deflagration density is ≤ 300 g/m ³ 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	(1) The chemical does not meet the criteria for Categories 1 and 2. (2) The chemical contains $\leq 1\%$ flammable components (by mass) and has a heat of combustion < 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.

NOTE 3: 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.3.2 Chemicals under pressure

B.3.2.1 Definition

Chemicals under pressure are liquids or solids (e.g., pastes or powders), pressurized with a gas at a pressure of 200 kPa (gauge) or more at 20 °C in pressure receptacles other than aerosol dispensers and which are not classified as gases under pressure.

NOTE: *Chemicals under pressure typically contain 50 % or more by mass of liquids or solids whereas mixtures containing more than 50 % gases are typically considered as gases under pressure.*

B.3.2.2 Classification criteria

B.3.2.2.1 Chemicals under pressure are classified in one of three categories of this hazard class, in accordance with Table B.3.2, depending on their content of flammable components and their heat of combustion

B.3.2.2.2 Flammable components are components which are classified as flammable in accordance with the GHS criteria, *i.e.*:

- Flammable gases (*see* B..2 of this section);
- Flammable liquids (*see* B.6 of this section);
- Flammable solids (*see* B.7 of this section).

Table B.3.2: Criteria for chemicals under pressure

Category	Criteria
1	Any chemical under pressure that: (a) contains ≥ 85 % flammable components (by mass); and (b) has a heat of combustion of ≥ 20 kJ/g.
2	Any chemical under pressure that: (a) contains > 1 % flammable components (by mass); and (b) has a heat of combustion < 20 kJ/g; or that: (a) contains < 85 % flammable components (by mass); and (b) has a heat of combustion ≥ 20 kJ/g.
3	Any chemical under pressure that: (a) contains $\leq 1\%$ flammable components (by mass); and (b) has a heat of combustion of < 20 kJ/g.

NOTE 1: *The flammable components in a chemical under pressure do not include pyrophoric, self-heating or water-reactive, substances and mixtures because such components are not allowed in chemicals under pressure in accordance with the UN Model Regulations.*

NOTE 2: *Chemicals under pressure do not fall additionally within the scope of section B.3.1 (aerosols), B.2.2 (flammable gases), B.2.5 (gases under pressure), B.2.6 (flammable liquids) and B.2.7 (flammable solids). Depending on their contents, chemicals under pressure may however fall within the scope of other hazard classes, including their labelling elements.*

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 (ΔH_c), in kilojoules per gram (kJ/g), is the product of the theoretical heat of combustion (ΔH_{comb}), and a combustion efficiency, usually less than 1.0 (a typical combustion efficiency is 0.95 or 95%).

For a composite formulation, the chemical heat of combustion is the summation of the weighted heats of combustion for the individual components, as follows:

$$\Delta H_c(\text{product}) = \sum_i^n [w(i) \times \Delta H_c(i)]$$

where:

$\Delta H_c(\text{product})$ = specific heat of combustion (kJ/g) of the product;

$\Delta H_c(i)$ = specific heat of combustion (kJ/g) of component i in the product;

$w(i)$ = mass fraction of component i in the product;

n = total number of components in the product.

B.3.3.3 The chemical heats of combustion shall be found in literature, calculated or determined by tests: (*see* ASTM D240; Sections 86.1 to 86.3 of ISO 13943; and NFPA 30B (incorporated by reference; see §1910.6)).

B.3.3.4 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 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 10156:1996, ISO 10156:2017 or 10156-2:2005 (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 10156:1996, ISO 10156:2017 or 10156-2:2005 (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 temperature ¹ 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 of this appendix.

B.6.2 Classification criteria

A flammable liquid shall be classified in one of four categories in accordance with Table B.6.1 of this appendix:

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), or any method specified in 29 CFR 1910.106(a)(14). It may also be determined by 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.

⁹ To determine the appropriate flammable liquid storage container size and type, the boiling point shall be determined by § 1910.106(a)(5). 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 and the classification for storage differs from the classification listed in Section 2 of the SDS.

B.7 FLAMMABLE SOLIDS

B.71 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 Part III, sub-section 33.2.1 of UN ST/SG/AC.10 (incorporated by reference; see §1910.6), 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 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: 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.

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 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 Part II, section 28 of UN ST/SG/AC.10, (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 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 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 UN ST/SG/AC.10 (incorporated by reference; see §1910.6), in accordance with Table B.9.1 of this appendix:

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 UN ST/SG/AC.10 (incorporated by reference; see §1910.6), in accordance with Table B.10.1 of this appendix:

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, in tests performed in accordance with test method N.4 in Part III, sub-section 33.3.1.6 of 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 Greiner 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 UN ST/SG/AC.10 (incorporated by reference, see §1910.6), in accordance with Table B.12.1 of this appendix:

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 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 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, of UN ST/SG/AC.10 (incorporated by reference, see §1910.6) or test O.3 in Part III, sub-section 34.4.3 of UN ST/SG/AC.10/11 (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.
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 -O-O- 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 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 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 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 aluminum 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.

B.17 DESENSITIZED EXPLOSIVES

B.17.1 Definitions and general considerations

Desensitized explosives are solid or liquid explosive chemicals which are phlegmatized¹⁰ 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.17.1.1 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.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

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.10/11/Rev.6 (incorporated by reference, see §1910.6) is greater than 1200 kg/min; or

(b) Its exothermic decomposition energy is less than 300 J/g.

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).

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.10/11/Rev.6 (incorporated by reference, see §1910.6)) because information about its sensitivity 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.

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.10/11/Rev.6 (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.10/11/Rev.6 (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 (AC) equal to or greater than 300 kg/min but not more than 1200 kg/min
2	Desensitized explosives with a corrected burning rate (AC) equal to or greater than 140 kg/min but less than 300 kg/min
3	Desensitized explosives with a corrected burning rate (AC) equal to or greater than 60 kg/min but less than 140 kg/min
4	Desensitized explosives with a corrected burning rate (AC) 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/AC.10/11/Rev.6 (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.10/11/Rev.6 (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.10/11/Rev.6 (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.10/11/Rev. 6 (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.

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 explosives 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. If the same medical response statement is triggered multiple times, 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 must 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 $\geq 1\%$, 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)

Hazard category	Signal word	Hazard statement
1	Danger	Fatal if swallowed
2	Danger	Fatal if swallowed
3	Danger	Toxic if swallowed

Pictogram
Skull and crossbones



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. <i>- if immediate administration of antidote is required.</i> 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 to 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. <i>- if immediate measures such as specific cleansing agent is advised.</i> 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
Skull and crossbones

Hazard category	Signal word	Hazard statement
3	Danger	Toxic in contact with skin



Precautionary statements			
Prevention	Response	Storage	Disposal
Wear protective gloves/protective clothing. Chemical manufacturer, importer, or distributor to 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. <i>- if immediate measures such as specific cleansing agent is advised.</i> 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
4	Warning	Harmful in contact with skin

Pictogram Exclamation mark



Precautionary statements			
Prevention	Response	Storage	Disposal
Wear protective gloves/protective clothing. Chemical manufacturer, importer, or distributor to 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. <i>- if measures such as specific cleansing agent is advised.</i> 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. - <i>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.</i>	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. - <i>if immediate administration of antidote is required.</i>	Store in a well-ventilated place. Keep container tightly closed. - <i>if the chemical is volatile and may generate a hazardous atmosphere.</i> 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 the substance/mixture is determined to be corrosive to the respiratory tract leading to lethality, the corrosivity hazard must also be communicated with the corrosive pictogram and hazard statement "corrosive to the respiratory tract".

C.4.3 ACUTE TOXICITY – INHALATION (CONTINUED)
(Classified in Accordance with Appendix A.1 of this section)

Hazard category	Signal word	Hazard statement
3	Danger	Toxic if inhaled

Pictogram Skull and crossbones



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. <i>- if immediate specific measures are required.</i>	Store in a well-ventilated place. Keep container tightly closed. <i>- if the chemical is volatile and may generate a hazardous atmosphere.</i> 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

4

Signal word

Warning

Hazard statement

Harmful if inhaled

Pictogram
Exclamation mark



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)

Hazard category	Signal word	Hazard statement
1A to 1C	Danger	Causes severe skin burns and eye damage

Pictogram
Corrosion



Precautionary statements			
Prevention	Response	Storage	Disposal
Do not breathe dusts or mists. <i>- if inhalable particles of dusts or mists may occur during use.</i> 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 to 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]. <i>- text in square brackets to be included where the chemical manufacturer, importer or distributor considers it appropriate for the specific chemical.</i> 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.

Note: If the classifier determines, based on skin data, that the chemical may be corrosive to the respiratory tract, then the corrosivity hazard must also be communicated with the corrosive pictogram and hazard statement "corrosive to the respiratory tract".

C.4.4 SKIN CORROSION/IRRITATION (CONTINUED)
(Classified in Accordance with Appendix A.2 of this section)

Hazard category

2

Signal word

Warning

Hazard statement

Causes skin irritation

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. Wear protective gloves. Chemical manufacturer, importer, or distributor to 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 (<i>see ... on this label</i>) ... 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)

Hazard category

1

Signal word

Danger

Hazard statement

Causes serious eye damage

Pictogram
Corrosion



Precautionary statements			
Prevention	Response	Storage	Disposal
Wear eye protection/face protection. Chemical manufacturer, importer, or distributor to 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.		

Note: If the classifier determines, based on eye data, that the chemical may be corrosive to the respiratory tract, then corrosivity hazard must also be communicated with the corrosive pictogram and hazard statement "corrosive to the respiratory tract".

C.4.5 EYE DAMAGE/IRRITATION (CONTINUED)
(Classified in Accordance with Appendix A.3 of this section)

Hazard category	Signal word	Hazard statement
2A	Warning	Causes serious eye irritation

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. Wear eye protection/face protection. Chemical manufacturer, importer, or distributor to 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 <i>No Pictogram</i>

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)

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

Pictogram
Health hazard



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)

Hazard category

1 (including both sub-categories 1A and 1B)

Signal word

Warning

Hazard statement

May cause an allergic skin reaction

Pictogram
Exclamation mark



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 to 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)

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)

Pictogram
Health 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/... 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)

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)

Pictogram
Health 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/... 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/... 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)

Hazard category

No designated number

(See Table A.7.1 in Appendix A.7)

Signal word

No signal word

Hazard statement

May cause harm to breast-fed children

Pictogram
No pictogram

Precautionary statements			
Prevention	Response	Storage	Disposal
Obtain special instructions before use. Do not breathe dusts or mists. <i>- if inhalable particles of dusts or mists may occur during use.</i> 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)

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)

Pictogram
Health 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.

Note: If the chemical is determined to be corrosive to the respiratory tract, corrosive to the respiratory tract must be communicated with the hazard statement "corrosive to the respiratory tract, if inhaled" and corrosive pictogram, in lieu of current hazard statement and pictogram.

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (CONTINUED)
(Classified in Accordance with Appendix A.8 of this section)

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)

Pictogram
Health 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.

Note: If the substance/mixture is determined to be corrosive to the respiratory tract, corrosivity must be communicated with the hazard statement "corrosive to the respiratory tract, if inhaled" and corrosive pictogram in lieu of current hazard statement and pictogram.

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (CONTINUED)
(Classified in Accordance with Appendix A.8 of this section)

Hazard category	Signal word	Hazard statement
3	Warning	May cause respiratory irritation; or May cause drowsiness or dizziness

Pictogram Exclamation mark



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. <i>- if the chemical is volatile and may generate a hazardous atmosphere.</i> 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)

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)

Pictogram
Health 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)

Hazard category	Signal word	Hazard statement
1	Danger	May be fatal if swallowed and enters airways

Pictogram
Health hazard



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
Unstable explosive	Danger	Unstable explosive

Pictogram
Exploding bomb



Precautionary statements			
Prevention	Response	Storage	Disposal
Obtain special instructions before use. Do not subject to grinding/shock/friction/... – <i>if the explosive is mechanically sensitive.</i> ...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)

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

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 wetted with... <i>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).</i> Keep only in original packaging. Ground and /bond container and receiving equipment. <i>- if the explosive is electrostatically sensitive.</i> Do not subject to grinding/shock/.../friction. <i>- if the explosive is mechanically sensitive.</i> ...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-personalprotective equipment.	In case of fire: Explosionrisk. 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 asapplicable.

Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless thehazard 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
Exploding bomb¹

Hazard category	Signal word	Hazard statement



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. <i>- if the explosive is electrostatically sensitive.</i> Do not subject to grinding/shock/.../friction. <i>-if the explosive is mechanically sensitive.</i> ...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. <i>- except for explosives of division 1.4 (compatibility group S) in transport packaging.</i> In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion. <i>- for explosives of division 1.4 (compatibility group S) in transport packaging.</i>	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 packagings 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... <i>-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).</i> ... Chemical manufacturer, importer, or distributor to specify appropriate material. Keep only in original packaging. Ground and /bond container and receiving equipment. <i>- if the explosive is electrostatically sensitive.</i> Do not subject to grinding/shock/.../friction. <i>-if the explosive is mechanically sensitive.</i> ...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 packagings 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 packagings 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)

Hazard category	Signal word	Hazard statement
1A	Danger	Extremely flammable gas
1B	Danger	Flammable gas

Pictogram
Flame



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. <i>– if emphasis of the hazard statement is deemed necessary.</i> 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 tables 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.3.1 of this section)

			Pictogram <i>No symbol</i>
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.4.16 CHEMICAL UNDER PRESSURE
(Classified in Accordance with Appendix B.3.2 of this section)

Hazard category	Signal word	Hazard statement
1	Danger	Extremely flammable chemical under pressure May burst if heated.
2	Warning	Flammable chemical under pressure May burst if heated.

Pictogram
Gas Cylinder and Flame



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.	In case of leakage, eliminate all ignition sources. Stop leak if safe to do so.	Protect from sunlight. Store in a well-ventilated place.	

C.4.16 CHEMICAL UNDER PRESSURE
(Classified in Accordance with Appendix B.3 of this section)

Pictogram
Gas Cylinder



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.	Stop leak if safe to do so.	Protect from sunlight. Store in a well-ventilated place.	

C.4.17 OXIDIZING GASES
(Classified in Accordance with Appendix B.4 of this section)

Hazard category	Signal word	Hazard statement
1	Danger	May cause or intensify fire; oxidizer

Pictogram
Flame over circle



Precautionary statements			
Prevention	Response	Storage	Disposal
Keep away from clothing and other combustible materials. Keep valves and fittings freefrom 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)

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

Pictogram
Gas cylinder



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)

Hazard category	Signal word	Hazard statement
Refrigerated liquefied gas	Warning	Contains refrigerated gas; may cause cryogenic burns or injury

Pictogram Gas cylinder



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)

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

Pictogram
Flame



Precautionary statements			
Prevention	Response	Storage	Disposal
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). Keep container tightly closed. <i>– if the liquid is volatile and may generate an explosive atmosphere.</i> Ground /and bond container and receiving equipment. <i>– if the liquid is volatile and may generate an explosive atmosphere.</i> Use explosion-proof [electrical/ventilating/lighting/...] equipment. <i>– if the liquid is volatile and may generate an explosive atmosphere</i> <i>– text in square brackets may be used to specify specific electrical, ventilating, lighting, or other equipment if necessary and as appropriate.</i> Chemical manufacturer, importer, or distributor to specify other equipment. Use non-sparking tools. <i>– 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).</i> Take action to prevent static discharge. <i>– if the liquid is volatile and may generate an explosive atmosphere.</i> 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]. <i>– text in square brackets to be included where the chemical manufacturer, /importer, or distributor considers it appropriate for the specific chemical.</i> In case of fire: Use ... to extinguish. <i>– if water increases risk.</i> <i>... Chemical manufacturer, importer, or distributor to specify appropriate media.</i>	Store in a well-ventilated place. Keep cool. <i>– for flammable liquids Category 1 and other flammable liquids that are volatile and may generate an explosive atmosphere.</i>	Dispose of contents/container to... <i>... in accordance with local/regional/national/ international regulations (to be specified).</i> 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. <i>- if water increases risk.</i> ... Chemical manufacturer, importer, or distributor to specify appropriate media.	Store in a well-ventilated place. <i>- for flammable liquids Category 1 and other flammable liquids that are volatile and may generate an explosive atmosphere.</i>	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. <i>- if the solid is electrostatically sensitive.</i> Use explosion-proof [electrical/ventilating/ lighting/...] equipment. <i>if dust clouds can occur.</i> <i>- text in square brackets may be used to specify specific electrical, ventilating, lighting or other equipment if necessary and as appropriate.</i> 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 <i>- if water increases risk.</i> ... 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. <i>- may be omitted if storage temperatures are listed on the label.</i> Ground and bond container and receiving equipment. <i>– if electrostatically sensitive and able to generate an explosive atmosphere.</i> 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. <i>- except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.</i> Store at temperatures not exceeding ...°F (°C). ... Chemical manufacturer, importer, or distributor to specify temperature using applicable temperature scale. <i>- if temperature control is required (see Appendix B.2.3) or if otherwise deemed necessary.</i> 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
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. - <i>may be omitted if storage temperatures are listed on the label.</i> Ground and bond container and receiving equipment. - <i>if electrostatically sensitive and able to generate an explosive atmosphere.</i> 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]. - <i>text in square brackets to be included if water increases risk.</i> ... Chemical manufacturer, importer, or distributor to specify appropriate media.	Store in a well-ventilated place. - <i>except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.</i> Store at temperatures not exceeding ...°F (°C). if temperature control is required (see Appendix B.2.3) 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. <i>except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.</i> Store at temperatures not exceeding ...°F (°C). – if temperature control is required (see Appendix B.2.3) 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. - <i>if emphasis of the hazard statement is deemed necessary.</i> 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 - <i>if water increases risk.</i> ... Chemical manufacturer, importer, or distributor to specify appropriate media.		

C.4.23 PYROPHORIC SOLIDS
(Classified in Accordance with Appendix B.10 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. <i>- if emphasis of the hazard statement is deemed necessary.</i> 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 <i>- if water increases risk.</i> ... 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. <i>- may be omitted if storage temperatures are listed on the label.</i> 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. <i>- if emphasis of the hazard statement is deemed necessary.</i> Handle and store contents under inert gas/... Protect from moisture. <i>- if the substance or mixture reacts readily with moisture in air.</i> ... 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 <i>- if water increases risk.</i> ... 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)**

Hazard category	Signal word	Hazard statement
3	Warning	In contact with water releases flammable gas

Pictogram
Flame



Precautionary statements			
Prevention	Response	Storage	Disposal
Handle and store contents under inert gas/... Protect from moisture. <i>- if the substance or mixture reacts readily with moisture in air.</i> ... 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. <i>- if water increases risk.</i> ... 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)

Hazard category	Signal word	Hazard statement
1	Danger	May cause fire or explosion; strong oxidizer

Pictogram
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 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. - <i>if water increases risk.</i> ... 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
2	Danger	May intensify fire; oxidizer
3	Warning	May intensify fire; oxidizer

Pictogram
 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 the appropriate personal protective equipment.	In case of fire: Use ... to extinguish. <i>- if water increases risk.</i> ... 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
1	Danger	May cause fire or explosion; strong oxidizer

Pictogram
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. - <i>if water increases risk.</i> ... 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. <i>- if water increases risk.</i> ... 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. – <i>except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.</i> Protect from sunlight. Store at temperatures not exceeding ...°F (°C). - <i>if temperature control is required or if otherwise deemed necessary.</i> ... 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	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. <i>- may be omitted if storage temperatures are listed on the label.</i> Ground and bond container and receiving equipment. <i>- if electrostatically sensitive and able to generate an explosive atmosphere.</i> 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] <i>- text in square brackets to be used if water increases risk.</i> ... Chemical manufacturer, importer, distributor to specify appropriate media.	Store in a well-ventilated place. <i>- except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.</i> Protect from sunlight. Store at temperatures not exceeding...°F (°C). <i>- if temperature control is required or if otherwise deemed necessary.</i> 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. - <i>may be omitted if storage temperatures are listed on the label.</i> Ground and bond container and receiving equipment. - <i>if electrostatically sensitive and able to generate an explosive atmosphere.</i> 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. - <i>if water increases risk.</i> ... Chemical manufacturer, importer, distributor to specify appropriate media.	Store in a well-ventilated place. - <i>except for temperature controlled self-reactive substances and mixtures or organic peroxides because condensation and consequent freezing may take place.</i> Protect from sunlight. Store at temperatures not exceeding ...°F (°C). - <i>if temperature control is required or if otherwise deemed necessary.</i> 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)

Hazard category

1

Signal word

Warning

Hazard statement

May be corrosive to metals

Pictogram
Corrosion



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)

Pictogram
Flame



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.

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
4	Warning	Fire 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 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/international 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
Simple Asphyxiant	Warning	May displace oxygen and cause rapid suffocation

No pictogram

No pictogram

Hazard category	Signal word	Hazard statement
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.] <i>Text in square brackets may be used when the material can only create a combustible dust hazard due to the creation of small particles during the processing or handling of the chemical</i>

² 1) 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, that follows the approach described 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.

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

	Headings	Subheadings
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 Identification	(a) Classification of the chemical in accordance with paragraph (d)(1)(i) of §1910.1200; (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 classified under paragraph (d)(1)(ii) of § 1910.1200; (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 $\geq 1\%$ 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. <i>Note: When CAS number is not available or claimed as a trade secret, the preparer must indicate the source of unique identifier.</i> (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, and/or concentration (exact or range) of the composition has been withheld as a trade secret is required. When the concentration or concentration range is withheld as a trade secret, the prescribed concentration ranges used in §1910.1200(i)(1)(iv) – (vi) must be used.
4.	First aid measures	(a) Description of necessary measures, subdivided according to the different routes of exposure, <i>i.e.</i> , 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 (<i>e.g.</i> , 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 (includes odor threshold) (d) Melting point/freezing point (e) Boiling point (or initial boiling point or boiling range) (f) Flammability (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 (includes evaporation rate) (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 (<i>e.g.</i> , 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 (<i>e.g.</i>, 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 (Non-mandatory)	(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 (Non-mandatory)	Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.
14.	Transport information (Non-mandatory)	(a) UN number; (b) UN proper shipping name; (c) Transport hazard class(es); (d) Packing group, if applicable; (e) Environmental hazards (<i>e.g.</i>, 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 (Non-mandatory)	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.

† *Note: 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 and the classification for storage differs from the classification listed in section 2 of the SDS.*